Human Subjects and Approval by the Institutional Review Board

SEER Center Workshop January 12, 2017

One place to get started on your IRB Study is by drafting the answers to the **Research Design** section. This part of your application includes the following five sections. It will help determine the information and materials you will need for the other parts of your application.

1) Brief Description of Project

Summarize the overall research question and the primary objectives.

2) Research Design and Methods

Describe the overall research design and method(s) of data collection. Also, identify specific factors or variables and, if applicable, treatment and control conditions or groups.

3) Duration of Participation and Study Timeline

Describe the time commitment per activity per individual subject and provide the estimated total duration of participation. If known, also describe the anticipated duration to enroll all study subjects and the estimated time until completion of primary analyses.

4) Procedures

Describe in detail, and in sequence, all study procedures from the perspective of the participant. Begin with any procedure that involves interaction or collection of data to determine eligibility, if applicable. Separate any procedures that are part of regular practice from procedures that are specific to this research study. If procedures are long and complicated, use a table, flowchart or diagram to outline the study procedures

5) Data Analysis

Describe the data analysis plan, including any statistical procedures. For qualitative studies, specify the proposed analytic approaches.

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For your consideration: Think/Pair/Share
1) What are you planning to study?
2) What types of data do you plan to collect?
3) What data collection files do you think you will need to submit?