

RESEARCH INVESTIGATOR RESPONSIBILITIES

(Signature on project summary indicates these responsibilities have been acknowledged.)

- A. Research investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of this Institution's Federalwide Assurance. Research investigators may choose to delegate certain tasks to other members of their research staff. However, task delegation does not relieve the research investigator of primary responsibility for ensuring compliance with the Institution's Federalwide Assurance.
- B. Research investigators who intend to involve human research subjects will not make the final determination of exemption from applicable Federal regulations or provisions of this Institution's Federalwide Assurance. The OHSR will determine exemption.
- C. Research investigators are responsible for reporting any actual or perceived conflict of interest involving human subject research to the OHSR and the HHRI Conflict of Interest Committee, and will abide by the conflict of interest management recommendations put forth by the Conflict of Interest Committee and HSRC.
- D. Research investigators are responsible for maintaining copies of all study records and signed consent documents. All study records and correspondence and signed consent documents are to be retained for at least three years beyond the study completion date or as required by applicable regulations and/or award terms and conditions for the approved research. Research investigators are also responsible for providing a copy of the HSRC-approved, informed consent document to each subject at the time of consent, unless the HSRC has specifically waived this requirement.
- E. Research investigators will submit all proposed changes in previously approved research to the OHSR. The proposed changes will not be initiated without review and approval. Changes where necessary to eliminate apparent immediate hazards to the subjects that have not been approved will be reported within 5 working days to the OHSR.
- F. Research investigators are responsible for reporting progress of approved research (including study completion) to the OHSR, as often as and in the manner prescribed by the approving HSRC on the basis of risks to subjects, but no less than once per year.
- G. Research investigators will report within 5 working days any on-site serious adverse event (related or more likely related than unrelated), unanticipated problem involving risks to subjects or others (greater than minimal risk), and external new information that may alter risks to subjects or others (greater than minimal risk) to the OHSR. Research investigators will report within 30 days any on-site unrelated serious adverse event to the OHSR.
- H. Research investigators will report within 5 working days any reportable non-compliance in the conduct of the approved research to the OHSR. This includes any allegations of non-compliance and protocol deviations involving risks to subjects or others (greater than minimal risk) or compromising scientific integrity or validity of the research.
- I. Research investigators will allow access to their study records as needed to complete study audits or investigations initiated by the OHSR, or any other applicable agencies with regulatory or legal purview.
- J. No research investigator who is obligated by the provisions of this Institution's Federalwide Assurance, any associated Inter-Institutional Amendment, or IRB Authorization Agreement will seek to obtain research credit for, or use data from, patient interventions that constitute the provision of emergency medical care without prior HSRC approval. A physician may provide emergency medical care to a patient without prior review and approval, to the extent permitted by law (45 CFR Part 46.116[f]). However, such activities will not be counted as research nor will the data be used in support of research.

- K. Research Investigators are responsible for ensuring that if subjects enrolled in protocols under their direction are transferred to another institution and continued participation in the research protocol is anticipated, the OHSR, Office of Grants and Contracts, and other appropriate officials at both institutions will be notified in a timely manner. If the transfer of research subjects is a planned occurrence in the research protocol, the investigator is responsible for ensuring that the new institution possesses an OHRP-approved Federalwide Assurance.
- L. Research investigators are responsible to ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
- M. Research investigators are responsible to ensure that research staff are qualified (e.g., including but limited to appropriate training, education, expertise, credentials and, when relevant, privileges) to perform procedures assigned to them during the study.
- N. Research investigators are responsible for the recruitment of subjects in a fair and equitable manner.