SOP: Site Pre-Review for External IRB					
NUMBER	DATE	VERSION	AUTHOR	APPROVED BY	PAGE
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1 PURPOSE

1.1 The purpose of this process is to determine whether a local UM site can rely on an external IRB as the IRB of record.

1.2 This process begins when a site submits FORM: External IRB Reliance Application (HRP-216) materials for pre-review.

1.3 This process ends when the HSRO sends an acknowledgement to the site allowing the study to start at the UM.

2 GUIDING PRINCIPLES

2.1 When a UM investigator relies on an external IRB as the IRB of record, the HSRO must ensure that all regulatory and local requirements are met before the site can start the study.

3 REVISIONS FROM PREVIOUS VERSION

3.1 None.

3.2 Removed requirement for FORM: External IRB Reliance Application (HRP 216)

4 POLICY

4.1 Before a UM investigator relying on an external IRB as the IRB of record can start a study, the following requirements must be met:

- 4.1.1 An executed authorization agreement covering the proposed research must be in place
- 4.1.2 The HSRO must review the study materials to ensure that all local requirements are met
- 4.1.3 Study personnel must comply with training and financial reporting requirements
- 4.1.4 Documentation for all required ancillary reviews must be submitted and the following ancillary reviews must be completed, when applicable:
  - 4.1.4.1 Cancer Protocol Review Committee
  - 4.1.4.2 Data Security Ancillary Committee
  - 4.1.4.3 Radiation Safety
  - 4.1.4.4 Institutional Biosafety Committee
  - 4.1.4.5 Embryonic Stem Cell Oversight Committee
  - 4.1.4.6 Conflict of Interest Committee Review

5 RESPONSIBILITIES

5.1 HSRO staff generally carry out these procedures.

6 PROCEDURE

6.1 For studies that are not being review by the NCI CIRB, Review FORM: External IRB Reliance Application (HRP-216) for completeness and use CHECKLIST: External IRB Review (HRP-442) to determine whether the proposed research qualifies for a reliance.

- 6.1.1 If the study qualifies for a reliance, sign FORM: External IRB Reliance Application (HRP-216)
- 6.1.2 Advise team of determination and request eProst submission if the proposed study qualifies for a reliance.

6.2 Ensure reliance agreement covering the proposed research is in place.

6.3 Work with the site to obtain all required documentation, clarifications and revisions.

6.4 When the study documents are available, use CHECKLIST: External IRB Review (HRP-442) to conduct an Administrative Review

6.5 Record the IRB Decision

6.6 Upload completed Checklist HRP-442

6.7 Finalize Documents, if applicable

6.8 If all requirements are met, send LETTER: Acknowledge External IRB (HRP-857)

7 MATERIALS

7.1 FORM: External IRB Reliance Application (HRP-216)

7.2 CHECKLIST: External IRB Review (HRP-442)

7.3 WORKSHEET: Pre-Review (HRP-308)

7.4 LETTER: Acknowledge External IRB (HRP-857)

8 REFERENCES

8.1 None.