Issues to consider and address in medical records application

Retrospective vs. Prospective Record Review

**Retrospective**—all information in the record exists at the time you submit your IRB application to HSD (i.e. 7/1/2007 to 9/30/2011).

**Prospective**—the use of information placed in the MR after the date the IRB application is received by the Human Subjects Division (i.e. 1/1/2013 to 12/31/2017.)

**Combination retrospective and prospective**---Some information exists in the medical record, and you will continue to look at records generated in the future (i.e. 7/1/2007-6/31/2017).

Risks Exist

- Invasion of privacy
- Breach of confidentiality

**Example:** “Potential risks are related to invasion of privacy and breach in confidentiality. Invasion of privacy will be minimized by recording the minimum necessary data points from the medical record to conduct this study. The risk of breach of confidentiality will be minimized by coding the data and keeping identifiers separate. All data collected will remain confidential.”

Benefits

- Often no direct benefit—**State this.**
- Explain larger benefits to society and future patients

**Example:** “Patients will not directly benefit from participating in this study. The information we get may help us predict which patients are most likely to experience pain after surgery and the specific site of the pain. This may enable us to develop new protocols to prevent or treat pain in the future.”

Summary of Research Methods

- Provide a concise description of how you will collect information to accomplish the research aims

**Example:** “We will review the medical charts of all patients admitted to Harborview Medical Center intensive care units over approximately a ten-year period from July 1, 2001 to June 30, 2011. The study cohort will be identified using the ICD-9 code for SAH (430) and CPT codes for clipping, coiling or by-pass. After the sample has been identified, diagnosis will be manually checked to ascertain the eligibility and exclusion criteria. All patients with a spontaneous subarachnoid hemorrhage with a documented...”
aneurysm by computed tomography (CT) angiogram or digital subtraction angiography and have had surgical or interventional radiology treatment within 72 hrs will be included. Patients with non-aneurysmal bleeding or who are pregnant will be excluded. We will electronically record the relevant clinical variables from the medical record using the electronic medical record including ORCA, hospital administrative databases, and AMALGA system, a central electronic repository used by the hospital to store electronic medical records from different sources.”

Subject Numbers

- The subject number represents the # of records you will access to complete the study
- Should be within the scope of your data collection needs and slightly higher to account for error
- Provide age range of subjects (i.e. 19-90) and NOT a minimum limit (i.e. 18 +).

Waiver request

- Issue of practicability is key—If you are conducting a prospective record review, then why is it not practicable (or feasible) to obtain consent and authorization? Your justification will between retrospective studies where the patients have been discharged from the hospital vs. prospective studies where patients have not yet
- See Sample language for waiver requests for retrospective chart review

Confidentiality of Research Data

- Will you record direct identifiers from the medical record? If so, how will you protect identifiable data from breach of confidentiality?

UW Confidentiality Agreement

- Original inked signatures
- All investigators who will have access to identifiable information need to sign agreement
- Information consistent with the IRB application

Documents to include with submission:

- IRB application—Medical record review application form
- Data abstraction form (list all variables you will record for study. Include space for study code)
- UW Confidentiality Agreement if data are UW affiliated records