



Weill Cornell Medicine

New York-Presbyterian

TWIST Winter Holiday Roundtable

[JCTO.WEILL.CORNELL.EDU](https://jcto.weill.cornell.edu)



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Immediate Reporting Policy

TWIST's Winter Holiday Roundtable Immediate Reporting Policy

**Rosemary Kraemer, Ph.D., C.I.P.
Director, Human Research Protections Program
December 16, 2015**

Immediate Reporting Policy

- **Adverse event reporting**
- **Other Risk Reporting**
 - **Interim Analysis, change in FDA labeling, enrollment hold, subject complaint that indicated increased risk to subjects**
- **Protocol deviation**
- **Other Compliance Reporting**
 - **Finding of noncompliance, complaint of subject that cannot be resolved, prisoner incarceration**

Adverse Event Reporting

- The harm is “unexpected” when its specificity and severity are not accurately reflected in the WCMC consent document, Investigator’s Brochure (if applicable), or package insert (if applicable); AND
- The harm is “related or possibly related”, where there is a reasonable possibility that the harm may have been caused by the research procedure(s), or intervention(s) AND
- The harm suggests that the research places WCMC subjects at greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized

Protocol Deviations

- **Protocol deviation that harmed participants or others, or that indicates participants or others might be at increased risk of harm.**
- **Protocol deviation that represents a failure to follow the protocol or IRB policies and determinations due to the action or inaction of the investigator or research staff. (Exception: Rescheduling of research appointments due to holidays, vacations, accommodation of research subject, etc.)**
- **Protocol deviation that was made in order to eliminate an apparent immediate hazard to participants.**
- **Breach of confidentiality**

Protocol Deviations (continued)

- **Root Cause** – The underlying cause of a protocol deviation.
- **Corrective Action Plan** – A plan of action that is executed in order to manage the immediate cause of a research problem.
- **Preventative Action Plan** – Any actions taken to address the root cause of a research problem such that recurrence of the problem is prevented.

Protocol Deviations (continued)

- **Standard operating procedures; frequent meetings to discuss operations and deviation management**
- **If a deviation does occur, find out the information and provide as much detail as possible in the report**
- **Indicate what should have been done according to the protocol and/or IRB policies, and then indicate what was done instead and by whom, such that the interactions between the research team members and any affected parties are clear**
- **Make sure the preventive actions stipulated in your immediate report addresses the root cause**

Common Deviations

- **Over-enrollment**
 - No protocol in place to track enrollment
 - Research team not aware that once subject signs a consent, they are considered enrolled in the study.
- **Subject doesn't meet inclusion criteria**
 - Based on lab values obtained prior to screening rather than during screening
 - Subject was enrolled because investigator thought it would be beneficial to the patient

Common Deviations (continued)

- **Incorrect Informed consent used**
 - Wrong version on file
 - Research team not aware the ICF has been updated
- **Dosing error**
 - Research team did not understand dosing instructions provided in the protocol
 - Labs were not reviewed that would have indicated subject should not have received the study drug

Common Deviations (continued)

- **Member of the research team emailed PHI to an outside entity which was not listed in the HIPAA authorization**
 - **Lack of familiarity with redaction procedure or WCMC policy regarding sending PHI via email**
 - **Corrective action plan**
 - **Notify the Privacy Office**
 - **Contact the entity and confirm that the information has been destroyed and the emails have been deleted**
 - **Notify the affected subjects of the breach (in consultation with the Privacy Office)**

Common Reasons Protocol Deviation Reports Are Sent Back for Additional Information

Dosing Error: need to provide a thorough clinical assessment concerning whether risk posed to the subject was raised as a result of the dosing error-even if no harm ultimately occurred to the subject. This should be done taking into consideration of the subject's state of health at the time of the error and the known risk profile of the drugs. Information on how this assessment was made should also be included.

Common Reasons Protocol Deviation Reports Are Sent Back for Additional Information (Continued)

- **Subject enrolled that didn't fit inclusion criteria or fit exclusion criteria**
 - **Did the subject experience any adverse events as a result of being enrolled**
 - **Is subject still on the protocol**

- A new guidance document on submission of protocol deviations, as well as the immediate reporting policy and the immediate report form is available on our website at

http://researchintegrity.weill.cornell.edu/institutional_review_board/irb_adv.html

All immediate report forms should be send to
irb@med.cornell.edu

Rosemary Kraemer
rtkraeme@med.cornell.edu
646-962-4061



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Subject Recruitment & Communications

ClinCard – Subject Compensation

- First study November 2014
- Almost 900 cards in use across 47 studies & 12 disease areas
- Volunteer compensation time reduced from upwards of six weeks to within two business days of study visit
- Easy to use web-based system
 - Update-to-date history on all entries
 - Reports available upon request
- SOP & user guides on JCTO website > Researcher's Toolbox
- One-on-one tutorials available



Website 2.0

Significant update focusing on end user experience

- Reduced size of carousel
- Prominently feature / promote clinical trials for general public & physician referrals
 - Newly created database
 - Support enrollment for interventional & observational studies
 - Free text field for key word searches & drop down menus by disease & disorder
 - Updated clinical trial summary template – Researcher's Toolbox
http://jcto.weill.cornell.edu/sites/default/files/downloads/clinical_trials_summary_template.docx
 - Featured trials
- Getting Started in Research for the WCM Research Community
 - Guidance & templates covering all aspects of study activation & conduct
- Optimized for mobile use
- More to come in 2016!



Search Clinical Trial Description

or Apply Filter(s)

Select Disease

- None -

[Use Advanced Search](#)

[Or View All Trials](#)

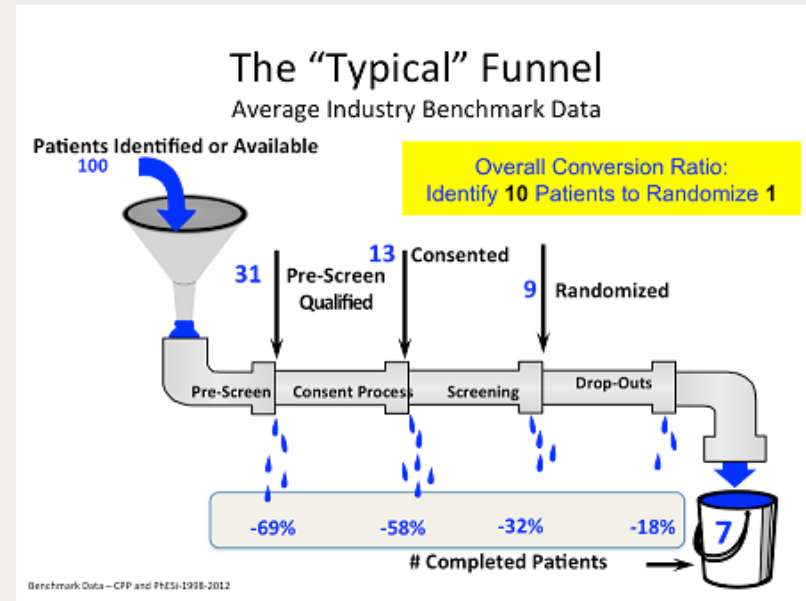
A screenshot of a search interface for clinical trials. It includes a search bar, a filter dropdown menu, a link to advanced search, and submit/reset buttons.

We need your studies!

Subject Recruitment

Helping volunteers find their way to research studies

- Feasibility
 - Do you have the patient population in your clinic?
 - External outreach?
 - Prior like studies?
 - Engaging previous volunteers?
- Budget
 - Include upfront for material development & tactical implementation
 - Dedicated employee time
- Outreach efforts (internal & external)
 - Materials
 - Print / online outlets
 - Electronic records
 - Third-party recruitment companies
 - Events
- Tracking success
 - How did they hear about the study?
 - What works / doesn't?



JCTO can help!

Questions?

Erica Bersin

Manager, Subject Recruitment &
Communications

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Follow the JCTO on Twitter
[@WCMNYPJCTO!](https://twitter.com/WCMNYPJCTO)



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JCTO Finance Reminders

JCTO Finance

Friendly Reminders:

- Please copy JCTO Finance on all clinical trial invoices to sponsors
- If you receive any clinical trial payments contact us at 646-962-8215 and we will send a messenger droid
- No need for interoffice mail



JCTO Finance

Payment Information

- When filling out sponsor payment forms make sure the correct contact information and address are used
- Our preferred method of payment is by paper check
 - If possible try to avoid wire payments unless the sponsor is willing to pay transfer fees



General Correspondence/ Payment Remittance:

Weill Medical College of Cornell University

Attention: Joint Clinical Trials Office

1300 York Avenue, Box 305

New York, NY 10065

Email: JCTOFinance@med.cornell.edu

Website: <http://jcto.weill.cornell.edu>

Phone Number: 646-962-8215



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JCTO Contract Intake Enhancements

Contract Intake Enhancements

JCTO Contracts

Lee Stetson, Assistant Director of Contracts and Compliance

December 16, 2016

Enhancements to the contract intake process

Minimize investigator frustrations with:

- **Multiple listservs**
- **Multiple forms**
- **Unclear documentation requirements**
- **Unclear ownership**

AND

Minimize central frustrations with:

- **Not receiving the appropriate documentation required**
- **Receiving agreements that should be managed by another team**
- **Unclear agreement types**
- **Unclear ownership**

Current Contract Intake Process in the JCTO

- Submit contract document to JCTO Contacts.
- Complete and submit Clinical Trial Synopsis Form to JCTO Contracts.
- Simultaneously complete the CSEC application.

Enhanced Contract Intake Process

- Utilize the new contract intake tool.
- For CTAs, you will be linked directly to RedCap CSEC Application Part A through the intake tool.
- The CSEC Part A form will replace the Synopsis Form.
- For other agreement types, the intake tool will help you determine what office handles the agreement and what information the JCTO needs to process.
- For agreements that are handled by the JCTO other than CTAs (i.e. DUAs), the intake tool will ask you important questions up front to expedite the process.

Using the CSEC Application for CTA Submission

- Upon implementation of the intake tool, the Clinical Trial Synopsis Form will be de-commissioned (estimated February 2016).
- The Part A application already asks you everything we need to know to start the contracting process—this removes duplicative work on your end!
- Part A also allows you to upload the CTA document.
- After completion of Part A, RedCap will automatically generate an email containing all the Part A information as well as a link to the uploaded CTA. This will be JCTO Contract's trigger to start the contracting process.



Questions?

JCTO Contracts

JCTOContracts@med.cornell
.edu

646-962-8215



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Clinical Study Evaluation Committee (CSEC) Score Sheets

The Easy Part



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JOINT CLINICAL TRIALS OFFICE (JCTO)

Clinical Study Evaluation Committee (CSEC)
Principal Investigator Score and Signature Sheet

PI Name:

Title:

IRB Protocol Number:

Scientific Merit

How will this impact the

1. High importance, with correlative/translational analysis
2. Intermediate importance with correlative/translational analysis
3. Intermediate importance without correlative/translational analysis
4. Low priority, including Phase IV

Scientific Community

Statistical Considerations

1. Endpoints are well defined, overall strategy, methodology, and analyses are well-reasoned and appropriate to accomplish the objectives of the study; if applicable, an accurate sample size justification and statistical analysis plan are provided.
2. Endpoints are well defined, but the overall strategy, methodology and analyses are problematic and do not adequately accomplish the objectives of the study; if applicable, an accurate sample size justification is provided but the statistical analysis plan is weak.
3. Endpoints are not well defined and require reconsideration, and the overall strategy, methodology and analyses are insufficient to accomplish the objectives as proposed. If applicable, no sample size justification/statistical analysis plan are provided.
4. Endpoints are not defined and there is lack of strategy, methodology and, if applicable, no sample size justification/statistical analysis plan are provided.

INVESTIGATOR ROLE IN STUDY DESIGN:

1. Cornell Investigator-initiated design; correlative studies; NIH/Grant funded
2. Cornell Investigator-initiated design; pharmaceutical or non-sponsored
3. Cornell Investigator involved in design
4. Cornell Investigator minor or no role in design

EXPECTED CORNELL ACCRUAL

1. Extensive track record in similar populations
2. Moderate track record in similar populations
3. No prior attempts of accrual in similar populations
4. Poor track record in similar populations

FINANCIAL/BUDGET

1. Favorable (Start Up of \$10,000 or more and \$10,000 - \$15,000 estimated per subject reimbursement)
2. Reasonable (Startup of \$7,500 or more and at least \$5,000 - \$10,000 estimated per subject reimbursement)
3. Marginally acceptable (Startup of \$5,000 or more and less than \$5,000 estimated per subject reimbursement)
4. Unfavorable (Unfunded, or startup of less than \$5,000 and less than \$1,000 estimated per subject reimbursement)

PROGRAMMATIC CONSIDERATIONS

How does this help

1. Addresses compelling programmatic needs
2. Addresses substantive programmatic needs
3. Addresses minimal programmatic needs
4. Programmatic needs argue against trial initiation as proposed

your department/Cornell

PLEASE DON'T!


Mark 1 for everything!

Forget to attach!

Attach but forget to save it with all the boxes filled in.

PLEASE DON'T!

Any Questions?

- For further information or questions you can reach me at:
- Hotline  : 646-962-9389
- Email: generalcsec@med.cornell.edu