**Relying Site Continuing Review**

**Study Name:** Click or tap here to enter text.

**UCSF IRB#:** Click or tap here to enter text.

**Instructions: This form must be provided to each study team that is relying on the UCSF IRB, be completed by the study team, and then returned and attached in iRIS as part of the renewal process. We recommend giving this form to relying sites well in advance of expiration. Note that if they are no longer an active site they should be fill out the closeout report form instead.**

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| **I. Relying Research Study Team** | |
| Site Name: | Click or tap here to enter text. |
| PI Name: | Click or tap here to enter text. |
| 1. Please confirm the following:   All prior contact details remain current.  All individuals involved in this research continue to meet all institutional training requirements for the conduct of human subjects research and are appropriately qualified by education, training, and institutional requirements (e.g., credential and eligibility) to participate in this research.  No new financial interests have been identified for individuals involved in the research and any prior financial interest, if any, continues to be accounted for by an institutionally derived conflict of interest management plan.  If unable to confirm all of the above, please contact your institutional point of contact and/or the lead study team to resolve the matter. | |
| **II. Research Progress** | |
| Please address the following with regards to your involvement in the research:  Enrollment Status:  No participants have been enrolled here  Enrollment is ongoing  Some participants have been enrolled but we are not actively recruiting  Closed to recruitment  Study activity Status:  Study activities have not yet commenced  Study is in progress and participants are currently participating in study procedures, interventions, and/or research activities (some participants may be in follow up)  Study intervention is complete for all participants but there is ongoing research-related follow-up contact with participants via questionnaires, phone calls, interviews, or mailings  Study procedures are complete for all participants but ongoing medical record review/biological specimen analysis continues (no ongoing participant contact)  Data analysis only – study is complete and the only activities at this site are data analysis and/or manuscript preparation  No remaining study activities, site no longer requires IRB oversight (closure)  Enrollment Status:   |  |  | | --- | --- | |  | **If none, enter 0** | | In the past year, how many people did you **enroll** (signed a consent form, regardless of whether they ended up participating in the study):  *Note: for this question and the rest of this table, “Past year” means since the last continuing review, or since the initial approval if this is the first year of the study* | Click or tap here to enter text. | | In the past year, how many of those enrolled were **screen failures or otherwise did not go on toward accrual**: | Click or tap here to enter text. | | In the past year, how many **dropouts** were there (withdrawn by PI, withdrew, lost to follow-up, otherwise did not complete and are no longer considered active participants): | Click or tap here to enter text. | | In the past year, how many participants did you **accrue** (from the above lines, take the number of people enrolled and subtract the number of people who did not meet eligibility criteria/did not become participants): | Click or tap here to enter text. | | In the past year, how many participants **completed** the study (no longer in follow-up): | Click or tap here to enter text. |   Have there been any unanticipated problems, protocol deviations, complaints, or other events that may have affected the rights, safety, or welfare of participants that have not yet been reviewed by the IRB?  No  Yes: please explain  Has there been any audit findings, corrective actions, disciplinary actions, or other restrictions or requirements placed on the study or study team?  No  Yes: please explain  Have there been any changes regarding the local study team, local context, or local implementation?  No  Yes: please explain  Examples include: new contact information, conflict of interest, institutional policy, or recruitment approach.  Are you aware of any new and relevant information that may be relevant to the continued approval of this research?  No  Yes: please explain  Examples include: expand inclusion criteria to include additional populations, reduce or change study procedures to minimize deviations or participation fatigue, new treatment alternatives or standards of care, new risk information or cautions for study-related procedures.  Do you have any concerns about this research meeting its objectives?  No  Yes: please explain | |
| **IV. Acknowledgements & Signature** | |
| Please review and acknowledge the following requirements (all boxes must be checked to submit):  You are responsible for and will comply with all applicable local policies, procedures, and institutional requirements in addition to the determination and requirements of the UCSF IRB;  You have been provided with, reviewed, and agree to comply with the UCSF sIRB SOPs;  You will promptly provide the Lead Study Team with any information and materials requested by the Lead Study Team or UCSF IRB; and  You will promptly notify the Lead Study Team of any relevant changes to the Site Information provided here, any required reports that may arise during the conduct of the study, and any other information that may be relevant to the UCSF IRB’s continued review.  By typing or signing your name below, you are confirming that all information provided in this form is accurate. If you are submitting this form on behalf of a site PI, you are also confirming the site PI has approved the information in this form and that you are authorized to submit this form on their behalf.   |  |  | | --- | --- | | Click or tap here to enter text. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name | Click or tap here to enter text.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date | | Click or tap here to enter text.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Title |  | | |