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 was 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. If the IRB votes to disapprove, suspend, or terminate a research protocol, it will include in its written notification a statement of the reasons for its decision. A principal investigator may appeal this decision by writing a letter to the IRB requesting reconsideration.
2.4. When applicable, serious or continuing non-compliance, suspension, and unanticipated problems will be promptly reported to outside agencies.
2.5. 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 (e.g. Tabled), the response will be reviewed by the IRB:
   4.4.1. Tabled items will be reviewed by the convened IRB
4.5. If an appeal to an IRB decision is received, at the discretion of the chair, the investigator may make such an appeal in person and/or in writing to the IRB. An appeal of a disapproved, suspended, or terminated research project must be reviewed at a full board meeting. After review and discussion of appeal materials and/or presentation by the researcher, the IRB will vote by simple majority whether to approve the appeal and allow the research to commence. If the IRB upholds its vote to disapprove, suspend, or terminate a project, the decision may not be appealed again. Nor may it be reversed by any administrator, other officer or agency
of the University of Florida, state government or Federal government. The IRB retains the final authority for approval of proposed research with human subjects.

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