RUTGERS UNIVERSITY
Office for Research

SOP: Expiration of IRB Approval

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1 PURPOSE

1.1 This procedure establishes the process for the IRB Chair to determine whether current subjects may continue in expired research.

1.2 The process begins when the IRB Chair is notified of a request by an investigator of a request for current subjects to continue expired research.

1.3 The process ends when the IRB Chair has communicated a decision and documented the decision in writing.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 If the study is granted approval with conditions and expires before responsive materials are reviewed and approved, these procedures are to be followed.

4 RESPONSIBILITIES

4.1 The IRB Chair is responsible for following these procedures.

5 PROCEDURE

5.1 Determine from the investigator which subjects need to continue in the expired research, what procedures are being requested to continue, and why.

5.2 Do not allow new subjects to be enrolled under any circumstances.

5.3 Determine which current subjects can continue in the research based on these principles:

5.3.1 In general, research procedures should be safely discontinued.

5.3.2 In general, the only research procedures that should continue are those that are not available outside of the research context. If the required procedures can be provided as standard of care, these should be provided as such.

5.3.3 In general, research procedures conducted to collect data with no direct benefit to the subject should not continue.

5.3.4 In some cases, an ethical issue may be raised where the above general principles may not be followed.

5.3.5 The IRB Chair has the option to defer the expired study to the convened board.

5.4 The review determination is communicated to the IRB Office via e-IRB+. IRB staff processes the communication. The e-IRB+ system forwards the correspondence to the investigator.

6 MATERIALSEFERENCES

6.1 None.