|  |  |
| --- | --- |
| **or-logo-stacked** | **Institutional Review Board****Human Research Protections****Administrative Reviewer’s Checklist – UCI is the Relying IRB***Version April 2025* |
| **IRB#:** X**Lead Researcher:** X |

|  |
| --- |
| **HRP ADMINISTRATIVE CHECKLIST** |
| [ ]  **Research Meets sIRB Eligibility Criteria** |
| [Ongoing Corrective Actions](https://uci.atlassian.net/wiki/spaces/ORA/pages/67605404/On-Going%2BCorrective%2BActions)  | [ ]  No impact to sIRB [ ]  Impact to sIRB, specify: |
| Level of Review  | [ ]  Not exempt research |
| Regulation and/or Policy Criteria | *Select the first criteria that applies* [ ]  HHS – Confirm the following is true:[ ]  Not research for which more than single IRB review is required by law[ ]  Not research for which any Federal department or agency determines and documents that the use of a single IRB is not appropriate[ ]  FDA – Confirm the following is true:[ ]  Not research for which more than single IRB review is required by law[ ]  Not research on drugs that are IND exempt [ ]  Not research on devices that are NSR [ ]  Not research on devices that are IDE exempt [ ]  Not an investigator initiated/authored clinical investigation [ ]  Not expanded access (all types), compassionate, or right to try [ ]  HRP Policy – Confirm the following is true:[ ]  Not involve any HHS or FDA exceptions listed above[ ]  External IRB is accredited/certified (AAHRPP, CARE-Q) or in process [ ]  SMART IRB Agreement v3.0 used  |
| [ ]  **All Applicable Ancillary Clearances Have Been Obtained**  |
| [ ]  COIOC Clearance | [ ]  Chair does not have a conflicting interest[ ]  Chair approved the COI Management Plan |
| [ ]  hSCRO Approval | [ ]  Use of the following human materials: gametes, embryos, adult pluripotent cells, fetal tissue, fetal stem cells, or embryonic stem cells. [ ]  Generation of new lines of human pluripotent stem cells [ ]  Introduction of human adult pluripotent cells, human fetal tissue, fetal stem cells, or human embryonic stem cells or their neural derivatives into a nonhuman animal [ ]  Transplantation of neural stem cells into humans |
| [ ]  IBC Approval | [ ]  Deliberate transfer of recombinant and synthetic nucleic acids, materials or microorganisms modified using recombinant and synthetic nucleic acids into one or more human research participants |
| [ ]  RSC Approval | [ ]  Radiation exposure to normal subjects and/or clinical human subjects when the exposure is not considered standard-of-care |
| [ ]  Other [Ancillary Clearances](https://research.uci.edu/wp-content/uploads/Ancillary-Partner-Impact-IRB-Chart.pdf)  |  Specify: |
| [ ]  **Study Personnel Appear Appropriate and Qualified** |
| [ ]  Study Team has complete the required CITI training (including GCP, as applicable)[ ]  For greater than minimal risk research that involves the application of an investigational drug, device, or surgical procedure, confirm the following is true:[ ]  Study team has sufficient expertise (i.e. departmental expertise, research procedures, vulnerable populations)[ ]  Sub-investigators/co-researchers involved, as necessary (i.e. large sample size) [ ]  Only a United States (US) licensed medical doctor or US licensed nurse practitioner finalizes the consent process [Medical Board of California [Search](https://www.mbc.ca.gov/License-Verification/default.aspx)]  |
| [ ]  **Recruitment Material Includes UCI Requirements OR** [ ]  **Not applicable**  |
| Standard Requirements:  | [ ]  Name of Institution, name of department[ ]  Name Lead Researcher, name contact person, and contact info [ ]  Purpose of the research and eligibility criteria [ ]  Straightforward, truthful description of the benefits[ ]  Location of the research and time commitment |
| [ ]  **Consent Form Includes UCI Requirements OR** [ ]  **Not applicable** |
| Standard Requirements:  | [ ]  Institution name above main title[ ]  Header block - SUB-INVESTIGATOR(S):[ ]  Confidentiality[ ]  Compensation for injury[ ]  Costs[ ]  Cancer statement[ ]  Financial Conflict of Interest[ ]  Questions[ ]  Consent/Signature section [ ]  Witness Signature section [ ]  UCI Bill of Rights - After signature section separated by a page break |
| Other Requirements, as applicable: | [ ]  Risks and Discomforts:[ ]  Incidental Findings [ ]  Randomization [ ]  Washout Period[ ]  Placebo[ ]  HIV/Hepatitis/Covid-19 Testing[ ]  Radiation Risk[ ]  Pregnancy Testing in Minors[ ]  Medical Care[ ]  Certificate of Confidentiality[ ]  Use of Research Specimen[ ]  CalGINA (Genetic Testing)[ ]  [Consent Addendum: Language for UCI-Advarra Reliance](https://research.uci.edu/wp-content/uploads/informed-consent-advarra.docx)[ ]  [Consent Addendum: Language for UCI-NCI CIRB Reliance](https://research.uci.edu/wp-content/uploads/uci-specific-nci-cirb-consent.docx)[ ]  [Consent Addendum: Language for UCI-WCG IRB Reliance](https://research.uci.edu/wp-content/uploads/informed-consent-wirb.docx) |
| [ ]  **HIPAA Authorization Has Been Addressed OR** [ ]  **Not applicable** |
| [ ]  Signed HIPAA Authorization Required[ ]  Partial and/or Total Waiver of HIPAA Authorization Granted[ ]  Not nonviable neonates [[§46.205(c)(5)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-b/index.html#46.205)][ ]  [UCOP Guidance – HIPAA Waivers & CA Law](https://uci.atlassian.net/wiki/spaces/ORA/pages/edit-v2/408847745):[ ]  Not data from alcohol and drug abuse program [ ]  Not data from a Part 2 program (federally assisted substance use disorder programs; substance use disorder patient records) [ ]  Not health care provider disclosing HIV test[ ]  Not identifiable HIV or AIDS information [ ]  Not psychotherapy notes [ ]  Not mental health information (not psychotherapy notes) [ ]  Not LPS records (certain inpatient psychotherapy records)  |

|  |
| --- |
| **ADMINISTRATIVE QUESTIONS AND NOTES FOR THE REVIEWER** |