PI Self Assessment Program
Policy and Procedure

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I. Policy

A. Principal Investigators conducting research will complete a self-assessment no more than once every three years.

B. The Office of the IRB (OIRB) administers the self-assessment program as part of the IRB quality improvement program to better the human research protections at the HSC. The self-assessment program provides an opportunity to educate investigators and research staff on federal, state, and HSC regulations and policies in the area of research recordkeeping; assist investigators in assessing their own programs; and assist the OIRB / IRB in identifying areas on which additional institutional educational programs may need to focus.

C. The self assessment program will be conducted in a manner that protects anonymity to foster candid feedback without the concern of punitive action.

II. Overview

A. This procedure starts approximately one to two months before an intramural study’s initial approval expiration date.

B. This procedure ends when the periodic results of studies reviewed are used to develop education and inform improvements in the Human Research Protection Program (HRPP).

C. Summary of responsibilities
   
   1. The Principal Investigator is responsible for completing a self assessment using the IRB self assessment instrument. The PI is encouraged to correct any deficiencies or omissions as part of the self assessment review.

   2. The Office of the IRB staff is responsible for maintaining the self assessment instrument to reflect current federal regulations governing human research protections, local IRB policies and procedures, and International Conference on Harmonisation (ICH) Good Clinical Practice (GCP).

   3. The Department of Epidemiology and Biostatistics (DEB) develops the assessment within the Informatics Data Exchange and Acquisition System (IDEAS), manages the distribution of self-assessment invitations, and the link to the IDEAS, creates and holds the link to identify PIs, notifies PI feedback from OIRB/IRB is available for review in IDEAS, and uses IDEAS to generate an aggregate report of responders for the OIRB/IRB.

   4. The OIRB/IRB review non-identifiable individual and aggregate data and provide feedback to the PI through the IDEAS.

   5. The IRB Associate Director or OIRB Analyst generates periodic reports summarizing the results and proposes educational or policy interventions as needed.

III. Procedure
A. Approximately once a month, the OIRB staff searches the OIRB database to identify intramural research studies due to reach the end of the current approval period one to two months from the date of the search. Approximately ten PIs will be randomly selected from this list.

B. The OIRB staff sends the PI a notice to expect an invitation from the DEB to complete the on-line self assessment instrument. If a PI informs the OIRB that the study is not active (closed or not enrolled any subjects), the PI will be removed from the current list and added back into the pool to be selected to complete the assessment in the future.

C. The OIRB staff provides the list of Principal Investigators to the Department of Epidemiology and Biostatics. DEB creates accounts for each Principal Investigator and e-mails the invitation including the information necessary to access the self-assessment instrument. The PI or designee completes the self-assessment following the instructions provided with the instrument. The instrument is web-based and is accessible by the PI, OIRB, and DEB. The online assessment does not include any identifying information (i.e., Protocol number, study title, name of PI, etc).

D. The PI will have four weeks to complete the self-assessment. If the PI has not completed the assessment within two weeks, DEB will send a reminder. If the self-assessment has not been completed after four weeks, access to the assessment will be disabled and the PI will be added back into the pool to be selected to complete the assessment in the future.

E. Approximately one month after the initial invitations were sent, the OIRB will run a report to determine the non-completers by name only. At that time, the OIRB will add those PIs back into the pool to be selected to complete the assessment in the future.

F. The online instrument provides immediate feedback to the PI depending upon the PI responses to each item. The immediate feedback includes one of the following response types for each item:

1. No action recommended;

2. Recommend corrective actions address:

   a) minor errors or omissions noted on the instrument. Minor errors or omissions do not pose a risk to participants. The reviewer will recommend corrective actions the PI or research team can take without reporting issues to the IRB (e.g., obtain missing documents, additional training of research team, etc.)

   b) major errors or omissions noted on the instrument. Major errors or omissions may pose a risk to participants. The reviewer will recommend immediate corrective actions to protect participants from possible harm. Depending on the nature of the issue, the reviewer may recommend to the PI that prompt reporting to the IRB, sponsor (if applicable) and institution (e.g., VA R&D Service) is appropriate (e.g., noncompliance, unanticipated problems, scientific misconduct)

G. In addition to the immediate feedback provided within the instrument, every study assessment is reviewed by the IRB Associate Director or OIRB analyst. The reviewer provides customized feedback for each PI which is relayed to the PI through IDEAS.

H. The OIRB Staff summarizes the results of the PI Self-Assessment Program periodically and provides the results to the IRB Director, IRB Associate Director and Chairs.

I. The OIRB develops educational programs for investigator and research staff based on the results of the PI self-assessment reviews.

J. Based on other quality assessment and IRB review operations, the IRB, IRB Director, or IRBAD may direct a specific PI/protocol to complete the self-assessment instrument at times other than when randomly selected as part of the program.

IV. References
A. Definitions (see Glossary)

B. Regulatory (see Policy on Policies Policy and Procedure)