

Legal, Research Services Frequently asked questions

Overhead

What is subject to overhead? All funded research is subject to overhead, with the exception of Tri-Council funded research and philanthropic funds. To determine the exact percentage that should be paid for overhead, refer to the [University of Calgary Overhead Procedures](#). All items in the budget will be subject to the applicable overhead with the exception of Research Ethics Board fees if payable to the Research Ethics Board directly.

When is overhead taken? The applicable overhead rate will be removed off of every payment that is received by UCalgary.

General

What is the status of my agreement?

CSM legal receives a high volume of emails per day. In order to reduce this number, you can log in to our Contract Management SharePoint system and view the status of the agreement. You will only be able to see the status of the agreement if you are listed as either the Principle Investigator or as the Project Coordinator/Manager.

My agreement is fully executed, but the project number has not been assigned/fully set-up. What happens next?

If the agreement is fully executed, CSM Legal may need the following documentation to pass the file off to Research Accounting:

- Certifications (Such as Biohazard, Animal Care, Ethics)

What documents do I need to attach to my submission?

<u>Agreement Type (Clinical)</u>	<u>Documents Needed</u>
Confidential Disclosure Agreements	Draft agreement (Word document)

Clinical Trial Agreements/Clinical Research Contracts (Industry)	Draft agreement (Word document), protocol, *Ethics approval and *Budget
Clinical Trial Agreements/Clinical Research Contracts (Non-Industry)	Draft agreement (Word document), Protocol, RLS Specify AHS data form, *Ethics approval and *Budget
(OUTGOING) Data Transfer Agreements (Protocol belongs to UofC PI)	Protocol, RLS Specify AHS data form
(OUTGOING) Data Transfer Agreements (Protocol belongs to Counterparty PI)	Draft agreement (Word document), Protocol, RLS Specify AHS data form
Subsite Agreements (UofC coordinating center)	Subsite Budget
Amendments	Draft agreement (not needed if it is an amendment for a subsite) **additional documents may be needed depending on purpose of amendment (i.e. revised budget)

<u>Agreement Type (Non-Clinical)</u>	<u>Documents Needed</u>
Confidential Disclosure Agreements	Draft agreement (Word document – if provided by the counterparty)
Material Transfer Agreements (INCOMING)	Draft agreement (Word document), *Certifications
Material Transfer Agreements /Data Transfer Agreements (OUTGOING)	N/A
Research Grant Agreements	Draft agreement(Word document), Scope of Work, Budget, *Certifications
Non-Clinical Research Contracts	Draft agreement(Word document), Scope of Work, Budget, *Certifications
Data Transfer Agreements (INCOMING)	Draft agreement (Word document), *Certifications
Sub Grant Agreements (OUTGOING)	Prime Agreement, Scope of Work, Budget
Service Agreements (UofC being hired)	Draft agreement(Word document), a description of the work being completed, Budget, *Certifications

Service Agreements (UofC hiring)	Prime Agreement, Scope of Work, Budget
Amendments	Draft agreement(not needed if it is an amendment for a subsite) **additional documents may be needed depending on purpose of amendment (i.e. revised budget)

* Documents are required. However, they can be provided after the submission is made by sending the documents to csmlegal@ucalgary.ca

How do I obtain the RLS Specify AHS data form?

You can find the form by clicking [here](#).

Archiving fees

Do I have to pay archiving fees? Archiving fees must be built into the budget section of all clinical research contracts and agreements. As per university policy, all study data needs to be archived with UCalgary’s high density library for long-term storage once the study has been terminated or completed and absolutely **cannot** be kept onsite. If you have any questions or concerns regarding this policy, contact medrec@ucalgary.ca.

Closures

When do I have to close a project? All clinical research studies need to be closed out when archiving is collected, and before any money can be transferred to the residual project code by the research accounting team. The Cumming School of Medicine’s Legal, Research Services team (CSM Legal) is no longer processing closures. For assistance on completing a project closure, contact finanlgl@ucalgary.ca.

What are the benefits of quickly closing a project? The sooner a clinical research project is closed, the faster the surplus from that account can be transferred to the primary investigator’s residual project code. This allows more flexibility to what that money can be used for.

Residual accounts

What is a residual project? A project code that is used to deposit surplus from research project codes that have been completed and are ready for closure.

What are the benefits of having a residual account? One of the great benefits of having a residual project code is that the money that is transferred into a residual project code can be used for **anything** research related. For assistance creating a residual project code, contact finanlgl@ucalgary.ca.

Other

Who negotiates agreements with the sponsor? CSM Legal negotiates research agreements on behalf of the university to ensure the agreement complies with UCalgary policies and procedures. Other units on campus may be consulted, depending on the nature of the agreement. Once the review is complete, the proposed changes are communicated to the sponsor. When the negotiation is completed, the agreement execution process ensues.

What is the subsite agreements review process (where UCalgary is the coordinating centre for the overall study)? If a UCalgary principal investigator would like to set up subsites at other institutions on a UCalgary investigator-initiated study, and UCalgary will act as the coordinating centre for all subsites, then the following process will apply.

1. UCalgary principal investigator shall set up a UCalgary project code to administer the study. Depending on the source of funding (such as Tri-Council grants), the project code may be set up by the Research Services Office. This project code will act as the “parent project code” to the subsites.
2. The principal investigator will have to submit a new CTA and identify it as an Existing Submission for records purposes for a parent project code through the [CSM Legal Contract Management System](#). Attach the protocol, ethics approval letter, ethics certificate, letter of award or signed agreements, and any other relevant supporting documents for this study and to this parent project code.
3. The principal investigator will contact [CSM Legal](#) to arrange a meeting to discuss the study and subsites.
4. Simultaneously:

- If there are subsites outside of Canada, the principal investigator shall contact UCalgary's Risk Management team to discuss foreign insurance requirements. The principal investigator shall provide CSM Legal with a copy of Risk Management's decision.
 - CSM Legal will work with the principal investigator to finalize a budget template for the subsites.
 - CSM Legal will draft a subsite agreement for the study. The draft will be sent to the principal investigator for review and approval. Once the draft has been finalized, it will be used as a master subsite agreement template for that study.
5. The principal investigator will submit new subsites (one submission per subsite) through the [CSM Legal Contract Management System](#). In the submission please include:
 - Parent project code.
 - Subsite number to be assigned to the site (e.g. #03).
 - Whether or not an activity code is needed under the parent project code for the subsite (five digits activity code such as 00003 to match subsite # 03).
 - Subsite budget.
 - Subsite principal investigator's full name if subsite principal investigator is not the subsite contact for the contract.
 6. CSM Legal will tailor the master subsite agreement for the study with the subsite specific details and then send the draft to the subsite contract for review.
 7. CSM Legal will negotiate and finalize the subsite agreement and arrange for all contract signatures.

What are Master Agreements? There are different types of Master Agreements, but Master Agreements are usually non- principal investigator and non-study specific. Master Agreements contain contract terms that have been agreed between the institution and the sponsor. These are usually terms that appear in all research contracts. Master Agreements are intended to reduce negotiation time between the sponsor and the institution if the sponsor is funding multiple studies at the institution. If a Master Agreement is in place with a certain sponsor, the principal investigator will receive a study-specific contract that references and incorporates the terms of the applicable Master Agreement. Only study-specific terms will require negotiations. If a principal investigator receives a draft Master Agreement from the sponsor, contact [CSM Legal](#).

Where do I find W-8 or W-9 forms? A sponsor may request a W-8 or W-9 form within the contract. W-9 forms are not applicable to UCalgary. The principal investigator shall email [Accounts Receivable](#) and request for a completed W-8 form to be sent to the sponsor.

To whom are cheque payments made payable? Cheque payments shall be made payable to “The Governors of the University of Calgary” with reference to the corresponding project code.

Where do I obtain UCalgary’s banking information to receive wire payment? Request for UCalgary’s banking information for wire payments shall be sent to [Accounts Receivable](#) by the principal investigator. Accounts Receivable will send the banking information directly to the sponsor contact provided by the principal investigator. Ensure request to have the corresponding project code referenced for each payment and to be notified by the sponsor when payments are made.