**Individual Investigator Agreement**

**PI Questionnaire**

The IRB must determine whether Columbia University (CU) should act as IRB of record for staff engaged in research activities for this protocol who are not affiliated with CU. To aid in that determination, please respond to the following questions/requests.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Question** | **Yes** | **No** | **Response** |
| 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 the individual affiliated in any capacity, whether paid or unpaid, with Columbia, e.g., student, faculty, employee, volunteer? |  |  |  |
| 4.  | How will non-affiliates be trained, e.g., by whom, covering what topics?*Note that non-affiliates should take the CITI Human Subject Protection (HSP) training.** *Email askirb@columbia.edu to request instructions for accessing the training.*
 |  |  |  |
| 5.  | What procedures will non-affiliates be conducting, e.g., obtaining informed consent, administering surveys, collecting data, interacting with subjects, analyzing identifiable data? |  |  |  |
| 6.  | What is the risk level of the procedures in which the non-affiliates will be involved? |  |  | ☐ No greater than minimal risk ☐ Greater than minimal risk |
| 7.  | Describe how the Columbia study team will be communicating with non-affiliates and the subjects (e.g., research at external sites, international research, research with non-English speaking subjects). |  |  |  |
| 8.  | To what degree will the Columbia 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 enumerators, and safety of subjects (e.g., by ensuring that confidentiality, privacy, and contact procedures are being followed).* |  |  |  |
| 9.  | How many non-affiliates will be participating?*Provide the names of the non-affiliates* |  |  |  |
| 10. | Are any non-affiliates non-English speaking? |  |  |  |