

RESEARCH INVESTIGATOR RESPONSIBILITIES

- 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 MMRF 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 as soon as possible 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 promptly report any serious and/or unanticipated adverse events involving risks to subjects or others to the OHSR.
- H. Research investigators will promptly report any reportable non-compliance in the conduct of the approved research to the OHSR.
- 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.