

HSCL POLICY UPDATES

Responding to Clarifications Updates:

Due to the large number of studies we receive that require clarifications, initial submissions that have not received a response to clarification requests within 180 days will be administratively closed.

Studies that have already reached the 180 day mark prior to March 15, 2015 will receive an email from the IRB staff explaining that you have 14 days to respond to clarifications from the date you receive the email. If you do not respond to clarifications within this time frame, your study will be administratively closed and you must submit a new application before beginning research.

If your study exceeds the 180 day grace period after March 15, 2015, then you will receive an email from the IRB staff stating that your study has been closed and you will need to submit a new application before beginning research.

Lapsed Study Updates:

Studies will now be administratively closed 90 days after the expiration date (a year from its approval date) if HSCL has not received a continuing review request from the study team. Investigators will continue to receive notifications reminding the investigator to request a continuing review at 90, 60, 30 and 15 days before expiration, as well as a notice once the study has lapsed.

After your study has been closed, you will not be able to submit any modifications or a continuing review and you will need to submit a new application before beginning or conducting research.

****If you plan to conduct human subjects research, you must have approval from HSCL before you begin any human subjects research activities. Continuation of research activities without prior IRB review and approval is a violation of federal regulations.**

Updates for the Student Researcher:

The IRB has recently made a decision to require student researchers to assign their faculty supervisors as the primary contact. All notifications that are sent to the student regarding their study will now also be sent to their faculty supervisor to ensure that faculty supervisors are aware of the study's progression through the review process.

Please note that this does not change any other requirements for adding faculty supervisors as study team members on the study.