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| **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 | |

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| **HRP ADMINISTRATIVE CHECKLIST** | |
| **Research Meets sIRB Eligibility Criteria** | |
| [Ongoing Corrective Actions](https://uci.atlassian.net/wiki/spaces/ORA/pages/67605404/On-Going+Corrective+Actions) | 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) | |

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