Prospective Observational Studies

Issues to consider & address in the IRB application

General Points

- The IRB application is not a grant proposal, and needs to be written in non-technical lay language. Do not copy and paste straight from a grant proposal or protocol.
- The IRB application should contain minimal references to a grant proposal.
- Include a study protocol if one is available, but do not reference information in the protocol that is not detailed in the IRB application. The IRB application is a stand alone document and is considered the source of the IRB review.
- Be sure to answer every question/check each box, even if the answer is “none.”
- Be sure the information in the IRB application matches the information in the consent form and vice versa.

Study Purpose

- Clearly state the background and the purpose of the study in ½-1 ½ pages.

Study Procedures

- Clearly list the research procedures and not the clinical care procedures (see example 1). Provide a brief overview of each procedure and attach any data collection form you will use to perform the study procedure (i.e. questionnaire, interview guide, etc.).
- State how long each research procedure will take.
- Collection of data from the medical record is a study procedure. Don’t forget to list this and outline what type of information you will collect. Always attach a data abstraction form.
- If there is more than one subject population, explain procedures according to each population.
- Use formatting such as numbering, bullet points, instead of paragraph format.

Prescreening Activities

- Will you access the OR schedule or other medical record to identify potential subjects? If yes, then:
  - Complete waiver of consent and waiver of HIPAA Authorization forms—See HSD website to access information for pre-screening purposes.
  - Complete Confidentiality Agreement—See HSD website.
Approach and Consent Procedures

• Explain when, where, and who will do this.

• Is pre-operative approach and consent appropriate? If so, explain why. (See document entitled, pre-operative approach and consent for low risk research).

Subject Population

• In addition to inclusion/exclusion, provide a brief narrative of the subject population.

• State the maximum number of subjects—This # should include for screen fails.

Vulnerable Populations

• Vulnerable populations may include patients who lack decision-making capacity, questionable capacity, and those who may be “capable” but vulnerable because of a disease progress, etc. This may include minors, non-English speaking patients, patients who are intubated, pregnant patients, patients, etc.

• Explain how you will obtain informed consent or assent from vulnerable populations. For instance, explain if will obtain parental permission in the case of minors or LAR consent in the case of adult patients who cannot otherwise provide consent for themselves.

• If your study includes a vulnerable population in the study, then review, complete and submit the ‘supplemental form for vulnerable populations’ (See HSD website) with your IRB submission.

Risks

• Explain risks only related to the research—Do not include risks of standard clinical care.

• Consider all risks involved in the study and outline each one. This may include physical risks (i.e. discomfort from EEG electrodes), risks of stress (pain assessments), risks of invasion of privacy, etc.

• Explain how you will minimize risks to subjects.

Benefits

• Explain benefits only related to the research—Do not include benefits of standard clinical care.

• State if there are no direct benefits to individual subjects.

Voluntary Nature

• Be clear what is voluntary for research and what will happen regardless of the research study.
Subjects should have the ability to withdraw at any time—is this compromised by the design or subject population? Explain.

Privacy and Confidentiality

• Record only the minimum necessary from the medical record.
• Code data and keep links separate from study data.
• Give yourself enough time to break the link and destroy identifiers.
• Provide the date {DD/MM/YYYY} you will destroy identifiers for the study.

Example 1:

Overview of Research Procedures:

After written informed consent and HIPAA Authorization are obtained, the following research procedures will take place:

1. *Pre-op in the UWMC Surgery Pavilion:
   Prior to the clinical procedure and any sedation or medication given, the study team will ask subjects to assess the severity of any pain verbally on a 0-10 scale (10 being the worst imaginable pain) at 30-minute intervals in the PACU. This will take less than 5 minutes to complete.

2. *Post-op in the post-anesthesia care unit:
   We will ask subjects to identify the site of pain and evaluate the severity of pain verbally on a 0-10 scale (10 being the worst imaginable pain) at 30-minute intervals in the PACU. This will take less than 5 minutes to complete.

3. *Follow up pain assessments at 24 hours, 48 hours and 7 days after surgery:
   These follow up assessments may be done in person if the subject remains in the hospital for care, or by telephone in the case the subject is discharged as a patient. With these follow up pain assessments, we will ask the subject to identify the site of pain and evaluate the severity of pain verbally on a 0-10 scale (10 being the worst imaginable pain) over the past 24 hours. We will ask them how bothersome their pain is (0-5 scale). This will take less than 5 minutes to complete.

4. Collection of data from the medical record:
   We will access the subject’s UWMC medical record and record information about [explain]. We will collect information that exits in the EMR regarding their medical history and the clinical procedure, and we will collect information that is created in the EMR up until 6 months post clinical procedure. Attached is the data abstraction sheet that lists all variables we will record from the medical record to use as research data for this study.

*While pain assessments may take place for standard clinical care, these research assessments are at specific research time points and may be in addition to clinical assessments.