

**Human Research**

**Protection Program**

Institutional Review Board (IRB) Quality Improvement Unit (QIU) Gamete, Embryo and Stem Cell Research Committee (GESCR)

490 Illinois Street, Floor 6

San Francisco, CA 94143

tel: 415.476.1814 irb@ucsf.edu

www.ucsf.edu irb.ucsf.edu

[Date]

To whom it may concern:

RE: Annual Reminder for Research Sites Relying on the UCSF IRB

The University of California, San Francisco (UCSF) is the reviewing IRB for the study called [enter study name]. This letter is a friendly annual reminder that the items below need to be reported to your lead study team at UCSF.

At this time, and at any time during the year, there are several institutional requirements you must adhere to while this study is active. **You are required to submit the following to the lead study team when appropriate:**

* [Modification](http://irb.ucsf.edu/modification)s: You must submit a modification request and receive IRB approval prior to implementing any changes to this study. This includes changes to your PI and study contact that might be listed in the consent form or other IRB reviewed study material.
* [Adverse Events](http://irb.ucsf.edu/adverse-event), [Protocol Violations or Incidents](http://irb.ucsf.edu/protocol-violation-or-incident), and other types of Events or Safety Information: See the [Post-Approval Reporting Requirements Summary Sheet](http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/post-approval-reporting-summary-sheet.pdf) to determine if/when you need to report to the IRB.
* [Enrollment Exception Request](http://irb.ucsf.edu/protocol-enrollment-exception-request): To allow enrollment of a single individual who does not meet the entry criteria of your study, you may submit a request for a one-time enrollment. Approval from the IRB is required prior to enrollment of the individual.
* [Study Closeout Report](http://irb.ucsf.edu/study-closeout-report): Once the research has been completed or is permanently inactive, submit a Study Closeout Report.

The lead study team is responsible for providing you with any IRB approved materials that pertain to your site. Please contact your lead study team if you have any questions.

Thank you,

UCSF IRB