1. PURPOSE

To define the procedures utilized to prepare a compliance activity report and disseminate the report findings.

2. SCOPE

This procedure applies to all investigator compliance activities performed by the Education and Compliance Office for Human Subject Research.

3. RESPONSIBILITIES

The Education and Compliance Coordinators are responsible for preparing reports for each compliance activity performed and disseminating the report findings.

4. PROCEDURES

4.1. The heading of the report should include the following information:

   a) The type of compliance review
   b) The IRB number and the title of the research study
   c) The name of the principal investigator
   d) The name of the research coordinator
   e) The date(s) on which the activity was conducted
   f) The date of the report
   g) The source of funding
   h) The level of risk of the research study
   i) The name(s) of the Education and Compliance Office staff involved in the activity
   j) The name(s) of the Education and Compliance Office staff responsible for preparing the report

4.2. The introduction of the report should include but not be limited to the following:

   a) The reason for the review
   b) A brief summary of the research study
   c) The number of subjects enrolled in the study
   d) The source of subject recruitment
   e) The time period over which the subjects were enrolled
   f) A summary of the pre-activity interview

4.3. The body of the report should include a summary of the following:

   a) IRB correspondence as described in the SOP for IRB protocol file review
   b) The number of research records reviewed for the audit
   c) The review of informed consent documentation and the outcome of the review
   d) Screening procedures reviewed and the outcome of the review
Inclusion/exclusion criteria reviewed and the outcome of the review
f) Study procedures reviewed and the outcome of the review
g) The occurrence and reporting of adverse events / UAPs
h) Data and Safety Monitoring Plan and findings
i) Research data collection and research documentation

Recommendations shall be made for each of the summaries as indicated or if necessary, the investigator shall be requested to provide written clarification(s) or outline a plan of corrective procedures.

4.4 Before the report is distributed to the investigator, it must be reviewed by the compliance sub-committee as outlined in SOP #I-A-15.

4.5 Each compliance activity reports will be sent to the:

- Principal investigator (PI)
- Study coordinator
- PI’s immediate supervisor
- PI’s mentor for student researchers
- Director of the Education and Compliance Office for Human Subject Research

Others, e.g. the Director of Research, the PI’s Department Chairman or the Dean of the School may be copied on the report as deemed necessary.

4.6 A transmittal letter shall be included with each report.

4.7 The principal investigator shall be given approximately two weeks to provide a written response to the IRB Executive Committee. If there are extenuating circumstances, the principal investigator may request an extension of the response due date.

4.8 Compliance activity reports requiring review by the IRB EC will be reviewed as outlined in SOP #I-A-15. For all other compliance activity reports, the ECO-HSR will assess the adequacy of the investigator’s response and take the appropriate steps to ensure the appropriate resolution of the identified issues.

4.9 When all issues are resolved, the lead auditor will prepare a brief audit summary report. The audit summary will be included in the quality assurance database. If the audit was requested by an IRB Committee, the summary report will be provided to the vice chair of the requesting committee.

4.10 When the audit process is complete, a copy of the audit summary and related, pertinent correspondence will be placed in the respective IRB protocol file or uploaded into OSIRIS by a member of the ECO.

5. REFERENCES/DOCUMENTATION

For the purpose of maintaining confidentiality, a copy of the report is not included in this section. Reports may be accessed with the assistance of the Education and Compliance Office staff or the systems analyst.

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