PI WORKSHEET: New Study Submission – No Reliance

Please use this checklist to help prepare for your IRB submission in ZOT IRB:

☐	The Principal Investigator (PI) is eligible to serve as a PI at UCI either on their own or with a Faculty Advisor. Refer to the University of California Systemwide Contract and Grant Manual (Subchapter 1-500) for more information.
☐	The PI and Study Team review the Investigator's Manual. The Investigator's Manual specifies expectations for conducting human subject research at UCI.
☐	The PI and Study Team review the Human Research Protection Program Plan to understand the human subject program at UCI, what constitutes human subject research and importantly, IRB submission types that may be self-determined.
☐	The PI and Study Team can locate the HRP Toolkit. All pertinent IRB submission materials, above referenced guides and HRPP standard operating materials may be found within the HRP Toolkit.
☐	Access the HRP Toolkit. Complete the applicable version of the Protocol Narrative that corresponds to your study type.
☐	**When completing the Protocol Narrative:** Ensure all activities / procedures involving subjects are explained in a step-by-step, consistent manner.
☐	Recruitment and selection of participants must be equitable. Exclusions are scientifically justified.
☐	Be mindful of additional considerations and protections for vulnerable populations. Complete the applicable PI Worksheets as found in the HRP Toolkit and as prompted by selections made in the Protocol Narrative. PI Worksheets are required to address special populations and help the Institutional Review Board (IRB) to confirm applicable subparts of the federal regulations.
☐	Reasonable risks and potential benefits to participants and society are explained adequately.
☐	For Greater than minimal risk research, a data and safety monitoring plan has been developed.
☐	The consent form addresses areas required by federal regulations and is written at the eighth- grade level or lower language when possible. Refer to the HRP Toolkit for all consent templates.
☐	Complete any assent, consent and recruitment documents as found in the HRP Toolkit. Use the Protocol Narrative as a guide to determine which documents are needed.
☐	If creation, use, or disclosure of Protected Health Information is applicable: Indicate whether subjects will sign a written HIPAA research authorization If a waiver of HIPAA Authorization is requested, ensure the research meets the criteria. Remember! Complete the applicable PI Worksheets as found in the HRP Toolkit and as prompted by selections made in the Protocol Narrative. If HIPAA Research Authorization applies, when the study is IRB approved, ensure that the HIPAA Research Authorization is attached to the IRB approved consent form.
☐	Gather the completed Word documents. Initiate the new study in the ZOT IRB SmartForm.
☐	**When completing the SmartForm in ZOT IRB:** Ensure the Brief Description of the study is concise and addresses all aspects of the study in language understandable to a non-scientist reviewer.

☐	When completing the Study Team section, keep the following points in mind: List only those as necessary per the Research Team Table. Use the Template – UCI Research Team Log to track study team outside of ZOT IRB. If collaborators at UCI need read only access to the protocol, they may be added to the Guest List in the main study space. Refer to this HRP Listserv for more information on this process. Refer to the same HRP Listserv for enabling the PI Proxy. All Study Team members listed formally in ZOT IRB must complete the applicable CITI training.
☐	Include all drugs and devices required by the protocol. If using an experimental drug or device, or using a marketed product off-label, provide the IND / IDE number or confirm IND/IDE exempt criteria. If marketed (on-label) drugs or devices will be used as part of research procedures (not as part of standard clinical care), list the products and their marketing status under drug or medical devices in the protocol application. Use discretion for those drugs or devices that are well known or understood (e.g., standard MRI, Tylenol, etc.).
☐	Non-standard questionnaires are provided.
☐	All applicable approvals for other committee reviews have been obtained or are in process.
☐	If research will be funded by an external sponsor (grant, contract, or gift), contact Sponsored Projects.
☐	If research will take place off-site, or data or materials, will be shared between institutions, proper documentation (permission letter, Federalwide Assurance for off-site entity, off-site research agreement, data use agreement (DUA), material transfer agreement (MTA), etc.) has been obtained or is in progress. Wanda Seang handles all DUA related inquiries or referrals for non-Industry organizations. The Clinical Trial Team handles human subject data agreements with industry. When transferring tangible research material to an organization, please contact UCI Beall Applied Innovation.
☐	Review the IRB approval letter. Understand what is required to conduct human subject research at UCI. Refer back to the Human Research Protection Program Plan and the Investigator's Manual throughout the research, as needed.
☐	Refer to Documentation for Sponsors in the HRP Toolkit for information that may be helpful for sponsors or publishers.