



Weill Cornell Medicine



New York-Presbyterian

T.W.I.S.T.

Your Budgets, Your Contracts: The Essentials

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Weill Cornell Medicine

New York-Presbyterian

Joint Clinical Trials Office Finance

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March 22nd, 2016
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JCTO Finance Overview

Pre Clinical Research Contract Execution

- Budget and payment terms review and recommendations
- Assist with budget development and negotiations on an as needed basis

Post Clinical Research Contract Execution

- Process study fund set-up
- Request plan codes for studies with hospital procedures
- Invoice for initial administrative fees per contract terms
- Invoice sponsors for IRB continuing reviews and amendments
- Process invoices and payments for research billables including Investigational Pharmacy, NYP, PO, and ClinCard
- Follow up with sponsors on status of study payments
- Receive, process and deposit all study payments
- Conduct financial reconciliation and study close-outs

What is the Purpose of the Budget and Payment Terms Central Review?

- As of July 1, 2015, JCTO Finance began conducting a central review of all clinical research budgets and payment terms
- Purpose:
 - Ensure correct and consistent inclusion of fees, indirect cost rates, payment terms and contact information
- Budget and payment terms review and approval process must be completed prior to research contract execution
- Submit documents to JCTO Finance prior to finalizing negotiations

Study team emails jctofinance@med.cornell.edu the budget and payment terms for review.



JCTO Finance reviews the budget and payment terms. Questions and recommendations are communicated to the study team.



JCTO Finance sends JCTO Contracts the final budget and payment terms copying the study team.

What types of recommendations have been made as part of the budget and payment terms review?

- Central fee (IRB, CSEC, JCTO, Pharmacy) corrections
- Indirect cost rate corrections
- Calculation corrections
- Matching payments terms to budget
- Matching invoiceable fees to budget grid
- Adding indirect cost to invoiceable fees (not applicable to pass-through fees)
- Reducing payment terms to maximum 45 days (ideal 30 days)
- Removing start up payment qualifiers
- Removing time to invoice restrictions
- Removing quantity caps from invoiceable items
- Removing screen failure ratio caps
- Reducing withholding amount to a maximum of 10%

What types of recommendations have been made as part of the budget and payment terms review?

- Ensure our correct payment address is used: Weill Medical College of Cornell University Attn: Joint Clinical Trials Office 1300 York Avenue, Box 305 New York, NY 10065
- Ensure payments are made by paper check instead of wire unless wire transfer fee funding is provided by sponsor
- Ensure all payments include detailed breakdown / description
- Ensure financial reconciliation agreed to by both parties prior to final payment or allow for final payment amount dispute after final payment received
- Ensure the sponsors invoice email address is included in the payment terms
- Ensure there is sufficient coverage if ClinCard is used for subject stipend or reimbursement
- Ensure payment mechanism is clearly described

Recommended Budget and Payment Terms Submission Email Template: Funded Clinical Research

Subject Line: Budget and Payment Terms Submission: IRB#, PI Name, Sponsor Name

Body of Email:

Attached for your review are the budget and payment terms for the following study:

IRB# :

PI Name :

Sponsor Name :

Sponsor Protocol # :

The indirect cost, verification of Hospital and Investigational Pharmacy services billable to the study are specified below.

Indirect Cost Rate:

Verification of Research Hospital Services Billable to the Study: Yes or No (Select One)

Verification of Investigational Pharmacy Services Billable to the Study: Yes or No (Select One)

Other Items:

Recommended Budget and Payment Terms Submission Email Template: Non-Funded Clinical Research

Subject Line: JCTO Finance Review for Study Without Funding: IRB#, PI Name

Body of Email:

We will not receive funding for the below mentioned trial. This email serves as verification for research related Investigational Pharmacy, PO and / or hospital services.

IRB# :

PI Name :

Verification of Research PO Services Billable to the Study : Yes or No (Select One)

Verification of Research Hospital Services Billable to the Study : Yes or No (Select One)

Verification of Investigational Pharmacy Services Billable to the Study: Yes or No (Select One)

If Yes is answered to any of the above, please respond to the following:

We agree to pay for any changes incurred for this study from the PO, NYP or pharmacy. These expenses can be charged to SAP account: _____

Frequently Asked Questions

Where are the charge masters located?

Preparation

It is important to take the time to identify costs before reviewing the sponsor's proposed budget so that the numbers presented do not influence the initial cost assessment. During this process, the JCTO or study team will also evaluate each study procedure to identify those that are standard of care and those being performed for research purposes only.

What resources do I need to develop a budget?	Where do I get them?
Schedule of Assessments	Included in the Protocol
Standard Institutional Fees	See Standard Fees Below
Evaluation and Procedure Charges, including CPT codes	<ul style="list-style-type: none">• Clinical Diagnostic Laboratory Fee Schedule 2016• Drug Vaccine Charge Master 2016• Medicare Research Rates 2015• NYP Charge Master 2016• NYP Inpatient Rate 2016• WCM POBO Charge Master 2016
Staff Allocation and Hourly Rates	PI and Study Team

- The charge masters are located in the Budget Development and Cost section of the JCTO website
<http://jcto.weill.cornell.edu/investigators/finance/budget-development>
- The charge masters are updated on a yearly basis
- Recommendation: For each budget development, visit the JCTO website and use the fees from the charge masters
- Recommendation: Consider a 5% inflation rate per study year
- If there is a fee missing from any of the charge masters email jctofinance@med.cornell.edu provide the cpt code and procedure name

Frequently Asked Questions

Which charge master should I use when developing a budget?

Charge master use is dependent on funding source, study initiator, and location of where procedure will occur

Professional Component of Procedure Fee

- Federally Funded Study: Use the Medicare fee schedule. Refer to the Par Amount Column
- Non-Federally Funded Study: Use the PO fee schedule. The PO fee schedule is broken up into 4 categories. Fee dependent on study initiator (Investigator or Sponsor) and location of where the procedure will occur (Office or Facility)

2016 POBO research rates effective January 1st, 2016. For any inquiries, please contact the Joint Clinical Trials Office at JCTOFinance@med.cornell.edu					
CPT	Description	Investigator Initiated/ Non-Federally Sponsored Office	Investigator Initiated/ Non-Federally Sponsored Facility	Sponsor Initiated/ Non-Federally Sponsored Office	Sponsor Initiated/ Non-Federally Sponsored Facility
	Per unit anesthesia	\$88.58	\$88.58	\$99.65	\$99.65
0073T	Delivery comp imrt	\$736.72	\$736.72	\$828.81	\$828.81
10021	Fna w/o image	\$276.83	\$131.94	\$311.44	\$148.43

Frequently Asked Questions

Which charge master should I use when developing a budget?

Charge master use is dependent on funding source, study initiator, and location of where procedure will occur

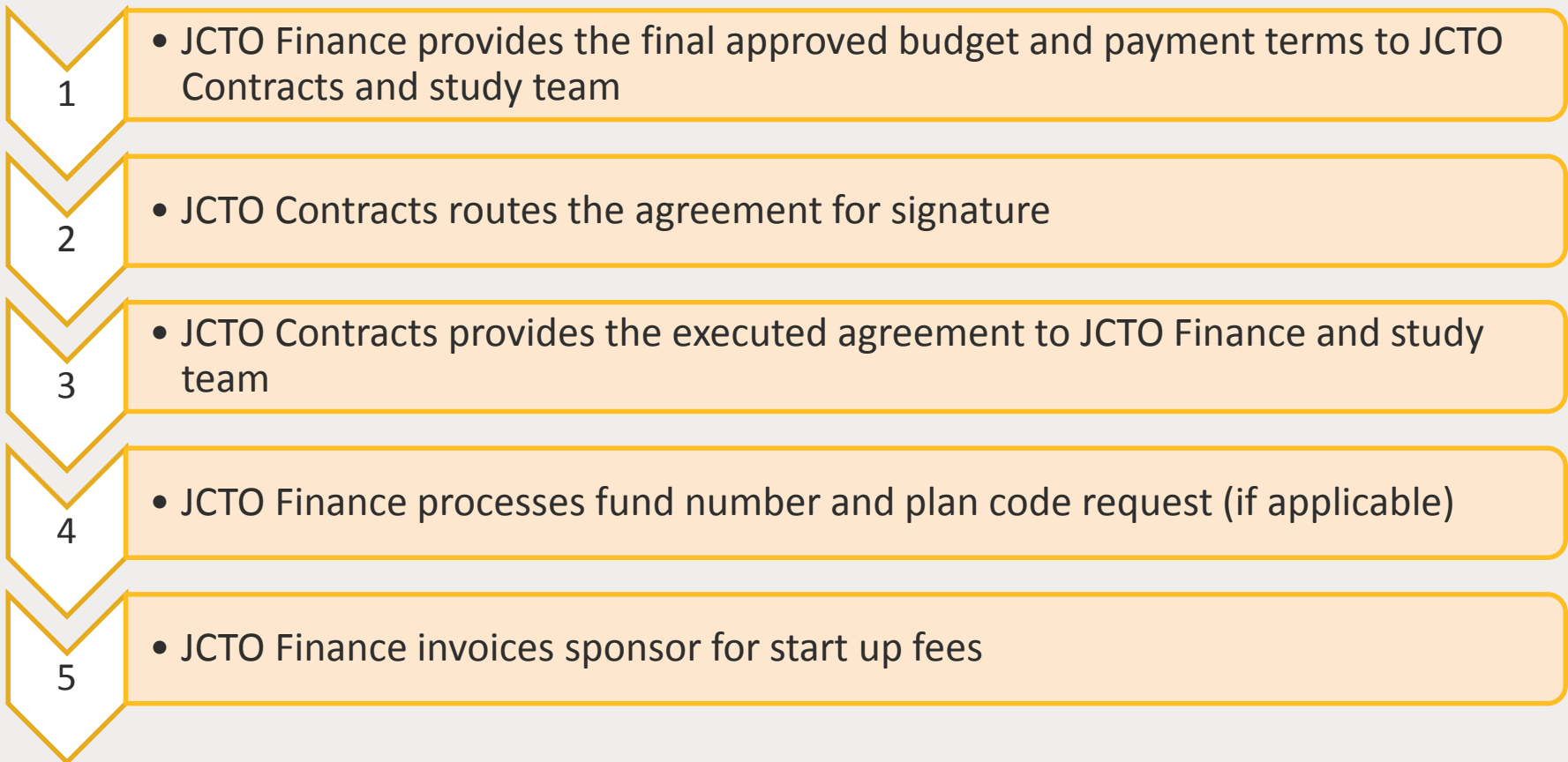
Technical Component of Procedure Fee

- Federally Funded Study: Use the Medicare fee schedule. Refer to the Par Amount Column
- Non-Federally funded study and procedure will occur at WCM: Use the PO fee schedule. The PO fee schedule is broken up into 4 categories. Fee dependent on study initiator (Investigator or Sponsor) and location of where the procedure will occur (Office or Facility)
- Federally and Non-Federally funded study and procedure will occur at NYP: Use the NYP charge master. Refer to the Net Price column

2016 NYP charge master effective January 1st, 2016. For any inquiries, please contact the Joint Clinical Trials Office at JCTOfinance@med.cornell.edu										
SI	DEPARTMENT	Department Name	CHARGE CODE	Commercial CPT	Medicare	Medicaid	DESCRIPTION	PRICE	RCC	Net Price
A	1202	CLINIC VISIT	22910000	36415	36415	36415	VENIPUNCT/PHLEBTOMY	19.35	91%	17.60
A	1202	CLINIC VISIT	22920000	90471	G0008	G0008	VACCINE ADMINISTRATION	31.61	91%	28.75
A	1202	CLINIC VISIT	CIMA0004	36415	36415	36415	VENIPUNCT/PHLEBTOMY	19.35	91%	17.60

Frequently Asked Questions

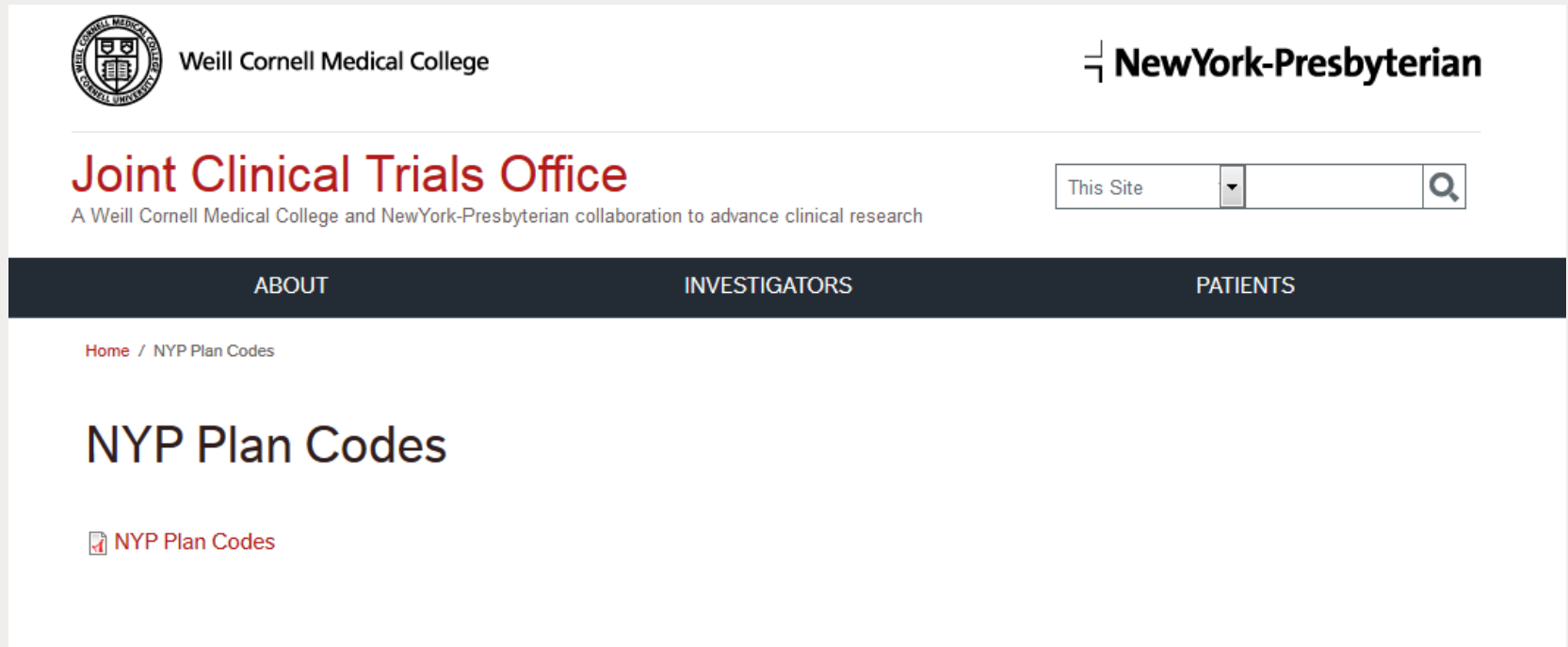
What happens after JCTO Finance approves the budget and payment terms?



Frequently Asked Questions

Where can I find plan codes and fund numbers for the clinical trials I'm coordinating?

- The plan codes and fund numbers are available on the JCTO website located here: <http://jcto.weill.cornell.edu/downloads/nyp-plan-codes>



The screenshot displays the JCTO website header and navigation. The header includes the Weill Cornell Medical College logo and the NewYork-Presbyterian logo. The main title is "Joint Clinical Trials Office" with the subtitle "A Weill Cornell Medical College and NewYork-Presbyterian collaboration to advance clinical research". A search bar is visible with the text "This Site" and a search icon. The navigation menu includes "ABOUT", "INVESTIGATORS", and "PATIENTS". The main content area shows the breadcrumb "Home / NYP Plan Codes" and the title "NYP Plan Codes". A link icon for "NYP Plan Codes" is also present.

What invoices does JCTO Finance send to sponsors?

- JCTO Finance invoices sponsors for:
 - » Start up fees (JCTO, CSEC, Initial IRB, Departmental Start up, Initial Pharmacy)
 - » IRB Continuing Reviews and Amendments
- Departments are responsible for invoicing all other fees per budget and payments terms
 - » JCTO Finance provides assistance with invoice tracking, close-outs and financial reconciliations by request
 - Email jctofinance@med.cornell.edu



Frequently Asked Questions

Will JCTO Finance follow up with sponsors on payment status?

▼ Contract and Budget Tools and Templates

-  ClinCard Request Form➔
-  Clinical Laboratory Fee Schedule 2016➔
-  Clinical Trial Budget and Payment Terms Review Guide➔
-  Clinical Trial Budget Template.xls➔
-  Clinical Trials Synopsis Form.pdf➔
-  Data Use Agreement Routing Form.pdf➔
-  Drug Vaccine Charge Master 2016➔
-  Fund Center Form➔
-  Human Research Billing Analysis Form Template.xls➔
-  Instructions for Human Research Billing Analysis Form➔
-  Invoice Template➔

- JCTO Finance tracks all invoices sent by JCTO Finance and all invoices sent by study teams when JCTO Finance is copied on the invoice email
- Copy JCTO Finance jctofinance@med.cornell.edu when invoicing sponsors and JCTO Finance will follow up with sponsors on payment status
- Use the invoice template located on the JCTO website when invoicing sponsors
<http://jcto.weill.cornell.edu/investigators/study-activation-and-conduct/researchers-toolbox>

Frequently Asked Questions

How can we track payments that have been received?

- JCTO Finance emails study teams when payments have been received. Copies of checks and transaction notifications are provided to study teams
- If you are not receiving transaction notification emails, email jctofinance@med.cornell.edu and provide us with a list of studies you are coordinating and we will add you to the transaction notification email list



Which bills will we receive from JCTO Finance?

JCTO Finance has centralized the billing process for NYP research procedures, PO research procedures, Investigational Pharmacy, and ClinCard services

- NYP Research Bills are sent to study teams on a monthly basis
- ClinCard bills are sent to study teams on a bi-monthly basis
- Investigational Pharmacy: Batch bill to recurring bill
 - » 01/01/2014 – 04/30/2015 processed
 - » 05/01/2015 – 02/29/2016 bill forthcoming
- PO Research Procedures: Batch Bill 01/01/2013 – 12/31/2015
 - » Process to be updated late spring or summer 2016; PO bill processing will occur entirely in EPIC



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Questions?

JCTO Finance

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JCTO Contracts

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March 2016
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Updates First!

CTA Submissions through CSEC Part A application

- All CTAs will be submitted through REDCap via the CSEC Part A application starting TODAY!
- 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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