

Directions for Submitting a Corporate Contract for Parallel Review/Negotiation

Introduction:

The Corporate Contracts group in the Office of Research Services strongly encourages the submission of contracts for all corporate-sponsored research, including clinical trials, as soon as a researcher is reasonably certain that he or she wishes to pursue a specific project with a company and the company is ready to discuss a contract. Contracts with for-profit companies typically require negotiation. Accordingly, submission to corporate contracts at the earliest possible opportunity helps increase the likelihood that negotiations will not interfere with initiating the research.

While the Penn ERA approval process needs to be completed before a contract may be signed, it does not need to be completed in order for a contract negotiation to be started. Also, it is not necessary for a budget to be negotiated or for any IRB submission to have been completed to submit a contract for parallel negotiation. Contracts are generally assigned and managed on a first-in, first negotiated basis. It is expected that requests for parallel review will be made by the individual designated by his or her department to make submissions in Penn ERA for corporate-sponsored research, typically the Business Administrator.

Step-by-Step Directions:

Create a New Proposal by Completing the New Proposal Questionnaire in Penn ERA.

Complete the Setup Questions; Please be sure to note in “Other funding information, guidelines, or restrictions” any other outside funding that will be used for the project.

Open the eForm for Parallel Review of Corporate Contracts in Internal Documents and follow the directions on the form (copy provided below for reference).

Parallel Review of Corporate Contracts

Supporting Documents

Upload Word version of agreement provided by sponsor.
If sponsor has agreed to start with a Penn template for the agreement, upload a copy of the communication in which the sponsor so agreed or, if there is no documentation, create a file memo that documents the discussion in which the sponsor so agreed and upload the memo.

Research Plan

For clinical trials, please upload the informed consent document or the protocol; for other sponsored research, please upload the research plan (in Word format). Drafts are acceptable.

Internal Documents

Please complete Proposal Transmittal eForm, including Sponsoring Agency/Granting Organization Information; please wait to make the certification until the budget is finalized and the submission is complete.

Please answer the questions below:

Please identify any other source of funding to be used to support this project (as other funding sources may significantly impact agreement terms) if you have not previously provided information on other funding sources in response to the Set-up Questions:

Please indicate who developed the protocol/research plan:

If the research involves a device in a clinical trial, is CMS approval for billing necessary? ☐ Yes ☐ No
If the device is being purchased, has UPHS Purchasing been advised? ☐ Yes ☐ No
Please explain as appropriate.

Please advise of any special considerations relating to any deadlines identified in the proposal, including sponsor requirements to conclude agreement by the end of a fiscal period, closing window of opportunity to enroll in a clinical trial with competitive enrollment and the like. Please provide specific, factual information affecting timing.

Send an email to ORSCORP@exchange.upenn.edu

advising that you are requesting parallel review and providing the PennERA Institution Number.
Please note that if Corporate Contracts does not receive a notice from you that the necessary information has been uploaded into PennERA, we will not know that you are requesting parallel review.

Please keep in mind:

Conflict of Interest Disclosure requirements: If any individual responsible for the design, conduct or reporting of this research has a financial interest related to this research, s/he may be required to submit a financial disclosure in connection with this protocol/research plan. For guidance as to when disclosure is required and the disclosure process, please visit the Office of the Vice Provost for Research website at <http://www.upenn.edu/research/> . For human subject research, you are strongly encouraged to make a determination no later than the time of IRB submission as to whether disclosure is required so that any necessary review and management may occur simultaneously with the negotiation of the agreement and IRB review. Failure to timely disclose a financial interest may result in a delay of finalizing an agreement.

The PennERA proposal will need to be fully completed and approved before the related agreement may be signed. You are strongly encouraged to route the record for approval as soon as the budget is finalized so that lack of internal approvals does not delay the signing of a fully negotiated agreement.

Questions? Please call 215 573 6709. Thank you for taking the time to make a parallel review submission.