UNITEDHEALTH GROUP

OFFICE OF HUMAN RESEARCH AFFAIRS (OHRA)
Principal Investigator Responsibilities & Assurance

Through the act of submitting research to the OHRA, and being named as the principal investigator (PI) of that research, the PI is agreeing to assume the overall responsibility for the research conduct. By doing so, they are agreeing to:

1. Personally conduct or supervise the research and document delegated tasks & responsibilities
2. Ensure that each individual to whom a task is delegated, is qualified by virtue of education, training, and experience (e.g., hospital certification, human subjects research training, state license) to perform each of their delegated tasks
3. Protect the rights, safety and welfare of the participants who will be under their care. To accomplish this they are agreeing that the research:
    a. is conducted in accordance with all federal regulatory requirements, state law and UHG policies (including UHG Office of Human Research Affairs (OHRA) SOPs if applicable)
    b. is conducted in accordance with the IRB or appropriate regulatory determination approved plan
    c. is managed in such a way that will ensure the accuracy, security and integrity of the research data and the subsequent analysis of that data
4. Provide an application to the UnitedHealth Group (UHG) Office of Human Research Affairs (OHRA) which contains all necessary materials for review and approval.
5. Engage any internal support offices/centers/review entities required for the project and provide any additional materials needed to those entities in order to grant approval.
6. Ensure that all external partners in the project have appropriate contracts or agreements in place aligning with their role in the project and/or any data or specimen access and retention that may occur within the context of the project or broad future use.
7. Confirm that any required human participant training is completed and documented for yourself and your engaged project staff.
8. Maintain an active record of all submissions for the project and inform any research support office/center/review entity of any proposed modifications that may impact their review. No revisions to the planned project may occur prior to securing approval of the revisions by the OHRA (including any revisions of project execution and/or engagement by research partners).
9. Confirm whether there are any financial conflicts of interest for you or any engaged project staff. If no such conflicts exist, documentation of those conditions must be included with the personnel listing for the project. If conflicts do exist, investigators must report potential conflict(s) for assessment and potential management.
10. Provide any ongoing required correspondence to the OHRA for your project (i.e. annual renewals – if required, issues that occur during conduct of the project, revisions, etc.)
11. Inform the OHRA and any appropriate entities within UHG (legal, privacy, etc.) of any changes with project execution or purpose which may impact generalized presentation of research project outcomes.

I attest:
Principal Investigator Signature _____ **Date:** _____

Email Address: _____