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Human Research Protection Program Policy

Effective: 11/23/2015
Reviewed: 11/23/2017

Policy Statement

Palmetto Health is committed to protecting the rights and welfare of subjects in Human Research. To this end, Palmetto Health has established the Human Research Protection Program to comply with ethical and legal requirements for the conduct and oversight of Human Research.

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DEFINITIONS

1. “Case Report”: Retrospective analysis of one, two, or three clinical cases. If more than three cases are involved, the Investigator usually starts asking specific research questions which lead to a formal systematic collection of data and a prospectively designed research study. Thus with four or more cases, the activity is Human Research and must be reviewed by Palmetto Health’s Institutional Review Board (IRB).
2. “Clinical Trial”: A biomedical or behavioral research study of human subjects designed to answer specific questions about therapeutic interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new therapeutic interventions are safe, efficacious, and effective.

3. “Engaged in Human Research”: Palmetto Health is engaged in Human Research when its employees or workforce members interact or intervene with Human Subjects for the purpose of conducting Research. Palmetto Health follows the guidance of The Office for Human Research Protections (“OHRP”) on “Engagement of Institutions in Research” to apply this definition.

4. “Human Research”: Any activity that is either of the following:
   4.1. is “Research” as defined by DHHS and involves “Human Subjects” as defined by DHHS (“DHHS Human Research”) or
   4.2. is “Research” as defined by FDA and involves “Human Subjects” as defined by FDA (“FDA Human Research”).

5. “Human Subject” as Defined by DHHS: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through Intervention or Interaction with the individual or (2) information that is both Private Information and Identifiable Information. For the purpose of this definition:
   5.1. “Intervention” means physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
   5.2. “Interaction” means communication or interpersonal contact between investigator and subject.
   5.3. “Private Information” means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).
   5.4. “Identifiable Information” means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

6. “Human Subject” as Defined by FDA: An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used.

7. “Investigator”: The person responsible for the conduct of the Human Research at one or more sites. If the Human Research is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

8. “Research” as Defined by DHHS: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

9. “Research” as Defined by FDA: The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations (21 CFR 50.3(c),
21 CFR 56.102(c)). Any experiment that involves a test article and one or more human subjects and that meets any one of the following:

9.1. must meet the requirements for prior submission to the FDA under section 505(i) of the Federal Food, Drug, and Cosmetic Act, meaning any use of a drug, other than the use of an approved drug, in the course of medical practice;

9.2. must meet the requirements for prior submission to the FDA under section 520(g) of the Federal Food, Drug, and Cosmetic Act, meaning any activity that evaluates the safety or effectiveness of a device; or

9.3. any activity the results of which are intended to be later submitted to or held for inspection by the FDA as part of an application for a research or marketing permit.

10. **“Workforce Member”**: Any individual, including employees, independent contractors, volunteers, students, trainees, medical residents, fellows, and other persons, whose conduct in the performance of work for Palmetto Health is under the control of the organization, regardless of whether the individuals are receiving compensation from Palmetto Health. Legal counsel has the ultimate authority to determine whether someone is acting as a workforce member of Palmetto Health.

**POLICY SPECIFICATIONS:**

1. **Purpose**
   
   1.1. Palmetto Health (“Palmetto Health” or “PH”) is committed to protecting the rights and welfare of subjects in Human Research. The purpose of this policy is to describe Palmetto Health’s program to comply with ethical and legal requirements for the conduct and oversight of Human Research.

   1.2. Palmetto Health’s Human Research Protection Program (“HRPP”) is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research. The HRPP is based on all individuals in this organization along with key individuals and committees fulfilling their roles and responsibilities as described in this policy.

2. **Mission**

   2.1. The mission of Palmetto Health’s HRPP is to protect the rights and welfare of subjects involved in Human Research that is overseen by Palmetto Health.

3. **Ethical Requirements**

   3.1. In the oversight of all Human Research, Palmetto Health (including its investigators, research staff, students involved with the conduct of Human Research, the PH institutional review boards (“IRBs”), IRB members and chairs, IRB staff, the Signatory Official, employees, and workforce members) follows the ethical principles outlined in the April 18, 1979 report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, “Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” also known as “The Belmont Report.”

   • Respect for Persons
   • Beneficence
4. Legal Requirements

4.1. Palmetto Health commits to apply its ethical standards to all Human Research regardless of funding.

4.2. All Human Research must undergo review by one of Palmetto Health’s designated IRBs. Activities that do not meet the definition of Human Research (e.g., most classroom activities, quality improvement activities, case reports with less than four cases, program evaluation, and surveillance activities that do not meet the definition of Human Research) do not require review and approval by one of Palmetto Health’s IRBs and do not need to be submitted to one of Palmetto Health’s IRBs, unless there is a question regarding whether the activity is Human Research.

4.3. When Palmetto Health is engaged in DHHS Human Research that is conducted, funded, or otherwise subject to regulations by a federal department or agency that is a signatory of the Common Rule, Palmetto Health commits to apply the regulations of that agency relevant to the protection of Human Subjects.

4.4. When Palmetto Health is engaged in FDA Human Research, Palmetto Health commits to apply the FDA regulations relevant to the protection of Human Subjects.

4.5. Any questions about whether an activity meets the regulatory definitions of Human Research should be referred to the IRB Administration Office for a determination.

5. Other Requirements

5.1. For clinical trials, Palmetto Health commits to apply the “International Council on Harmonisation – Good Clinical Practice E6” as adopted by the FDA.


5.3. Palmetto Health prohibits payments to professionals in exchange for referrals of potential subjects (“finder’s fees”) and payments designed to accelerate recruitment that are tied to the rate or timing of enrollment (“bonus payments”).

5.4. When Human Research is conducted or funded by the Department of Justice (“DOJ”), PH commits to apply 28 CFR 22. When Human Research is conducted with the federal Bureau of Prisons (“BOP”), Palmetto Health commits to comply with 28 CFR 512.

5.5. When Human Research is conducted or funded by the Department of Defense (“DOD”), Palmetto Health commits to apply the DOD Directive 3216.02, which includes the requirement to apply 45 CFR 46 Subparts B, C, and D. When Human Research is conducted or funded by the Department of the Navy, Palmetto Health commits to apply SECNAVINST 39000.39D.

5.6. When Human Research is conducted or funded by the Department of Education (“ED”), Palmetto Health commits to applying 34 CFR 97 Subpart D (equivalent to 45 CFR 46 Subpart D), 34 CFR 98.3, 34 CFR 98.4, 34 CFR 356.3, and 34 CFR 99.

5.7. When Human Research is conducted or funded by the Department of Energy (“DOE”), Palmetto Health commits to applying the DOE O 443.1A and to using the “Checklist for
IRBs to Use in Verifying That HS Research Protocols Are in Compliance with the Department of Energy (DOE) Requirements.”

5.8. When Human Research is conducted or funded by or when the results of research are intended to be submitted to or held for inspection by the Environmental Protection Agency (“EPA”), Palmetto Health commits to applying 40 CFR 26, which includes the requirement to apply 45 CFR 46 Subparts B and D.

5.9. When reviewing Human Research, regardless of the funding, Palmetto Health commits to apply 45 CFR 46 and Subparts B, C and D.

6. Sponsored Human Research
6.1. For both sponsored and non-sponsored Human Research, Palmetto Health abides by its ethical principles, regulatory requirements, and its policies and procedures.

7. Scope of Human Research Protection Program
7.1. The categories of Human Research not overseen include:

- research conducted or funded by the Veteran Administration (“VA”);
- classified research;
- international/transnational research;
- research involving fetuses;
- research involving in vitro fertilization;
- research involving non-viable neonates;
- research involving neonates of uncertain viability; and
- research involving children, pregnant women, fetuses, or neonates that is not otherwise approvable without approval of an agency secretary or director.

8. HRPP Policies and Procedures
8.1. Policies and procedures for the HRPP are posted on the Palmetto Health IRB Website.
8.2. Changes to policies and procedures are communicated through the Palmetto Health communication mechanisms.

9. HRPP Components
9.1. Signatory Official
9.1.1. The Vice President for Research is designated as the Signatory Official.
9.1.2. The Signatory Official has the authority to take the following actions or to delegate authority for these actions to a designee:

- create the HRPP budget;
- allocate resources within the HRPP budget;
- appoint and remove IRB members and IRB chairs;
- hire and fire research review staff;
- determine what IRBs Palmetto Health will rely upon;
- approve and rescind authorization agreements for IRBs;
- place limitations or conditions on an investigator’s or on a research staff member’s privilege to conduct Human Research;
• create policies and procedures related to the HRPP that are binding on Palmetto Health;
• suspend or terminate research approved by one of Palmetto Health’s IRBs; and
• disapprove research approved by one of Palmetto Health’s IRBs.

9.1.3. The Signatory Official has the responsibility to take the following actions or to delegate these responsibilities to a designee:
• oversee the review and conduct of Human Research under the jurisdiction of the HRPP;
• periodically review this plan to assess whether it is providing the desired results and recommend amendments as needed;
• establish policies and procedures designed to increase the likelihood that Human Research will be conducted in accordance with ethical and legal requirements;
• institute regular and effective educational and training programs for all individuals involved with the HRPP;
• ensure that the research review process is independent and free of coercion or undue influence and ensure that officials of Palmetto Health cannot approve research that has not been approved by one of the IRBs designated by Palmetto Health;
• implement a process to receive and act on complaints and allegations regarding the HRPP;
• implement an auditing program to monitor compliance and to improve compliance in identified problem areas;
• investigate and remediate identified systemic problem areas and, where necessary, remove individuals from involvement in the HRPP;
• ensure that the HRPP has sufficient resources, including IRBs, appropriate for the volume and types of Human Research to be reviewed so that reviews are accomplished in a thorough and timely manner;
• review and sign federal wide assurances (“FWA”) and addenda; and
• fulfill educational requirements mandated by OHRP.

9.2. All workforce members of Palmetto Health

9.2.1. All individuals within Palmetto Health have the responsibility to:
• be aware of the definition of Human Research;
• consult Palmetto Health’s IRB when there is uncertainty about whether an activity is Human Research;
• not conduct Human Research or allow Human Research to be conducted without review and approval by an IRB designated by the Signatory Official;
• report allegations of undue influence regarding the oversight of the HRPP or concerns about the HRPP to the Signatory Official; and
• report allegations or finding of non-compliance with the requirements of the HRPP to the IRB.
9.3. IRBs

9.3.1. The list of IRBs designated by the Signatory Official to be the IRBs relied upon by the HRPP and the scope of review of these IRBs is listed in the IRB rosters available from Palmetto Health’s IRB Administration Office.

9.3.2. Palmetto Health may rely upon IRBs of another organization provided that one of the following is true:

- the IRBs are part of an AAHRPP accredited organization;
- Palmetto Health’s investigator is a collaborator on Human Research that is conducted primarily at another organization, and the investigator’s role does not include interaction or intervention with subjects;
- Palmetto Health is engaged in the Human Research solely because it is receiving federal funds. (Workforce members of Palmetto Health do not interact or intervene with subjects, do not gather or possess private identifiable information about subjects, and do not obtain the consent of subjects.)


9.3.3. The IRBs relied upon by PH have the authority to:

- approve, require modifications to secure approval, and disapprove all Human Research overseen and conducted by Palmetto Health. All Human Research must be approved by one of the IRBs designated by the Signatory Official. Officials of Palmetto Health may not approve Human Research that has not been approved by one of Palmetto Health’s IRBs;
- suspend or terminate approval of Human Research not being conducted in accordance with an IRBs’ requirements or that has been associated with unexpected serious harm to subjects;
- observe, or have a third party observe, the consent process and the conduct of the Human Research;
- determine whether an activity is Human Research; and
- evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan, if any, allow the Human Research to be approved.

9.3.4. IRB members and IRB staff have the responsibility to follow HRPP policies and procedures that apply to IRB members and staff.

9.4. Investigators and Research Staff

9.4.1. Investigators and research staff have the responsibility to:

- follow the HRPP requirements described in the Investigator Manual;
- follow the HRPP policies and procedures that apply to Investigators and research staff; and
- comply with all determinations and additional requirements of the IRB, the IRB Chair, and the Signatory Official.
9.5. Department Chairs/Directors

9.5.1. Department Chairs/Directors or designee have the responsibility to oversee the evaluation of the scientific/scholarly validity of research proposed by faculty or staff.

9.6. Legal Counsel

9.6.1. Legal Counsel has the responsibility to:

- provide advice upon request to the Signatory Official, IRB, and other individuals involved with the HRPP;
- determine whether someone is acting as a workforce member of PH;
- determine who meets the definition of “legally authorized representative” and “children” when Human Research is conducted in jurisdictions not covered by policies and procedures; and
- resolve conflicts among applicable laws.

9.7. Research Compliance

9.7.1. Research Compliance has the responsibility to review Human Research for:

- conflicts of interest;
- compliance with Legal Requirements and Other Requirements provided in this policy; and
- compliance with Palmetto Health’s policies and procedures.

9.7.2. Research Compliance is responsible for providing the results of such reviews to Palmetto Health’s IRB.

10. Education and Training

10.1. The Signatory Official, IRB members, IRB staff, and others involved in the review of Human Research must complete the online Collaborative Institutional Training Initiative (“CITI”) human subject online training program. See the IRB Web site for a link to this training. The training is valid for a two-year period, after which time the training must be renewed. IRB staff provide training to IRB members on policies, PGRs, and IRB CHECKLISTS.

10.2. Investigators and research staff must complete the online CITI human subject online training program. See the IRB Web site for a link to this training. This training is valid for a two-year period, after which time the training must be renewed.

11. Questions and Additional Information

11.1. Questions, requests for information, or feedback regarding the HRPP should be directed to IRB Administration. Contact information for the IRB Administration is:

   Email: research-assist@PalmettoHealth.org
   (803) 434-2884

12. Reporting and Management of Concerns

12.1. Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the HRPP may be reported orally or in writing. Concerns may be reported to the IRB Chair, the IRB Administration Manager, the
Director of Research, the Signatory Official, or Palmetto Health’s Compliance Officer. Employees are permitted to report concerns on an anonymous basis through the Corporate Compliance Hotline (1-888-398-2633 or http://palmettohealth.silentwhistle.com).

12.2. The IRB has the responsibility to investigate allegations and findings of non-compliance and to take corrective actions as needed. The Signatory Official has the responsibility to investigate all other reports and to take corrective actions as needed.

12.3. Employees who report in good faith possible compliance issues should not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the Signatory Official or to the Compliance Officer.

13. Monitoring and Auditing

13.1. In order to monitor and ensure compliance with this Policy, internal or external auditors who have expertise in federal and state statutes, regulations, and signatory requirements will conduct periodic audits. Audits will focus on areas of concern that have been identified by any entity, i.e., federal, state, or institutional. Random audits may also be conducted.

14. Disciplinary Actions

14.1. The Signatory Official may place limitations or conditions on an investigator’s or a research staff member’s privilege to conduct Human Research whenever – in the opinion of the Signatory Official – such actions are required to maintain the HRPP.

15. Approval and Revisions to the Plan

15.1. This HRPP Plan is approved by the Chief Executive Officer. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The Signatory Official has the responsibility to review this Plan to assess whether it is providing the desired results. At the request of the Signatory Official, the Chief Executive Officer has the authority to amend this Plan as deemed necessary.

REFERENCES
Huron’s HRPP SOPs, ©2009-2010 Huron Consulting Services, LLC. Use and distribution subject to End User License Agreement at http://www.huronconsultinggroup.com/SOP.

Charles Beaman
CEO
11/23/2015
Policy Statement

It is the policy of Palmetto Health (PH) to protect the rights and welfare of human subjects participating in research. This includes the right of each individual to voluntarily make his or her own decisions with regard to matters involving research participation and requires the provision of information to allow the individual to make an informed decision. The subject, or his or her legally authorized representative, has the right to assert informed consent or informed refusal of participation in research. Informed consent for research will be handled in a manner consistent with the “The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research”, 45 CFR Part 46, 21 CFR Part 50, ICH E6 Good Clinical Practice Guidelines as adopted by the FDA, federal law, South Carolina law, local law, Palmetto Health policy, and other legal/ethical considerations which relate to subject choice. This policy does not preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

DEFINITIONS

1. **Applicable Clinical Trial**: An interventional Phase II-IV clinical trial of a marketed drug, biological product, or a medical device trial or a new use/indication of a marketed drug, biological product, or medical device subject to FDA regulation AND involves a drug, biological product, or device manufactured in the U.S. (or its territories) AND the trial is conducted under an investigational new drug application (IND) or investigational device exemption (IDE) AND the trial was initiated on or after September 27, 2007. Applicable clinical trials include:
   1.1. Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation;
   1.2. Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric post-market surveillance.
2. **Assent:** A minor's agreement to participate in research. Mere failure to object should not be construed as assent. Not all minors are capable of assent due to their age, maturity, and psychological state.

3. **Department of Health and Human Services (DHHS):** The U.S. Department of Health and Human Services is the principal agency for protecting the health of all Americans.

4. **Food and Drug Administration (FDA):** The Food and Drug Administration is an agency within the U.S. Department of Health and Human Services.

5. **Human Research:** Any activity that is either of the following:
   5.1. is “Research” as defined by DHHS and involves “Human Subjects” as defined by DHHS (“DHHS Human Research”) or
   5.2. is “Research” as defined by FDA and involves “Human Subjects” as defined by FDA (“FDA Human Research”).

6. **“Human Subject” as Defined by DHHS:** A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through Intervention or Interaction with the individual or (2) information that is both Private Information and Identifiable Information. For the purpose of this definition:
   6.1. “Intervention” means physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
   6.2. “Interaction” means communication or interpersonal contact between investigator and subject.
   6.3. “Private Information” means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).
   6.4. “Identifiable Information” means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

7. **“Human Subject” as Defined by FDA:** An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used.

8. **Impartial Witness:** A person who is independent of the research, who cannot be unfairly influenced by people involved with the research, who attends the informed consent process if the subject or the subject's legally authorized representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

9. **Informed Consent:** A process by which a subject voluntarily confirms his or her willingness to participate in a particular research after having been informed of all aspects of the research that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.
10. **Institutional Review Board (IRB):** An administrative body composed of scientists and non-scientists formally designated to protect the rights and welfare of human subjects recruited to participate in research.

11. **Investigator:** An individual having the background and training in scientific and administrative oversight to conduct and manage research activities. Investigator includes principal investigators, sub-investigators, and co-investigators.

12. **Legally Authorized Representative (LAR):** An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedures involved in the research. Refer to “IRB Legally Authorized Representative, Children and Guardians PGR.”

13. **Permission:** The agreement of parent(s) or guardian to the participation of their child or ward in research.

14. **“Research” as Defined by DHHS:** A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

15. **“Research” as Defined by FDA:** The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations (21 CFR 50.3(c), 21 CFR 56.102(c)). Any experiment that involves a test article and one or more human subjects and that meets any one of the following:
   15.1. must meet the requirements for prior submission to the FDA under section 505(i) of the Federal Food, Drug, and Cosmetic Act, meaning any use of a drug, other than the use of an approved drug, in the course of medical practice;
   15.2. must meet the requirements for prior submission to the FDA under section 520(g) of the Federal Food, Drug, and Cosmetic Act, meaning any activity that evaluates the safety or effectiveness of a device; or
   15.3. any activity the results of which are intended to be later submitted to or held for inspection by the FDA as part of an application for a research or marketing permit.

16. **Test Article:** A drug for human use (including botanical, biological, and gene therapy and genetically-derived products), a medical device for human use, an electronic product, or any other article subject to regulation under the jurisdiction of the FDA.

17. **Vulnerable Subjects:** Individuals who lack the capacity to provide informed consent or whose willingness to participate in research may be subject to undue influence or coercion. Vulnerable subjects include, for example, children, prisoners, individuals with emotional or cognitive disorders/impairments, and economically- or educationally-disadvantaged persons.

**POLICY SPECIFICATIONS**

1. **GENERAL REQUIREMENTS**
   1.1. No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the
subject's legally authorized representative (LAR), unless:

1.1.1. The Institutional Review Board (IRB) has approved a waiver/alteration of consent; or

1.1.2. It is a life-threatening situation in which standard acceptable treatment is not available, and there is not time to convene a quorum for full-board IRB review and approval. Refer to “IRB Emergency Use or Compassionate Use Review PGR.”

1.2. An investigator may seek consent only under circumstances that provide the prospective subject or the LAR with sufficient opportunity to consider whether or not to participate while under circumstances that minimize the possibility of coercion or undue influence.

1.3. The information that is given to the subject or the LAR must be in language understandable to the subject or the representative.

1.4. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights or include any exculpatory language which releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

2. ELEMENTS OF INFORMED CONSENT

2.1. The following information must be included in the informed consent, unless a waiver/alteration of consent is approved by the IRB:

2.1.1. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

2.1.2. A description of any reasonably foreseeable risks or discomforts to the subject.

2.1.3. A description of any benefits to the subject or to others which may reasonably be expected from the research.

2.1.4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

2.1.5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and, when appropriate, that notes the possibility that the Food and Drug Administration (FDA) may inspect the records.

2.1.6. For research involving more than minimal risk, an explanation as to whether any compensation and whether any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained.

2.1.7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights and whom to contact in the event of a research-related injury to the subject.

2.1.8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

2.2. When the consent is for applicable clinical trial, the following statement must be included: “A description of this clinical trial will be available on
http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”

2.3. When appropriate, one (1) or more of the following elements of information must also be provided to each subject:

2.3.1. A statement that the particular practice, treatment, or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

2.3.2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

2.3.3. Any additional costs to the subject that may result from participation in the research.

2.3.4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

2.3.5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

2.3.6. The approximate number of subjects involved in the study.

3. PALMETTO HEALTH STANDARD LANGUAGE

3.1. The following information must be included:

“If you have questions, concerns, or complaints or think the research has hurt you, talk to the investigator [Insert name of the investigator] or research team at [Insert contact information for the research team]

This research has been reviewed and approved by the Palmetto Health Institutional Review Board. You may talk to them at (803) 434-2884 or Research-Assist@palmettohealth.org for any of the following:

• Your questions, concerns, or complaints are not being answered by the research team.
• You cannot reach the research team.
• You want to talk to someone besides the research team.
• You have questions about your rights as a research subject.
• You want to get information or provide input about this research.”

3.2. For research involving more than minimal risk the following information must be included:

“If you need medical care because of taking part in this research study, contact the investigator, and medical care will be made available. Generally, the financial costs this care will continue to be your responsibility and will be billed to you or to your insurance. Palmetto Health has no program to pay for medical care for research-related injuries.” In the event the research sponsor is assuming responsibility for payment of research-related injury, the above paragraph may be revised as appropriate, but in no case can imply that the Palmetto Health will assume any financial responsibility. The language should be as identical as possible to that on the clinical trial agreement while incorporating the above paragraph as closely as possible.

3.3. For research involving genetic studies include the following information must be included:
“In some cases, a federal law called the Genetic Information Nondiscrimination Act (GINA) makes it illegal for health insurance companies, group health plans, and employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

But you should know that there are limitations to this law. For example, it does not apply to life insurance, disability insurance, or long-term care insurance. An abnormal genetic test could result in denial or much higher rates for life insurance, disability insurance, or long-term care insurance if your genetic test results were to become known. If you have questions about GINA or the risks of research on genetic information, please ask your study doctor or nurse.”

4. ALTERATION / WAIVER OF INFORMED CONSENT

4.1. The IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent or that waives the requirement to obtain informed consent provided the IRB finds and documents that:

4.1.1. The research involves no more than minimal risk to the subjects;
4.1.2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
4.1.3. The research could not practicably be carried out without the waiver or alteration; and
4.1.4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

4.2. The IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent or that waives the requirements to obtain informed consent provided the IRB finds and documents that:

4.2.1. The research or demonstration project is to be conducted by, or subject to the approval of, state or local government officials and is designed to study, evaluate, or otherwise examine:
4.2.1.1. Public benefit or service programs;
4.2.1.2. Procedures for obtaining benefits or services under those programs;
4.2.1.3. Possible changes in or alternatives to those programs or procedures; or
4.2.1.4. Possible changes in methods or levels of payment for benefits or services under those programs; and
4.2.2. The research could not practicably be carried out without the waiver or alteration.

4.3. The IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent or that waives the requirements to obtain
informed consent provided the IRB finds and documents that all of the requirements for emergency research are met. Refer to the CHECKLIST Waiver of Consent Process for Emergency Research.

5. DOCUMENTATION OF INFORMED CONSENT

5.1. Informed consent must be documented by the use of a written consent form approved by the IRB that is signed and dated by the subject or the subject's LAR at the time of consent, unless the IRB has waived the requirement for a signed consent form. A copy must be given to the person signing the form.

5.2. The consent form may be either of the following:
   5.2.1. A written consent document that embodies the elements of informed consent required by Section 2, Elements of Informed Consent. The form may be read to the subject or the subject's LAR, but, in any event, the investigator must provide either the subject or the LAR with an adequate opportunity to read it before it is signed;
   5.2.2. A short form written consent document stating that the elements of informed consent required by Section 2, Elements of Informed Consent, have been presented orally to the subject or the subject's LAR. When this method is used, there must be a witness to the oral presentation. Also, the IRB will approve a written summary of what is to be said to the subject or the LAR.

   5.2.2.1. Only the short form is to be signed and dated by the subject or the LAR.
   5.2.2.2. The witness must sign and date both the short form and a copy of the summary.
   5.2.2.3. The person actually obtaining consent must sign and date a copy of the summary.
   5.2.2.4. A copy of the summary will be given to the subject or the LAR, in addition to a copy of the short form.

5.3. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
   5.3.1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; or
   5.3.2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
   5.3.3. For cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

6. VULNERABLE SUBJECTS

6.1. The IRB will require additional elements of informed consent when research involves vulnerable subjects, including pregnant women, fetuses, neonates, and children.

REFERENCES
The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research
45 CFR Part 46
21 CFR Part 50
ICH E6 Good Clinical Practice Guidelines
Informed Consent Policy

Spinale, Francis (VP, Research)
11/04/2015
NOTHING CONTAINED IN THIS POLICY OR IN ANY OTHER POLICY CREATES A CONTRACT RIGHT. CONSISTENT WITH SOUTH CAROLINA LAW, ALL EMPLOYEES ARE EMPLOYED "AT WILL," WHICH MEANS THAT THE EMPLOYEE HAS THE RIGHT TO TERMINATE HIS OR HER EMPLOYMENT AT ANY TIME, WITH OR WITHOUT NOTICE OR CAUSE, AND THAT PALMETTO HEALTH RETAINS THE SAME RIGHT. EXCEPTIONS TO THE POLICY THAT ALL EMPLOYEES ARE EMPLOYED "AT WILL" MAY BE MADE ONLY BY WRITTEN AGREEMENT SIGNED BY THE PRESIDENT AND CEO OF PALMETTO HEALTH.

IRB Review Fees

Policy Statement
To establish a fee schedule for the federally mandated responsibility to protect human subjects involved in research. Institutional Review Board (IRB) review fees will be charged to maintain the expertise and efforts needed to perform the numerous components of appropriate review, assessment and approval of research protocols. The IRB fee must be included as part of the IRB review proposal at the time of submission.

DEFINITIONS

1. **Adverse event:** Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject’s participation in the research, whether or not considered related to the subject’s participation in the research. Adverse events encompass both physical and psychological harms.

2. **Institutional Review Board (IRB):** An administrative body composed of scientists and non-scientists established to protect the rights and welfare of human subjects recruited to participate in research.

3. **Investigator:** An individual having the background and training in scientific and administrative oversight to conduct and manage research activities. Investigator includes principal investigators and sub/co-investigators. The Food and Drug Administration (FDA) uses the term sub-investigators. For purposes of these policies the term co-investigator will be used.

4. **Principal Investigator (PI):** The individual ultimately responsible for oversight of all research activities. He/she is ultimately responsible for all communication with the IRB (via
the Office of Research Administration) regarding that research. The principal investigator accepts responsibility for training all personnel associated with the study in compliance with the human subject regulations of 45 CFR 46.

5. **Unanticipated problem involving risks to subjects or others (Unanticipated problem):**

   Any incident, experience, or outcome that meets all of the following criteria:

   5.1. Unexpected (in terms of nature, severity, or frequency) given:

   5.1.1. the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol, and any applicable investigator brochure, the current IRB-approved informed consent document, and other relevant sources of information, such as product labeling and package inserts; and

   5.1.2. the characteristics of the subject population being studied or the expected natural progression of any underlying disease, disorder, or condition of the subject experiencing the adverse event and the subject’s predisposing risk factor profile for the adverse event;

   5.1. Related or possibly related to a subject’s participation in the research (possibly related means there is a reasonable possibility that the adverse event, incident, experience or outcome may have been caused by the procedures involved in the research); and

   5.1. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

**POLICY SPECIFICATIONS**

1. **Protocol Processing Fee Structure**

<table>
<thead>
<tr>
<th>Types of Review</th>
<th>Full Board</th>
<th>Expedited</th>
<th>Exempt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Review</td>
<td>$2500.00</td>
<td>$1500.00</td>
<td>$500.00</td>
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<tr>
<td>Facilitated Review</td>
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<td>$500.00</td>
<td>n/a</td>
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<tr>
<td>(One time fee)</td>
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<tr>
<td>Continuing Review</td>
<td>$500.00</td>
<td>$250.00</td>
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</tr>
<tr>
<td>Amendment</td>
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<td>$150.00</td>
<td>$100.00</td>
</tr>
<tr>
<td>Reportable Event*</td>
<td>$20.00</td>
<td>$10.00</td>
<td>n/a</td>
</tr>
</tbody>
</table>

   *Reportable Event submissions other than the categories of information required by IRB Reporting New Information PGR.

   1.1. The initial IRB protocol review fee is a one-time non-refundable charge. Investigators submitting applications for new industry-sponsored clinical trials need to include a line item in the budget that reflects these charges.

   1.2. The continuing review, modification and adverse event fee is incurred at the time of the submission.

   1.3. Palmetto Health IRB requires payment at the time of submission.

   1.4. Payment of IRB fees are the responsibility of the Principal Investigator. It is expected that Investigators will incorporate and negotiate the applicable IRB fees into the research contract.

2. **Approved/Tabled/Denied**
2.1. The review process and timetable for submissions will remain the same. The IRB review fee is payable regardless of approval and is used to offset costs associated with the review process.

2.2. The IRB review fee will be incurred even if subjects are not enrolled, the study terminates, expenditures exceed revenue, desired results or expectations are not met, and/or contract has not reached finality. If there is uncertainty as to contract finality, the sponsor, and PI may wish to delay incurring these charges until all plans are final.

3. IRB Fee Review

3.1. The fee amounts will be reviewed periodically and are subject to change at the discretion of Palmetto Health.

4. Fee Exclusions

4.1. The following submissions are not subject to this policy:
   4.1.1. Protocols sponsored by Federal, State, County, and Local government, or not for profit organizations.
   4.1.2. Investigator initiated protocols without sponsorship.
   4.1.3. Protocols sponsored by funding agencies that prohibit payment of IRB fees.
   4.1.4. Applications for a non-research use of a Humanitarian Use Device.
   4.1.5. Applications for emergency use of an investigational drug or device.

5. Checks should be sent to the Palmetto Health IRB office. Checks should be made payable to “Palmetto Health IRB”, referencing “IRB Fee” and the assigned Palmetto Health IRB number or Pro number, to the attention of the Business Analyst. Electronic payment arrangements can be coordinated through the Business Analyst.

Katherine Stephens
Sys VP, Medical Ed. & Research
03/16/2015
DEFINITIONS:

3. *Non-Compliance*: Failure to follow the regulations, or the requirements or determinations of the IRB.

RESPONSIBLE POSITIONS (TITLE):

IRB Consent Observer

EQUIPMENT NEEDED:

NA

PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATION

1. **PURPOSE**
   
   1.1. This procedure establishes the process to observe the consent process.
   
   1.2. The process begins when the IRB determines that the consent process should be observed.
   
   1.3. The process ends when the IRB determines that the consent process no longer should be observed.

2. **GUIDELINES**
2.1. The IRB may consider observation of the consent process when:
   2.1.1. The IRB wants verification from sources other than the investigator that no material changes have taken place since prior IRB review.
   2.1.2. There are Allegations or Findings of Non-Compliance.
   2.1.3. The nature of the research indicates that the consent process can be improved through observation.
   2.1.4. The observation will be utilized for quality improvement of the human research protection program.

2.2. The IRB, Organizational Official, or designee designates who conducts the observation. The IRB may have the observation conducted by:
   2.2.1. IRB Administration staff or Research Compliance staff.
   2.2.2. IRB members.
   2.2.3. An independent person hired by the IRB, but paid for by the investigator’s funds.

3. PROCEDURE
   3.1. Observe the consent process and determine whether the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject or the subject’s legally authorized representative, and that informed consent was freely given by the subject or the legally authorized representative.
      3.1.1. If no, indicate to the principal investigator that consent is not legally effective and the prospective subject may not be entered into the research. Document in writing that the consent process was observed and that the informed consent given by the subject or legally authorized representative was not legally effective.
      3.1.2. If yes, document in writing that the consent process was observed and that informed consent was freely given by the subject or legally authorized representative.
   3.2. Submit the written documentation to the IRB.

REFERENCES
NA
Definitions

1. **Legal Counsel:** A licensed attorney employed by Palmetto Health to function in that professional capacity who is overseen by General Counsel of Palmetto Health.

2. **Minimal Risk:** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Responsponsible Positions

**Principal Investigator**

Procedure Steps, Guidelines, or Reference

1. **PURPOSE**
   1.1. This guideline establishes Palmetto Health Legal Counsel’s opinion of which individuals meet the following US Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) definitions when the research is conducted in South Carolina:
      1.1.1. Legally authorized representative
      1.1.2. Children
      1.1.3. Guardian

2. **GUIDELINES**
2.1. Under DHHS and FDA regulations, a “legally authorized representative” means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research. Unless the IRB has waived the requirement to obtain consent, when research involves adults who are unable to consent, permission must be obtained from a legally authorized representative. When research is conducted in South Carolina, the following individuals meet this definition:

2.1.1. For medical research and Minimal Risk non-medical research:
   2.1.1.1. Persons who follow the order of priority described in Palmetto Health Policy No. B.09, Informed Consent.
   2.1.1.2. Individual, organization or agency, if one has been appointed legal guardian of the potential subject found to be incompetent by a court of competent jurisdiction.

2.1.2. For all other research, Legal Counsel has to determine that the individuals proposed to serve as legally authorized representatives meet the federal definition of “legally authorized representative.”

2.2. For research outside of South Carolina, a determination of who meets the DHHS and FDA definitions of “legally authorized representative” is to be made in consultation with Legal Counsel.

2.3. Under DHHS and FDA regulations, “children” are persons who have not attained the legal age to consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. Subpart D of the DHHS must be applied if and only if an individual involved in the research meets this definition. When research is conducted in South Carolina, all individuals under the age of 18 (eighteen) years meet this definition with the following exceptions:

2.3.1. Emancipated minors, defined as individuals who meet one (1) of the following criteria, do not meet the DHHS and FDA definition of “children”:
   2.3.1.1. Married/widowed/divorced;
   2.3.1.2. A court order emancipating the minor.

2.3.2. Individuals under the age of 18 (eighteen) when the research procedures are limited to:
   2.3.2.1. Diseases dangerous to the public health;
   2.3.2.2. Drug dependency (but not alcohol dependency); or
   2.3.2.3. Pregnancy, unless the procedures involved in the research include abortion as described below.

2.3.3. Exception: If the research procedures involve abortion, females under the age of 18 (eighteen) who are not (and have never been) married meet the DHHS and FDA definition of “children.”

2.4. For research outside South Carolina, a determination of who meets the DHHS and FDA definitions of “children” is to be made in consultation with Legal Counsel.

2.5. Under DHHS and FDA regulations, a “guardian” means an individual who is authorized under applicable state or local law to consent (to general medical care) on
behalf of a child. When research involves children and parental permission is required, consent may only be obtained from parents (biologic or adoptive) or a guardian as defined by DHHS and FDA regulations.

REFERENCES
45 CFR 46.102, 45 CFR 46.402
21 CFR §50.3
DEFINITIONS:

1. **Non-Disclosure Agreement**: An agreement that imposes obligations on a party receiving confidential information from a disclosing party; the main obligation of the receiving party is not to disclose such private information to a third party.

RESPONSIBLE POSITIONS (TITLE):

IRB Administrator
IRB Chair
IRB Vice-Chair

EQUIPMENT NEEDED:

FORM: IRB Guest Non-Disclosure Agreement

PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATION

1. **Purpose**
   1.1. This procedure establishes the process for allowing guests to attend an IRB meeting.
   1.2. The process begins when the IRB Administrator is advised of a request for attendance.
   1.3. The process ends when the IRB meeting ends and the documentation is filed with the IRB Administration office.

2. **Procedure**
   2.1. Individuals not associated with Palmetto Health IRB, are considered guests and may be permitted to observe an IRB meeting as guests under the following conditions:
       2.1.1. Persons interested in attending an IRB meeting should contact the local IRB Administrator prior to the meeting date.
       2.1.2. Guest attendance will be allowed at the discretion of the IRB Chair, relevant Vice Chair, and/or IRB Administrator.
2.1.3. Principal Investigator, Co-Investigator, and/or Research Staff that attend the IRB meeting solely for the presentation of their research are not guests for the purpose of this guidance.

2.2. Non-Disclosure Agreement

2.2.1. Guests who attend an IRB meeting will be reminded of the confidential nature of the Palmetto Health IRB’s meetings.

2.2.2. Guests who attend an IRB meeting must sign the IRB Guest Non-Disclosure Agreement prior to the start of the meeting.

2.2.3. The IRB Administrator will maintain the signed IRB Guest Non-Disclosure Agreement on file in the IRB Administration office for as long as the IRB Minutes are retained.
Definitions

1. National Cancer Institute (NCI) Central Institutional Review Board (CIRB) Independent Review: A review process for NCI sponsored research studies under which the CIRB is the sole IRB of Record responsible for both study review as well as review of local context considerations.

Responsible Positions

IRB Manager or designee
Principal Investigator or designee
Study Staff

Equipment Needed

Clinical Trials Support Unit (CTSU) access
IRBManager access
National Cancer Institute Central Institutional Review Board (NCI CIRB) Initiative access

Procedure Steps, Guidelines, or Recommendations

1. PURPOSE
   1.1. This document details the documentation of NCI CIRB reviewed and approved studies.
2. GUIDELINES
   2.1. The “Studies” section of IRBManager lists all active studies and all studies ever reviewed.
submitted to the NCI CIRB.

2.2. The NCI CIRB “Participant’s Area” contains all study specific-documents related to NCI CIRB reviews prior to September 26, 2014.

2.3. The CTSU “Regulatory” section contains study specific documents related to NCI CIRB reviews since September 26 2014.

3. PROCEDURE

3.1. Submission of Worksheets in IRBManager

3.1.1. The IRB Manager completes and submits the “Annual Institutional Worksheet about Local Context.”

3.1.2. The Principal Investigator completes and submits the “Annual Principal Investigator Worksheet about Local Context.”

3.1.3. The Principal Investigator completes and submits the “Study-Specific Worksheet about Local Context” to open a study.

3.1.4. The Principal Investigator completes and submits the “Study Closure or Transfer of Study IRB Review Responsibilities” to close a study or transfer study IRB review responsibility from the CIRB to another IRB.

3.1.5. The Principal Investigator completes and submits the “Potential Unanticipated Problem or Serious or Continuing Noncompliance” to report potential unanticipated problems or serious or continuing noncompliance to the CIRB.

3.2. The Principal Investigator has the responsibility of merging the CIRB-approved local boilerplate text into the CIRB-approved consent document. No further CIRB review is required because both components are already CIRB-approved.

3.3. The Principal Investigator has the responsibility to maintain a regulatory file for each study reviewed by NCI CIRB.

3.4. Actions to ensure the safe and appropriate performance of the research include:

3.4.1. Ensuring the initial and ongoing qualifications of investigators and study staff through validation of CITI training prior to submitting the “Annual Institutional Worksheet about Local Context.”

3.4.2. Inclusion of NCI CIRB approved studies in the Research Audit program.

3.4.3. Inclusion of a mechanism to receive and address concerns from participants and others in the boilerplate language.

3.5. Whenever a Principal Investigator is no longer the responsible party for a study, the IRB Manager notifies the NCI CIRB at 1-888-657-3711 or via email ncicirbcontact@emmes.com.

3.6. When a regulatory deficiency has been cited on an audit that occurred during the NCI CIRB approval period the IRB Manager notifies the NCI CIRB at 1-888-657-3711 or via email ncicirbcontact@emmes.com.
IRB User Management PGR

Effective: 05/18/2016
Reviewed: 05/18/2018

Name of Associated Policy: Human Research Protection Program Policy

DEFINITIONS:

1. **Collaborative Institutional Training Initiative (CITI):** A web-based provider of research education training.

2. **eIRB:** A web-based system for IRB submissions, review, and management. It is a paperless, electronic method to submit, track, and route all submission types through the approval process and provides a means to document information required for the review of human subject research. This includes the initial application, amendments, reportable events and continuing renewal submissions.

3. **Health Sciences South Carolina (HSSC):** A state-wide biomedical research collaborative.

4. **Independent Contractor:** A self-employed person who provides certain services to a second-party or to a third party on behalf of a client. An independent contractor is under the control, guidance or influence of the client or second party and unlike an employee does not owe a fiduciary duty. To be legally designated as an independent contractor, an individual must (1) be free from the control of the client, (2) be able to exercise his or her judgment as to the manner and methods to accomplish the end-result and (3) be responsible for the end-result only under the terms of the contract.

5. **InfoEd:** A web-based IRB administration application.

6. **Institutional Review Board (IRB):** An administrative body composed of scientists and non-scientists established to protect the rights and welfare of human subjects recruited to participate in research.

7. **Investigator:** An individual having the background and training in scientific and administrative oversight necessary to conduct and manage research activities.

8. **National Cancer Institute (NCI):** The federal government’s principal agency for cancer research and training.

9. **Research Staff:** Individuals who assist in a research project overseen by an Investigator.

10. **Workforce Member:** Refers to employees, independent contractors, volunteers, students, trainees, medical residents, fellows and other persons whose conduct in the performance of
work for Palmetto Health is under the control of the organization, regardless of whether the individuals are receiving compensation from Palmetto Health.

RESPONSIBLE POSITIONS:

IRB Manager or designee

EQUIPMENT NEEDED:

eIRB access
Internet access

PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATIONS

1. PURPOSE
   1.1. This procedure describes the process to manage requests for access to electronic research systems.
   1.2. The process begins when a request is received.
   1.3. The process ends when a notification is sent indicating the request for access is approved or denied.

2. PROCEDURE
   2.1. To manage eIRB User accounts refer to the HSSC document “Managing eIRB User Registration.”
   2.1.1. If the request is from a Workforce Member assign access rights (User Roles) based on the individual’s research related function (Appendix). Make certain Student/Trainee? is “No.” Variations may be requested at the discretion of the Director of Research.
   2.1.2. If the request is from a non-workforce Member affiliated with a HSSC organization, instruct the individual to register through the affiliated organization.
   2.1.3. If the request is from a non-workforce member not affiliated with a HSSC organization:
   2.1.3.1. If access is required to support research overseen by Palmetto Health, assign access rights (User Roles) based on the individual’s research related role (Appendix).
   2.1.3.2. If access is not required to support research overseen by Palmetto Health, notify the individual of the reason access is denied.

2.2. To manage CITI Administrator accounts contact citisupport@med.miami.edu. Include the following information:
   2.2.1. the username or member ID and name of the person to be granted admin access,
   2.2.2. the research categories this account should have access to (humans, lab animals, RCR),
   2.2.3. if this person should receive email notifications when a learner completed a course.

2.3. To manage Additional Site Access as necessary for IRB function:
2.3.1. for HSSC accounts (Redmine, Testing, Switcher, Wiki) submit the request through Service Desk – OBIS Issue Tracker.

2.3.2. for NCI CIRB accounts instruct the user to complete the CTSU Registration application. When registration is complete add user to the Regulatory Support System (RSS) roster, IRBManager and NCI CIRB Participant’s area.

2.3.3. for InfoEd accounts create a User account, and assign Institutional Administrator Role.
## Appendix

### User Role by IRB Function

<table>
<thead>
<tr>
<th>IRB Function</th>
<th>eIRB User Role</th>
<th>CITI User Role</th>
<th>Additional Site Access</th>
</tr>
</thead>
</table>
| Investigator / Research Staff | • Co-Investigator  
                                 | • Principal Investigator  
                                 | • Registered User  
                                 | • Study Coordinator  
                                 | • Study Staff | • Not Applicable | • Not Applicable |
| IRB Member                  | • IRB Committee Member  
                                 | • Registered User  
                                 | • Study Staff | • Not Applicable | • Not Applicable |
| IRB Chair, IRB Vice Chair   | • IRB Committee Chair  
                                 | • IRB Committee Member  
                                 | • Registered User  
                                 | • Study Staff | • Not Applicable | • Not Applicable |
| Ancillary Committee         | • Ancillary Committee Roles  
                                 | • Dept/Div Approvers  
                                 | • Registered User  
                                 | • Study Staff | • Not Applicable | • Not Applicable |
| IRB Administration Staff    | • Account Managers*  
                                 | • Account Managers – PH*  
                                 | • CITI Administrators – PH*  
                                 | • IRB Committee Lead  
                                 | • IRB Committee Member  
                                 | • IRB Coordinator  
                                 | • IRB Lead*  
                                 | • IRB Staff (Parent role)  
                                 | • Palmetto IRB Staff  
                                 | • Principal Investigator  
                                 | • Registered User  
                                 | • Study Coordinator  
                                 | • Study Staff | • Institutional Administrator* | • HSSC*  
                                 | • Dashboard – HSSC - SCTR Wiki  
                                 | • Service Desk – OBIS Issue Tracker  
                                 | • eIRB Switcher  
                                 | • eIRB Staging Test  
                                 | • NCI*  
                                 | • CTSU  
                                 | • IRBManager  
                                 | • NCI CIRB Participant’s Area  
                                 | • InfoEd*  
<pre><code>                             | • Institutional Administrator |
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* As necessary, determined by IRB Manager
IRB Incoming Information PGR

Effective: 03/02/2015
Reviewed: 03/02/2015

Name of Associated Policy: Human Research Protection Program

Responsible Positions
Equipment Needed
Procedure Steps
References

RESPONSIBLE POSITIONS (TITLE):
IRB Administrator
IRB Coordinator
IRB Manager

EQUIPMENT NEEDED:
eIRB access

PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATION

1. PURPOSE
   1.1. This procedure describes how information received by the IRB is processed.
   1.2. The procedure begins when any information is received by the IRB.
   1.3. The procedure ends when appropriate action is determined.

2. PROCEDURE
   2.1. Date stamp paper information with received date.
   2.2. If the information is a submission for review and approval (new study, continuing
         review, or amendment), or a determination of Exempt Human Subject Research or Not
         Human Subject Research follow “IRB Pre-Review PGR”.
   2.3. If the information is a response to a modification required for approval, follow “IRB
         Modifications Required for Approval PGR”.
   2.4. If the information represents a prior notification of or a five day notification after, an
         emergency use of a test article, assign to a Non-Committee Reviewer to follow “IRB
         Emergency Use or Compassionate Use Review PGR”.
   2.5. If the information is a request from an investigator to continue subjects in an expired
         study, assign to a Non-Committee Reviewer to follow “IRB Review of Request to
Continue Subjects in an Expired Study PGR”.

2.6. If the information represents a completed IRB review, follow “IRB Post-Review PGR”.

2.7. If the information is a request for eIRB access, follow “eIRB User Management PGR”.

2.8. If the information does not fit into the above categories (i.e. a question, concern or complaint):

   2.8.1. Document the information, date received and the contact information of the person submitting the information.

   2.8.2. Answer questions that are basic or general in nature. For more complicated questions inform the person when and how you will follow up with the information.

   2.8.3. Follow “IRB Reportable New Information PGR”.

REFERENCES
- eIRB User Management PGR
- IRB Emergency Use or Compassionate Use Review PGR
- IRB Modifications Required for Approval PGR
- IRB Post-Review PGR
- IRB Pre-Review PGR
- IRB Reportable New Information PGR
- IRB Review of Request to Continue Subjects in an Expired Study PGR
IRB Pre-Review PGR

Effective: 10/21/2015
Reviewed: 10/21/2015

Name of Associated Policy: Human Research Protection Program

Definitions

1. Administrative Review: Any of the following:
   1.1. Not Human Research Determination
   1.2. Exempt Human Research Determination
   1.3. Review of Reportable Event submission not involving:
       1.3.1. Serious Non-Compliance or,
       1.3.2. Continuing Non-Compliance or,
       1.3.3. Serious and Continuing Non-Compliance or,
       1.3.4. An Unanticipated Problem Involving Risk to Subjects or Others.
   1.4. Review of Status Change
   1.5. Review of Study Closure
2. Non-Committee Reviewer: An Expedited Reviewer or an Administrative Reviewer.
3. Non-Committee Review: An Expedited or Administrative Review.
4. Expedited Review: Any of the following:
   4.1. Review of non-exempt research using the expedited procedure.
   4.2. Determinations of which subjects can continue in expired research.
   4.3. Review of notifications of emergency uses of test articles.

RESPONSIBLE POSITIONS (TITLE):

IRB Administrator

EQUIPMENT NEEDED:
PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATION

1. PURPOSE
   1.1. This procedure establishes the process for pre-review of a request for approval (approval of new research study, continuing review of research, or an amendment to previously approved research) or a determination whether an activity is exempt Human Research or is not Human Research.
   1.2. The procedure begins when a request for approval or determination is submitted.
   1.3. The procedure ends when the determination letter is sent or the submission is assigned to a Non-Committee Reviewer or placed on an IRB agenda.

2. PROCEDURE
   2.1. If the submission is a response to modifications required to secure approval:
      2.1.1. Evaluate whether the investigator made the required modifications.
      2.1.2. If the investigator made the required modifications, follow IRB Post-review PGR to issue an approval.
      2.1.3. If the investigator did not make the required modifications, contact the investigator. Offer the investigator the opportunity to make the required modifications.
         2.1.3.1. If the investigator will make the required modifications, have the investigator resubmit and stop processing the current submission.
         2.1.3.2. If the investigator will not provide additional information, continue processing.
   2.2. For all other submissions complete the CHECKLIST: Pre-Review or review the previously completed CHECKLIST: Pre-Review and revise as needed, note all remaining contingencies in the “Final Contingencies” section and upload with “Log Private Comment”.
   2.3. If the research represents a type of research which according to “HUMAN RESEARCH PROTECTION PROGRAM” policy the organizational does not conduct or oversee, inform the investigator.
      2.3.1. If the investigator withdraws the submission, stop processing the current submission.
2.3.2. If the investigator will not withdraw the submission, inform the investigator the research is not overseen by Palmetto Health and will not be reviewed.

2.4. If the information is not complete, return the submission to the investigator with “Changes Required by IRB Staff”.

2.4.1. If the investigator will not provide additional information, inform the investigator incomplete application will not be reviewed.

2.5. If the request is for a determination of Not Human Subject Research:

2.5.1. Complete the CHECKLIST: Human Subject Research Determination and upload with “Log Private Comment”.

2.5.2. Complete and send, TEMPLATE LETTER: Not Human Subject Research.

2.6. If the request is for a determination of exemption without a HIPAA waiver or alteration:

2.6.1. Complete the CHECKLIST: Exempt Determination and upload with “Log Private Comment”.

2.6.2. Complete and send, TEMPLATE LETTER: Exempt Human Subject Research.

2.7. If the request is for a study closure complete and send TEMPLATE LETTER: Acknowledgement of Protocol Closure.

2.8. If the request can be handled through Non-Committee Review follow IRB Non-Committee Review Preparation.

2.9. If the request cannot be handled through Non-Committee Review schedule the protocol to be reviewed by the next convened IRB.
IRB Modifications Required for Approval PGR

Effective: 02/22/2013
Reviewed: 01/29/2015

Name of Associated Policy: Human Research Protection Program

**Responsible Positions**
**Equipment Needed**
**Procedure Steps**
**References**

**RESPONSIBLE POSITIONS (TITLE):**
IRB Administrator

**EQUIPMENT NEEDED:**
eIRB Access

**PROCEDURE STEPS, GUIDELINES, OR REFERENCE**

1. **PURPOSE**
   1.1. This procedure establishes the process to handle investigator submissions of modifications required to secure approval.
   1.2. The process begins when a response to modifications required to secure approval are received by the IRB.
   1.3. The process ends when the acceptance or rejection of the modifications is provided to the investigator.

2. **PROCEDURE**
   2.1. Confirm whether the investigator made the required changes.
   2.2. If the investigator made the required changes within 90 days of the IRB meeting date, follow “IRB Post-Review PGR” to issue an approval and stop further processing.
   2.3. If the investigator made the required changes after 90 days of the IRB meeting date, follow “IRB Pre-Review PGR.”
   2.4. If the investigator did not make the required changes, contact the investigator and offer the opportunity to make the changes.
      2.4.1.1. If the investigator will make the changes, return the submission to the investigator to allow investigator to make the changes.
2.4.2. If the investigator will not make the changes, follow “IRB Pre-Review PGR.”
IRB Emergency Use or Compassionate Use Review PGR

Effective: 10/21/2015
Reviewed: 10/21/2017

Name of Associated Policy: Human Research Protection Program

Definitions
Responsible Positions
Equipment Needed
Procedure Steps
References

DEFINITIONS:

1. Expedited Reviewer: The IRB chair or an experienced IRB member designated by the chair.
2. Emergency: A situation in which all of the following conditions exist:
   2.1. Life-threatening disease or serious condition.
   2.2. No generally accepted alternative for treating the condition is available
   2.3. There is no time to use existing procedures to obtain FDA approval of an IDE.
3. Non-Compliance: Failure to follow the regulations, or the requirements or determinations of the IRB.
   3.1. In the case of research funded or conducted by the Department of Defense (DOD), Non-Compliance includes failure of a person, group, or institution to act in accordance with Department of Defense (DOD) instruction 3216.02, its references, or applicable requirements.
4. Test article: Any drug (including a biological product for human use), medical device for human use, or any other article subject to regulation under the act or under sections 351 and 354–360F of the Public Health Service Act.

RESPONSIBLE POSITIONS (TITLE):

Expedited Reviewer

EQUIPMENT NEEDED:

eIRB access
CHECKLIST: Emergency/Compassionate Use

PROCEDURE STEPS, GUIDELINES, OR REFERENCE

1. PURPOSE
   1.1. This procedure establishes the process to review notifications of:
1.1.1. Emergency use of a drug, biologic, or device in a life-threatening situation.
1.1.2. Compassionate use of an unapproved device for a serious condition, with an IDE supplement and FDA concurrence.
1.2. The process begins when the IRB receives a notification of a proposed or actual use.
1.3. The process ends when a Designated Reviewer has:
   1.3.1. Determined whether the proposed or actual use will follow or has followed FDA-regulation and guidance; and
   1.3.2. Notified the physician and IRB staff of the determination.

2. GUIDANCE
   2.1. Whenever possible physicians are to notify the IRB of a proposed emergency use of a drug, biologic, or device in a life-threatening situation in advance of the use.
   2.2. Physicians are to notify the IRB of a proposed compassionate use of an unapproved device with an IDE supplement and FDA concurrence for a serious condition.
   2.3. Under FDA regulations, the emergency use of a test article, other than a medical device, is a clinical investigation, the patient is a participant, and the FDA may require data from an emergency use to be reported in a marketing application.
   2.4. DHHS regulations do not permit data obtained from patients to be classified as human subject research, nor permit the outcome of such care to be included in any report of a research activity subject to DHHS regulations.

3. PROCEDURE
   3.1. Use the “CHECKLIST: Emergency/Compassionate Use” to determine whether the circumstances will meet the regulatory and guidance criteria and indicate the results of this determination to the physician.
      3.1.1. If met, inform the physician that the physician can proceed with the use.
      3.1.2. If not met, inform the physician that if the physician proceeds with the use, the IRB will consider that action to be Non-Compliance.
   3.2. For notifications after the emergency use of a test article in a life-threatening situation use the “CHECKLIST: Emergency/Compassionate Use” to determine whether the circumstances met the regulatory and guidance criteria.
   3.3. Inform IRB staff of the results of the evaluation.

REFERENCES
21 CFR 50.23
21 CFR 56.104(c)
21 CFR 812.35(a)(2)
21 CFR 812.150(a)(4)
DEFINITIONS:

1. **Continuing Non-compliance**: A pattern of repeated actions or omissions taken by an Investigator that indicates a deficiency in the ability or willingness of an Investigator to comply with Federal regulations, Palmetto Health policies and/or PGRs, determinations of the Institutional Review Board, or provisions of the approved research study.

2. **Non-Compliance**: Failure to follow the regulations, or the requirements or determinations of the IRB.
   
   2.1. In the case of research funded or conducted by the Department of Defense, Non-Compliance includes failure to comply with the Department of Defense directives regarding protection of Human Subjects.
   
   2.2. In the case of research funded or conducted by the Department of the Navy, Non-Compliance includes failure to comply with the Department of the Navy instructions regarding protection of Human Subjects.

3. **Research misconduct**: Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting results. Research misconduct does not include honest error or differences of opinion.

4. **Serious Non-Compliance**: An action or omission taken by an Investigator that any other reasonable Investigator would have foreseen as compromising the rights and welfare of a participant. The following events will in most cases be considered Serious Non-compliance:
   
   (i) the conduct of any non-exempt research involving human subjects without IRB review and approval;
   
   (ii) enrollment of any human subject in a research study involving greater than minimal risk without informed consent; or
   
   (iii) implementation of substantive modifications
involving possible risks to human subjects or others without IRB review and approval.

5. **Suspension of IRB Approval**: An action initiated by the IRB to stop temporarily some or all research procedures pending future action by the IRB or by the Investigator or his/her study personnel.

6. **Termination of IRB Approval**: An action initiated by the IRB, IRB designee, Organizational Official, or designee of the Organizational Official to stop permanently some or all research procedures. Termination of IRB Approval due to expiration of approval is not reportable.

7. **Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO)**: In general, any incident, experience, or outcome that meets all of the following criteria:
   - 7.1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
   - 7.2. related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
   - 7.3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, social, or legal) than was previously known or recognized. (Examples include but are not limited to: (1) death; (2) life threatening adverse experience; (3) hospitalization - inpatient, new, or prolonged; (4) disability/incapacity - persistent or significant; (5) birth defect/anomaly; (6) breach of confidentiality and (7) other problems, events, or new information (i.e. publications, DSMB reports, interim findings, product labeling change) that in the opinion of the local investigator may adversely affect the rights, safety, or welfare of the subjects or others, or substantially compromise the research data.)

**RESPONSIBLE POSITIONS (TITLE):**
IRB Administrator
IRB Manager
IRB Chair

**EQUIPMENT NEEDED:**
eIRB Access

**TEMPLATE LETTER:** Reportable New Information

**CHECKLIST:** Reportable New Information

**PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATION**
1. **PURPOSE**
1.1. This procedure establishes the process to manage information reported to the IRB to ensure that information that represents Non-Compliance, Unanticipated Problems Involving Risks to Subjects or Others, Suspensions of IRB Approval, and Terminations of IRB Approval are managed to protect the rights and welfare of subjects.

1.2. The process begins when the IRB receives an information item.

1.3. The process ends when the information item is determined not to represent a problem that requires management, is managed administratively, or referred to the convened IRB for review.

2. PROCEDURE

2.1. Review each item of information and answer the following question. (See attached flowchart for a diagram of the flow of this procedure.)

2.1.1. Is this an Allegation of Non-Compliance?

2.1.2. Is this a Finding of Non-Compliance?

2.1.3. Is this an Unanticipated Problem Involving Risks to Subjects or Others?

2.1.4. Is this a Suspension or Termination of IRB Approval?

2.2. If you are unable to answer a question, consult the IRB manager or IRB chair.

2.3. If the IRB manager or IRB chair are unable to answer a question, follow “IRB Investigations PGR.”

2.4. If the answer is “no” to all questions, skip section 2.5 and continue with section 2.6.

2.5. If the answer is “yes” to one or more questions, then follow the corresponding sections below.

2.5.1. Allegations of Non-Compliance: Determine whether each Allegation of Non-Compliance has any basis in fact.

2.5.1.1. If yes, follow the procedures under Findings of Non-Compliance.

2.5.1.2. If no, follow any other corresponding sections.

2.5.2. Findings of Non-Compliance: Determine whether each Finding of Non-Compliance is Serious Non-Compliance or Continuing Non-Compliance.

2.5.2.1. If no, follow the procedures under Non-Serious/Non-Continuing Non-Compliance.

2.5.2.2. If yes, follow the procedures under Serious or Continuing Non-Compliance.

2.5.3. Non-Serious/Non-Continuing Non-Compliance

2.5.3.1. Work with the individual or group responsible for the Non-Compliance to develop and implement a suitable corrective action plan.

2.5.3.2. If unable to work with the individual or group responsible for the Non-Compliance to develop and implement a suitable corrective action plan, consider the Non-Compliance to be Continuing Non-
Compliance and follow the procedures for Serious or Continuing Non-Compliance.

2.5.4. Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others

2.5.4.1. Confirm your decision with the IRB chair or IRB manager.

2.5.4.2. Complete Section 1 of “CHECKLIST: Reportable New Information”.

2.5.4.3. Place on the agenda for the next available convened IRB meeting in an IRB with appropriate scope as an item of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others.

2.6. If in your opinion the rights and welfare of subjects might be adversely affected before the convened IRB can review the information, contact the IRB manager or IRB chair to consider a Suspension of IRB Approval following the “Suspension or Termination of IRB Approval PGR.”

2.7. If the notification involves an allegation of Research Misconduct, follow the Research Misconduct Policy.

2.8. If the notification involves a subject becoming a prisoner in a study not approved by the IRB to involve prisoners inform the investigator that all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-subject must be stopped immediately until the regulatory requirements for research involving prisoners are met, unless the investigator asserts that it is in the best interests of the subject to remain in the research study while incarcerated and promptly submits a modification to the IRB to include prisoners.

2.9. Take any additional actions required to resolve any concerns or complaints associated with the information.

2.10. If the research is conducted or funded by the Department of the Navy and involves any of the following, report the information to the Undersecretary of the Navy.

2.10.1. Allegations of Non-Compliance.

2.10.2. The initiation and results of investigations of Allegations of Non-Compliance.

2.10.3. Audits, investigations, or inspections.

2.10.4. Audits, investigations, or inspections of the organization’s human research protection program conducted by outside entities (e.g., FDA or OHRP).

2.10.5. Significant communication between the organization and other federal departments or agencies regarding compliance and oversight.

2.10.6. All restrictions, suspensions, or terminations of the organization’s Federalwide Assurance (FWA).

2.11. If the information does not involve a Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or
Unanticipated Problem Involving Risks to Subjects or Others and a response is expected, complete and send a “TEMPLATE LETTER: Reportable New Information” to the person submitting the information.

2.12. Flowchart

REFERENCES

21 CFR §56.108(b)
45 CFR §46.103(b)(5), 45 CFR §46.108(a)

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IRB Investigations PGR

Effective:  08/06/2013
Reviewed:  09/14/2015

Name of Associated Policy: Human Research Protection Program

Definitions

Responsible Positions

Equipment Needed

Procedure Steps

DEFINITIONS:

1. **Designated Institutional Official**: The individual authorized by Palmetto Health who assumes the obligations of Palmetto Health’s Federalwide Assurance (FWA) with the Office for Human Research Protections (OHRP) and who assumes the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to research. Also referred to as the designated Signatory Official.

2. **Research misconduct**: Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting results. Research misconduct does not include honest error or differences of opinion.

RESPONSIBLE POSITIONS (TITLE):

Investigative Committee Members
IRB Administrator
Designated Institutional Official or designee

EQUIPMENT NEEDED:

NA

PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATION

1. PURPOSE
   1.1. This procedure establishes the process to conduct investigations.
   1.2. The process begins when the IRB staff members and chair cannot answer a question required by “IRB Reportable New Information PGR”.
   1.3. The process ends when the investigation is complete and the answer has been provided to the Designated Institutional Official or designee and the IRB.
2. PROCEDURE
  2.1. The IRB Administrator
      2.1.1. Reports allegations of research misconduct to the Department of Research Compliance or a Compliance Officer, and the allegation will be managed per the Research Misconduct Policy; OR
      2.1.2. Notifies the Designated Institutional Official or designee when the IRB staff members and chair cannot answer a question required by “IRB Reportable New Information PGR”, and the remainder of this PGR will be followed.
  2.2. The Designated Institutional Official or designee
      2.2.1. Appoints the members of the investigative committee based on the expertise and background needed to answer the question.
      2.2.2. Appoints a chair of the investigative committee.
      2.2.3. Charges the investigative committee with the question to be answered.
      2.2.4. Notify the investigator that an investigation is being conducted, the question to be answered, and the time frame for completion.
      2.2.5. Forward the written report to the IRB.
  2.3. The Investigative Committee
      2.3.1. Determines what information to gather and what individuals to interview.
      2.3.2. Gathers information and interview individuals.
      2.3.3. Repeats information gathering and interviews until a decision can be made.
      2.3.4. Investigative committee members make their decisions based on a preponderance of the evidence.
      2.3.5. Investigative committee decisions are made by majority vote.
      2.3.6. Individuals being interviewed may have counsel present. However, counsel cannot address the investigative committee. The investigative committee by a vote of the majority may exclude counsel when in the opinion of the investigative committee that person’s presence is disruptive.
      2.3.7. The investigative committee provides a written report of the investigative committee’s decision to the Designated Institutional Official or designee.
      2.3.8. The investigative committee carries out these procedures within 60 days.

REFERENCES
    Research Misconduct Policy
IRB Suspension or Termination of Approval PGR

Effective: 02/22/2013
Reviewed: 01/29/2015

Name of Associated Policy: Human Research Protection Program

Definitions

1. **Designated Institutional Official**: The individual authorized by Palmetto Health who assumes the obligations of Palmetto Health’s Federalwide Assurance (FWA) with the Office for Human Research Protections (OHRP) and who assumes the obligations imposed by the Federal laws, regulations, requirements and conditions that apply to research. Also referred to as the designated Signatory Official.

2. **Suspension of IRB Approval**: An action of the IRB, IRB designee, Designated Institutional Official, or designee of the Designated Institutional Official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a Termination of IRB Approval. Suspended studies remain open and are subject to continuing review.

3. **Termination of IRB Approval**: An action of the IRB, IRB designee, Designated Institutional Official, or designee of the Designated Institutional Official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review.

Responsible Positions

**RESPECTIVE POSITIONS (TITLE):**

Designated Institutional Official
IRB Administrator
IRB Chair
IRB Manager

References
**EQUIPMENT NEEDED:**

- eIRB Access

**TEMPLATE LETTER: Suspension or Termination of IRB Approval**

**PROCEDURE STEPS, GUIDELINES, OR REFERENCE**

1. **PURPOSE**
   1.1 This procedure establishes the process for someone other than the convened IRB to institute a Suspension of IRB Approval or a Termination of IRB Approval.
   1.2 The process begins when the Designated Institutional Official or designee institutes a Suspension of IRB Approval or a Termination of IRB Approval.
   1.3 The process ends when the Suspension of IRB Approval or a Termination of IRB Approval has been placed on the agenda for review by the convened IRB.

2. **GUIDELINES**
   2.1 The IRB chair or IRB manager may institute a Suspension of IRB Approval when in the opinion of the IRB chair or IRB manager subjects may be at risk of adverse effects on their rights and welfare before action may be considered by the convened IRB.
   2.2 The Designated Institutional Official or designee may institute a Suspension of IRB Approval or Termination of IRB Approval for any reason.
   2.3 Whenever possible the individual following these procedures communicates with investigators orally and in writing.

3. **PROCEDURE**
   3.1 Notify the investigator of the Suspension of IRB Approval or Termination of IRB Approval along with the reasons for the decision.
   3.2 Ask the investigator for a list of Human Subjects currently involved in the research.
   3.3 Ask the investigator whether any actions are required to protect those subjects’ rights and welfare or to eliminate an apparent immediate hazard.
   3.4 Consider whether any of the following additional actions are required to protect those or other subjects rights and welfare or to eliminate an apparent immediate hazard:
      3.4.1 Transferring subjects to another investigator.
      3.4.2 Making arrangements for clinical care outside the research.
      3.4.3 Allowing continuation of some research activities under the supervision of an independent monitor.
      3.4.4 Requiring or permitting follow-up of subjects for safety reasons.
      3.4.5 Requiring adverse events or outcomes to be reported to the IRB and the sponsor.
      3.4.6 Notification to current Human Subjects.
3.4.7 Notification to former Human Subjects.

3.5 Notify the IRB Administrator of the Suspension of IRB Approval or Termination of IRB Approval.

3.6 When notified the IRB Administrator,

3.6.1 Adds the study to the agenda for a convened IRB meeting in an IRB with appropriate scope as an item of Suspension of IRB Approval or Termination of IRB Approval.

3.6.2 Completes and sends to the investigator a “TEMPLATE LETTER: Suspension or Termination of IRB Approval.”

REFERENCES

21 CFR 56.108(b)(3)
21 CFR 56.113
45 CFR 46.103(b)(5)(ii)
45 CFR 46.108(a)
45 CFR 46.113
IRB Emergency Use or Compassionate Use Post-Review PGR

Effective: 08/06/2013
Reviewed: 09/14/2015

Name of Associated Policy: Human Research Protection Program

**Definitions**

1. *Non-Committee Reviewer*: The IRB chair or an experienced IRB Member designated by the IRB chair to conduct non-committee reviews.

2. *Non-Compliance*: Failure to follow the regulation, or the requirements or determinations of the IRB.

**RESPONSIBLE POSITIONS (TITLE):**

IRB Administrator

**EQUIPMENT NEEDED:**

eIRB Access

TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Met

TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria Not Met

TEMPLATE LETTER: Review of Emergency Use - Criteria Met

TEMPLATE LETTER: Review of Emergency Use - Criteria Not Met
PROCEDURE STEPS, GUIDELINES, OR REFERENCE

1. PURPOSE
   1.1. This procedure establishes the process to communicate the review of:
      1.1.1. Emergency use of a drug, biologic, or device in a life-threatening situation.
      1.1.2. Compassionate use of an unapproved device for a serious condition, with an
              IDE supplement and FDA concurrence.
   1.2. The process begins when the Non-Committee Reviewer has notified IRB staff of
        whether an actual or proposed use has followed or will follow FDA regulations
        and guidance.
   1.3. The process ends when the IRB staff has communicated the results to the physician
        and if necessary initiated the non-compliance process.

2. GUIDELINE
   2.1. Whenever possible physicians are to notify the IRB of a proposed emergency use of a
        test article in a life-threatening situation in advance of the use.
   2.2. Physicians are to notify the IRB of a proposed compassionate use of an unapproved
        device with an IDE supplement and FDA concurrence for a serious condition.
   2.3. Data obtained from uses covered by this procedure cannot be used in a non-exempt
        systematic investigation designed to develop or contribute to generalizable knowledge.

3. PROCEDURE
   3.1. If the Non-Committee Reviewer has indicated that the proposed use will follow FDA
        regulations:
      3.1.1. Complete a “TEMPLATE LETTER: Pre-Review of Emergency Use - Criteria
              Met” and send to the physician.
      3.1.2. Set a 5 day deadline for receipt of the 5 day report.
   3.2. If the Non-Committee Reviewer has indicated that the proposed use will NOT follow
        FDA regulations, complete a “TEMPLATE LETTER: Pre-Review of Emergency Use
        - Criteria Not Met” and send to the physician.
   3.3. If Non-Committee Reviewer has indicated that the actual use followed FDA
        regulations
      3.3.1. Complete a “TEMPLATE LETTER: Review of Emergency Use - Criteria Met”
              and send to the physician.
      3.3.2. For uses of drugs and biologics, set a 30 day deadline for receipt of a protocol.
   3.4. If the Non-Committee Reviewer has indicated that the proposed use did NOT follow
        FDA regulations:
      3.4.1. Complete a “TEMPLATE LETTER: Review of Emergency Use - Criteria Not
              Met” and send to the physician.
      3.4.2. Manage under “IRB Reportable New Information PGR” as Non-Compliance.

REFERENCES
21 CFR 50.23
21 CFR 56.104(c)
Designating Non-Committee IRB Reviewers PGR

Effective: 10/21/2015
Reviewed: 10/21/2015

Name of Associated Policy: Human Research Protection Program Policy

Definitions

1. Administrative Review: Any of the following:
   1.1. Not Human Research Determination
   1.2. Exempt Human Research Determination
   1.3. Review of Reportable Event submission not involving:
      1.3.1. Serious Non-Compliance or,
      1.3.2. Continuing Non-Compliance or,
      1.3.3. Serious and Continuing Non-Compliance or,
      1.3.4. An Unanticipated Problem Involving Risk to Subjects or Others.
   1.4. Review of Status Change
   1.5. Review of Study Closure
2. Administrative Reviewer: An IRB Administrator or the IRB Manager
3. Non-Committee Reviewer: An Expedited Reviewer or an Administrative Reviewer.
4. Experienced IRB Member: An IRB member the IRB chair considers to have sufficient experience in and knowledge of conducting IRB reviews.
5. Expedited Review: Any of the following:
   5.1. Review of non-exempt research using the expedited procedure.
   5.2. Determinations of which subjects can continue in expired research.
   5.3. Review of notifications of emergency uses of test articles.
6. Expedited Reviewer: The IRB chair or an experienced IRB member designated by the chair.

Responsible Positions (Title):
IRB staff members
EQUIPMENT NEEDED:
DATABASE IRB Roster
TEMPLATE Non-Committee Reviewer Appointment Letter

PROCEDURE STEPS, GUIDELINES, OR REFERENCE
1. PURPOSE
   1.1. This procedure establishes the process for the IRB chair to designate IRB members
        who can conduct Non-Committee Reviews.
   1.2. The process begins when the IRB chair instructs IRB staff to designate an Experienced
        IRB Member to conduct Non-Committee Reviews.
   1.3. The process ends when the IRB member has been noted in the IRB roster to conduct
        Non-Committee Reviews.
2. PROCEDURE
   2.1. Obtain from the IRB chair the name of the IRB member designated to conduct Non-
        Committee Reviews.
   2.2. Complete and send to the IRB member, TEMPLATE: Non-Committee Reviewer
        Appointment Letter.
   2.3. Update the DATABASE: IRB Roster to indicate that the IRB member is a Non-
        Committee Reviewer.

REFERENCES
21 CFR 56.110(b); 45 CFR 46.110(b)
IRB Non-committee Review Preparation PGR

Effective: 10/21/2015
Reviewed: 10/21/2015

Name of Associated Policy: Human Research Protection Program

Definitions

Responsible Positions

Equipment Needed

Procedure Steps

References

DEFINITIONS:

1. Administrative Review: Any of the following:
   1.1. Not Human Research Determination
   1.2. Exempt Human Research Determination
   1.3. Review of Reportable Event submission not involving:
       1.3.1. Serious Non-Compliance or,
       1.3.2. Continuing Non-Compliance or,
       1.3.3. Serious and Continuing Non-Compliance or,
       1.3.4. An Unanticipated Problem Involving Risk to Subjects or Others.
   1.4. Review of Status Change
   1.5. Review of Study Closure
2. Non-Committee Reviewer: An Expedited Reviewer or an Administrative Reviewer.
3. Non-Committee Review: An Expedited or Administrative Review.
4. Expedited Review: Any of the following:
   4.1. Review of non-exempt research using the expedited procedure.
   4.2. Determinations of which subjects can continue in expired research.
   4.3. Review of notifications of emergency uses of test articles.

RESPONSIBLE POSITIONS (TITLE):

IRB Administrator
EQUIPMENT NEEDED:

DATABASE: IRB Roster
WORKSHEET: Review Materials

PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATIONS

1. PURPOSE
   1.1. This procedure establishes the process to prepare for a Non-Committee Review.
   1.2. The process begins when an IRB staff member identifies an application as being possibly eligible for Non-Committee Review.
   1.3. The process ends when the IRB staff member provides the materials to the Non-Committee Reviewer.

2. GUIDELINES
   2.1. IRB rosters are maintained using “DATABASE: IRB Roster.”
   2.2. Individuals are expected to review the materials listed in the “WORKSHEET: Review Materials” according to their role: “Documents Provided to All IRB Members and Alternate IRB Members,” and “Additional Items Provided to Primary Reviewer.”

3. PROCEDURE
   3.1. Refer to “DATABASE: IRB Roster” and select a Non-Committee Reviewer.
       3.1.1. If a Non-Committee Reviewer is not available, schedule the protocol to be reviewed by the next convened IRB.
   3.2. Prepare the review materials using the “WORKSHEET: Review Materials” and include all materials listed under the columns according to the individual’s role.
       3.2.1. Add to the review materials any relevant minutes or correspondence.
   3.3. Assign the review to the Non-Committee Reviewer within three business days of receipt of a complete submission.

REFERENCES
21 CFR 56.110(b)
45 CFR 46.110(b)
DEFINITIONS:

1. **Administrative Review:** Any of the following:
   1.1. Not Human Research Determination
   1.2. Exempt Human Research Determination
   1.3. Review of Reportable Event submission not involving:
       1.3.1. Serious Non-Compliance or,
       1.3.2. Continuing Non-Compliance or,
       1.3.3. Serious and Continuing Non-Compliance or,
       1.3.4. An Unanticipated Problem Involving Risk to Subjects or Others.
   1.4. Review of Status Change
   1.5. Review of Study Closure
2. **Administrative Reviewer:** An IRB Administrator or the IRB Manager
3. **Non-Committee Reviewer:** An Expedited Reviewer or an Administrative Reviewer.
4. **Experienced IRB Member:** An IRB member the IRB chair considers to have sufficient experience in and knowledge of conducting IRB reviews.
5. **Expedited Review:** Any of the following:
   5.1. Review of exempt research with a HIPAA Waiver of Authorization using the expedited procedure.
   5.2. Review of non-exempt research using the expedited procedure.
   5.3. Determinations of which subjects can continue in expired research.
   5.4. Review of notifications of emergency uses of test articles.
6. **Expedited Reviewer:** The IRB chair or an experienced IRB member designated by the chair.
RESPONSIBLE POSITIONS:
Non-Committee Reviewer

EQUIPMENT NEEDED:
eIRB access
CHECKLIST: Exempt Determination
CHECKLIST: Expedited Initial Review
CHECKLIST: Expedited Minor Modification
CHECKLIST: Expedited Continuing Review
CHECKLIST: Emergency Use of a Test Article
CHECKLIST: Human Subject Research Determination

PROCEDURE STEPS, GUIDELINES, OR REFERENCE

1. **PURPOSE**
   1.1. This procedure establishes the process for a Non-Committee Reviewer to conduct a Non-Committee Review.
   1.2. The process begins when the Non-Committee Reviewer is assigned the review in eIRB.
   1.3. The process ends when the Non-Committee completes the review and submits the review via eIRB.
   1.4. Non-Committee Reviewers may not disapprove research.

2. **PROCEDURE**
   2.1. Review submitted materials.
   2.2. If consultation is needed follow “Consultation to the IRB PGR” or contact the IRB Administrator.
   2.3. If the review is for a Not Human Subject Research determination, complete the CHECKLIST: Human Subject Research Determination.
   2.4. If the review is for an Exempt determination, complete the CHECKLIST: Exempt Determination.
   2.5. If the review is for an initial approval using the expedited procedure, complete the CHECKLIST: Expedited Initial Review and all required checklists.
   2.6. If the review is for a minor modification to an approved study, complete the CHECKLIST: Expedited Minor Modification and all required checklists.
   2.7. If the review is for a continuing review or a modification using the expedited procedure, complete the CHECKLIST: Expedited Continuing Review and all required checklists.
   2.8. If the review is for an Emergency Use of a Test Article, complete the CHECKLIST: Emergency Use of a Test Article.
   2.9. If the review is a response to modifications required to secure approval, confirm whether the investigator made the required changes.
   2.10. Submit the completed review and applicable checklist via eIRB within 5 business days of receipt of materials.
REFERENCES
21 CFR 56.110(b); 45 CFR 46.110(b)
Huron’s HRPP SOPs, ©2009-2010 Huron Consulting Services, LLC. Use and distribution subject to End User License Agreement at http://www.huronconsultinggroup.com/SOP.
IRB Review of Request to Continue Subjects in an Expired Study PGR

Effective: 02/15/2013
Reviewed: 01/29/2015

Name of Associated Policy: Human Research Protection Program

**Responsible Positions**

**Equipment Needed**

eIRB access

**Procedure Steps**

RESPONSIBLE POSITIONS (TITLE):

Non-Committee Reviewer

EQUIPMENT NEEDED:

eIRB access

CHECKLIST: Request to Continue Subjects in an Expired Study

PROCEDURE STEPS, GUIDELINES, RULES, OR REFERENCE

1. PURPOSE
   1.1. This procedure establishes the process for a Non-Committee Reviewer to determine whether current subjects may continue in expired research.
   1.2. The process begins when the Non-Committee Reviewer is notified of a request by an investigator for current subjects to continue in expired research.
   1.3. The process ends when the Non-Committee Reviewer has communicated a decision to the IRB Administrator.

2. GUIDANCE
   2.1. Determine from the investigator which subjects need to continue in the expired research, what procedures are being requested to continue, and why.
   2.2. Do not allow new subjects to be enrolled under any circumstances.
   2.3. Determine which subjects can continue in the research based on these principles:
       2.3.1. In general, research procedures should be safely discontinued.
       2.3.2. In general, the only research procedures that should continue are those that are not available outside of the research context. If the required procedures can be provided as standard of care, these should be provided as such.
       2.3.3. In general, research procedures conducted to collect data with no direct benefit to the subject should not continue.
2.3.4. In some cases, an ethical issue may be raised where the above general principles may not be followed.

3. **PROCEDURE**
   3.1. Complete the CHECKLIST: Request to Continue Subjects in an Expired.
   3.2. Submit the determination to the IRB Administrator.
IRB Meeting Preparation PGR

Effective: 10/21/2015
Reviewed: 10/21/2015

Name of Associated Policy: Human Research Protection Program

DEFINITIONS:
1. eIRB: A web-based system for IRB submissions, review, and management. It is a paperless, electronic method to submit, track, and route all submission types through the approval process and provides a means to document information required for the review of human subject research. This includes the initial application, amendments, reportable events and continuing renewal submissions.
2. Quorum: A majority of committee members, including at least one member whose primary concerns are in scientific areas, one member whose primary concerns are in nonscientific areas, one unaffiliated member and one member who represents the general perspective of subjects.

RESPONSIBLE POSITIONS (TITLE):
IRB Administrator

EQUIPMENT NEEDED:
Internet access with eIRB privileges
WORKSHEET: IRB Meeting Attendance
WORKSHEET: IRB Review Materials

PROCEDURE STEPS, GUIDELINES, OR REFERENCE
1. PURPOSE
   1.1. This procedure establishes the process to prepare for a convened IRB meeting.
   1.2. The process begins when the agenda is closed, approximately 14 days before a meeting.
   1.3. The process ends when the IRB meeting agenda materials have been distributed to the IRB members.
2. GUIDELINES
   2.1. Protocols are reviewed by IRB members or consultants with sufficient expertise.
2.2. When IRB members review research that involves vulnerable subjects, at least one individual who is knowledgeable about or experienced in working with such subjects will be present at the meeting.

2.3. IRB members are provided sufficient information so that each member can provide an opinion on whether the regulatory criteria for approval are met.

2.4. Alternate IRB members serve the same function as other IRB members, except that if the alternate IRB member and the regular IRB member for whom the alternate member is substituting are both present only one member may vote.

2.5. Review materials are provided to all IRB members at least 7 days before convened meetings.

3. PROCEDURE

3.1. Preparation of agenda for the meeting

3.1.1. Confirm which IRB members will be present at the meeting.

3.1.2. Use “WORKSHEET: IRB Meeting Attendance” to ensure that the meeting will be appropriately convened and to ensure the IRB will have the appropriate expertise for each protocol.

3.1.2.1. If the meeting will not meet the quorum and expertise requirements, take steps to obtain the required attendance of members and consultants or cancel the meeting.

3.1.3. Follow the procedures in “Consultation to the IRB PGR” to obtain consultants. Note any consultants on the agenda.

3.1.4. Review all submissions placed on the agenda. If there is a need to limit the number of items on the agenda consult with the IRB Manager. Confirm the CHECKLIST: Pre-Review is completed and attached for the agenda items. Cancel the meeting if there are no submissions.

3.1.5. Assignment of IRB Reviewers

3.1.5.1. Assign a primary reviewer to each agenda item.

3.1.5.2. Assign a secondary reviewer to each agenda item being submitted as a new protocol.

3.1.5.3. When making reviewer assignments, the IRB Administrator considers the following:

3.1.5.3.1. Reviewer’s scientific and /or scholarly expertise in the area of the research.

3.1.5.3.2. Reviewer experience

3.1.5.3.3. Reviewer’s status as a scientist or nonscientist

3.1.5.3.4. Reviewer workload

3.1.5.3.5. Potential conflicts of interest

3.1.6. Use “WORKSHEET: IRB Review Materials” to include and confirm the CHECKLIST(s) needed to review each agenda item.
3.1.7. Include and confirm that all educational materials have been added on the IRB agenda.

3.1.8. Include and confirm that all other business items have been added on the IRB agenda.

3.1.9. Confirm that all non-committee review items that have occurred since the previous Committee meeting are included on the IRB agenda:
   3.1.9.1. List of exemptions granted.
   3.1.9.2. List of protocols granted approval using the expedited procedure.
   3.1.9.3. List research approved with modifications to secure approval and granted approval by the chair or designee after confirmation that the modifications were made.

3.1.10. Confirm that a draft of the previous IRB meeting minutes are included on the IRB agenda.

3.1.11. Confirm that the approved minutes from the alternate IRB are included as Information to the Board on the agenda. The minutes of the alternate IRB are shared so both Palmetto Health IRB #1 and IRB #2 are informed of the actions and discussions made by the alternate committee.

3.1.12. Distribution of IRB meeting agenda
   3.1.12.1. The IRB Administrator sends the agenda to the IRB members electronically. The IRB members and consultants receive a meeting agenda notification through email. The IRB members have access to all documents submitted for IRB review through eIRB. Consultants are provided information through email.

3.1.13. Agenda Addendum
   3.1.13.1. When an addendum to a finalized agenda is warranted, the IRB Administrator will assure:
      3.1.13.1.1. Assignment of primary and/or secondary reviewer.
      3.1.13.1.2. Posting the addendum item to the agenda in a timely manner that allows ample time for adequate review of the addendum item.
      3.1.13.1.3. Distribution of the information in a timely manner that allows ample time for adequate review of the addendum item.
      3.1.13.1.4. Committee members are notified of the addendum.
Definitions

1. **Defer**: An action to remove an item from current meeting agenda and place on the next agenda due to loss of quorum or lack of time to review.

2. **eIRB**: A web-based system for IRB submissions, review, and management. It is a paperless, electronic method to submit, track, and route all submission types through the approval process and provides a means to document information required for the review of human subject research. This includes the initial application, amendments, reportable events and continuing renewal submissions.

3. **Quorum**: A majority of committee members, including at least one member whose primary concerns are in scientific areas, one member whose primary concerns are in nonscientific areas, one unaffiliated member and one member who represents the general perspective of subjects.

RESPONSIBLE POSITIONS (TITLE):

IRB chair
IRB vice chair

EQUIPMENT NEEDED:

eIRB access
CHECKLIST: Additional Federal Agency Criteria
CHECKLIST: Full Board Review
CHECKLIST: Humanitarian Use Device
CHECKLIST: Non-significant Risk Device
PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATION

1. **PURPOSE**
   1.1. This procedure establishes the process to conduct convened meetings.
   1.2. The process begins when the IRB members gather for a convened meeting.
   1.3. The process ends when the meeting is adjourned.

2. **GUIDELINES**
   2.1. All IRB members have laptops to access eIRB.
   2.2. The chair protects his/her impartial position by exercising his/her voting right only when the vote would affect the outcome, in which case he/she can either vote and thereby change the results or abstain. If the chair abstains he/she announces the results with no mention of his/her abstention.
   2.3. If a quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored.
   2.4. If a member required for a quorum (e.g. non-scientific) leave the room and the quorum is lost votes cannot be taken until the quorum is restored, even if half of the members are still present.
   2.5. A vice-chair chairs an IRB meeting in the chair’s absence.

3. **PROCEDURE**
   3.1. Call the meeting to order when notified by IRB staff the quorum requirements as defined in WORKSHEET: IRB Meeting Attendance are met.
   3.2. Ask IRB members to review minutes of previous IRB meeting. Ask for a vote to approve as distributed or approve with modifications if members identify any needed corrections or modifications.
   3.3. Ask IRB members whether anyone has a conflict of interest in any item on the agenda and have the IRB staff note the responses.
   3.4. For each business item involving review of a protocol:
3.4.1. Defer the item when notified by IRB staff the requirements for quorum and expertise as defined in WORKSHEET: IRB Meeting Attendance are not met.1

3.4.2. If the Investigator is present, ask the investigator to present the study to the IRB. Invite the IRB to ask questions and then ask the investigator to leave before discussion and voting.

3.4.3. If there are IRB members with a conflict of interest, invite the IRB to ask questions of those members and then ask those members to leave for discussion and voting.

3.4.4. If there is a consultant present, ask the consultant to present his or her review to the IRB.

3.4.5. If a consultant provided written information to the IRB, present that information to the IRB.

3.4.6. Ask the primary reviewer to lead the IRB through a discussion of the criteria in the CHECKLIST: Full Board Review, and all referenced checklists (listed below) to have the convened IRB determine which regulatory criteria are met (or continue to be met), which are not met (or no longer met), and which would be met if the investigator modified the protocol as requested by the IRB.

3.4.7. If a secondary reviewer is assigned, ask the secondary reviewer to present items for discussion.

3.4.8. For new information (Unanticipated Problem Involving Risks to Subjects or Others, Serious or Continuing Non-Compliance, or Suspension or Termination of IRB Approval) have the primary reviewer use the CHECKLIST: Reportable New Information, to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects.

3.4.9. Restate the IRB’s consensus regarding any protocol specific findings justifying a determination when required by a checklist and not previously determined and documented.

3.4.10. Ask the primary reviewer to make a motion for one of the following actions:

3.4.10.1. Approve (with a specific continuing review interval for initial or continuing review): Made when all criteria for approval are met. Include in motions for initial and continuing review the period of approval and the level of risk.

3.4.10.2. Approve with Contingencies (with a specific continuing review interval for initial or continuing review): Made when IRB members require specific modifications such that an IRB staff member, the chair or designated IRB member can determine whether an investigator has made the required changes without judging whether

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1 “Deferred” is not an action of the IRB, but is a status based on the inability of the IRB to take action.
a change meets the regulatory criteria for approval. When making this motion, the primary reviewer restates the modifications required by the IRB members and the IRB member’s reasons for those changes.

3.4.10.3. Table: Made when the research does not qualify for Approval or Approve with Contingencies and the IRB has recommendations that might make the protocol approvable. When making this motion, the primary reviewer describes the IRB’s reasons for the decision and describes recommendation to make the research approvable. The response to the recommendations will be reviewed at a convened IRB meeting of the initial committee.

3.4.10.4. Disapprove: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has no recommendations that might make the protocol approvable. When making this motion, the primary reviewer describes the IRB member’s reasons for the decision.

3.4.10.5. Suspension or Termination of IRB Approval: Made when current approved research does not qualify for Approval or Modifications Required to Secure Approval. When making this motion, have the primary reviewer use the CHECKLIST: Reportable New Information to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects. The assigned primary reviewer describes the IRB member’s reasons for the decision.

3.4.11. Open the floor for additional discussion.

3.4.12. Review any modifications required to secure approval to ensure that the IRB staff has recorded them.

3.4.12.1. Ensure that the required modifications include all final contingencies on CHECKLIST: Pre-Review.

3.4.13. Call for a vote.

3.4.13.1. Only IRB members may vote.

3.4.13.2. If a member and an alternate are both present, only one may vote.

3.4.13.3. Consultants may not vote.

3.4.13.4. For a motion to be passed, it needs the approval of more than half of the members present at the meeting. (If there are 10 or 11 members present at the meeting, 6 votes are required for approval, which is greater than 5 and 5.5, respectively.)

3.4.14. Re-invite IRB members with a conflict of interest back into the meeting.

3.5. Ask assigned individual(s) to provide information and lead discussion of Other Business Items.
3.6. Ask assigned individual(s) to provide information and lead discussion of Education Items.

3.7. Adjourn the meeting when notified by IRB staff that quorum has been lost or when there is no further business.

REFERENCES
21 CFR 50.20, 50.25, 50.27, 56.109, 56.111
45 CFR 46.109, 46.116, 46.117
IRB Attendance Monitoring PGR

Effective: 10/21/2015
Reviewed: 10/21/2015

Name of Associated Policy: Human Research Protection Program

Definitions
Responsible Positions
Equipment Needed
Procedure Steps
References

DEFINITIONS:
1. **Quorum:** A majority of committee members, including at least one member whose primary concerns are in scientific areas, one member whose primary concerns are in nonscientific areas, one unaffiliated member and one member who represents the general perspective of subjects.

RESPONSIBLE POSITIONS (TITLE):
IRB Administrator

EQUIPMENT NEEDED:
WORKSHEET: IRB Meeting Attendance

PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATION
1. PURPOSE
   1.1. This guidance describes the process to monitor quorum at convened IRB meetings.
   1.2. The process begins when a quorum is present.
   1.3. The process ends when the meeting is adjourned.
2. PROCEDURE
   2.1. At meetings consult the “WORKSHEET: IRB Meeting Attendance” to determine that the meeting is appropriately convened by meeting the quorum requirements and notify the IRB chair when the meeting is appropriately convened.
   2.2. Before each protocol consult the “WORKSHEET: IRB Meeting Attendance” to determine that the meeting is appropriately convened by meeting the expertise requirements and notify the IRB chair when the meeting is not appropriately constituted for the review of that protocol.
2.3. When a member leaves the meeting room for any reason (including a conflicting interest) consult the “WORKSHEET: IRB Meeting Attendance” to determine that the meeting continues to be appropriately convened by meeting the quorum requirements and notify the IRB chair when the meeting is not appropriately convened.

REFERENCES
45 CFR 46.108(b)
21 CFR 56.108(c)
IRB Meeting Minutes PGR

Effective: 10/22/2015
Reviewed: 10/22/2015

Name of Associated Policy: Human Research Protection Program

Definitions
Responsible Positions
Equipment Needed
Procedure Steps

DEFINITIONS:
1. Absent: Absent for the discussion and voting for reasons other than conflict of interest.
2. Abstain: Present for the vote, but not voting “Yes” or “No.”
3. Approval Denied: A convened IRB determination indicating the research does not qualify for Approved or Approved with Contingencies and the IRB has no recommendations that might make the protocol approvable.
4. Approved with Contingencies: A convened IRB determination indicating the research has been reviewed and contingent upon specific modifications such that an IRB staff member, the chair or designated IRB member can determine whether an investigator has made the required changes without judging whether a change meets the regulatory criteria for approval. Initial and continuing review approvals with contingencies include the period of approval and the level of risk.
5. Approved: An IRB determination indicating the research has been reviewed and all criteria for approval are met. Initial and continuing review approvals include the period of approval and the level of risk.
6. Deferred: An administrative activity to remove an item from current meeting agenda and place on the next agenda indicating the research was not reviewed by the IRB due to reasons unrelated to the application (e.g., loss of quorum, non-scientific member not present and/or appropriate expertise is not available at the meeting.) Deferred is not an action of the IRB, but is a status based on the inability of the IRB to take action.
7. Quorum: A majority of committee members, including at least one member whose primary concerns are in scientific areas, one member whose primary concerns are in nonscientific areas, one unaffiliated member and one member who represents the general perspective of subjects.
8. **Recused:** Absent from the meeting during the discussion and voting because of a conflict of interest.

9. **Suspend:** An action of the IRB, IRB designee, Designated Institutional Official, or designee of the Designated Institutional Official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a Termination of IRB Approval. Suspended studies remain open and are subject to continuing review. Suspend does not include interruptions in research resulting from the expiration of a project approval period.

10. **Tabled:** A convened IRB determination indicating the research does not qualify for Approved or Approved with Contingencies and the IRB has recommendations that might make the protocol approvable. The response to the recommendations is reviewed at a convened IRB meeting of the initial committee.

11. **Terminate:** An action of the IRB, IRB designee, Designated Institutional Official, or designee of the Designated Institutional Official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review. Terminate does not include interruptions in research resulting from the expiration of a project approval period.

**RESPONSIBLE POSITIONS (TITLE):**
- IRB Administrator
- IRB Chair
- IRB Manager

**EQUIPMENT NEEDED:**
- DATABASE: IRB Roster
- eIRB access

**PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATION**

1. **PURPOSE**
   1.1. This procedure establishes the process to record minutes for convened meetings.
   1.2. The process starts when the IRB meeting is called to order.
   1.3. The process ends when the minutes have been approved by the convened IRB.

2. **GUIDELINES**
   2.1. Minutes are to comply with regulatory and guidance requirements.
   2.2. Minutes are to record separate deliberations for each action.
   2.3. Minutes are included on the agenda for the next meeting of the committee.
   2.4. IRB members may make corrections to minutes.
   2.5. Minutes are officially approved by the convened IRB.
2.6. Minutes may not be altered by anyone including a higher authority once approved by the convened IRB.

3. PROCEDURE

3.1. Use eIRB to record observations at meetings.
3.2. Send the agenda to “Meeting in Process State.”
3.3. Open the “Agenda Editor.”
3.4. On the “Meeting Information” page:
   3.4.1. Record the number of members required for quorum. (Divide the number of members by two and select the next whole number. For example, if there are 10 IRB members on the “DATABASE: IRB Roster,” then \(10/2 = 5\) and the next whole number is 6. If there 13 IRB members on the “DATABASE: IRB Roster,” then \(13/2=6.5\) and the next whole number is 7.)
   3.4.2. Record the meeting start time.
3.5. On the “Call to Order and Education” page:
   3.5.1. In the “Call to Order” section enter/edit text to appear in the minutes.
   3.5.2. In the “Education” section enter/edit text to appear in the minutes.
3.6. On the “Minutes from Past Meetings” page:
   3.6.1. Record the motion and the vote on minutes for the previous meeting.
   3.6.2. Indicate if Minutes are approved.
   3.6.3. Enter any discussion notes.
3.7. On the “Other Business” page:
   3.7.1. In the “Other Discussion Items” section enter/edit text to appear in the minutes.
   3.7.2. In the “Policies and Procedures Discussion” section enter/edit text to appear in the minutes.
3.8. On the “Conflict of Interest” page enter any conflict of interest discussions or disclosures.
3.9. On the “Meeting Attendance” page record each voting member (regular members and alternates) present at the meeting at any time. (Do not record non-voting alternates under “Actual Committee Members Present.”)
   3.9.1. For alternate members who are substituting for a regular member, record the name of the regular member for whom the alternate member is substituting in the “Call to Order” section.
   3.9.2. In the “Others Present” section record any other persons who were present at the meeting.
3.10. Record a summary of each business item that was discussed.
3.11. For each protocol reviewed record:

3.11.1. Type(s) of review: Initial review, continuing review, review of amendments to previously approved research, or review of Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, or Termination of IRB Approval.

3.11.2. Protocol Title.

3.11.3. Investigator name.

3.11.4. IRB identification number.

3.11.5. In the “Items Submitted for Review” section enter/edit documents reviewed.

3.11.6. In the “Agenda Item Notes” section enter/edit a summary of issues useful to understand the agenda item. For example, a brief history of recent IRB actions.

3.11.7. In the “Committee Discussion” section add any notes of discussion that should appear in the minutes including:

3.11.7.1. Consultant report: Summarize the key information provided or attach report as “Discussion Attachments”.

3.11.7.2. Controverted issues (when the IRB members express a difference of opinion among themselves) and the resolution. If there was no resolution, indicate this.

3.11.7.3. Determinations and findings that require documentation: If the research involves waiver or alteration of consent, waiver of written documentation of consent, children, pregnant women, neonates, prisoners, or cognitively impaired adults, include one or more of the “Determination/Protocol Specific Findings” tables in the “TEMPLATE FORM - Determination-Protocol Specific Findings” or enter “See IRB records for this protocol” and ensure that the corresponding completed checklist is in the IRB records. Otherwise delete.

3.11.7.4. Rationale for a significant/non-significant device determination: Describe the rationale for the determination. Otherwise delete.

3.11.7.5. Contingencies required to secure approval: Include the contingencies/modifications required to secure approval and the corresponding rationale, otherwise omit if there were no contingencies required to secure approval.

3.11.7.6. Reasons the IRB deferred the protocol: omit if the IRB did not defer the protocol.

3.11.7.7. Reasons for the table, disapproval, suspension, or termination and recommended changes: omit if the IRB did not table, disapprove, suspension, or termination the research.
3.11.8. Motion: Approved, Approved with Contingencies, Tabled, Approval Denied, Suspended, or Terminated. For initial or continuing review add the period of approval to the motion. If the protocol was deferred, indicate this.

3.11.9. Vote: Record as the number of members Yes, No, abstaining, absent, or recused. List the names of IRB members who were absent or recused. Do not count votes of consultants. If both a regular IRB member and the alternate IRB member are present at the meeting record the vote of just one.

3.11.9.1. Yes: Voting for the motion.
3.11.9.2. No: Voting against the motion.
3.11.9.3. Absent: Present for the vote, but not voting “Yes” or “No.”
3.11.9.4. Absent: Listed under “Members Present” but not present for the discussion and vote on this protocol for reasons other than a Conflict of Interest. List the names of absent members in the vote. For example: “Yes Votes: 7 No Votes: 3 Abstained Votes: 2 Absent: 2 (Alice Baker, Charlie Delta) Recused: 0 Substitutions: 0”.

3.11.9.5. Recused: Listed under “Members Present” but not present for the discussion and vote on this protocol because of a Conflict of Interest. List the names of recused members in the vote. For example: “Yes Votes: 7 No Votes: 3 Abstained Votes: 2 Recused: 2 (Evelyn Foxtrot, George India)”.

3.11.9.6. When a protocol is deferred, record the vote as “Yes Votes: 0 No Votes: 0 Abstained Votes: 0 Recused: 0”.

3.11.10. Level of risk determined by the convened IRB: Minimal Risk, Greater than Minimal Risk or None.

3.12. Record the meeting end time.

3.13. Within 2 business days revise minutes for accuracy and provide them to the IRB Chair or IRB Manager for review.

3.14. When the minutes are approved by the committee email a copy to the Institution Official or designee.

3.15. Attach the following documents to the approved minutes:
    3.15.1. List of exemptions granted.
    3.15.2. List of protocols granted approval using the expedited procedure.

REFERENCES
45 CFR 46
IRB Conflict of Interests of Members PGR

Effective: 10/21/2015
Reviewed: 10/21/2015

Name of Associated Policy: Human Research Protection Program

Definitions

Responsible Positions

Equipment Needed

Procedure Steps

References

DEFINITIONS:

1. Conflict of Interest: An individual involved in research review is automatically considered to have a conflict of interest when the individual or the individual’s Immediate Family have any of the following:
   1.1. Involvement in the design, conduct, or reporting of the research.
   1.2. Ownership interest, stock options, or other ownership interest Related to the Research of any value exclusive of interests in publicly-traded, diversified mutual funds.
   1.3. Compensation Related to the Research of any amount in the past year or of any amount expected in the next year, including compensation for costs directly related to conducting research.
   1.4. Proprietary interest Related to the Research including, but not limited to, a patent, trademark, copyright or licensing agreement.
   1.5. Any other reason for which the individual believes that he or she cannot be independent

2. Immediate Family:
   2.1. A spouse or dependent children.

3. Related to the Research: A financial interest is Related to the Research when the interest is in:
   3.1. A sponsor of the research;
   3.2. A competitor of the sponsor of the research;
   3.3. A product or service being tested; or
   3.4. A competitor of the product or service being tested.
RESPONSIBLE POSITIONS (TITLE):
IRB members (regular and alternate)

EQUIPMENT NEEDED:
N/A

PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATION

1. PURPOSE
1.1. This procedure establishes the process to identify and manage Conflict of Interest of IRB members.
1.2. The process begins when an IRB member is asked to review an IRB submission.
1.3. The process ends when an IRB member has either identified a Conflict of Interest and notified IRB staff, or when an IRB member has determined that he or she does not have a Conflict of Interest.

2. GUIDELINES
2.1. IRB members are responsible to know the definition of Conflict of Interest and self-identify when they have a Conflict of Interest.

3. PROCEDURE
3.1. Before reviewing research, IRB members are to determine whether they have a Conflict of Interest with research.
3.2. If an IRB member has a Conflict of Interest for review outside a meeting (e.g., the expedited procedure), he or she is to notify the IRB staff and return all materials.
3.3. If an IRB member has a Conflict of Interest for review of a submission for which he or she has been assigned, he or she is to notify the IRB staff so the submission can be re-assigned.
3.4. If an IRB member has a Conflict of Interest for review of research at a meeting, he or she is to notify the meeting chair, stay in the meeting room only to answer questions about the research, and to leave the meeting room for discussion and voting regarding that research.

REFERENCES

21 CFR 56.107(e)
45 CFR 46.107(e)
Consultation to the IRB PGR

Effective:  11/02/2012  
Reviewed:  09/19/2016

Name of Associated Policy:  Human Research Protection Program

Definitions

Equipment

Responsible Positions

Procedure Steps

References

DEFINITIONS:

1.  **Conflict of Interest:** The circumstance where an individual involved in research review or the individual’s Immediate Family have any of the following:
   1.1. Involvement in the design, conduct, or reporting of the research.
   1.2. Ownership interest, stock options, or other ownership interest related to the research of any value exclusive of interests in publicly-traded, diversified mutual funds.
   1.3. Compensation related to the research of any amount in the past year or of any amount expected in the next year, including compensation for costs directly related to conducting research.
   1.4. Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
   1.5. Any other reason for which the individual believes that he or she cannot be independent.

2.  **Consultant:** An individual with competence in a special area who assists in the review of issues which require expertise beyond or in addition to that available on the IRB. Consultants with a conflict of interest may not provide information to the IRB. A consultant may not vote with the IRB.

3.  **Immediate Family:** An individual’s spouse, domestic partner, and dependent children.
RESPONSIBLE POSITIONS (TITLE):
IRB Administrator for review by a convened IRB
Designated Reviewer for Non-Committee Review

EQUIPMENT NEEDED:
eIRB Access
Institutional Review Board Guest Non-Disclosure Agreement

PROCEDURE STEPS, GUIDELINES, RULES, OR REFERENCE

1. PURPOSE
   1.1. This procedure establishes the process for the IRB to obtain consultants.
   1.2. The process begins when the IRB staff or IRB member has identified the need for consultation.
   1.3. The process ends when the consultant has provided additional expertise to the IRB.

2. PROCEDURE
   2.1. Identify a consultant with the required expertise who can provide a review.
   2.2. Contact the consultant and determine availability for review.
   2.3. Determine whether the consultant has a Conflict of Interest as defined in above. If so, obtain another consultant.
   2.4. Obtain a signed Non-disclosure agreement and Contract for Services from consultants who are not Palmetto Health employees.
   2.5. Determine which documents to make available to the consultant so the IRB can obtain the additional expertise needed, and make these documents available to the consultant. If the additional expertise needed does not require review of any materials, no materials need be provided.
   2.6. For review by the convened IRB:
      2.6.1. Make the consultant’s written comments, if any, available to the IRB members attending the meeting.
      2.6.2. If the consultant did not provide a written report or if requested by an IRB member, invite the consultant to the IRB meeting.
   2.7. For Non-Committee Review:
      2.7.1. Directly obtain the information (oral or written) from the consultant.
      2.7.2. Document information received with the name of the consultant.
REFERENCES
21 CFR §56.107(f), 45 CFR §46.107(f)
IRB Post-Review PGR

Effective: 10/21/2015
Reviewed: 10/21/2015

Name of Associated Policy: Human Research Protection Program

Responsible Positions
Equipment Needed
Procedure Steps
References

RESPONSIBLE POSITIONS (TITLE):
IRB Administrator
IRB Manager

EQUIPMENT NEEDED:
eIRB access
IRB Pre-Review PGR
WORKSHEET: Calculation of Approval Intervals
WORKSHEET: Communication of Review Results

PROCEDURE STEPS, GUIDELINES, RULES, OR REFERENCE

1. PURPOSE:
   1.1. This procedure outlines the process for communications after a protocol is reviewed.
   1.2. The process begins when:
      1.2.1. A Designated Reviewer has completed a Non-Committee Review and provided completed materials to the IRB staff; OR
      1.2.2. The IRB meeting has adjourned; OR
      1.2.3. The IRB administrator has verified that modifications required to secure approval have been made.
   1.3. The process ends when all correspondence related to IRB determinations and actions have been sent and additional tasks have been completed.
2. GUIDANCE
   2.1. The IRB reports its findings and actions to the investigator.
   2.2. The IRB reports its findings and actions to the institution.
   2.3. When the IRB disapproves research, it provides the investigator with a statement of the reasons for the decision and gives the investigator an opportunity to respond in person or in writing.
   2.4. The IRB reports its findings and actions to the investigator within 10 business days of the IRB meeting or receipt of a completed Non-Committee review.
   2.5. The IRB reports its findings involving an unanticipated problem involving risks to subjects or others, serious or continuing non-compliance with the regulations or the requirements or determinations of the IRB, or a suspension or termination of IRB approval within 30 days.

3. PROCEDURE
   3.1. If the Non-Committee Review indicated a Conflicting Interest or a lack of expertise, follow “IRB Pre-Review PGR.”
   3.2. Refer to “WORKSHEET: Calculation of Approval Intervals” to calculate approval and expiration dates.
   3.3. Stamp all approved consent documents.
   3.4. Refer to “WORKSHEET: Communication of Review Results” and
       3.4.1. Have the letter signed by the individual specified on the template letter.
       3.4.2. Send the letter PI and cc list as directed by the letter.
       3.4.3. An External Report must be sent within 30 days of recognition of the reportable event.
Annual Evaluation of the Human Research Protection Program PGR

Effective: 01/20/2016
Reviewed: 01/20/2018

Name of Associated Policy: Human Research Protection Program

DEFINITIONS:

1. Designated Institutional Official: The individual authorized by Palmetto Health who assumes the obligations of Palmetto Health’s Federalwide Assurance (FWA) with the Office for Human Research Protections (OHRP) and who assumes the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to research. Also referred to as the designated Signatory Official.

RESPONSIBLE POSITIONS (TITLE):

Designated Institutional Official
IRB Chair
IRB Manager

EQUIPMENT NEEDED:

BROCHURE: Becoming a Research Volunteer
TEMPLATE LETTER: IRB Member Appreciation
TEMPLATE: IRB Member and Chair Evaluation Tool
WORKSHEET: IRB Composition

PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATION

1. PURPOSE

1.1. This procedure establishes the process to conduct annual evaluations of the human research protection program.

1.2. The process begins the first business day of each October.

1.3. The process ends when all evaluations have been completed and communicated to those evaluated.
2. GUIDELINES
   2.1. The human research protection program is evaluated annually.
   2.2. The subject outreach program includes making the document “BROCHURE: Becoming a Research Volunteer” available to the subject population.

3. PROCEDURE
   3.1. Evaluate the resources (including but not limited to space, personnel, HRPP education program, legal counsel, conflict of interest and quality improvement) provided to the human research protection program and make adjustments as part of the budgeting process.
   3.2. Evaluate whether the number of IRBs is appropriate to the volume and types of research reviewed.
      3.2.1. Provide a copy of the evaluation to the Designated Institutional Official or designee.
      3.2.2. If the number of IRBs is not appropriate to the volume and types of research reviewed, work with the Designated Institutional Official or designee to modify the IRB structure.
   3.3. Use the “WORKSHEET: IRB Composition” to evaluate whether the composition of the IRB meets regulatory and organizational requirements.
      3.3.1. Provide a copy of the evaluation to the Designated Institutional Official or designee.
      3.3.2. If the composition of an IRB does not meet regulatory and organizational requirements, work with the Designated Institutional Official or designee to modify the IRB composition.
   3.4. Have the IRB chair and IRB members evaluate their knowledge, skills, and performance using the IRB Member and Chair Evaluation Tool.
      3.4.1. Provide a copy of the evaluation to the Designated Institutional Official or designee.
      3.4.2. Have the IRB Chair or IRB Manager provide feedback to each IRB member.
      3.4.3. Have the Organizational Official or designee provide feedback to the IRB Chair.
      3.4.4. Send a copy of the “TEMPLATE LETTER: IRB Member Appreciation” to:
         3.4.4.1. The IRB member’s supervisor for employees.
         3.4.4.2. The Medical Staff Affairs office for credentialed IRB members.
      3.4.5. If needed, work with the IRB chair and IRB member to develop a plan to improve the individual’s knowledge, skills, and performance.
   3.5. Follow the Human Resources annual employee evaluation process to evaluate the knowledge, skills, and performance of IRB staff.
   3.6. Follow the Community Research Education PGR to evaluate the subject outreach plan.
   3.7. Check whether each member of the IRB has been a member longer than 2 years, and if so, send the member a “TEMPLATE LETTER: IRB Member Appointment.”
3.8. Check when the last time each IRB was registered. If more than 2 years, update the registration.¹

3.9. Check when the last time the Federalwide Assurance (FWA) was updated or renewed. If more than 2 years, update/renew the Federalwide Assurance (FWA).²

REFERENCES
Huron’s HRPP SOPs, ©2009-2010 Huron Consulting Services, LLC. Use and distribution subject to End User License Agreement at http://www.huronconsultinggroup.com/SOP.


IRB Routine Tasks PGR

Name of Associated Policy: Humans Subjects Protection Program

**Responsible Positions**
- IRB Administrator
- IRB Coordinator
- IRB Manager

**Equipment Needed**
- eIRB Access

**Procedure Steps**

**RESPONSIBLE POSITIONS (TITLE):**
- IRB Administrator
- IRB Coordinator
- IRB Manager

**PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATIONS**

1. **PURPOSE:**
   1.1. This procedure establishes the process to complete routine tasks required to monitor and protect human subjects.
   1.2. The process begins each day and ends when the tasks have been completed.

2. **PROCEDURE:**
   2.1. All IRB Staff
       2.1.1. Daily: check eIRB inbox and follow “IRB Incoming Information PGR.”
   2.2. IRB Administrator
       2.2.1. Daily: check for expired protocols. Follow “IRB Expiration of Approval PGR”.
   2.3. IRB Coordinator
       2.3.1. Weekly: complete filing.
2.3.1.1. Follow “IRB Files PGR”.
2.3.2. Monthly: destroy closed study files
   2.3.2.1. Follow “IRB Files PGR”.

2.4. IRB Manager
   2.4.1. Daily: check “User Management / New User Campus User Account Requests”.
           2.4.1.1. Follow “eIRB User Management PGR”.
   2.4.2. Daily: check CITI training for expired IRB members. Send TEMPLATE LETTER: Expired CITI.
   2.4.3. Annually: update non-affiliated IRB members AD/Network Login annually.
           2.4.3.1. Follow “eIRB User Management PGR”.
   2.4.4. Annually: update and publish IRB meeting and IRB submission calendars.

REFERENCES
N/A
DEFINITIONS:

1. **Expiration**: A lapse in IRB approval of research when the investigator has failed to provide continuing review information to the IRB or the IRB has not conducted continuing review and re-approved the research – with or without conditions – by the expiration date of IRB approval.

RESPONSIBLE POSITIONS (TITLE):

IRB Administrator
IRB Manager

EQUIPMENT NEEDED:

eIRB Access
TEMPLATE LETTER: Expiration of Approval

PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATIONS

1. **Purpose**
   1.1. This procedure establishes the process for closing a study when IRB approval expired.
   1.2. The process begins the day following the last day of IRB approval or the next business day.
   1.3. The process ends when the correspondence is sent and all tasks are completed.

2. **Procedure**
   2.1. Complete the TEMPLATE LETTER: Expiration of Approval.
   2.2. Send the TEMPLATE LETTER: Expiration of Approval to the Principal Investigator.

3. Change the eIRB state from Expired to Complete.
IRB Files PGR

Effective: 10/21/2015
Reviewed: 10/21/2015

Name of Associated Policy: Human Research Protection Program Policy

Definitions

1. Institutional Review Board (IRB): An administrative body composed of scientists and non-scientists established to protect the rights and welfare of human subjects recruited to participate in research.
2. Investigator: An individual having the background and training in scientific and administrative oversight to conduct and manage research activities.
3. IRB Files:
   3.1. Protocol files
   3.2. Meeting minutes.
   3.3. Current and previous Institution/Organization (IORG) registration.
   3.4. Current and previous IRB registration (IRB).
   3.5. Current and previous Federal Wide Assurance (FWA).
   3.7. Current and previous IRB member files.
   3.8. Current and previous policies and procedures, checklists, worksheets and templates.

Responsible Positions (Title):

IRB Administrator
IRB Coordinator
IRB Manager

Equipment Needed:

Database: Closed Protocols
PROCEDURE STEPS, GUIDELINES, RULES, OR REFERENCE

1. PURPOSE

1.1. This procedure establishes the process to maintain IRB files.
1.2. The process begins when information is received or created.
1.3. The process ends when the information has been filed.

2. PROCEDURE, GUIDELINES

2.1. Electronic files are maintained on a secure server.
2.2. Electronic records are retained indefinitely.
2.3. Protocol Files will include, as applicable:
   2.3.1. Submitted materials.
   2.3.2. Protocols.
   2.3.3. Investigator Brochures.
   2.3.4. Scientific evaluations.
   2.3.5. Recruitment materials.
   2.3.6. Consent documents.
   2.3.7. DHHS-approved sample consent document and protocol, as applicable.
   2.3.8. Progress reports submitted by investigators.
   2.3.9. Reports of injuries to subjects.
   2.3.10. Records of continuing review activities.
   2.3.11. Data and safety monitoring board reports.
   2.3.12. Amendments.
   2.3.13. Reports of unanticipated problems involving risks to subjects or others.
   2.3.14. Documentation of non-compliance.
   2.3.15. Copies of correspondence between the IRB and the investigator related to the protocol.
   2.3.16. Significant findings and statements about them provided to subjects.
   2.3.17. For initial and continuing review of research by Expedited Review.
      2.3.17.1. The specific permissible category.
      2.3.17.2. Description of action taken by the reviewer.
      2.3.17.3. Documentation of determinations required by laws, regulations, codes and guidance.
   2.3.18. For exempt determinations the specific category of exemption.
   2.3.19. Unless documented in the IRB minutes, determinations required by laws, regulations, codes and guidance, and protocol-specific findings supporting those determinations for:
      2.3.19.1. Waiver or alteration of the consent process.
      2.3.19.2. Research involving pregnant women, fetuses, and neonates.
2.3.19.3. Research involving prisoners.
2.3.19.4. Research involving children.
2.3.19.5. Significant/non-significant device determinations.
2.3.19.6. Waiver or alteration of HIPAA Authorization.

2.3.20. For each protocol’s initial and continuing review, the frequency of the next continuing review.

2.3.21. Internal or local serious adverse events.

2.4. Paper Protocol Files are maintained in chronological order with the latest information in front, on the right side of a protocol folder, with an index tab divider for each year.

2.5. Retention of closed paper Protocol Files

2.5.1. The paper files relating to research conducted at Palmetto Health is retained for at least 3 years after completion of the research study, including studies without participant enrollment. Paper files are accessible for inspection and copying by authorized representatives of federal agencies or departments at reasonable times and in a reasonable manner.

2.5.2. Paper files are located in labeled cabinets by year and in chronological order.

2.5.3. Paper files of closed protocol studies are destroyed 3 years after closure in a secure and confidential manner.

2.5.4. The InfoEd record related to a closed research study is deleted after the paper file has been destroyed.

2.5.5. The Database: Closed Protocols is updated to reflect the date the paper file was destroyed.

2.6. Exempt Paper Protocol Files

2.6.1. Exempt studies are filed by year and in chronological order.

2.6.2. Exempt study files are destroyed in a secure and confidential manner after 5 years.

2.6.3. The Database: InfoEd record related to the exempt research study is deleted.

2.7. Emergency Use Paper Files

2.7.1. Emergency use paper files are located in a labeled cabinet in chronological order.

2.8. Meeting Minutes

2.8.1. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of study protocol related issues and their resolution.

2.8.2. Paper Meeting Minutes are filed in binders by year through 2011. The records are retained indefinitely.

2.8.3. eIRB Meeting Minutes are filed electronically.

2.9. Institution/Organization (IORG) registration

2.9.1. The IORG is filed in paper form or electronically.

2.10. Federal Wide Assurance (FWA)
2.10.1. The FWA is filed in paper form or electronically.

2.11. Authorization Agreements
   2.11.1. The original Authorization Agreement is filed and a copy is kept electronically.

2.12. IRB Member Files
   2.12.1. A file (paper or electronic) containing a CV and/or resume and IRB appointment letter is kept for each active member of the IRB.

2.13. Policies and Procedures/Guidelines/Rules (PGR), checklists, worksheets and templates are maintained in paper form or electronically.

2.14. Protocol Files are available only to the IRB, IRB Administration and Research Compliance staff, and authorized representatives of federal agencies or departments.
   2.14.2. Paper Protocol Files removed from the file room, are signed out indicating the PH IRB number, name of personnel removing the file, date and time signed out, and date and time signed in when the file is returned.
   2.14.3. Protocol Files are accessible for inspection and copying by authorized representatives of federal agencies or departments at reasonable times and in a reasonable manner.
DEFINITIONS:

1. **Designated Institutional Official**: The individual authorized by Palmetto Health who assumes the obligations of Palmetto Health’s Federalwide Assurance (FWA) with the Office for Human Research Protections (OHRP) and who assumes the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to research. Also referred to as the designated Signatory Official.

RESPONSIBLE POSITIONS (TITLE):

IRB Manager

EQUIPMENT NEEDED:

MyManuals access
R:\Common\02) Institutional Review Board access

PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATION

1. PURPOSE
   1.1 This procedure establishes the process to create and update policies, procedures/guidelines/rules (PGR’s), and associated checklists and worksheets.
1.2 The process begins when the IRB manager or Designated Institutional Official or designee determines that a policy, PGR and associated checklists and worksheets need to be created or modified.

1.3 The process ends when the new or revised policy, PGR and associated checklists and worksheets have been approved and filed.

2. PROCEDURE

2.1 The MyManuals system is the approved electronic tool used for retrieval, maintenance, and archiving of policies and PGR’s.

2.2 Assign an author, writer(s) if necessary, reviewer(s) and approver.

2.3 Have the author create or update the policy, PGR and associated checklists and worksheets.

2.4 Submit the policy or PGR to reviewers and approvers to approve the document.

2.5 Revise/update the policy or PGR in response to reviewers or approvers.

2.6 Once approved:

2.6.1 Post the approved policy or PGR on the Palmetto Health IRB Web site.

2.6.2 Post the approved checklists and worksheets on the common drive in CHECKLISTS or WORKSHEETS.

2.6.3 File the old checklists and worksheets on the common drive in CHECKLISTS/Archive or WORKSHEETS/Archive.

2.6.4 Send an email to affected individuals informing them of the change.
IRB Update Awaiting Receipt Database PGR

Effective: 10/21/2015
Reviewed: 10/21/2015

Name of Associated Policy: Human Research Protection Program

Responsible Positions
Equipment Needed
Procedure Steps
References

RESPONSIBLE POSITIONS (TITLE):
IRB Administrator

EQUIPMENT NEEDED:
DATABASE: Awaiting Receipt

PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATIONS

1. PURPOSE
   1.1. This procedure establishes the process to update the “DATABASE: Awaiting Receipt.”
   1.2. The process begins when a deadline is set or cleared.
   1.3. The process ends when the “DATABASE: Awaiting Receipt” has been updated

2. PROCEDURE
   2.1. For new entries enter the following fields in a new entry:
      2.1.1. Name: Enter the name of the investigator or individual responsible for response.
      2.1.2. Contact Information: The contact information for the responsible individual.
      2.1.3. Date Entered: Enter the date the letter was sent that included the request.
      2.1.4. Items Awaiting Receipt: Enter one of:
         2.1.4.2. Protocol for Emergency Use.
         2.1.4.3. Reportable Event follow-up.
2.1.4.4. Research Compliance Audit report follow-up.

2.1.5. Deadline:
   2.1.5.1. Enter a deadline of 5 days for “Five-Day Report of Emergency Use.”
   2.1.5.2. Enter a deadline of 30 days for “Protocol for Emergency Use.”
   2.1.5.3. For other items enter the deadline required by the IRB.

2.1.6. Date of Response: Leave blank.

2.1.7. Type of Response: Leave blank.

2.2. To update entries enter the following in the appropriate row:
   2.2.1. Date of Response: Date of response.
   2.2.2. Type of Response: Items submitted/ actions.
   2.2.3. Restricted: Y if the IRB has placed restrictions on the investigator otherwise N.
   2.2.4. Comments.

REFERENCES
NA
IRB Formation PGR

Effective: 03/02/2015
Reviewed: 03/02/2015

Name of Associated Policy: Human Research Protection Program Policy

Definitions
Responsible Positions
Equipment
Procedure Steps
References

DEFINITIONS:

RESPONSIBLE POSITIONS (TITLE):
Contracts/Compliance Administrator
IRB Administration Manager

EQUIPMENT NEEDED:
DATABASE: IRB Roster
FORM: IRB Member Information
IRB Member Appointment PGR
WORKSHEET: IRB Composition
PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATIONS

1. PURPOSE
   1.1. This procedure establishes the process to form or rely on a new IRB.
   1.2. The process begins when the Signatory Official or designee determines the need for a new IRB.
   1.3. The process ends when the IRB is registered, the Federalwide assurance (FWA) is updated, and the “DATABASE: IRB Roster” is updated.

2. PROCEDURE
   2.1. Determine from the Signatory Official or designee whether the IRB will conduct all reviews without limitation or will be limited to certain types of reviews. Indicate this on the “IRB Scope” tab of the “DATABASE: IRB Roster.”
   2.2. For external IRBs:
      2.2.1. Ensure that one or more of the following are true:
         2.2.1.1. The IRBs are part of an Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) accredited organization.
         2.2.1.2. The investigator is a collaborator on Human Research primarily conducted at another organization and the investigator’s role does not include interaction or intervention with subjects.
         2.2.1.3. The organization is engaged in the Human Research solely because it is receiving federal funds. (Employees and agents of the institution do not interact or intervene with subjects, gather or possess private identifiable information about subjects, nor obtain the consent of subjects.)
      2.2.2. Request the Contracts/Compliance Administrator to execute an IRB Authorization Agreement with the IRB.
      2.2.3. Upon receipt of a copy of the executed IRB Authorization Agreement from the external IRB:
         2.2.3.1. Update the FWA with the new IRB.
         2.2.3.2. File the FWA.
         2.2.3.3. Update the “DATABASE: IRB Roster.”
   2.3. For internal IRBs:
      2.3.1. Select:
         2.3.1.1. At least five individuals to serve as IRB members.
         2.3.1.2. Additional individuals to serve as alternate IRB members, if needed.
         2.3.1.3. At least one of the individuals to be the IRB chair.
      2.3.2. Follow “IRB Member Appointment PGR” for each IRB member.
      2.3.3. Use “WORKSHEET: IRB Composition” and revise the selected individuals as needed to ensure that the IRB is appropriately constituted.
      2.3.4. When all individuals have been appointed:
2.3.4.1. Update the IRB Registration\textsuperscript{i} with the new IRB information.
2.3.4.2. File the IRB Registration.
2.3.4.3. Update the FWA\textsuperscript{ii} with the new IRB.
2.3.4.4. File the FWA.
2.3.4.5. Update the “DATABASE: IRB Roster.”

REFERENCES
45 CFR 46.107, 45 CFR 46.103(b)(3), 45 CFR 46.115(a)(5)
21 CFR 56.107, 21 CFR 56.115(a)(5)

\textsuperscript{i} http://ohrp.cit.nih.gov/efile/IrbRnwStart.aspx
\textsuperscript{ii} http://ohrp.cit.nih.gov/efile/FwaStart.aspx
DEFINITIONS:
1. **Designated Institutional Official**: The individual authorized by Palmetto Health who assumes the obligations of Palmetto Health’s Federalwide Assurance (FWA) with the Office for Human Research Protections (OHRP) and who assumes the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to research. Also referred to as the designated Signatory Official.

RESPONSIBLE POSITIONS (TITLE):
IRB Manager

EQUIPMENT NEEDED:
DATABASE: IRB Roster
TEMPLATE LETTER: IRB Member Thank You

PROCEDURE STEPS, GUIDELINES, RULES, OR REFERENCE

1. PURPOSE
   1.1 This procedure establishes the process to remove an IRB.
   1.2 The process begins when the Designated Institutional Official or designee determines that an IRB is no longer needed.
   1.3 The process ends when the IRB is unregistered with OHRP and the federalwide assurance (FWA) is updated.

2. GUIDANCE
   2.1 IRB rosters are maintained using the “DATABASE: IRB Roster.”

3. PROCEDURE
   3.1 For internal IRBs:
3.1.1 For each IRB member who will no longer serve as an IRB member prepare a “TEMPLATE LETTER: IRB Member Thank You,” and send to the former IRB members.

3.1.2 Unregister the IRB with OHRP\(^1\).

3.1.3 Remove the IRB from the federalwide assurance (FWA)\(^2\).

3.1.4 Remove members from “DATABASE: IRB Roster”.

3.1.5 Remove the IRB from “DATABASE: IRB Roster”.

3.1.6 File:
   - 3.1.6.1 DATABASE: IRB Roster
   - 3.1.6.2 Federalwide assurance (FWA)
   - 3.1.6.3 TEMPLATE LETTER: IRB Member Thank You

3.2 For external IRBs follow the requirements of the inter-institutional agreement or contract.

3.2.1 Remove the IRB from the federalwide assurance (FWA)\(^2\).

3.2.2 Remove the IRB from “DATABASE: IRB Roster”.

3.2.3 File:
   - 3.2.3.1 DATABASE: IRB Roster
   - 3.2.3.2 Federalwide assurance (FWA)

REFERENCES
45 CFR §46.107, 45 CFR §46.103(b)(3), 45 CFR §46.115(a)(5).
21 CFR §56.107, 21 CFR §56.115(a)(5).


IRB Member Appointment PGR

Effective: 12/12/2012
Reviewed: 11/25/2014

Name of Associated Policy: Human Research Protection Program Policy

Definitions
Responsible Positions
Equipment Needed
Procedure Steps
References

DEFINITIONS:

1. Designated Institutional Official: The individual authorized by Palmetto Health who assumes the obligations of Palmetto Health’s Federalwide Assurance (FWA) with the Office for Human Research Protections (OHRP) and who assumes the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to research. Also referred to as the designated Signatory Official.

RESPONSIBLE POSITIONS (TITLE):

IRB Manager

EQUIPMENT NEEDED:

DATABASE: IRB Roster
FORM: IRB Member Information
TEMPLATE LETTER: IRB Member Appointment
TEMPLATE LETTER: New IRB Member Contact

PROCEDURE STEPS, GUIDELINES, RULES, OR REFERENCE

1. PURPOSE
   1.1. This PGR provides guidance on the process to add members to an IRB.
   1.2. The process begins when the Designated Institutional Official or IRB Chair identify the need to add a member to an IRB.
1.3. The process ends when the IRB member has been added to the DATABASE: IRB Roster and the IRB Registration with OHRP have been updated.

2. PROCEDURE

2.1. Ascertain from the Designated Institutional Official or designee the name, contact information, membership status (member or alternate), and office (chair or vice-chair) if applicable.

2.2. Use “WORKSHEET: IRB Composition” to ensure the IRB is appropriately constituted. Consult with Designated Institutional Official to revise membership as needed.

2.3. Prepare and send the TEMPLATE LETTER: New IRB Member Contact, to the individual.

2.4. When the individual has completed the training detailed in IRB Member Education:

2.4.1. Provide to the Designated Institutional Official for review and approval:

2.4.1.1. FORM: IRB Member Information.

2.4.1.2. Résumé or curriculum vita.

2.4.1.3. Completed “TEMPLATE LETTER: IRB Member Appointment.”

2.5. Once the appointment letter is signed by the Designated Institutional Official:

2.5.1. Send the signed “TEMPLATE LETTER: IRB Member Appointment” to the individual.

2.5.2. Update the registration of all affected IRBs.¹

2.5.3. Add the individual to the “Database: IRB Roster.”

2.6. File:

2.6.1. The FORM: IRB Member Information.

2.6.2. The individual’s résumé or curriculum vita.

2.6.3. A copy of the “TEMPLATE LETTER: IRB Member Appointment.”

REFERENCES
45 CFR §46.107, 45 CFR §46.103(b)(3), 45 CFR §46.115(a)(5)
21 CFR §56.107, 21 CFR §56.115(a)(5)

IRB Committee Member Removal PGR

Effective: 08/06/2013
Reviewed: 09/14/2015

Name of Associated Policy: Human Research Protection Program

Definitions

RESPONSIBLE POSITIONS (TITLE):

Institutional Official
IRB Chair
IRB Manager

EQUIPMENT NEEDED:

DATABASE: IRB Roster
IRB Member Appointment PGR
TEMPLATE LETTER: IRB Member Thank You
WORKSHEET: IRB Composition

PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATION

1. PURPOSE

   1.1. This procedure establishes the process to remove an IRB member.
1.2. The process begins when an IRB member resigns or is removed from one or more IRBs. This procedure applies if an individual is a member of more than one IRB and is being removed from some but not all IRBs.

1.3. The process ends when the IRB registration is updated.

2. PROCEDURE

2.1. The Institutional Official or designee may remove IRB members, alternate members, IRB chairs, and other officers (e.g., vice chairs). The Institutional Official may consult with the IRB chair or the IRB manager regarding the removal.

2.2. Remove the individual from “DATABASE: IRB Roster.”

2.3. Complete “WORKSHEET: IRB Composition” to ensure that the IRB is appropriately constituted.

2.4. If not, identify one or more replacement members and follow “IRB Member Appointment PGR.”

2.5. Prepare a “TEMPLATE LETTER: IRB Member Thank You” and send to the individual.

2.6. Update the registration of all affected IRBs.1

2.7. File:

2.7.1. DATABASE: IRB Roster

2.7.2. TEMPLATE LETTER: IRB Member Thank You

REFERENCES
45 CFR 46.107, 45 CFR 46.103(b)(3), 45 CFR 46.115(a)(5)
21 CFR 56.107, 21 CFR 56.115(a)(5)

IRB Meeting Scheduling and Notification PGR

Effective: 10/21/2015
Reviewed: 10/21/2015

Name of Associated Policy: Human Research Protection Program

Responsible Positions
Equipment Needed
Procedure Steps
References

RESPONSIBLE POSITIONS (TITLE):
IRB Manager

EQUIPMENT NEEDED:
NA

PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATION

1. PURPOSE
   1.1 This procedure establishes the process to schedule and notify individuals of convened meetings.
   1.2 The process begins when there are approximately fewer than six months of meetings on the current schedule.
   1.3 The process ends when meetings are scheduled at least six months in advance and individuals in the organization are notified of the schedule.

2. GUIDELINES
   2.1. Whenever possible the IRB schedules meetings at least 90 days in advance.
   2.2. Scheduled meetings are to occur at intervals appropriate for the quantity, complexity, and frequency of required actions, and to permit adequate oversight of the progress of approved research.
   2.3. Additional meetings may be scheduled on an ad hoc basis.

3. PROCEDURE
   3.1. Create a schedule of meetings for each IRB. Verify the meeting room availability.
   3.2. Post the schedule on Palmetto Health’s external Web site.
3.3. Notify the following individuals of the updated schedule through the Palmetto Health communication mechanisms:
   3.3.1. IRB members.
   3.3.2.Investigators and research staff on the IRB email list.
   3.3.3. Organizational Official or designee.

REFERENCES
ICH-GCP E6 3.3.2
Informed Consent Process for Research PGR

Effective: 11/25/2015
Reviewed: 11/25/2015

Name of Associated Policy: Informed Consent for Research Policy

**Responsible Positions**

**Equipment Needed**

**Procedure Steps**

**DEFINITIONS:**

1. **Assent:** A minor's agreement to participate in research. Mere failure to object should not be construed as assent. Not all minors are capable of assent due to their age, maturity, and psychological state.

2. **Impartial Witness:** A person who is independent of the research, who cannot be unfairly influenced by people involved with the research, who attends the informed consent process if the subject or the subject's legally authorized representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

3. **Investigator:** means a principal investigator or an individual authorized by the principal investigator and approved by the IRB to obtain consent for the specific protocol, such as a co-investigator, research assistant, or coordinator.

4. **Subject/representative:** means:
   - 1.2 The subject when the subject is an adult capable of providing consent.
   - 1.3 Legally authorized representative when the subject is an adult unable to give consent.
   - 1.4 One or both biologic or adoptive parents when the subject is a child or in the absence of a parent, a person authorized under applicable law to consent on behalf of the child to the child’s general medical care.

**RESPONSIBLE POSITIONS (TITLE):**

The principal investigator is responsible to ensure these procedures are carried out.

**EQUIPMENT NEEDED:**

IRB Legally Authorized Representatives, Children, and Guardians PGR
**IRB Written Documentation of Consent PGR**

Long form of consent documentation:
- Consent form

Short form of consent documentation:
- Short consent form
  - Summary (same information as the English consent form used for long form of consent documentation)

Requirement for written documentation of the consent process has been waived by the IRB:
- Consent script (same as consent form used for long form of consent documentation except that signature block is optional)

**PROCEDURE STEPS, GUIDELINES, RULES, OR REFERENCE**

1. **PURPOSE**
   1.1. This procedure establishes the process to obtain informed consent from subjects, the legally authorized representatives of adults unable to consent, or the parents or guardians of children.
   1.2. The process begins when an individual identifies a subject as a potential candidate for a research study.
   1.3. The process ends when a subject or the subject’s legally authorized representative provides legally effective informed consent or declines to do so.

2. **GUIDELINES**
   2.1. If the subject/representative understands more than one language, whenever possible, conduct the consent process in the preferred language of the subject/representative.
   2.2. If the subject is an adult unable to consent:
      2.2.1. The IRB must have specifically approved the protocol to allow the enrollment of adults unable to consent.
      2.2.2. Permission is obtained from a legally authorized representative.
      2.2.3. A legally authorized representative must be in the class or persons approved by institutional policy or the IRB. See [IRB Legally Authorized Representatives, Children, and Guardians PGR](http://www.huronconsultinggroup.com/SOP).
   2.3. If the subject is a child:
      2.3.1. The IRB must have specifically approved the protocol to allow the enrollment of children.
      2.3.2. Permission is obtained from both parents unless:
         2.3.2.1. One parent is deceased, unknown, incompetent, not reasonably available;
         2.3.2.2. Only one parent has legal responsibility for the care and custody of the child;
            or
         2.3.2.3. The IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.
2.3.3. In the absence of a parent, permission may be obtained from an individual authorized to consent under applicable law on behalf of a child to general medical care.

2.4. If the subject/representative cannot speak English:
   2.4.1. The IRB must have specifically approved the protocol to allow the enrollment of subjects who speak the language the subject understands.

2.5. Conduct all discussions in a private and quiet setting.

2.6. Any study staff member may:
   2.6.1. Review the study with subject/representative to determine preliminary interest.
   2.6.2. If the subject/representative is interested, notify an investigator.
   2.6.3. If the subject/representative is not interested, take no further steps regarding recruitment or enrollment.

3. PROCEDURE

3.1. If the consent process will be documented in writing with the long form of consent documentation:
   3.1.1. Obtain the current IRB approved consent form.
   3.1.2. Verify that you are using the most current IRB-approved version of the study specific consent form and that the consent form is in the language understandable to the subject/representative.
   3.1.3. Provide a copy of the consent form to the subject/representative. Whenever possible provide the consent form to the subject/representative in advance of the consent discussion.
   3.1.4. If the subject/representative cannot read, obtain an Impartial Witness to be present during the entire consent discussion to attest that the information in the consent form and any other information provided was accurately explained to, and apparently understood by, the subject/representative, and that consent was freely given. The Impartial Witness may be a family member or friend. The Impartial Witness may not be a person involved in the design, conduct, or reporting of the research study.
   3.1.5. If the subject/representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. Follow the Palmetto Health Policy and PGRs to procure the services of an interpreter.
   3.1.6. Read the consent document (or have an interpreter read the translated consent document) with the subject/representative. Explain the details in such a way that the subject/representative understands what it would be like to take part in the research study.

3.2. If the consent process will be documented in writing with the short form of consent documentation:
   3.2.1. Obtain the current IRB approved short consent form and summary (same as the English consent form used for long form of consent documentation).
3.2.2. Verify that you are using the most current IRB-approved version of the study specific short consent form and summary and that the short consent form is in language understandable to the subject/representative.

3.2.3. Provide copies to the subject/representative. Whenever possible provide the short consent form and summary to the subject/representative in advance of the consent discussion.

3.2.4. Obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. Follow the Palmetto Health Policy and PGRs to procure the services of an interpreter.

3.2.5. Obtain the services of an Impartial Witness who is fluent in both English and the language spoken by the subject/representative to be present during the entire consent discussion to attest that the information in the short consent form, summary, and any other information provided was accurately explained to, and apparently understood by, the subject/representative, and that consent was freely given. The Impartial Witness and the interpreter may be the same person as described in 3.2.4. or the Impartial Witness may be a family member or friend. The Impartial Witness may not be a person involved in the design, conduct, or reporting of the research study.

3.2.6. Have the interpreter translate the summary (not the short consent form) to the subject/representative.

3.2.7. Through the interpreter explain the details in such a way that the subject/representative understands what it would be like to take part in the research study. When necessary provide a different or simpler explanation to make the information understandable.

3.2.8. Have the subject/representative read the short consent form or have the interpreter read the short consent form to the subject/representative.

3.3. If the requirement for written documentation of the consent process has been waived by the IRB:

3.3.1. Obtain the current IRB approved script.

3.3.2. Verify that you are using the most current IRB-approved version of the study specific script and that the script language is understandable to the subject/representative.

3.3.3. When possible provide a copy of the script to the subject/representative.

3.3.4. If the subject/representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. Follow the Palmetto Health Policy and PGRs to procure the services of an interpreter.

3.3.5. Read the script (or have an interpreter translated the script) with the subject/representative. Explain the details in such a way that the subject/representative understands what it would be like to take part in the research study.

3.4. Invite and answer the subject/representative’s questions.

3.5. Give the subject/representative time to discuss taking part in the research study with family members, friends and other care providers as appropriate.
3.6. Invite and encourage the subject/representative to take the written information and discuss the decision with family members and others before making a decision.

3.7. Ask the subject/representative questions to determine whether all of the following are true, and if not, either continue the explanation or determine that the subject/representative is incapable of consent:
   3.7.1. The subject/representative understands the information provided.
   3.7.2. The subject/representative does not feel pressured by time or other factors to make a decision.
   3.7.3. The subject/representative understands that there is a voluntary choice to make.
   3.7.4. The subject/representative is capable of making and communicating an informed choice.

3.8. If the subject/representative has questions about treatments or compensation for injury, provide factual information and avoid statements that imply that compensation or treatment is never available.

3.9. If the study is a clinical trial and the individual above is not a physician or physician extender, the physician or physician extender must complete the following steps.
   3.9.1. Invite and answer the subject/representative’s questions.
   3.9.2. Confirm that the following are true or repeat the above steps:
       3.9.2.1. The subject/representative understands the information provided.
       3.9.2.2. The subject/representative does not feel pressured by time or other factors to make a decision.
       3.9.2.3. The subject/representative understands that there is a voluntary choice to make.
       3.9.2.4. The subject/representative is capable of making and communicating an informed choice.

3.10. Once a subject/representative indicates that he or she does not want to take part in the research study, this process stops.

3.11. If the subject/representative agrees to take part in the research study:
   3.11.1. If the subject is a child:
       3.11.1.1. Whenever possible explain the research to the extent compatible with the child’s understanding.
       3.11.1.2. Request the assent (affirmative agreement) of the child unless:
           3.11.1.2.1. The capability of the child is so limited that the child cannot reasonably be consulted.
           3.11.1.2.2. The IRB determined that assent was not a requirement.
       3.11.1.3. Once a child indicates that he or she does not want to take part in the research study, this process stops.
   3.11.2. If the subject is an adult unable to consent:
3.11.2.1. Whenever possible explain the research to the extent compatible with
the adult’s understanding.

3.11.2.2. Request the assent (affirmative agreement) of the adult unless:
   3.11.2.2.1. The capability of the adult is so limited that the adult
cannot reasonably be consulted.
   3.11.2.2.2. The IRB determined that assent was not a requirement.

3.11.2.3. Once an adult unable to consent indicates that he or she does not want
to take part in the research study, this process stops.

3.11.3. Obtain written documentation of the consent process according to IRB Written
Documentation of Consent PGR.

REFERENCES
21 CFR 50.20, 50.25
45 CFR 46.116
E6: Good Clinical Practice
IRB Written Documentation of Consent PGR

Effective: 10/22/2015
Reviewed: 10/22/2015

Name of Associated Policy: Human Research Protection Program

Definitions

1. Investigator: means a principal investigator or an individual authorized by the principal investigator and approved by the IRB to obtain consent for the specific protocol, such as a co-investigator, research assistant, or coordinator.

2. Subject/representative: means:
   2.2 The subject, when the subject is an adult capable of providing consent.
   2.3 A legally authorized representative when the subject is an adult unable to give consent.
   2.4 One or both biologic or adoptive parents when the subject is a child or in the absence of a parent, a person authorized under applicable law to consent on behalf of the child to the child’s general medical care.

Responsible Positions

Principal Investigator

Equipment

TEMPLATE Consent Document
TEMPLATE Consent Document Short Form and Summary
PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATIONS

1. PURPOSE
   1.1. This procedure establishes the process to document the informed consent process in writing.
   1.2. The process begins when a subject agrees to take part in a research study.
   1.3. The process ends when the consent process is documented in writing to the extent required by this procedure.

2. PROCEDURE
   2.1. If the consent process will be documented in writing with the long form of consent documentation:
      2.1.1. Verify that the consent form is in a language understandable to the subject/representative.
      2.1.2. Print the name of the following individuals on the consent document:
              2.1.2.1. Subject/Representative
              2.1.2.2. Person obtaining consent
      2.1.3. Have the following individuals personally sign and date the consent document:
              2.1.3.1. Subject/Representative
              2.1.3.2. Person obtaining consent
      2.1.4. If the IRB required written documentation of assent, note on the consent document one of the following:
              2.1.4.1. Assent of the child was obtained.
              2.1.4.2. Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
      2.1.5. Have the person obtaining consent personally sign and date the consent document.
      2.1.6. If an impartial witness was part of the consent process:
              2.1.6.1. Print the name of the impartial witness on the consent document.
              2.1.6.2. Have the impartial witness personally sign and date the consent document to attest that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject, and that consent was freely given.
      2.1.7. Provided copies of the signed and dated consent document to the subject/representative. This may be accomplished either by making a photocopy or by having the above individuals sign and date two copies of the consent document.

   2.2. If the consent process will be documented in writing with the short form of consent documentation:
      2.2.1. Verify that the short consent form is in a language understandable to the subject/representative.
      2.2.2. Print the name of the following individuals on the short form consent document and the summary:
2.2.2.1. Subject/Representative  
2.2.2.2. Person actually obtaining consent  
2.2.2.3. Impartial witness  

2.2.3. Have the following individuals personally sign and date the short form consent document and the summary:  
2.2.3.1. Subject/Representative  
2.2.3.2. Person actually obtaining consent  
2.2.3.3. Impartial witness  

2.2.4. If the IRB required written documentation of assent, note on the short form consent document one of the following:  
2.2.4.1. Assent of the child was obtained.  
2.2.4.2. Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.  

2.2.5. Provide a copy of the signed and dated short consent document and a copy of the signed and dated summary to the subject/representative. This may be accomplished either by making photocopies or by having the above individuals sign and date two copies of the short consent document and summary.  

2.3. If the requirement for written documentation of the consent process has been waived by the IRB but, the IRB determined that the subject/representative had to be offered the opportunity to document his or her consent is writing, offer the subject/representative the option to document his or her consent is writing.  
2.3.1. If the subject/representative declines, take no further action.  
2.3.2. If the subject/representative accepts, follow the process to document consent in writing with the long or short form of consent documentation.  

2.4. Place the signed and dated documents in the subject’s binder.  

REFERENCES  
21 CFR 50.27  
45 CFR 46.117  
IRB Legally Authorized Representative, Children and Guardians PGR
DEFINITIONS:
NA

RESPONSIBLE POSITIONS (TITLE):
Principal Investigator (PI)
Co-Investigator(s)
Study Coordinator
Study Team Member(s)

EQUIPMENT NEEDED:
eIRB access

PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATIONS
1. PURPOSE
   1.1. This procedure describes the process for reporting New Information to the IRB.
   1.2. The process begins when the PI, or a Co-Investigator, or the Study Coordinator or a Study Team Member becomes aware of the New Information.
   1.3. The process ends when the PI reports the New Information to the IRB.

2. GUIDANCE
   2.1. Report the information items that fall into one or more of the following categories to the IRB within 5 business days:
2.1.1. Information that indicates a new or increased risk, or a safety issue. For example:

2.1.1.1. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.

2.1.1.2. An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk.

2.1.1.3. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.

2.1.1.4. Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm.

2.1.1.5. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm.

2.1.1.6. Any changes significantly affecting the conduct of the research.

2.1.2. Any harm experienced by a subject or other individual, which in the opinion of the investigator are unexpected and probably related to the research procedures.

2.1.2.1. A harm is “unexpected” when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.

2.1.2.2. A harm is “probably related” to the research procedures if in the opinion of the investigator, the research procedures more likely than not caused the harm.

2.1.3. Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.

2.1.4. Audit, inspection, or inquiry by a federal agency.

2.1.5. Failure to follow the protocol due to the action or inaction of the investigator or research staff.


2.1.7. Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.

2.1.8. Incarceration of a subject in a study not approved by the IRB to involve prisoners.

2.1.9. Complaint of a subject that cannot be resolved by the research team.

2.1.10. Premature suspension or termination of the research by the sponsor, investigator, or institution.

2.1.11. Unanticipated adverse drug or device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a drug or device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a drug or device that relates to the rights, safety, or welfare of subjects.)

2.2. Information that does not fall under any of the categories listed above does not require reporting to the IRB.
3. PROCEDURE
   3.1. In eIRB open a “New Reportable Event.”
   3.2. Complete the documentation.
   3.3. Submit the “New Reportable Event.”

REFERENCES
NA
Clinical Research Forums PGR

Effective: 09/16/2016
Reviewed: 09/16/2018

Name of Associated Policy: Human Research Protection Program

DEFINITIONS:
1. Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

RESPONSIBLE POSITIONS (TITLE):
Research Educator

EQUIPMENT NEEDED: NA

PROCEDURE STEPS, GUIDELINES, OR REFERENCE
1. The purposes of the forums are to provide an avenue by which investigators and their research staffs can:
   1.1. Stay abreast of changes in federal, international, and institutional regulations and good clinical practice guidelines in research to maintain competency in practice.
   1.2. Be exposed to the broader scope of clinical investigation by hearing presentations of research studies by investigators from various clinical disciplines.
   1.3. Have the opportunity to network and form professional relationships with other professionals involved in clinical research.
2. The forums are coordinated by the Research Educator in IRB Administration.
3. Forums are held six times each calendar year, usually on a bi-monthly schedule, and last an hour.
   3.1. The yearly schedule is distributed electronically
4. Attendance at the forums is voluntary, and anyone who has an interest in research may attend.
5. The Research Educator will maintain a roster of interested persons and their contact information.
6. Communication with the group is maintained between forums via email.
   6.1. A bi-monthly news sheet is sent to persons on the forum roster.
   6.2. Other items of interest received by the Research Educator (e.g., research news from federal websites, research articles, flyers and brochures regarding educational opportunities related to research, etc.) are distributed in a timely manner.
7. Speakers are encouraged to utilize slide presentations or other types of media with their
presentations and to offer accompanying handouts for the attendees as appropriate.

8. Attendees are requested to complete a form which evaluates each forum and the particular speaker and which also provides the opportunity to express learning needs.

8.1. Results of the evaluation are shared with each speaker.

8.2. The Research Educator will utilize the feedback regarding the forum, particularly any comments made and learning needs expressed, to improve the quality of the forum and/or programs.

REFERENCES
Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)
http://www.aahrpp.org/learn/accreditation/goals-principles-standards
DEFINITIONS:

1. **Institutional Review Board (IRB):** An administrative body composed of scientists and non-scientists established to protect the rights and welfare of human subjects recruited to participate research.

RESPONSIBLE POSITIONS (TITLE):

PH IRB Administration employees

EQUIPMENT NEEDED: NA

PROCEDURE STEPS, GUIDELINES, OR REFERENCE

1. **INITIAL EDUCATION REQUIREMENTS**
   1.1. As required by the departmental orientation program, all new employees in IRB Administration must complete The Basic Course for Institutional Review Board Members of the Collaborative IRB Training Initiative (CITI) training program at the following website: [http://www.citiprogram.org](http://www.citiprogram.org).
   1.2. All users must affiliate with Palmetto Health and complete the training requirements; users may be affiliated with multiple institutions.
   1.3. A passing score of 80% on each module in the course is required.
   1.4. See Appendix A for additional information regarding access and registration for CITI online programs.

2. **CONTINUING EDUCATION REQUIREMENTS**
   2.1. All IRB Administration staff must complete continuing education training in the protection of human subjects in research every two (2) years
   2.2. The requirement must be accomplished via the online Collaborative IRB Training Initiative (CITI) training program at the following website: [http://www.citiprogram.org](http://www.citiprogram.org).
2.3. IRB Administration staff members will be automatically notified by CITI program registration when the Institutional Review Board Members Refresher Course is due if:

2.3.1. The PH requirements and instructions for completion of the program are followed.

2.3.2. The current email address of the researcher is the one that has been registered with the CITI program.

2.4. All users must continue to affiliate with PH and complete the training requirements.

2.5. A passing score of 80% on each module in the course is required.

2.6. See Appendix A for additional information regarding access and registration for online programs and instructions for completing courses in cyclical manner.

REFERENCES

Objectivity in Research (Potential Conflict of Interest)

Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)
http://www.aahrpp.org/learn/accreditation/goals-principles-standards

APPENDIX A

Access and Registration
1. Go to the following website: https://www.citiprogram.org.
2. If you are a new user, complete the registration process, affiliate with Palmetto Health, and submit information to be given access to the main menu.
3. If you are already a registered user, login to access the main menu and affiliate with Palmetto Health if you have not previously done so.
4. Palmetto Health specific instructions for completing the courses may be accessed from the main menu.
5. The Basic Course and the two Refresher Courses must be completed in sequential order every two years as a continuing cycle.
DEFINITIONS:

1. **Credentialed Clinical Staff**: Nurses, pharmacists, therapists, technicians, dietitians, social workers, psychologists, counselors, and any other health care professionals who must be licensed, registered, or credentialed in any other manner to provide specialized clinical care for patients.

2. **Human Subject**: A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.

3. **Institutional Review Board (IRB)**: An administrative body composed of scientists and non-scientists established to protect the rights and welfare of human subjects recruited to participate in research.

RESPONSIBLE POSITIONS (TITLE):

Credentialed Clinical Staff and Their Supervisors at Palmetto Health (PH)

PROCEDURE STEPS, GUIDELINES, or RECOMMENDATIONS

1. All nurses, including contract nurses, in clinical nursing practice areas (excluding those that work in Palmetto Health-owned physician practices that are not involved in research) and all pharmacists at Palmetto Health must demonstrate and maintain sufficient knowledge of the ethical principles and federal, state, and institutional requirements for protecting human research participants. For all other credentialed clinical staff, this training is optional but strongly recommended.

   1.1 As these professionals participate in the delivery of care to patients who are participating in research studies, they acquire responsibilities in regard to research compliance.

   1.1.1 Their documentation on the patient’s medical record may be utilized as source documentation for a research study.

   1.1.2 They may be administering investigative drugs and/or assisting in the implementation of other treatments and procedures that are directly related to the requirements of the research protocol.
1.1.3. During their assessments of patients as they deliver care, they are often the first health professionals to become aware of unanticipated problems and adverse events that may be related to the treatments/procedures of the research study.

1.2. The basic PH online program, entitled “Protection of Human Subjects in Research,” has been formatted into three separate courses, depending upon the content that is needed for nurses, pharmacists, and all other professional specialties.

2. Nurses and pharmacists must successfully complete their practice-specific basic course with a score of at least 80% during their orientation program as a new PH employee. A refresher course of summarized content from the basic course and updated information regarding regulations and good clinical practices in research will be required for each nurse and pharmacist every two (2) years. For all other credentialed clinical staff, completion of the refresher course is optional but strongly recommended.

2.1. Nurses for whom this education is required will complete the basic course as part of new nurse employee orientation. On a bi-annual basis, a refresher course will also be required of these nurses as part of required training though the Nursing Orientation and Training educational system.

2.2. Pharmacists, all other credentialed staff, and other nurses for whom this training is not required but who elect to complete it should refer to Appendix A for information regarding access and registration for these online courses.

2.3. Verification of current completion status for the basic course and refresher courses (or CITI training as cited in 2.6 below) for nurses and pharmacists is the responsibility of the supervisor for each employee.

2.4. All newly hired nurses for clinical nursing practice areas, including contract nurses, and pharmacists are required to complete the basic course within three (3) months of their hire dates.

2.5. Nurses and pharmacists who have completed, maintained, and affiliated with PH for the PH-required “Collaborative IRB Training Initiative” (CITI) programs are exempt from completing the PH online basic and refresher courses.

2.5.1. For complete information about the CITI program, refer to the Human Research Protections Program PGR entitled, “Education for Investigators and Research Staff.”

REFERENCES

Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)
http://www.aahrpp.org/learn/accreditation/goals-principles-standards
APPENDIX A

Protection of Human Subjects in Research – Access Information via eUniversity

Directions for: Pharmacists, all other credentialed clinical staff and nurses for whom this education is not required.

*Note: Nurses for whom this education is required during orientation as a new employee or every two years as part of their annual training should utilize directions provided by Nursing Education and Professional Development for access to the research courses through a different system.*

1. Open myPal and follow path below to access eUniversity:

   *Human Resources* > *Organization Development* > *eUniversity*

2. Click on options in this order:
   - *Training and Registration*
   - *Online Learning and Development*
   - *Continuing Education* (Note login/password information at top of page which will be needed in step 4.)

3. Click on *Protection of Human Subjects in Research* to open a registration page.

4.a. If you have previously registered in the online education program, click on the words “click here.”
   
   (1) You will receive an email which confirms your registration for the event (referring to the tutorial) and contains a link to which allows access to the event. You will be required to enter your password again for the event page to open.
   
   (2) In the upper left area of the page, there are three (3) tutorials available: Nursing Staff, Pharmacists, and All Other (for all other credentialed clinical support staff). Click on the green button to the right of the appropriate tutorial for your professional specialty to open the tutorial.

4.b. If you have not previously registered in the online education program, complete the registration page and submit.

   (1) You will receive an email which confirms your registration for the event (referring to the tutorial) and contains a link to which allows access to the event. You will be required to enter your password again for the event page to open.
   
   (2) In the upper left area of the page, there are three (3) tutorials available: Nursing Staff, Pharmacists, and All Other (for all other credentialed clinical support staff). Click on the green button to the right of the appropriate tutorial for your professional specialty to open the tutorial.
IRB Education for Signatory Official and IRB Members PGR

Name of Associated Policy: Human Research Protection Program

DEFINITIONS:

1. Institutional Review Board (IRB): An administrative body composed of scientists and non-scientists established to protect the rights and welfare of human subjects recruited to participate research.

2. Signatory Official (SO): The Official legally authorized to represent Palmetto Health. The Signatory Official assures that human subject research to which the Federalwide Assurance for the protection of Human Subjects (FWA) applies is conducted in accordance with the terms of assurance.

RESPONSIBLE POSITIONS (TITLE):

Signatory Official
IRB Chair and Members

EQUIPMENT NEEDED:

Internet access

PROCEDURE STEPS, GUIDELINES, OR RECOMMENDED ACTION:

1. EDUCATION REQUIREMENTS FOR THE SIGNATORY OFFICIAL:
   1.1. Within six months of appointment the signatory official (SO) must complete the IRB Members course of the Collaborative IRB Training Initiative (CITI) training program at the following website: http://www.citiprogram.org.
   1.1.1. The SO must affiliate with Palmetto Health and complete the training requirements; the SO may be affiliated with multiple institutions.
1.1.2. A passing score of 80% on each module in the course is required.
1.1.3. See Appendix A for additional information regarding access and registration for CITI online programs.

1.2. The SO must complete continuing education training in the protection of human subjects in research every two (2) years
1.2.1. The SO will be automatically notified by CITI program registration when the Refresher Course is due if:
1.2.1.1. The PH requirements and instructions for completion of the program are followed.
1.2.1.2. The current email address of the SO is the one that has been registered with the CITI program.

2. EDUCATION REQUIREMENTS FOR IRB MEMBERS:
2.1. Candidates for IRB membership must complete the IRB Members course of the Collaborative IRB Training Initiative (CITI) training program at the following website: http://www.citiprogram.org prior to being approved and appointed to the IRB.
2.1.1. Users must affiliate with Palmetto Health and complete the training requirements; users may be affiliated with multiple institutions.
2.1.2. A passing score of 80% on each module in the course is required.
2.1.3. See Appendix A for additional information regarding access and registration for CITI online programs.

2.2. IRB members must complete continuing education training in the protection of human subjects in research every two (2) years
2.2.1. IRB members will be automatically notified by CITI program registration when the Refresher Course due if:
2.2.1.1. The PH requirements and instructions for completion of the program are followed.
2.2.1.2. The current email address of the IRB member is the one that has been registered with the CITI program.

2.3. The agenda for every convened meeting of the IRB will include time dedicated to the presentation of a continuing education topic that is pertinent to the roles and responsibilities of the board members.
2.3.1. Educational materials associated with the presentation will be hyperlinked to the agenda for the convenience of the board members and also included in a dedicated education folder in the electronic IRB (eIRB) software system.
2.3.2. In the event the length of a board meeting does not leave time for the educational presentation or the board meeting is cancelled, it is the responsibility of the board member to access the educational information in eIRB.

REFERENCES
Objectivity in Research (Potential Conflict of Interest)
Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)
http://www.aahrpp.org/learn/accreditation/goals-principles-standards

APPENDIX A

CITI Training
Training in the Protection of Human Subjects in Research

All Institutional Review Board (IRB) members are required to complete training on ethical principles and regulations pertaining to research with human subjects. The Palmetto Health Institutional Review Board uses the Collaborative Institutional Training Initiative (CITI) which is an Internet-based set of educational modules on the protection of human subjects in research.

Steps for CITI Training Completion

- Go to www.citiprogram.org
- Select “Create an Account - Register”
- Select “Palmetto Health” as the Participating Institution.
- Create your Username, Password, and Security Question/Answer.
- Enter your name and email address.
- Select the curriculum for “IRB Members,” which includes a “Conflict of Interest” mini-course.

Note: If you have previously affiliated with a different institution, you will need to:
- Affiliating with Palmetto Health by choosing the option, “Affiliate with New Institution” on the main menu page.
- Select the curriculum for “IRB Members,” which includes a “Conflict of Interest” mini-course.
- Previous course modules that you have completed within the past two years for courses at another institution may populate over to the IRB Members Course.

Completing the required modules will take approximately 4 to 6 hours of your time. A minimum score of 80% must be obtained. Those not reaching a passing score will need to review the content of the modules and re-take the exam until a score of ≥ 80% is obtained.

Every two years IRB members are required to renew their training. Members will be automatically notified by CITI program registration when the Refresher Course is due if:
- The PH requirements and instructions for completion of the program are followed.
- The current email address of the board member is the one that was previously registered with the CITI program. Thus, any time your email address changes, you should update the address in the CITI program to ensure that you get a reminder 3 months before the expiration of your training.
IRB Education for Investigators, Research Staff, and Physicians and Staff using HUDs PGR

Effective: 07/11/2016
Reviewed: 07/11/2018

Name of Associated Policy: Human Research Protection Program Policy

DEFINITIONS:

1. **Human Subject**: A living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.

2. **Humanitarian Use Device (HUD)**: A medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.

3. **Institutional Review Board (IRB)**: An administrative body composed of scientists and non-scientists established to protect the rights and welfare of human subjects recruited to participate research.

4. **Investigator**: An individual having the background and training in scientific and administrative oversight to conduct and manage research activities.

5. **Research**: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

6. **Research Staff**: Individual(s) who assist investigators in the conduction of research studies.

RESPONSIBLE POSITIONS (TITLE):

- Investigators
- Research Staff
- Physicians and Staff using HUDs

EQUIPMENT NEEDED:

- Internet Access
PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATIONS

1. INITIAL EDUCATION REQUIREMENTS FOR THE CONDUCT OF RESEARCH:
   1.1. Researchers (principal investigators, co-investigators, and research staff) involved in human subject research must complete a basic training course in the protection of human subjects in research before a study protocol is reviewed by the IRB.
   1.2. The requirement must be accomplished via the online Collaborative IRB Training Initiative (CITI) training program at the following website: [http://www.citiprogram.org](http://www.citiprogram.org).
   1.3. Users must affiliate with Palmetto Health and complete the training requirements; users may be affiliated with multiple institutions.
   1.4. Researchers involved in clinical research must complete the Basic Course for Biomedical Research Investigators.
   1.5. Researchers involved in psychosocial research must complete the Basic Course for Social & Behavioral Research Investigators.
   1.6. A passing score of 80% on each module in the course is required.
   1.7. See Appendix A for additional information regarding access and registration for CITI online programs.

2. CONTINUING EDUCATION REQUIREMENTS FOR THE CONDUCT OF RESEARCH:
   2.1. Researchers (principal investigators, co-investigators, and research staff) involved in human subject research must complete continuing education training in the protection of human subjects in research every two (2) years.
   2.2. The requirement must be accomplished via the online Collaborative IRB Training Initiative (CITI) training program at the following website: [http://www.citiprogram.org](http://www.citiprogram.org).
   2.3. Researchers will be automatically notified by CITI program registration when the Refresher Course is due if:
      2.3.1. The PH requirements and instructions for completion of the program are followed.
      2.3.2. The current email address of the researcher is the one that has been registered with the CITI program.
   2.4. Users must continue to affiliate with PH and complete the training requirements.
   2.5. Researchers involved in clinical research must complete the Refresher Course for Biomedical Research Investigators.
   2.6. Researchers involved in psychosocial research must complete the Refresher Courses for Social & Behavioral Research Investigators.
   2.7. A passing score of 80% on each module in the course is required.
   2.8. See Appendix A for additional information regarding access and registration for online programs and instructions for completing courses in a cyclical manner.

3. EDUCATION REQUIREMENTS FOR THE USE OF A HUD
   3.1. Physicians and staff involved in the use of a HUD within the FDA-approved indications must complete the CITI Humanitarian Use Device Course every two (2) years.
   3.2. Researchers (principal investigators, co-investigators, and research staff) involved in the research of a HUD must complete the CITI Humanitarian Use Device Course every two (2) years.
   3.3. Users must affiliate with Palmetto Health and complete the training requirements; users may be affiliated with multiple institutions.
   3.4. A passing score of 80% on each module in the course is required.
3.5. See Appendix A for additional information regarding access and registration for CITI online programs.

REFERENCES

Objectivity in Research (Potential Conflict of Interest)

Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP)
http://www.aahrpp.org/learn/accreditation/goals-principles-standards


From U.S. Department of Health & Human Services, Office of Human Research Protections: “Must investigators obtain training in the protection of human subjects?”
http://answers.hhs.gov/ohrp/questions/7224

APPENDIX A

Access and Registration
1. Go to the following website: https://www.citiprogram.org.
2. If you are a new user, complete the registration process, affiliate with Palmetto Health, and submit information to be given access to the main menu.
3. If you are already a registered user, login to access the main menu and affiliate with Palmetto Health if you have not previously done so.

4. Palmetto Health specific instructions for completing the courses may be accessed from the main menu.

5. The Basic Course and the available Refresher Courses (two for Biomedical Researchers and one for Social-Behavioral Researchers) must be completed in sequential order every two years as a continuing cycle.

6. The Conflict of Interest Course must be completed by Researchers (principal investigators, co-investigators, and research staff) every two years in addition to the required cyclical course.

4. Physicians and staff involved in the use of a HUD must complete the CITI Humanitarian Use Device Course every two (2) years.
Orientation of Candidates for IRB Membership

DEFINITIONS:

1. Institutional Review Board (IRB): An administrative body composed of scientists and non-scientists established to protect the rights and welfare of human subjects recruited to participate in research.

2. Mentor: An experienced IRB member who assists a new IRB member in acclimating to the role and functions of IRB members.

3. Signatory Official (SO): The Official legally authorized to represent Palmetto Health. The Signatory Official assures that human subject research to which the Federalwide Assurance for the protection of Human Subjects (FWA) applies is conducted in accordance with the terms of assurance.

RESPONSIBLE POSITIONS (TITLE):

IRB Administrator
IRB Manager
IRB Member Candidate
Research Educator

EQUIPMENT NEEDED:

CHECKLIST: Orientation of Candidates for IRB Membership
Orientation Packet of instructions and educational resource materials
Reference Books – Protecting Study Volunteers in Research and Institutional Review Board Member Handbook

PROCEDURE STEPS, GUIDELINES, OR RECOMMENDATION

1. PURPOSE
   1.1. This procedure establishes the process to orient candidates for IRB membership.
1.2. The procedure begins when the Research Educator is notified of a candidate for IRB membership.

1.3. The procedure ends when the completed orientation checklist is sent to the IRB Manager.

2. PROCEDURE

2.1. The Research Educator has the primary responsibility for assessing the new candidate’s learning needs and designing an orientation program based on the candidate’s prior knowledge and experience in research.

2.1.1. An orientation checklist will be utilized to document completion of the training for all candidates.

2.2. All candidates for IRB membership, regardless of prior knowledge and experience in research, must complete the required CITI training according to the instructions cited in “IRB Education for Signatory Official and IRB Members PGR.”

2.3. Additional training for all candidates will be tailored to meet each individual’s learning needs based on their prior knowledge and experience in research.

2.4. Additional training will be provided by the Research Educator, the IRB Administrator and the IRB Manager utilizing the following modalities:

2.4.1. Online educational modules

2.4.2. Face to face encounters for instruction

2.4.3. Electronic Institutional Review Board software (eIRB)

2.5. All candidates will receive personal copies of the following books for reference:

2.5.1. Protecting Study Volunteers in Research

2.5.2. Institutional Review Board Member Handbook

2.6. Each candidate for IRB membership will attend a minimum of one IRB meeting prior to appointment as a member of the IRB.

2.7. Each candidate must be able to efficiently navigate through the eIRB training software program prior to appointment.

2.8. Each newly appointed IRB member will be assigned an experienced IRB member as a mentor.

REFERENCES

Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) http://www.aahrpp.org/learn/accreditation/goals-principles-standards