

**OFFICE OF HUMAN RESEARCH AFFAIRS (OHRA)**

**New OHRA/IRB Application Cover Letter Guidance**

**New applications to the UHG OHRA require the following:**

**Clean draft of the protocol –** The copy of the protocol provided to OHRA for initial review should be clear of all previous tracked changes. Comments from any socialization and feedback may be kept but OHRA reserves the right to inquire about any comments that appear to be open ended or unresolved.

Note: Other study supporting documents may be included in an initial application but please be aware that the OHRA’s preference is to establish the protocol first then begin development of consent and other materials based on the final protocol.

**Signed PI Assurance Form** - OHRA must have on file ONE signed PI assurance document from the person who will serve as the Principal Investigator. All studies must identify a single PI. Other investigators may be CO-Investigators or Sub-Investigators. Please see <https://www.uhgohra.com/application> to download the PI Assurance form. Please complete the form and include with your emailed submission to the OHRA.

**Documentation of CITI training for all investigators –** Baseline CITI training requirements for all UHG investigators is completion of CITI training courses for Human Subjects Research Protections & Conflicts of Interest. Additional courses may be required based on the design of the research. PLEASE REVIEW THE OHRA CITI TRAINING JOB AID TO ENSURE YOU ARE SUBMITTING THE CORRECT TRAINING.

**Cover Letter –** A template cover letter outline is available below to help you write a request for initial OHRA review of your project. Other cover letter formats will certainly be accepted as long as the necessary information is included. Your cover letter should include**:**

* **a brief summary of the goals of this initial review.** Are you submitting to request a consultation on developing your protocol in a particular area? Are you submitting with the intent that you are prepared to launch the study? Are you submitting just to get the ball rolling?
* **pertinent information regarding the initiation of the study such as pending internal reviews, materials for launch that are still under development, etc.,**
* **A clear statement regarding conflicts of interest for the PI and all other affiliated research staff.** It should be clear that the PI and all research staff have read the details of conflicts that must be disclosed (as described in the OHRA Protocol Guidance) and confirmed they do not have a conflict to report or provide brief details of existing conflicts to support the conflict management discussion.
* **A complete list of the documents being submitted for review identified by name and version. If your protocol includes appendices, please identify the separate documents that are embedded in your protocol.** *(Please also note that all documents submitted must have a version identifier on the body of the document like a number, letter, date or combination. Every time you submit a document to the OHRA for approval of revisions, the version must be updated.)*
* **Identification of the internal approvals –** Starting a new study requires collaboration among and approval from many internal stakeholders. Before the OHRA or IRB can approve your study to begin, we must be apprised of how widely the project has been socialized to date. OHRA encourages socialization for feedback to be completed as much as possible BEFORE engaging OHRA for regulatory review. OHRA approval will be delayed / withheld until it is confirmed that all necessary socialization, feedback and revision processes have been completed.

**Cover Letter Template – Please copy the text below into a separate document. Do not submit the guidance on pg.1 to OHRA. All blue text is instructive and should be updated to fit your request.**

PI Name

PI preferred contact info

PI Department / Dept. supporting the submitted research

Name & preferred contact info for main study contact other than the PI

Submission Date: xx/xx/xxxx

RE: Initial application for (Project Title)

The following documents are included for review:

- Cover Letter, dated xx/xx/xxxx

- PI Assurance signed by NAME

- Human Subjects Research CITI Training for Name

- Conflict of Interest CITI training for Name

- Protocol v. x

- Informed Consent form v. x

- Call center script v. x

- Recruitment flyer v. x

- Study Survey v. x

- Enrollment website mockup or link

**a brief summary of the goals of this initial review. Are you submitting to request a consultation on developing your protocol? Are you submitting with the intent that you are prepared to launch the study? Are you submitting just to get the ball rolling while you finalize other aspects?** What is your assessment of the risk to participants presented by the study? Is it designed as quality improvement? Is it Research? What logistical or status information can you share for context? Are there sections of the protocol that are currently incomplete? Are there research partners that have not been finalized? Are there launch dates or other timelines to be aware of? Are there specific areas of uncertainty for which you are requesting specific OHRA guidance? **pertinent information regarding the initiation of the study such as pending internal reviews, materials for launch that are still under development, Identify anything still being worked on that will be submitted later,etc.,**

As part of this request for OHRA review, the following socialization details are provided

* All investigators and research staff assigned to this project have reviewed the details of conflicts that must be disclosed. There are no existing conflicts of interest for any investigator involved in this research OR First Name Last Name has identified a conflict of interest and is an investigator involved in the research.
* As acting leadership for **XDept.** supporting this research **First Name Last Name + Email Address** has reviewed the submitted protocol and approved the project to proceed**.**
* As acting Legal Counsel within **XDept.** supporting this research **First Name Last Name + Email Address** has reviewed the submitted protocol and will provide legal considerations and oversight in collaboration with Optum Labs Legal
* As acting Privacy Officer within **XDept.** supporting this research **First Name Last Name + Email Address** has reviewed the submitted protocol and will provide privacy considerations and oversight in collaboration with Optum Labs Privacy
* **If any components of your study will be executed at Clinical sites, please identify all Clinical Site leadership who will need to approve the project to take place at their site (if any). Letters of support are also acceptable.**
* **If your study requires enrollment and interaction with UHC members, please clearly state whether UHC Research Review Board has assessed your protocol already or if you need OHRA assistance with obtaining this level of review.**