I. Background
   (a) Exempt and non-exempt human subjects research studies must be reviewed by the IRB/ORCA on an ongoing basis to ensure that the research continues to meet exemption criteria or criteria for IRB approval under the Common Rule (45 CFR 46), as applicable. This policy outlines procedures for administrative check-in/continuing review of active studies.

II. Definitions
   (a) Administrative Check-In: The process by which minimal risk exempt and non-exempt human subjects research studies are reviewed annually by the IRB/ORCA in order to keep UCSC updated on the status of active studies for which it has an oversight responsibility and to ensure that the research continues to meet exemption criteria or criteria for IRB approval under the Common Rule (45 CFR 46).
   (b) Administrative Check-In Date: The date by which a Principal Investigator is required to provide the IRB/ORCA an update on a study’s status and progress, to allow for a determination that the research continues to meet exemption criteria or criteria for IRB approval under the Common Rule (45 CFR 46), as applicable.
   (c) Continuing Review: The process by which minimal risk and greater than minimal risk non-exempt human subjects research studies are reviewed by the IRB to ensure that the research continues to meet the criteria for IRB approval under the Common Rule (45 CFR 46).
   (d) Expiration Date: The date after which IRB approval is no longer effective until/unless the IRB conducts a continuing review and renews its approval.
   (e) Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of the general population or during the performance of routine physical or psychological examinations or tests.
   (f) Renewal: The reinstatement of IRB approval, as the result of continuing review, for a study that was previously approved and for which approval is expiring or has expired.

III. Approval Periods
   (a) Studies subject to Department of Justice (DOJ) or FDA regulations must be reviewed annually.
   (b) The Common Rule (45 CFR 46) requires a human subjects research study that has been determined by the IRB to pose greater than minimal risk to subjects be reviewed at least annually until it has progressed to a point where:
      (1) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
(2) where no subjects have been enrolled and no additional risks have been identified; or
(3) where the remaining research activities are limited to data analysis.

(c) Upon meeting one of the 3 criteria above, the IRB may determine that an annual administrative check-in to provide information about the status of the study is acceptable. This determination is subject to change based on any subsequent changes in a study’s risk level.

(d) Studies that have been determined by the IRB to pose minimal risk to subjects and meet the eligibility criteria for expedited review under 45 CFR 46.110 will require an annual administrative check-in to provide information about the status of the study.

(e) Studies that are determined to be exempt from IRB review under 45 CFR 46.104, including studies reviewed by the IRB in accordance with the limited IRB review described in 45 CFR 46.104(d)(2)(iii) or 45 CFR 46.104(d)(3)(i)(C), will require an annual administrative check-in to provide information about the status of the study.

(f) The IRB, at its discretion, may require studies to receive continuing review more often than annually, and may require studies that would otherwise qualify to receive annual administrative check-in to receive continuing review. For example, due to the nature of the study, degree of uncertainty regarding the risks involved, the vulnerability of the subject population, the inexperience of the investigator, prior noncompliance with the investigator or sponsor, or use of novel therapies.

IV. Administrative Check-In and Continuing Review Requirements and Procedures

(a) The Principal Investigator (PI) is required to keep track of approval periods and submit a Renewal Submission no less than 30 days prior to the study administrative check-in/expiration date (see the UCSC IRB Policy on Administrative Check-In and Continuing Review).

(b) Investigators must, as part of the Renewal Submission, verify that approved materials are still in use, that there have been no unapproved changes, that details/information for any non-UCSC sites/investigators relying on the UCSC IRBs/ORCAs review of the study are included.

(c) Investigators are expected to submit and obtain approval for any changes (see the UCSC IRB Policy on Modifications), report any unanticipated problems involving risks to subjects or others (see the UCSC IRB Policy on Unanticipated Problems Involving Risks to Subjects or Others), report any noncompliance (see the UCSC IRB Policy on Noncompliance), and to close out the study once the human subjects research activities are complete (see the UCSC IRB Policy on Study Closure and Withdrawal).

(d) As a courtesy, ORCA sends email reminders to investigators at roughly 60 days, 45 days, 30 days, and 15 days before expiration.

(e) ORCA does an administrative review of all Renewal Submissions in the order of receipt and sends comments/questions to investigators if needed.

(f) Once investigators respond, studies that are eligible for exempt review are reviewed by ORCA staff, studies that are eligible for expedited review are forwarded to the IRB
Chair or an experienced IRB member designated by the Chair for review, and studies that are potentially greater than minimal risk or do not meet exempt or expedited criteria are reviewed at a convened IRB meeting.

V. Renewal Submission Review and Actions
(a) The IRB or ORCA (see below) will review the Renewal Submission for continued compliance with IRB criteria for approval under 45 CFR 46.111.

(1) Continuing review focuses on risk assessment and monitoring to determine if any new information is provided that would alter the IRB’s previous conclusion that (1) the risks to subjects are minimized, and (2) the risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result; the adequacy of the process for obtaining informed consent; if there are any investigator or institutional issues; and how the human subjects research is progressing.

(2) Continuing review includes consideration of new federal regulations, guidance, or institutional policy, amendments being made at time of continuing review, review of subject complaints and unanticipated problems, and information brought forth to the IRB from outside entities.

(b) Exempt review: Exempt determinations may be renewed administratively.

(c) Expedited review: The IRB Chair or an experienced IRB member designated by the Chair conducts the review and decides whether to approve the Renewal Submission, require modifications, or refer it to the full board.

(d) Full committee review: A quorum of the IRB meets to discuss the Renewal Submission and reviews it based on the criteria above. The Board can approve it, require modifications if the comments are specific and direct, defer it if they cannot determine criteria for approval based on the information provided, or disapprove continuing the research if risks outweigh benefits.

(e) Outside verification: In cases of complex procedures, investigators with prior noncompliance, discrepancies in application or materials submitted compared to approved study, or randomly selected projects, the IRB may check with third parties such as a sponsor or other study team members to ensure no unapproved changes have occurred in the research.

VI. Documentation and Notification of Review
(a) Modifications required: If ORCA (exempt studies), a designated reviewer, or the full board requires modifications before a Renewal Submission can be approved, the investigator will be notified and provided with the issues that must be addressed in a letter from ORCA/the IRB Chair. For renewals requiring full board review, the required modifications are also documented in the IRB meeting minutes. Investigators must respond in writing. Regardless of whether the initial application required full board review, the investigator’s response to required modifications may be reviewed by an experienced IRB reviewer designated by the Chair (expedited procedures). The
reviewer may determine that the IRB’s issues are satisfied or else request further modifications from the investigator, in which case the investigator will be notified and provided with the remaining issues. Again, the investigators must respond in writing and the review cycle continues until all IRB issues are resolved.

(b) Deferral: If the full Board votes to defer a Renewal Submission, the investigator notified and provided with the issues that must be addressed. The IRB’s issues are documented in a letter from ORCA/the IRB Chair and in the IRB meeting minutes. Investigators must respond in writing. The investigator’s response to a deferral must be reviewed by the full IRB at a convened meeting.

(c) Approval: Once approved, the investigator will be notified of the approval, including which previously approved consent waivers are renewed and whether previous approval for the inclusion of any special populations is renewed, the effective date, and the new approval period per the above. The approval is documented in a letter from ORCA/the IRB Chair. For renewals requiring full Board review, the approval, controverted issues, and their resolution will be documented in the meeting minutes.

(d) Disapproval: If the IRB disapproves the Renewal Submission, ORCA notifies the investigator and provides them with the IRB’s reasons for the disapproval. The reasons for the disapproval are documented in a letter from the IRB Chair and in the IRB meeting minutes. The investigator may submit a different study for initial review based on the IRB’s feedback, discontinue the research, or appeal the IRB’s determination in writing. Investigator appeals must be reviewed at a convened meeting of the full IRB.

VII. Expiration
(a) The Renewal Submission must be approved before the expiration date; otherwise, all research activities must cease until either IRB approval is reinstated (allowed at the IRB’s discretion if request was received prior to expiration) or a new Initial Submission has been reviewed and approved.
(b) The Renewal Submission must be received with adequate time for the IRB to conduct their review. If not received before the Study expiration date, the investigators must submit a new Initial Submission.

VIII. References
(a) OHRP Guidance on Continuing Review
(b) 45 CFR 46.109, 45 CFR 46.110, and 45 CFR 46.111
(c) Stanford University HRPP Policy Manual