Institutional Review Board (IRB) receives and reviews study documentation

Items from PHARR Process Reviewed by IRB:
- Conflict of Interests
- Impacted Services
- Scientific Review Committee Recommendations
- Study Agreement/Contract/Grant (e.g. subject injury and privacy requirements)
- Coverage Analysis (subjects’ monetary responsibility to participate in the study)

Protocol, Investigator’s Brochures, Instructions for Use
Study Subject Population
Risk/Benefit for Participating Subjects
Determination of Human Subjects Research
Informed Consent Document and Consent Process
Privacy and Confidentiality of Patient Health Information
Study Personnel Training
Advertisements
IRB Approval Letter Issued