According to a report published last year by South Carolina Department of Health and Environmental Control, diabetes was one of the top ten leading causes of death in South Carolina, with one in six African Americans living with the disease in the state\(^1\). In an effort to mitigate risk of diabetes for residents in the Midlands area, the Diabetes Prevention Program (DPP) was established at Prisma Health. Prisma Health’s DPP is a nationally recognized program that seeks to increase diabetes awareness through education, lifestyle intervention, and community partnerships. The DPP is managed through the Office of Community Health, and is one of their many initiatives.

In 2017, Prisma Health’s DPP gained further national attention being one of four sites selected out of 25 sites nationally to participate in an evaluability assessment in collaboration with the Centers for Disease Control and Prevention (CDC) and the National Opinion Research Center (NORC) at the University of Chicago. The assessment was a three-day site visit performed by NORC, which identified successful strategies for improving diabetes-related outcomes among minorities. At the conclusion of this project, Prisma Health’s DPP was highly commended by collaborators for its strong data collection and evaluation capacity, innovation and strong community connections – later resulting in Prisma Health’s DPP being one of two programs selected to undergo a rigorous 24 month evaluation conducted by CDC and RTI International.

The most current partnership with the American Medical Association (AMA) and Physician Consortium for Performance Improvement (PCPI) researches the use of three prediabetes quality measures – abnormal blood glucose screening, intervention for prediabetes, and retesting of abnormal glucose in patients with prediabetes. The study monitors those measures captured in electronic medical records (EMR) to determine feasibility, validity and reliability. Feasibility assesses whether it is plausible to systematically document and calculate the three measures in the EMR. Validity and reliability testing cross-reference measure data generated from the EMR with manually abstracted data to ensure consistency in EMR performance data. It is hoped that results from this study will be used to enhance guidelines for prediabetes measures found in EMR systems, ultimately supporting physicians in delivering quality care to patients at risk for diabetes.

The invaluable work conducted through the Diabetes Prevention Program represents our institutional commitment to providing quality care, and highlights stimulating research piloted at Prisma Health–Midlands. For more information about this program, contact the Office of Community Health at 803-296-3070.

Upcoming IRB Monthly Clinic Hours
IRB Administration staff are here to assist you with study submission preparation, training, and support to ensure your research is carried out in a safe and ethical manner. Monthly clinic hours are established for one-on-one personalized attention. No appointment needed, just drop-by during the dates and times listed below:

- Monday, Oct. 14, 2–4 p.m., 5 Med Park Classroom 1B
- Monday, Nov. 11, 10 a.m.-Noon, 5 Med Park Classroom 1B
- Friday, Dec. 13, 10 a.m.-Noon, 9 Med Park Classroom 130

Clinical Research Forum
IRB: Reportable Events, Wednesday, Oct. 23, 12–12:45 p.m., 7 Med Park, Derrick Room

Discover USC 2020,
Friday, April 17, 2020
Columbia Metropolitan Convention Center
It's never too early to mark your calendars. Discover USC showcases research, scholarship, leadership and creative projects by undergraduate and graduate students, postdoctoral scholars and medical scholars representing the USC System and Prisma Health. More information regarding the Discover USC 2020 will be forthcoming.

IRB Administration Contacts
Mitzi Epting, BSBA
IRB Coordinator
803-296-3852
Mitzi.Epting@PrismaHealth.org

Thomasena Williams, MPH
Manager, IRB
803-296-6091
Thomasena.Williams@PrismaHealth.org
(or email IRBAdmin@PrismaHealth.org)

Grant Applications and Funding
Amy London, Grants Administrator

Obtaining grant funds may one day be a critical step in your career. Finding the appropriate funding stream is often a challenge. Federal agencies, such as the National Institute of Health (NIH), and the Health Resources and Services Administration (HRSA), post all of their Program Announcements on www.grants.gov. This website is user friendly, and not only has funding opportunities, but also provides assistance for you to familiarize yourself with the process under the “Learn Grants” tab.

On www.grants.gov you can identify the right types of funding opportunities for your project(s), learn about the reporting requirements you will need to comply with if awarded funding, and search for a specific grant program. To search for grants, simply enter your keywords where prompted. If you find very few programs (or too many!), keep refining your keywords, until you have a manageable list from which to work. It is recommended that you obtain at least three to four program announcements to read and compare with one another during the program selection phase of your work.

Grant funding is very competitive. So before you fully get started, be sure your idea is significant, innovative, and has a sound approach. **Significance** is how the proposed project will improve scientific knowledge, technical capability and/or clinical practice in one or more broad fields. **Innovation** refers to how novel the concept is, and if the project seeks to shift current research or clinical practice paradigms. The **approach**, often the most critical portion of the application, describes the overall strategy, methodology and analyses to be used to accomplish the specific aims of the project.

If you get overwhelmed, or are not sure what direction to take (R01 or R21), please contact Amy London, Grants Administrator, at 434-8977 or Amy.London@PrismaHealth.org.
In the last edition of *The Research Insider*, an overview of Good Clinical Practice (GCP) was introduced. As mentioned in the article, two of the sections of the ICH GCP guideline titled, Guideline for Good Clinical Practice E6(R2), have direct implications on research conduct at the site level: Section 4, Investigator, and Section 8, Essential Documents for the Conduct of Clinical Trials.

**Section 4, Investigator,** stresses that the Investigator controls the overall conduct of the study and how they must maintain accurate oversight of parties involved. They are responsible for the conduct of the clinical trial at a trial site. If a team of individuals at a trial site conducts a trial, the Investigator is the responsible leader of the team and may be called the Principal Investigator.

This section of the guidance provides the specific qualifications and supervision responsibilities of an Investigator. One part notes, “The Investigator is responsible for supervising any individual or party to whom the Investigator delegates study tasks conducted at the trial site.” Meaning, study team members must be qualified to perform tasks that are delegated to them. Validating and documenting the delegation process ensures the integrity of the study tasks performed and all data generated.

Other important topics covered in the Investigator section are maintaining compliance with the protocol and informed consent of trial subjects. This section directly reflects the Food and Drug Administration’s guidance on the Investigator’s supervisory responsibilities.

**Section 8, Essential Documents,** specifically addresses the maintenance of the documentation necessary for research. Essential documents are those that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. In the ICH Guidelines, essential documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of GCP and with applicable regulatory requirements. These documents also serve other important purposes. Filing essential documents at the investigator and sponsor sites in a timely manner greatly assists in successful management of a trial by the investigator, sponsor and monitor. These documents are usually audited by the sponsor’s independent audit function and inspected by regulatory authorities as part of the process to confirm the validity of the trial conduct and the integrity of data collected.

The necessary documents are listed and grouped in three sections according to the stage of the trial during which they are normally generated: 1–before the clinical phase of the trial commences (section 8.2), 2–during the clinical conduct of the trial (section 8.3), and 3–after completion or termination of the trial (section 8.4). It can be acceptable to combine some of the documents, provided the individual elements are readily identifiable.

Essential documents must be kept up to date. A trial master file should be established at the beginning of a study, both at the investigator’s site and at the sponsor’s office, to consolidate and organize all essential documents.

The ICH guidelines encourage implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording and reporting while ensuring human subject protection and reliability of trial results. Compliance with GCP and ICH guidelines will ensure quality data, improve the review process for new drugs and decrease the costs to sponsors.

*See sections 8.2–8.4 of the ICH guidelines on page 4.*
The sponsor should ensure that the investigator has control of and continuous access to the CRF data reported to the sponsor. The sponsor should not have exclusive control of those data.

When a copy is used to replace an original document (e.g., source documents, CRF), the copy should fulfill the requirements for certified copies. The investigator/institution should have control of all essential documents and records generated by the investigator/institution before, during, and after the trial.

### 8.2 Before the Clinical Phase of the Trial Commences

During this planning stage the following documents should be generated and should be on file before the trial formally starts

<table>
<thead>
<tr>
<th>Title of Document</th>
<th>Purpose</th>
<th>Located in Files of</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>8.2.1 INVESTIGATOR'S BROCHURE</strong></td>
<td>To document that relevant and current scientific information about the investigational product has been provided to the investigator</td>
<td>Investigator/ Institution</td>
</tr>
<tr>
<td><strong>8.2.2 SIGNED PROTOCOL AND AMENDMENTS, IF ANY, AND SAMPLE CASE REPORT FORM (CRF)</strong></td>
<td>To document investigator and sponsor agreement to the protocol/amendment(s) and CRF</td>
<td>Investigator/ Institution</td>
</tr>
<tr>
<td><strong>8.2.3 INFORMATION GIVEN TO TRIAL SUBJECT</strong></td>
<td>To document the informed consent</td>
<td>Investigator/ Institution</td>
</tr>
<tr>
<td>- INFORMED CONSENT FORM (including all applicable translations)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- ANY OTHER WRITTEN INFORMATION</td>
<td>To document that subjects will be given appropriate written information (content and wording) to support their ability to give fully informed consent</td>
<td>Investigator/ Institution</td>
</tr>
</tbody>
</table>

### 8.3 During the Clinical Conduct of the Trial

In addition to having on file the above documents, the following should be added to the files during the trial as evidence that all new relevant information is documented as it becomes available

<table>
<thead>
<tr>
<th>Title of Document</th>
<th>Purpose</th>
<th>Located in Files of</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>8.3.1 INVESTIGATOR'S BROCHURE UPDATES</strong></td>
<td>To document that investigator is informed in a timely manner of relevant information as it becomes available</td>
<td>Investigator/ Institution</td>
</tr>
<tr>
<td><strong>8.3.2 ANY REVISION TO:</strong></td>
<td>To document revisions of these trial related documents that take effect during trial</td>
<td>Investigator/ Institution</td>
</tr>
<tr>
<td>- protocol/amendment(s) and CRF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- informed consent form</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- any other written information provided to subjects</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- advertisement for subject recruitment (if used)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 8.4 After Completion or Termination of the Trial

After completion or termination of the trial, all of the documents identified in Sections 8.2 and 8.3 should be in the file together with the following

<table>
<thead>
<tr>
<th>Title of Document</th>
<th>Purpose</th>
<th>Located in Files of</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>8.4.1 INVESTIGATIONAL PRODUCT(S) ACCOUNTABILITY AT SITE</strong></td>
<td>To document that the investigational product(s) have been used according to the protocol. To document the final accounting of investigational product(s) received at the site, dispensed to subjects, returned by the subjects, and returned to sponsor</td>
<td>Investigator/ Institution</td>
</tr>
<tr>
<td><strong>8.4.2 DOCUMENTATION OF INVESTIGATIONAL PRODUCT DESTRUCTION</strong></td>
<td>To document destruction of unused investigational products by sponsor or at site</td>
<td>Investigator/ Institution</td>
</tr>
<tr>
<td>(if destroyed at site)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>8.4.3 COMPLETED SUBJECT IDENTIFICATION CODE LIST</strong></td>
<td>To permit identification of all subjects enrolled in the trial in case follow-up is required. List should be kept in a confidential manner and for agreed upon time</td>
<td>Investigator/ Institution</td>
</tr>
<tr>
<td><strong>8.4.4 AUDIT CERTIFICATE (if available)</strong></td>
<td>To document that audit was performed</td>
<td>Investigator/ Institution</td>
</tr>
<tr>
<td><strong>8.4.5 FINAL TRIAL CLOSE-OUT MONITORING REPORT</strong></td>
<td>To document that all activities required for trial close-out are completed, and copies of essential documents are held in the appropriate files</td>
<td>Investigator/ Institution</td>
</tr>
</tbody>
</table>
“There is a fine line between inappropriate disclosure and social media,” explains Shanna Wright, as she stresses the importance of separating personal life from work relations on social media. Wright is the Midlands Privacy Officer, with over ten years in this role, and nearly 20 years of career experience at Prisma Health. Originally, from Camden, South Carolina, she graduated from Mercer University in Macon, Georgia, with a bachelor’s degree in engineering, and later received a master’s degree in business administration from Webster University.

With social media being such popular platforms for personal expression, Wright cites how its use has influenced her career as a privacy officer. She strongly encourages health care employees to take extra heed of the content posted on their social accounts, as posts may quickly cross into a violation of privacy. Simply put, Wright advises, “don’t do it, personal friend, family member, or not” – referring to employees posting other patient’s health statuses on social media.

Cases in which a patient alleges a team member has posted private health information on a social media platform are investigated by the Privacy Office. In these cases, Wright enjoys her role as investigator. She credits the implementation of the electronic medical record systems audit trail with helping sort through details of how the information was potentially accessed and by whom.

In health care settings, Wright emphasizes the importance of properly securing any care-related documents, even scribbled notes from a medical consultation, that may contain patient health information (PHI). She recalls a scenario where a resident physician’s vehicle was broken into and a bag with a notebook inside was stolen. That stolen notebook contained jotted notes of PHI. As the use of mobile devices has become routine in health care, handwritten notes are often overlooked when considering how to implement privacy safeguards into our everyday routines. However, when identifiers are displayed, whether handwritten on paper or typed into a device, the information is subject to privacy regulations and should be secured at all times.

Wright serves on the Board of Directors for the Palmetto Health Credit Union, and is a member of Health Care Compliance Association (HCCA) and Healthcare Financial Management Association (HFMA). She enjoys reading, and aspires to become a world traveler one day. Three words she chooses to describe herself are: honest, curious, and integrity.

Research Insider Content Suggestion Form
Please share with us any interesting or exciting research news or updates going on with you or in your department. Submissions may include research announcements, new awards, publications, conference presentations, or a standout researcher you would like to highlight.

Complete the form by clicking this [Form Link](mailto:Samantha.Scott2@PrismaHealth.org), or simply email Samantha Scott at Samantha.Scott2@PrismaHealth.org to share your suggestions.
SOCRA: Palmetto Area Chapter

Society of Clinical Research Associates (SOCRA) is a membership organization geared towards mentorship, networking, education, and certification opportunities for individuals involved in any capacity of clinical research. There is an active SOCRA Palmetto Area chapter for those interested in joining a clinical researcher network. Visit www.socra.org for more information.

Research Policy/PGR Updates

The Investigator Manual has recently been updated. Please refer to this manual for guidance through policies and procedures related to conducting Human Subject Research, specific to Prisma Health.

This Manual, and other research PGRs are available in PolicyTech accessed from myPal. Externally, the IRB Policies and PGR can be found on the IRB webpage, and Research Compliance Policies and PGRs on the Research Compliance webpage. Please remember that it remains the responsibility of research personnel to regularly visit our websites to obtain the most current versions of Prisma Health’s Research Policies and PGRs.

IRB Helpful Hint of the Quarter

Do not begin your research until you receive approval from the IRB office.

• Your research requires an approval letter from both, IRB and Prisma Health Administrative Research Review (PHARR) before beginning your research.
• The eIRB system will notify you with a ‘Request for Changes’ if any revisions to your eIRB application are needed. Be sure to submit upon completion of these necessary changes.