Attachment
Institutional Official Responsibilities

Draft Example of Guidance to be Developed Drawing on Current OHRP Materials, Draft VA Guidance, and Subpart A Subcommittee Suggestions

Who should be the Institutional Official (IO)?

- The Institutional Official (IO) is the individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance.
- The IO is responsible for ensuring that the Human Research Protection Program (HRPP) functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents the institution named in the Federalwide Assurance (FWA).
- The IO should be an individual of sufficient rank who has the authority to ensure that all obligations of the HRPP are carried out effectively and efficiently. This person is usually the President, Chancellor, Director General, Chief Executive Officer, or Chief Operating Officer for the legal entity that constitutes the institution conducting research. The IO should be at a level of responsibility sufficient to allow authorization of necessary administrative or legal action should that be required. Thus, department chairs, division directors or other officials who only have authority over one portion of the institution would generally not be an appropriate IO. Similarly, OHRP recommends that the IO not be the chair or member of any IRB designated under the FWA.

What are the general administrative obligations of the IO?

- Designating one or more Institutional Review Boards (IRBs) that will review research covered by the institution's FWA;
- Providing sufficient resources, space, and staff to support the IRB's review and record keeping duties;
- Providing training and educational opportunities for the IRB and investigators;
- "Setting the tone" by promoting an institutional culture of respect and conscience, so that the ethical conduct of human subjects research is supported at the highest levels of the organization;
- Ensuring effective institution-wide communication and guidance on human subjects research;
- Ensuring that investigators fulfill their responsibilities;
- Encouraging that all staff engaged in the conduct or oversight of human subject research participate in education activities;
- Serving as a knowledgeable point of contact for OHRP and other federal agencies, or delegating this responsibility to another appropriate individual;
- Depending on the organizational structure at a given institution, other administrative arrangements may be appropriate.

What can the IO or designee not do?

- Approve research that has been disapproved (or not yet approved) by the IRB.

What are some responsibilities that may be delegated by the IO to a designee?

The IO may delegate the performance of certain oversight and operational duties to one or more individuals. Any delegation of duty must be in writing. Upon designation of a new IO, all delegation letters must be reviewed and renewed by the new IO if the new IO chooses to maintain delegation.

- Appointing IRB members. Suspending or terminating the IRB membership of any individual for whom it has been determined that he/she is not fulfilling membership responsibilities and or obligations;
- Appointing the IRB chair or co-chairs. Suspending or terminating the appointment of any chair or co-chair who is fulfilling his/her responsibilities and or obligations;
- Performing periodic evaluation of the performance of the IRB chairs and co-chairs and administrative staff;
- Managing and administering funds. Ensuring that adequate personnel, space and other resources are allocated to the HRPP;
- Reviewing and signing memoranda of understanding and cooperative agreements between the institution and other organizations, including those that establish reliance on IRBs of record for collaborative research (e.g., IRB Authorization Agreements, Individual Investigator Agreements);
- Being the point of contact for correspondence addressing human subjects research with the OHRP, FDA and other agencies as applicable, including reports to federal agencies;
- Ensuring that IRB members and investigators are knowledgeable to conduct research in accordance with ethical standards and all applicable regulations;
- Developing and implementing an educational plan for IRB members, staff and investigators;
- Ensuring that IRB members and investigators are knowledgeable to conduct research in accordance with ethical standards and all applicable regulations;
- Performing periodic evaluation of the performance of the IRB members and administrative staff;
- Recruiting qualified members to include expert, non-scientific and unaffiliated representation on the IRB;
- Reviewing and approving Standard Operating Procedures (SOPs) for the IRB and HRPP;
- Overseeing daily operations of the IRB and HRPP in accordance with the SOPs.

What responsibilities should *not* be delegated by the IO to a designee?

- Signatory authority for the FWA;
- Completing recommended Assurance training for the IO;
- Ensuring that the IRB functions independently and that its chair or chairs and members have direct access to the IO for appeal if they experience undue influence or if they have concerns about the function of the IRB;
- Ensuring that adequate resources, including funds, space, and personnel are provided to support the operation of the HRPP.