Pease review this checklist to ensure that your human subjects application packet is complete before you submit the IRB Application to the IRB for review.

☐ Protocol Regulatory and Internal Congruence Worksheet [Use for your initial IRB application documents, prior to submission]

☐ All applicable sections of the IRB Application should be completed.

☐ The Lead Researcher has either a paid UCI faculty appointment greater than or equal to 50% or a Faculty Sponsor.

☐ All Departmental and/or Research Unit approvals should be secured.

☐ If using an experimental drug/device, the IND or IDE number and filing date are provided in the IRB Application.

☐ All potential co-investigators and research personnel have been listed as appropriate (in application and protocol narrative, on consent if involved in the informed consent process).

☐ The purpose of the research is explained adequately.

☐ The subject population and size is justified in the context of the proposed research (Consider providing a power analysis, if appropriate).

☐ Equitable inclusion of women and minorities has been assured.

☐ The proposed recruitment and consent methods guarantee voluntary participation. If the proposed subject population may be vulnerable to coercion, explain how this will be minimized.

☐ Subject inclusion/exclusion criteria explained in sufficient detail.

☐ Adverse event reporting and treatment is addressed.

☐ All activities involving subjects are thoroughly explained.

☐ Probable risks to participants and potential benefits to participant 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.

☐ Data collection instruments and/or citations are provided.

☐ 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. Be mindful of if International Data Protection Laws may apply.

☐ If research will be funded by an external sponsor (grant, contract, or gift), proposal paperwork has been filed with Sponsored Projects.

☐ All applicable approvals for other committee reviews have been obtained or are in process.

☐ Recommended Reading, "Common IRB Submission Errors."