**OIA Procedure for Study Terminations**

*With an early study termination, whether due to notice of federal termination of an award or another cause, we need to ensure safe and compliant closure of active study protocols that involve human participants. Closure of human subject protocols should consider the steps below and should prioritize the safety of the participants.*

***Checklists****:*

*For studies relying on UCSD IRB as IRB of record:*

* If appropriate, create a safe discontinuation plan for subjects.
* If appropriate, create a subject notification plan.
* If appropriate, create materials to notify subjects (see letter/message template example).
* Submit via amendment pathway a notification informing the IRB of the termination along with the safe discontinuation plan, notification plan, and any notification materials.

*NOTE: If the study does not involve electronic or in person interaction with subjects, or all interactions have been completed/the subjects are not expecting to hear from you in the future, the above four steps do not apply. Proceed with submission of your Close Request in Kuali IRB as described below.*

* Submit a Close Request in Kuali IRB ([Kuali Knowledge Base Article (KBA) on submission of closures)](https://support.ucsd.edu/research?id=kb_article_view&sysparm_article=KB0034388)
	+ Upload to Attachments section of Closure:
		- Funder Notification
		- Any other relevant documentation

*For studies relying on an external IRB:*

* Follow your IRB of record’s procedures to determine if a safe discontinuation of subjects plan or a subject notification plan is needed.
* If required by your IRB of record, follow their procedures for approval of a safe discontinuation of subjects plan, a notification to subjects plan, and communication templates, if applicable.
* Submit for closure as required by the IRB of record.
* Once closure is acknowledged/accepted by the IRB of record, submit a Close Request to the file in Kuali IRB (see the [Kuali Knowledge Base Article (KBA) on submission of closures](https://support.ucsd.edu/research?id=kb_article_view&sysparm_article=KB0034388) for step-by-step instructions with screenshots):
	+ Upload documentation of approval of safe discontinuation of subjects plans and subject notification plans and communication templates, if applicable.
	+ Upload documentation of acceptance/acknowledgement of study closure.

***Detailed instructions:***

1. Determine which projects (by IRB number) are impacted by the termination. A closure submission will need to be made to each project.
2. Follow your IRB of record’s requirements to determine if a safe discontinuation of subjects plan is needed.

***When UCSD is the IRB of record:*** If the study involves interactions with subjects that have not yet occurred, or if there are interventions/treatments that participants are actively receiving, or if there is a possible risk to participant safety from stopping study procedures early, determine how subjects will be discontinued safely. This should include an accounting of the subjects affected and a written plan for discontinuation procedures.

* 1. Consider any instructions to the discontinuing participants for their safety:
		1. Do they need to return to the study site for safe discontinuation assessments?
		2. Do they need to follow up with a health care professional (e.g., primary care)?
		3. Should provisions for referrals be made?
1. Follow your IRB of record’s requirements to determine if a notification of subjects plan is needed.

***When UCSD is the IRB of record:*** If the study involves interactions for which participants are expecting to hear from you in the future (for example, regarding future visits or providing compensation for activities thus far completed), determine how subjects will be notified of study discontinuation. Document your plan and create a template for written communication, as needed. Letter/message template examples are available. (The template does not have to be used, but provides considerations for the communication.)

* 1. Consider other pertinent information that needs to be provided to discontinuing participants:
		1. What will the study team do with any private, identifiable information of theirs? (e.g., will it be retained and confidentiality measures maintained or will it be destroyed, or will just identifying information be destroyed? Etc.)
		2. Is a compensation close-out plan needed? Do participants need to be provided with owed compensation or notified that compensation can no longer be provided?
		3. What contact information should they be given in case they have any questions?
1. Follow your IRB of record’s procedures for approval of safe discontinuation of subjects plans and notification to subjects plans and communication templates, if applicable.

For external IRBs, this may first require an amendment submission, or they may allow you to submit the plans & notification with the closure submission. ***You should contact your IRB of record to determine their requirements.***

***When UCSD is the IRB of record***: Follow the steps for submitting an Amendment request when there is a safe subject discontinuation plan or notification plan. You will submit your closure once your plans have been approved and executed.

1. Please see the [Kuali Knowledge Base Article (KBA) on submission of amendments](https://support.ucsd.edu/research?id=kb_article_view&sysparm_article=KB0034313) for step-by-step instructions with screenshots.
2. In Section E of the Amendment request application, you can indicate the purpose of this submission, including its relation to an early termination.
3. To upload documents, such as a safe subject termination plan or notification plan and materials, you will unlock the “Supporting Information” section and upload them there.

If you do not need a safe subject discontinuation or notification plan, or yours have been approved and executed, submit a Close Request in Kuali IRB.

* + 1. Please see the [Kuali Knowledge Base Article (KBA) on submission of closures](https://support.ucsd.edu/research?id=kb_article_view&sysparm_article=KB0034388) for step-by-step instructions with screenshots.
		2. In Section A of the Closure Request application, under Indicate Study Progress at UCSD/RCHSD, select “Study was started, but is being closed before completion.” This populates a text field, “Explain.” This is where the reason for the closure can be described.
		3. Step 6 in the KBA discusses submission of documents associated with the closure to the Attachments section of the Closure form. This is where any communications from the funder regarding termination should be uploaded, along with any other relevant documentation.

***Close-out Fees***

OIA does not charge a review fees for closure, but there may be IRB review fees accrued previously that need to be paid.