TITLE: **Process Improvement of the Human Subjects Protection Program**

PURPOSE: Outline the process for continuous improvement of the Human Subjects Protection Program to maintain compliance, and achieve targeted levels of quality, efficiency, and effectiveness.

RESPONSIBILTIES: HSPP staff

PROCEDURES:

Investigator Evaluations

Investigators may volunteer for the Process Improvement activity, be selected at random, or chosen by the IRB or research compliance administration.

- Complete "T534 - Investigator Process Improvement Assessment"
- Send a request for Process Improvement for five (5) to ten (10) investigators/protocols per year.
- For each protocol selected for review, document the following items from the IRB file:
    - Current expiration date.
    - Current type and version of each informed consent document.
        - Review the consent documents to ensure that all the required elements of consent are present and all applicable.
        - Document if any re-consent was required. If re-consent was required but no report is on file regarding the status of the re-consent, follow-up with the investigator to obtain a copy of the report.
    - The IRB-approved number of study subjects to be enrolled.
    - Current protocol/grant in effect.
    - Current drug/device information in effect.
- Meet with the investigator and study coordinator to review the Process Improvement Assessment.
    - Review the current working study documents to ensure that they are IRB approved.
    - Review the signed consenting documents. If there are a large number of consent forms, review a representative number of each type of document for the following:
        - The number of subjects enrolled is consistent with the number of subjects that the IRB approved for enrollment.
        - Subject signatures and signature dates. Research procedures may not occur prior to subject consent.
        - If consent, assent, or permission was not obtained and the IRB required such consent, confirm that proper documentation is present in the file.
    - If any reportable items are noted during the visit, instruct the investigator to submit the items in accordance with "F224: Reportable Information Items that are Potentially Problematic."
    - Ask the investigator if follow up education with the HSPP office is desired.
- After the meeting with the investigator and study coordinator, prepare a written summary of the items discussed and attach it to the Process Improvement Assessment. The summary should include:
    - Who was present during the meeting,

  - The items reviewed,
  - Any findings,
  - General discussion,
  - If follow-up education was requested, and
  - If additional quality improvement is necessary.
- Review the results of all Process Improvement Assessments, track the results, and examine for trends.
  - If the results demonstrate high variability, implement an intervention to reduce variability.
  - If the results are outside indicate a specific area or concern, implement an intervention to achieve improvement.
- Send the summaries of each visit, along with the revised tracking changes to the HSPP Director with a description of any proposed interventions.

Human Subject Protection Program evaluations

- Complete "Minutes Process Improvement Assessment" for a representative sample (1-2 sets of minutes per IRB) of each IRB.
- In addition, individual project files may be pulled for process improvement. For files pulled for a process improvement activity:
  - Review the HSPP Correspondence Forms for the last 1-12 months, depending on the number of items, and review for compliance with standard operating procedures.
  - For documents requiring revision, meet with the HSPP staff member responsible and discuss the corrections.
  - Summarize the findings of the file audit and provide to the IRB coordinator and their supervisor.
- Review the results of all file audits, track the results, and examine for trends.
  - If the results demonstrate high variability, implement an intervention to reduce variability.
  - If the results are outside indicate a specific are or concern, implement an intervention to achieve improvement.
- Send the summaries of assessment, along with the revised tracking changes to the HSPP Director or designee with a description of any proposed interventions.

MATERIALS

- SOP-013: Reportable Items
- C430 - Investigator Process Improvement Assessment
- C431 – Minutes Process Improvement Assessment
- T534 - Investigator Process Improvement Assessment

REFERENCES

- 45 CFR 46.115(a)
- 21 CFR 56.115(a)

REVIEW/REVISIONS:

From 10/01/2010 version: Indicated that the IRB or research compliance administration may request an investigator go through a Process Improvement activity.

From 8/01/11 version: Removed requirement for timelines; Clarified number of minutes needing review.

From 01/2014 version: Renumbered from P&P-011; Reference to P&P-024 revised to SOP-013 to reflect new numbering system