



## INSTITUTIONAL REVIEW BOARD

### PARKVIEW HEALTH INSTITUTIONAL REVIEW BOARD PRESENTER'S FORMAT FORM

- Use this form when presenting Protocols to the PH IRB
  - Presentation time should not exceed five minutes
  - No PowerPoint
1. Provide **Purpose of the Study** – aims and hypotheses to be tested.
  2. Provide **Background and Significance** – information should support the scientific aims of the research. What is the normal standard of care? How does background relate to standard of care?
  3. Provide **Design and Procedures** – clearly identify procedures/tests/interventions performed exclusively for research purposes, identify their purpose and which are considered experimental. Describe questionnaire tools and/or surveys to be used.
  4. **Risk/Benefit Assessment**
    - a. Thoroughly describe how risks and discomforts will be minimized (per [45CFR46.111\(a\) \(1 & 2\)](#) and [21CFR56.111\(a\)\(1 & 2\)](#)).
    - b. State what special precautions will be used to minimize risks, if vulnerable populations are to be included (such as children, pregnant women, prisoners, or cognitively impaired adults).
    - c. Identify what available alternatives the person has if he/she chooses not to participate in the study.
  5. **Subject Identification Recruitment and Compensation** – describe recruitment procedures, including how you will ensure that subject selection is equitable and all relevant demographic groups have access to study participation (per [45CFR46.111\(a\) \(3\)](#) and [21CFR56.111\(a\)\(3\)](#)). Include information about approximately how many subjects will be recruited. If subjects are to be compensated provide specific prorated amounts to be provided for expenses such as travel and /or lost wages, and/or compensation for participation.
  6. **Subject Competency – Informed Consent**
    - a. If subject is not competent to give consent, is this information included in the Informed Consent? Describe how competency will be assessed.
    - b. Who can provide consent if subject is not capable?
  7. **Costs to the Subject** – describe and justify any costs that the subject will incur as a result of participation. If no health insurance will cover it, is there a patient Advanced Billing Notification process in place? Does the Informed Consent adequately cover the potential costs to the subject? If this study involves the use of an approved drug, who will pay for the drug? If this study involves laboratory and/or clinical procedures not part of ordinary management, who will pay for these procedures?
  8. **Data Analysis and Monitoring** – summarize the statistical/analytical methods to be used. If a data monitoring committee will be used, describe its operation, including stopping, rules, and frequency of review (per [45CFR46.111\(a\)\(6\)](#) and [21CFR56.111\(a\)\(6\)](#)).