Guideline for Investigator Responsibilities
When Conducting Exempt Research

Investigator responsibilities after receiving written documentation of determination of an exemption from the IRBO include the following:

Responsibilities before the research begins:

- Based on the study design and the type of research that will be conducted, investigators may wish to complete additional training available via the NIH CITI Portal prior to initiating the project. For example:
  - If conducting recruitment via social media → CITI course, *Social Media and Research Recruiting*
  - If conducting research using the Internet → CITI module, *Internet-Based Research* (available within the Social and Behavioral Modules)
  - If conducting community-based research → CITI course, *Community Engaged and Community-based Participatory Research*
- As applicable, train the study staff regarding protocol implementation. For example:
  - How recruitment of subjects should be conducted;
  - If the project involves collecting new data from humans, how the privacy of the subjects will be protected; and
    - When social media will be used for recruitment purposes or data collection, the team should be familiar with the *NIH Social Media Guidelines*.
    - If you will be using third-party vendors to recruit and screen prospective research participants (e.g., using MTurk, Buildclinical, Qualtrics), review the guidance *Use of 3rd Party Vendors for Recruitment and Screening* under Policy 302, Subject Recruitment and Compensation on the OHSRP Policy and Guidelines webpage.
  - If identifiers will be collected, explain how the confidentiality of the data will be ensured.

Responsibilities during the conduct of the research:

- Maintain a regulatory file with current and accurate records of all study documentation including, at minimum, the finalized protocol, the IRB outcome letter regarding the exempt determination, and as applicable, other approved study documents. See NIH Manual Chapter 1743 – *Managing Federal Records* and the *NIH Intramural Records Retention Schedule*. See the *Privacy Act*, if personally identifiable information will be maintained as part of the research.
- Oversee the conduct of all research activities. PIs may delegate responsibilities, but the PI must maintain oversight of all research activities and must ensure both the protocol and the research team's actions are compliant with law, regulation, and policy.

- Conduct research in compliance with the finalized protocol and submit any changes to the research (protocol, recruitment material/methods, or other study materials) for review by the IRBO and confirmation of the continued exempt status of the project, prior to implementation.
- As applicable, train the study staff regarding any changes in protocol implementation with each amendment as the study progresses.
- Maintain adequate and accurate subject study records and documentation to demonstrate compliance with the approved protocol.
- Ensure that any subject questions, concerns, and complaints are properly addressed, and the resolution documented in the study record. Subjects can also be directed to call the NIH Office of IRB Operations at 301-402-3713, who will usually refer subject complaints to the OHSRP Division of Compliance and Training if they wish to discuss their concerns with members outside of the study team. Report these per Policy 104 – *Managing Research Related Complaints from Subjects*.
- Report research-related events per Policy 801 - *Reporting Research Events*, Policy - 802 *Non-Compliance in Human Subjects Research* and the *Guidance: Reporting Research Events and Non-compliance*.
- If departing the NIH and exempt research activities will continue at the NIH, the PI must submit an amendment to change the PI prior to their departure. (See *Policy 300 – Investigator Responsibilities*.)
- If the project involves collecting new data from humans, and the research meets the definition of clinical research, submit annual cumulative inclusion enrollment data as part of the Progress Report.