Weill Cornell Medicine | NewYork-Presbyterian

JCTO Contracts

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jcto.weill.cornell.edu

Updates First!

CTA Submissions through CSEC Part A application

- All CTAs should be submitted through REDCap via the CSEC Part A application as of March 22nd!

- The Clinical Trial Synopsis Form is no longer required.

- Part A will allow you to upload the CTA document, so when you submit your Part A application, an email will automatically be submitted to JCTO Contracts.

Updates continued

Enhanced Investigator Report

- First issued on March 4th.
- Features streamlined, user-friendly format for greater readability.
- Investigators can review the report easily on their mobile device, and can contact the appropriate JCTO or OSRA contract specialist directly from the report.
- Please let us know if you want to be added to your investigator's report.

Email **investigatorreports@med.cornell.edu**

Sample Enhanced Investigator Report

Principal Investigator	Doe, Jane
Team	JCTO

Sponsor	Study Title	Contract Type
Pharma Co LLC	Clinical trial	Contract (CTA)

Contract Status	Date	Action/Comments
Complete	2/25/2016	Pending final budget: agreement terms are final.

Specialist Contact Name	Specialist Contact Email
John Smith	example@med.cornell.edu

JCTO Contracts Overview

- Negotiate clinical trial agreements and related clinical research contracts
- Advise research teams on matters of contract compliance
- Produce weekly investigator reports
- Review informed consent forms to ensure consistency with contractual subject injury protections
- Release completed contracts to the IRB

Types of contracts managed by the JCTO

- Industry-sponsored clinical trial agreements
- Investigator-initiated clinical trial agreements
- Confidentiality agreements
- Contract amendments
- Data use agreements
- Registry agreements
- Clinical material transfer agreements
- Clinical services agreements
- Master clinical trial agreements

What is a Confidentiality Agreement?

- Confidential Disclosure Agreement (CDA) or Non-Disclosure Agreement (NDA) obligates one or both parties to maintain the confidential information of the other.
- Often required by sponsors before they disclose their protocol to our investigator.
- JCTO Contracts needs to know whether your investigator is disclosing information, or only receiving.
- All CDAs must be submitted to JCTO Contracts.
- If your investigator is sharing an investigator-initiated protocol with another site or a sponsor, it is strongly recommended that a CDA be put in place.

What is a Clinical Trial Agreement?

- A clinical trial agreement (“CTA”) is a legally binding document that establishes and defines the relationship between WCM-NYPH and the sponsor or WCM-NYPH and the sub-site, with respect to conducting a clinical trial.
- The sponsor typically provides study drug or device, financial support, and/or proprietary information.
- WCM-NYPH provides data, publications, intellectual property, and/or medical expertise.
- If WCM-NYPH is the prime site, we may provide funding, drug, or proprietary information.

What is a CTA Amendment?

- Simply put, an amendment is a document that changes the terms of an existing contract.
- In the context of clinical trials, CTA amendments are used to account for changing circumstances during a trial.
- Most often CTA amendments are issued by the sponsor, and they involve alterations to the budget.
- JCTO Contracts should review each amendment because amendments, like CTAs, require all parties to agree.

How does the contract impact how I operate my clinical trial?

- Data Collection/case report forms
- Invoicing/Payments
- Subject enrollment
- Adverse Event Reporting
- Record retention
- Legal Ramifications
- Publication timelines
- Subject injury compensation

What can I do while the contract is under negotiation?

- Complete CSEC and IRB review processes.
- Negotiate budget and payment terms and submit to JCTO Finance.
- Review weekly investigator reports for updates in the contract negotiation process.
- Answer questions from JCTO Contracts during the course of negotiation.
- Send the final draft informed consent form to JCTO Contracts to review injury language.

Key Contract Provisions: Publication

- We must protect WCM-NYPH's academic freedom to publish scientific data.
- Sponsors will want the right to review manuscripts.
- Sponsors will want us to remove confidential information.
- We may need to wait to publish until a multi-center publication is released.

Key Contract Provisions: Indemnification

- Indemnification is the process by which one party promises to provide compensation for another party's loss.
- In sponsored clinical trials, the sponsor agrees to take on substantial risk because it is manufacturing the drug/device and initiating the trial: they should "indemnify" WCM-NYPH for any loss experienced during the trial.
- WCM-NYPH should also receive some limited indemnity for investigator-initiated trials.
- WCM-NYPH does NOT indemnify!

Key Contract Provisions: Intellectual Property

- When an “invention” is made during a sponsored trial by using the sponsor’s product, the sponsor will want to own it.
- An invention in the context of a clinical trial may be a new use or indication of the study drug.
- Even if the sponsor insists on owning new inventions related to their drug/device, WCM-NYPH should retain a non-exclusive license to use the invention for academic non-commercial purposes.
- For investigator-initiated trials WCM-NYPH should seek ownership of inventions made using our investigator-initiated protocol.

Key Contract Provisions: Subject Injury

- For sponsored trials, the sponsor should reimburse WCM-NYPH and/or the study subject for injuries that result from participation in the trial.
- This is distinguishable from indemnity because here the company is directly paying for medical care, versus indemnity where the sponsor is representing WCM-NYPH in court.
- This is considered an ethical obligation of the sponsor to take responsibility for adverse events that result from the proper use of their drug/device.
- It is common to not receive subject injury protection in investigator-initiated trials because the company did not design the protocol.
- The informed consent form must correctly advise the subject whether or not the sponsor is providing subject injury coverage.

Key Contract Provisions: Data

- Sponsors will want to review study data.
- The contract will indicate that the collection, transmission, and inspection of data will be in accordance with the informed consent form.
- For sponsored trials, the sponsor will seek to own the data, and WCM-NYPH will retain the right to publish and use the data for non-commercial research.
- For investigator-initiated trials, WCM-NYPH should own all data.
- WCM-NYPH always owns medical records.

Contact us!

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