UCI Office of Research

IRB EQUIP TIPS - PROTOCOL PREPARATION CHECKLIST

V 3.0 November 2023

Please review this checklist to ensure that your IRB Application is complete before you submit:

☐	All applicable sections of the IRB Application in **KR Protocols** must be completed.
☐	The **Lead Researcher** has either a paid UCI faculty appointment greater than or equal to 50% or a Faculty Sponsor (see "Eligibility Table" for details).
☐	**Co-investigators and Research Personnel** have been listed per **Research Personnel Heat Map** as follows: • In the "Study Team" section of KRP or tracked in a Study Team Tracking Log. • If needing access to view or edit KRP, added under the "Permissions" tab in KRP. • For Greater than minimal risk research, list personnel involved in the consent process on the consent.
☐	The **purpose of the research** is explained adequately.
☐	The **subject population and size are justified** in the context of the proposed research. • Consider providing a power analysis, if appropriate.
☐	**Drugs / Devices:** • If using an **experimental drug or device**, or using a **marketed product off-label**, provide the **IND / IDE number** or check and verify IND/IDE exempt criteria in the protocol application. • 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.
☐	**Recruitment and selection** of participants must be **equitable** within the study.
☐	Subject **inclusion/exclusion criteria** are explained. • Include sufficient detail for all populations. • Be mindful of additional considerations and protections for **vulnerable populations**.
☐	All **activities / procedures** involving subjects are explained, step-by-step in a consistent manner.
☐	Probable and reasonable **risks** and **potential benefits** to participants and society are explained adequately.
☐	The **consent form** addresses all areas required by federal regulations, and is written at the eighth-grade level or lower • Resource: IRB Forms → Checklists → Checklist – Informed Consent • Template: IRB Forms → Consent Forms
☐	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.
☐	**Data collection tools** (e.g., measures, questionnaires) and/or citations are provided.
☐	All applicable approvals for **other committee reviews** have been obtained or are in process.
☐	For Greater than minimal risk research, **a data and safety monitoring plan** has been developed.
☐	If research will be funded by an **external sponsor** (grant, contract, or gift), proposal paperwork has been filed with Sponsored Projects.
☐	If research will take place **off-site**, proper documentation (permission letter, Federalwide Assurance for off-site entity, off-site research agreement, etc.) has been obtained or is in progress.

	• **IRB FAQs** - *I am conducting human subjects research Off-Site (at a non-UCI location). What are the requirements?*
☐	Research involving **International Sites**: Review HRP Policy # 27 • Be mindful of if International Data Protection Laws may apply. • European Union's General Data Protection Regulation (the "GDPR") • China's Personal Information Protection Law (PIPL) • Refer to the Office of Research – Export Controls webpage • OFAC website for active sanctions programs