The purpose of this checklist is to provide support for Office of IRB Administration (OIA) staff conducting pre-review to issue clearance for a study to be reviewed by an external IRB. This checklist, or equivalent, is to be used. It does not need to be completed or retained.

### Pre-Review

- [ ] The **human subjects research** is **minimal risk**
  - Or
  - The **human subjects research** is greater than **minimal risk** and reviewing IRB is accredited by Association for the Accreditation of Human Research Protection Programs (AAHRPP), Consortium for Applied Research Ethics-Quality (CARE-Q), or equivalent body
  - Or
  - The **human subjects research** is greater than **minimal risk** and reviewing IRB has an internal quality review process to ensure compliance with ethical principles, applicable law and guidance, and OIA director/medical director or institutional official has agreed to cede review

- [ ] The UCSD Investigator(s) has completed required training. Not required for clearance, but required for acceptance

- [ ] The external reliance **administrative review** application includes the following items:
  - Master protocol/research protocol
  - Overall study approval from the reviewing institution/IRB
  - Investigator brochure(s)/package insert/instructions for use (as applicable to the research)
  - Recruitment material template(s) from sponsor or reviewing institution/IRB, as applicable (for non-commercial IRBs only)
  - Informed consent template(s) from sponsor or reviewing institution/IRB (for commercial IRBs only)
  - Informed consent template with UCSD required institutional language added and tracked (for non-commercial IRBs only)
  - The reliance agreement (when necessary)

### Initial Administrative Review

- [ ] The protocol is complete and understandable.
- [ ] UCSD local context has been taken into consideration in the application and consent form(s).
  - [ ] N/A, commercial IRB or National Cancer Institute Central IRB with master reliance agreement
  - [ ] Ancillary reviews have been triggered (when applicable).
- [ ] If the study is a Phase I clinical trial, the OIA director/medical director has provided sign-off to be reviewed by an external IRB.
- [ ] The **research** is acceptable; there is no apparent error or omission in the approval of the reviewing IRB based on regulatory criteria for approval of human subjects research.

- [ ] Clearance sent to investigator (include clearance statement in a 'revisions required' action). Investigator to send approval documentation from the reviewing IRB for the addition of UCSD as a relying site, before final reliance acceptance letter is issued.

  **OR**

- [ ] Any deficiency in documentation or other item is conveyed to the investigator for reconciliation with criteria for clearance.