1. **PURPOSE**

1.1. This procedure establishes the process for communications after a protocol is reviewed.

1.2. This procedure begins when:

1.2.1. The Reviewer has submitted their Expedited Review in myIRB

1.2.2. An IRB meeting has adjourned

1.3. This procedure ends when all correspondence related to IRB determinations and correspondences have been sent via myIRB to the PI and study team.

2. **POLICY**

2.1. The IRB informs the investigator of findings and actions via myIRB.

2.2. When the Board tables or disapproves research, correspondence to the investigator will include the reasons of the decisions. If a submission is tabled, the investigator will have the ability to submit a response for review. If the submission was disapproved, the investigator may submit a new study with the required changes and recommendations.

2.3. When applicable, serious or continuing non-compliance, suspension, and unanticipated problems will be promptly reported to outside agencies.

2.4. Non-compliance and suspension reporting for the VA will be per the applicable handbook.

3. **RESPONSIBILITY**

3.1. IRB staff members carry out these procedures, with consultation from the IRB Chair and General Counsel when applicable.

4. **PROCEDURE**

4.1. Upon approval of a new study or continuing review, enter the approval period in myIRB.

4.2. Finalize any newly approved consent documents and all other applicable submitted materials with the approval and expiration dates.

4.3. Approved, Approved with Contingencies, and Needs Reply correspondence should be completed within 5 business days of the review. Tabled correspondence should be completed within 2 business days after the convened meeting. Suspension correspondence should be completed within 1 business day of the motion. Correspondence to the study staff from myIRB will be sent to:

4.3.1. The Principal Investigator

4.3.2. Study Coordinator or study contact

4.3.3. Other individuals or organizations determined to be appropriate by the Assistant Director of IRBs, IRB Chair, General Counsel, or Director of Research Services and Operations.

4.4. When researchers submit a response to an item that was not approved, the response will be reviewed by the IRB:

4.4.1. Tabled items will be reviewed by the convened IRB

4.4.2. Items Approved with Contingencies will be reviewed for approval by the IRB chair, or designated IRB member. Explicit contingencies may be reviewed and approved by IRB staff who are approved by the Board.

4.4.2.1. If not a newly submitted study, and if the research expires before the conditions are reviewed and approved, all research activities must stop until approval is obtained.

5. **REFERENCES**
5.1. 21 CFR §50.54
5.2. 45 CFR §46.207 and §46.407
5.3. DOD Instruction 3216.02 November 8, 2011