1 PURPOSE

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

1.2 The process begins when:

1.2.1 A designated reviewer has completed a non-committee review and notified the Office of IRB Administration (OIA) staff; OR

1.2.2 An IRB or Stem Cell Research Oversight (SCRO) meeting has adjourned; OR

1.2.3 An OIA staff member has verified that modifications required to secure approval have been made.

1.3 The process ends when all correspondence related to IRB and/or SCRO determinations and actions has been sent and additional tasks have been completed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 REQUIREMENTS

3.1 The IRB and/or SCRO reports its findings and actions to the investigator.

3.2 The IRB and/or SCRO reports its findings and actions to the institution.

3.3 When the IRB disapproves research, it provides the investigator with a statement of the reasons for the decision and gives the investigator an opportunity to respond in person or in writing.

3.4 These reporting procedures are to be completed within 15 business days of the IRB and/or SCRO meeting(s) or receipt of the completed non-committee review materials.

3.5 Reporting to regulatory agencies (e.g., Office for Human Research Protections, Food and Drug Administration, Department of Defense, etc.) of serious non-compliance; continuing non-compliance; suspension of IRB approval; termination of IRB approval; and unanticipated problem involving risks to subjects or others/unanticipated problem report is to take place within 30 business days from the date of the final determination.

3.6 When an analyst is logged into the electronic submission system using a valid username and password, and uses the system to generate correspondence that communicates the results of IRB and/or SCRO decisions, including approval determinations and HIPAA waivers, the correspondence is considered to have been signed by the analyst under the authority of the IRB and/or SCRO chair and the OIA director or designee.

4 RESPONSIBILITIES

4.1 OIA staff members carry out these procedures.

5 PROCEDURE

5.1 If the non-committee review indicated a conflicting interest or a lack of expertise, the review cannot be completed and must be completed by designated reviewer without conflicting interest and with appropriate expertise. Follow *OIA-031 SOP: Non-Committee Review Preparation* to have the review conducted.

5.2 Check the accuracy of *OIA-401 CHECKLIST: Pre-Review*, or equivalent, and revise as needed.

5.3 Refer to *OIA-302 WORKSHEET: Calculation of Approval Intervals*, or equivalent, to calculate approval intervals.

5.4 Affix approval date to all newly approved consent, assent, and local site-created recruitment materials.

5.5 Refer to *OIA-303 WORKSHEET: Communication of Review Results*, or equivalent, and send all applicable letters.

5.5.1 Send the letter to the inside addresses and cc list as directed by the letter.

5.5.2 If not available electronically, attach all dated consent, assent, and recruitment materials.

6 MATERIALS

6.1 *OIA-001 SOP: Definitions*

6.2 *OIA-031 SOP: Non-Committee Review Preparation*

6.3 *OIA-302 WORKSHEET: Calculation of Approval Intervals*

6.4 *OIA-303 WORKSHEET: Communication of Review Results*

6.5 *OIA-401 CHECKLIST: Pre-Review*

7 REFERENCES

7.1 21 CFR 56.108(a)(1)
7.2 21 CFR 50.24(e)
7.3 21 CFR 812.66
7.4 45 CFR 46.108(a)(3)(i)
7.5 45 CFR 46.305(c)
7.6 45 CFR 46.306(a)(1)
7.7 45 CFR 46.407(a)