

IIA Questions

1. How will non-affiliated research staff (non-affiliates) be selected, i.e., by what criteria or with what qualifications?
2. Will any non-affiliate(s) conduct research activities for this study as an employee of an institution or organization? If yes, indicate whether the institution or organization has an FWA and whether it regularly conducts research. Does that institution or organization have an IRB and is the proposed research required to be submitted to that IRB? Appropriate documentation (e.g., IRB approval at affiliate's institution/organization; attestation that IRB approval at the affiliate's institution/organization is not required, etc.) should be provided.
3. Is any individual affiliated in any capacity, whether paid or unpaid, with Ohio University, e.g., student, faculty, employee, volunteer?
4. Describe how non-affiliates will be trained, e.g., by whom, covering what topics, etc. The non-affiliates are expected to review the following items: 1) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research; 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46; 3) the FWA and applicable Terms of the FWA as posted on the Office for Human Research Protections (OHRP) website; and 4) the relevant Ohio University (OU) institutional policies and procedures for the protection of human subjects as found on the Ohio University Research Compliance website at: <http://www.ohio.edu/research/compliance/>.
5. What procedures will non-affiliates be conducting, e.g., obtaining informed consent, administering surveys, collecting data, interacting with subjects, or analyzing identifiable data?
6. Why is the researcher proposing to engage individuals who are not associated with Ohio University or another institution in this project?
7. What is the risk level of the procedures in which the non-affiliates will be involved?
8. Describe how the Ohio University study team will be communicating with non-affiliates and the subjects (e.g., research at external sites, international research, or research with non-English speaking subjects).
9. To what degree will the Ohio University study team be supervising/monitoring the non-affiliates? Provide a plan for monitoring compliance (e.g., by assessing whether study procedures are being followed), security of data while it is in the possession of the non-affiliates, and safety of subjects (e.g., by ensuring that confidentiality, privacy, and contact procedures are being followed).
10. How many non-affiliates will be participating?
11. Are any non-affiliates non-English speaking?