Human Research Protection (HRP) Review Form when Relying on External IRB

This form should be completed and attached in the protocol section of the Click IRB application for the study which is requesting HRP review from the University of Rochester. As Rochester is not the Reviewing IRB for this project, the full protocol is not reviewed and approved by URochester. It is the responsibility of the Rochester study team to ensure that the information below is consistent with the protocol and approved by the Reviewing IRB. HRP Activation of this study at the University of Rochester is based upon the information provided below. Any inconsistencies between the information below and Reviewing IRB approved documents, will be considered non-compliance.

STUDY #:

1. Will subjects be enrolled by the local study team members?

    a. If yes, what is the *local* enrollment goal?

2. Indicate the age range of subjects:

3. Does the study include Vulnerable Populations?
   (as per federal regulations or Institutional policy)

    a. If yes, list the vulnerable populations:

4. If applicable, are there procedures considered standard of care (SOC) at other sites, but are not considered SOC at the University of Rochester that need to be considered during this institutional review?

    a. If yes, please describe:

5. Is this study using any local recruitment materials?

    a. If yes, attach these documents on the Local Site Documents smart form under Q2 *Recruitment Materials*.

6. Do the local recruitment methods include cold calling?

7. Is a Waiver or Alteration of Consent requested?

    a. If yes, briefly state the purpose:

8. Will a legally authorized representative (LAR) be used to consent local adult subjects?

9. Will languages other than English be used to consent local subjects?

10. Is there payment offered to subjects?

    a. If yes, describe the total payment amount and method of payment:

11. Is a HIPAA Waiver or Alteration of Authorization requested?

    a. If yes, briefly state the purpose (e.g., recruitment, not obtaining signatures).

12. Does the study include genetic testing?

    a. If yes, will incidental findings relevant to individuals or families be communicated to the subjects?

    b. If yes, please describe how findings will be returned to subjects:

13. Will study information be documented in the subject's eRecord?

    a. If yes, ensure standard consent from language is included in the Rochester site consent form.

14. Will information about the HIV status of subjects be collected for the research?

15. Will HIV testing be performed as part of the research?

    a. If yes, ensure study is compliant with the OHSP Guideline for Research Involving HIV testing.

16. Does the study intend to save data collected from this research for future use?

    a. If yes, provide the types of data banked:

17. Does this study intend to save samples collected from this research for future use?

    a. If yes, provide the type(s) of specimens collected.

18. What is the status of review by the Reviewing IRB?

    a. If approved, what risk level was determined?