 LSU Health NEW ORLEANS Human Research Protection Program	STANDARD OPERATING PROCEDURES			
	REVIEW OF JOINT RENEWAL/AMENDMENT SUBMISSIONS ORIGINALLY APPROVED BY THE FULL BOARD			
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PURPOSE

- 1.1 This procedure establishes the process for review of a combined Renew + Amend application for a study originally reviewed by the Full Board.
- 1.2 The process begins when a combined Renew/Amend application for a Full Board study is submitted through Kualu.
- 1.3 The process ends when the LSUHSC IRB has issued, and the IRB Office has documented in Kualu, approval of the Renew/Amend application.

REVISIONS FROM PREVIOUS VERSION

- 2.1 None

POLICY

- 3.1 When a Renew/Amend application is submitted where both the renewal and amendment portions may be reviewed by the Expedited procedure, the application will be assigned to a Designated Reviewer who is both a member of the IRB Office Staff and also a voting or alternate member of the IRB for review.
- 3.2 When a Renew/Amend application is submitted where both the renewal and amendment require review by the Full Board, the application will be assigned to a Designated Reviewer, a (non-IRB Office staff) voting or alternate member of the IRB, and presented at the next meeting.
- 3.3 When a Renew/Amend application is submitted where one portion of the application requires Expedited review and the other portion requires Full Board review, the expedited portion will be assigned to (an IRB Office Staff) Designated Reviewer, and the Full Board portion will be assigned to a (non-IRB OfficeStaff) Designated Reviewer for review and presentation at the next meeting.

DEFINITIONS

- 4.1 Administrative Reviewer: a member of the IRB Office staff.
- 4.2 Designated Reviewer: any voting or alternate member of the IRB, including IRB Office staff appointed to the Board.


RESPONSIBILITIES

- 5.1 Specific responsibilities for Administrative and Designated Reviewers are described throughout this document.

PROCEDURES

6.1 Reviewer Responsibilities

- 6.1.1 Upon receipt of a Renew/Amend application for a Full Board study, an IRB Office Staff Member will be assigned as the Administrative Reviewer of the application and will determine if the application requires Expedited review, Full Board review, or a combination of both procedures.
- 6.1.2 If the application only requires Expedited Review:
 - 6.1.2.1 An IRB Office Staff Member, who is also *a voting or alternate member of the IRB*, will be

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assigned as the Designated Reviewer. In this scenario, the Administrative and Designated Reviewers may be the same person if they meet the definition of a Designated Reviewer.

- 6.1.2.2 The Designated Reviewer will document their review in the Quali Checklist associated with the application.
- 6.1.2.3 After review and resolution of any issues, if applicable, the Administrative Reviewer will document and communicate approval of the Renew/Amend application through Quali.
- 6.1.2.4 Approval of the application will be listed in the agenda of the next Full board meeting.
- 6.1.3 If the application only requires Full Board Review:
 - 6.1.3.1 The Administrative Reviewer will conduct an administrative review of the application.
 - 6.1.3.2 After administrative review is complete, the Administrative Reviewer will assign a Designated Reviewer, a (non-IRB Office staff) voting or alternate member of the IRB.
 - 6.1.3.3 The Designated Reviewer will document their review in the Quali Checklist associated with the application.
 - 6.1.3.4 After presentation at the next Committee meeting, resolution of any issues, and approval by the Board, the Administrative Reviewer will document and communicate approval of the Renew/Amend application through Quali.
- 6.1.4 If the application requires a combination of Expedited and Full Board Review:
 - 6.1.4.1 The Administrative Reviewer will assign An IRB Office Staff Member, a voting or alternate member of the IRB, as the Designated Reviewer of the portion of the application that can be reviewed by the Expedited procedure.
 - 6.1.4.2 Either simultaneously or after review of the Expedited portion, the Administrative Reviewer will assign a (non-IRB staff) Designated Reviewer for the Full Board portion of the application.
 - 6.1.4.3 Each Designated Reviewer will document their review in the Quali Checklist associated with the application. Each Designated Reviewer should select the appropriate review type (i.e., Expedited or Full Board) for the portion of the application for which they are responsible.
 - 6.1.4.4 After presentation of both the Expedited and Full Board portions of the application at the next Committee meeting, resolution of any issues, and approval by the Board, the Administrative Reviewer will document and communicate approval of the Renew/Amend application through Quali. The review type documented on the approval letter will denote the highest review procedure to which the application was subjected (i.e., Full Board).

MATERIALS

7.1 None

REFERENCES

8.1 None