# TWIST: Summer Roundtable

## Monday, June 20th 2016

with presentations by

Taylor Mazac, MPH

Lori Band

Nicolette Andolfo, Pharm D

Rachel Aletti, Pharm D

Rosemary Kraemer, PhD, CIP

Weill Cornell Medicine  NewYork-Presbyterian

# Weill Cornell Medicine DSMB

## Submitting a Periodic Report

Taylor Thomas Mazac, MPH
DSMB Administrator

Lauren Odynocki
QAU & DSMB Operations Coordinator

6.20.16
http://researchintegrity.weill.cornell.edu/dsmb/index.html

# Submitting A Periodic Report

- At the time of Periodic Review, as prescribed by the protocol (e.g., semiannually; quarterly), the research team submits a Periodic Report to the WCM DSMB according to the meeting dates and deadlines on the DSMB site (http://researchintegrity.weill.cornell.edu/dsmb/DSMB_dates.html)
    - While courtesy submission reminders are sent to the research team, it is the research team's responsibility to track when submission is required.
- Periodic Reports are submitted electronically via RedCAP's ePRF (electronic Periodic Report Form)

# Let’s Walk Through the ePRF

- https://redcap.ctsc.med.cornell.edu/redcap_protocols/surveys/?s=K38L4ARET7
- Return Code: Once you select “Save & Return Later,” the survey will provide you with a code. Write down, copy, or email the return code to continue where you left off.
- Upon submission, you will be prompted to provide an email address for the confirmation email.
- Once you submit the report, you will not be able to view it again, but a finalized ePRF submission will be provided to you as a PDF when you receive your review letter from the WCM DSMB.

# A Note on Requesting the WCM DSMB

- Principal Investigators can now signal that they intend to utilize the DSMB during the CSEC application phase. A question asks, “Will you be using the WCM DSMB?” If yes, the DSMB will reach out to you to develop your data and safety monitoring plan and arrange to present at an upcoming DSMB meeting.

    - Requesting the DSMB at the CSEC stage allows for work on the DSMP to begin earlier on, smoothing the forthcoming IRB and DSMB reviews of that portion of the protocol.

# A Note on Immediate Reporting to the WCM DSMB

- The DSMB shares the Immediate Reporting Policy with the IRB. If utilizing the WCM DSMB, all Immediate Reports sent to the IRB must also be CC'd to dsmb@med.cornell.edu for evaluation.

# Website and Contact

- **WCM DSMB Website**
  - **http://researchintegrity.weill.cornell.edu/dsmb/index.html**
    - FAQ on requesting the DSMB, when and how to submit a Periodic Report, adverse event reporting requirements, presenting to the DSMB
    - Link to the ePRF (electronic Periodic Report Form)
    - WCM DSMB Roster
    - Meeting dates and deadlines
    - Slides to use for presenting one's protocol to the DSMB
- **Contact**
  - dsmb@med.cornell.edu
    - Taylor Thomas Mazac, MPH – Cancer Clinical Trials - 646-962-6988 – ttm2001@med.cornell.edu
    - Lauren Odynocki – General Clinical Trials: 646-962-4065 – lao2003@med.cornell.edu

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# Key Elements of a Research Order

Lori Band
Research Pre-auth Coordinator
Weill Cornell Imaging (WCINYP)
lob2004@med.cornell.edu
646-962-7089

# Accepted orders and components

- Epic
- Ideal
- WCINYP Research order form
- Handwritten

Key Components: Same requirements as a clinical order plus:

1. IRB# (linking & HRBAF)
2. Indication if exam is sponsored (bill to grant) or standard of care (bill to insurance).
3. Grant # PI Coordinator Contact info Cycle time-points

# WCINYP's Workflow

1. Check order & HRBAF prior to arrival. Discrepancies can be addressed and corrected
2. Link exam in epic
3. Internal modifiers noting soc or sponsored
4. Radiologist dictation of type of research
5. Coders applying modifier/ICD10 for:

   insurance: Q1/Z00.6 or Sponsor : BG
6. Exam will be sent to insurance or directed to referring departments research charge review queue for further review.

# Investigational Drug Services

Presented By:

Rachael Aletti, PharmD

Nicolette Andolfo, PharmD

# Outline

- Overview of the Fo6 and Starr 3 IDS pharmacies
- Submission process for Section I Forms
- Drug Acquisition Process
- Site Initiation Visits and IDS
- 2016 Data

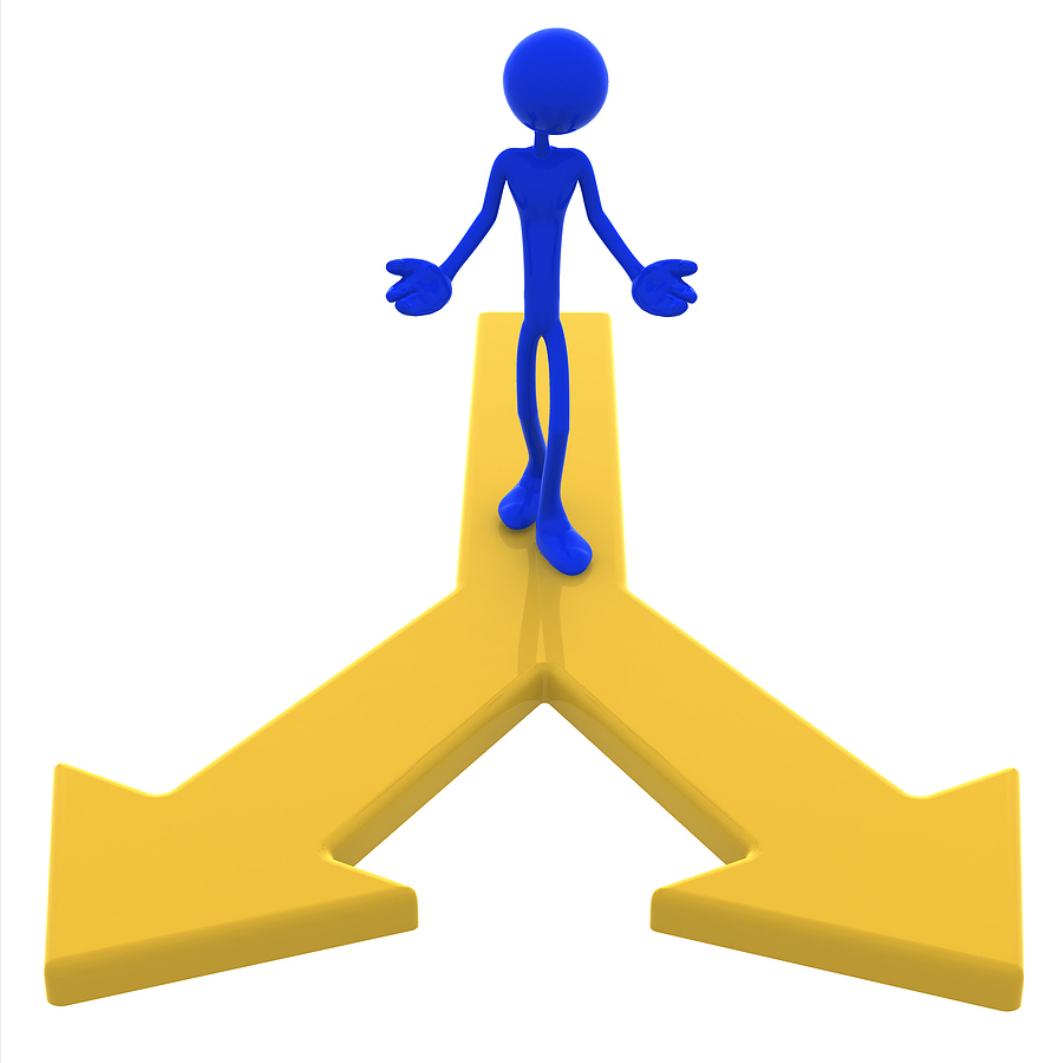
# How to Reach Us

- Mon-Fri 8:30am to 5pm
- Starr3-ids-pharm@nyp.org
  - 212-746-2533
- Fo6-ids-pharm@nyp.org
  - 212-746-0743

# Pharmacy Personnel

- Director
  - Cindy Ippoliti, PharmD, BCOP
- Manager
  - Hetal May, PharmD, BCOP
- Lead Pharmacist
  - Nicolette Andolfo, PharmD

- Fo6 Pharmacists
  - Rachael Aletti, PharmD
  - Paul Kim, PharmD
- Fo6 Technicians
  - Seada Zenunovic
  - Malissa Robinson
- Starr3 Pharmacists
  - Anna Rubinchik, PharmD
  - Joseph Tumino, PharmD
  - Lay Kaw, PharmD
- Starr3 Technicians
  - Jennifer Spallone
  - Tanja Holgate



Starr3

Fo6

# Starr 3 Pharmacy

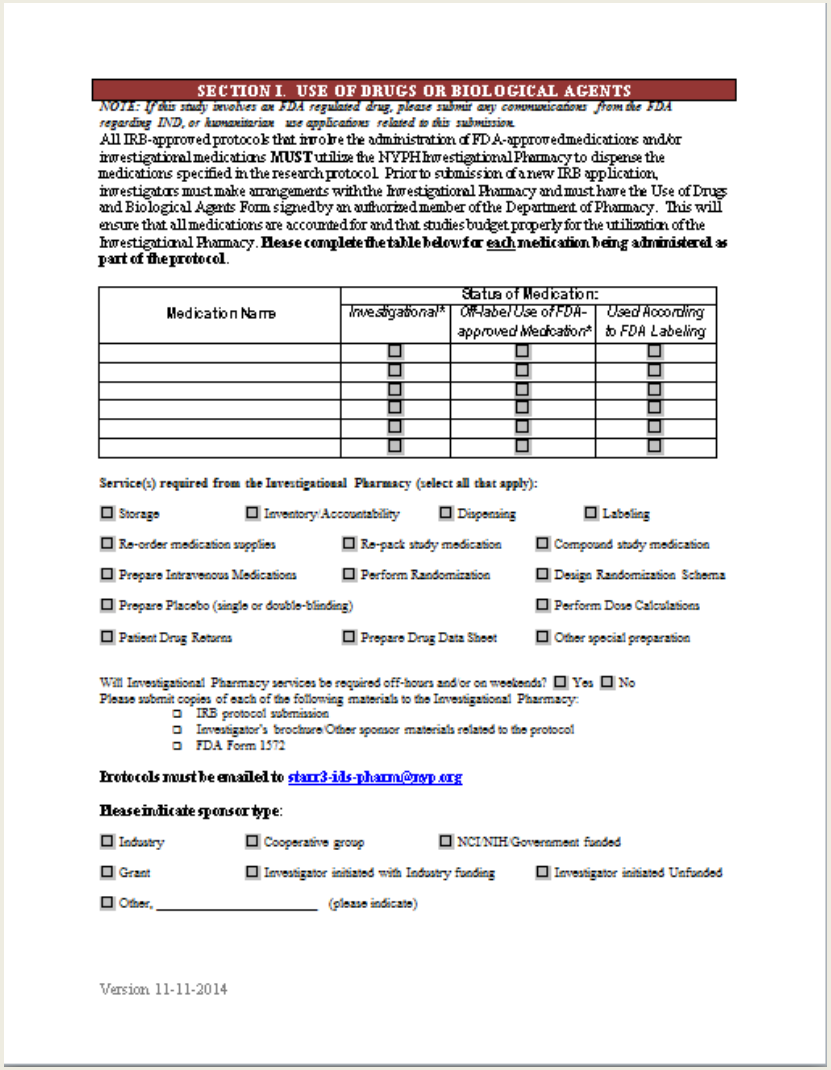
- Physical Location: K Building, Room 304
- E-mail: starr3-ids-pharm@nyp.org
- Study management:
  - IV hazardous investigational agent
  - Combination of:
    - IV hazardous agent (investigational or commercial/SOC infusions administered in Starr3) PLUS Oral non-hazardous/hazardous

# Fo6 Pharmacy

- Physical Location: F Building, Room o6-A
- E-mail: Fo6-ids-pharm@nyp.org
- Study management:
  - IV non-hazardous agent
  - Oral only non-hazardous/hazardous agents
  - Combination of IV non-hazardous agent PLUS oral non-hazardous/hazardous agents
  - IDS only dispenses oral agent and IV hazardous agent is prepared/dispensed by clinic pharmacy (NOT Starr-3 infusion center)

# Use of Drugs and Biological Agents Form

- Aka ‘Section I Form’
- Required for study activation
- Available through JCTO website
- Submit to starr3-ids-pharm@nyp.org (attn: Nicolette) along with:
  - eIRB protocol application
  - Protocol/IB/Pharmacy Manual
  - Completed FDA Form 1572
- 2-3 week turnaround time



**SECTION I. USE OF DRUGS OR BIOLOGICAL AGENTS**

*NOTE: If this study involves an FDA regulated drug, please submit any communications from the FDA regarding IND, or humanitarian use applications related to this submission.*

All IRB-approved protocols that involve the administration of FDA-approved medications and/or investigational medications **MUST** utilize the NYPH Investigational Pharmacy to dispense the medications specified in the research protocol. Prior to submission of a new IRB application, investigators must make arrangements with the Investigational Pharmacy and must have the Use of Drugs and Biological Agents Form signed by an authorized member of the Department of Pharmacy. This will ensure that all medications are accounted for and that studies budget properly for the utilization of the Investigational Pharmacy. **Please complete the table below for each medication being administered as part of the protocol.**

| Medication Name | Status of Medication: | | |
|---|---|---|---|
| | *Investigational** | *Off-label Use of FDA-approved Medication** | *Used According to FDA Labeling* |
| | ☐ | ☐ | ☐ |
| | ☐ | ☐ | ☐ |
| | ☐ | ☐ | ☐ |
| | ☐ | ☐ | ☐ |
| | ☐ | ☐ | ☐ |
| | ☐ | ☐ | ☐ |

**Service(s) required from the Investigational Pharmacy (select all that apply):**

☐ Storage ☐ Inventory/Accountability ☐ Dispensing ☐ Labeling

☐ Re-order medication supplies ☐ Re-pack study medication ☐ Compound study medication

☐ Prepare Intravenous Medications ☐ Perform Randomization ☐ Design Randomization Schema

☐ Prepare Placebo (single or double-blinding) ☐ Perform Dose Calculations

☐ Patient Drug Returns ☐ Prepare Drug Data Sheet ☐ Other special preparation

Will Investigational Pharmacy services be required off-hours and/or on weekends? ☐ Yes ☐ No

Please submit copies of each of the following materials to the Investigational Pharmacy:

- ☐ IRB protocol submission
- ☐ Investigator's brochure/Other sponsor materials related to the protocol
- ☐ FDA Form 1572

**Protocols must be emailed to starr3-ids-pharm@nyp.org**

**Please indicate sponsor type:**

☐ Industry ☐ Cooperative group ☐ NCI/NIH/Government funded

☐ Grant ☐ Investigator initiated with Industry funding ☐ Investigator initiated Unfunded

☐ Other, _____ (please indicate)

Version 11-11-2014

# IDS Fee Structure

## Fees

- Initial Pharmacy Fee
  - $2500 x 1
- Monthly Maintenance Fee
  - $125/month
- Dispensation Fees
  - Low Complexity - $50/dose
  - Moderate Complexity - $100/dose
  - High Complexity - $150/dose

## Discounts

- Industry or Non-NYPWC affiliated
  - Total paid in full
- Federally Funded
  - Total discounted by 33%
- Investigator Initiated/COOP
  - Total discounted by 50%

# Drug Procurement

- Investigational agents
  - Sponsor provides

- Commercially available products (possibilities):
  - Sponsor provides
  - Sponsor does not provide and subjects will need to fill at an outside pharmacy (e.g. oral agents for outpatient use)
  - Sponsor does not provide, but agents are readily available at NYPH + billable to subject's insurance (e.g. SOC chemotherapy)
  - Sponsor does not provide, but will cover the cost of drug
    - **Follow IDS drug acquisition process**

# IDS Drug Acquisition Process

Step 1: Contact IDS to determine cost of drug

Step 2: An invoice is generated by IDS and sent directly to JCTO Finance

Step 3: JCTO finance will send Hetal and Nicolette an email with the JIRA ticket #

- JIRA ticket # = Confirmation that a check requisition has been placed for the invoiced amount
- Checks should be made out to: **NewYork-Presbyterian Hospital**
- Mail or deliver checks to:
  NewYork-Presbyterian Hospital
  Department of Pharmacy
  525 E. 68th St, Rm K-04
  New York, NY 10065
  *Attn: Curtis Kellner/Tatiana Hernandez*

Step 4: Pharmacy will proceed to purchase drug

** This process will apply to initial and subsequent drug orders**

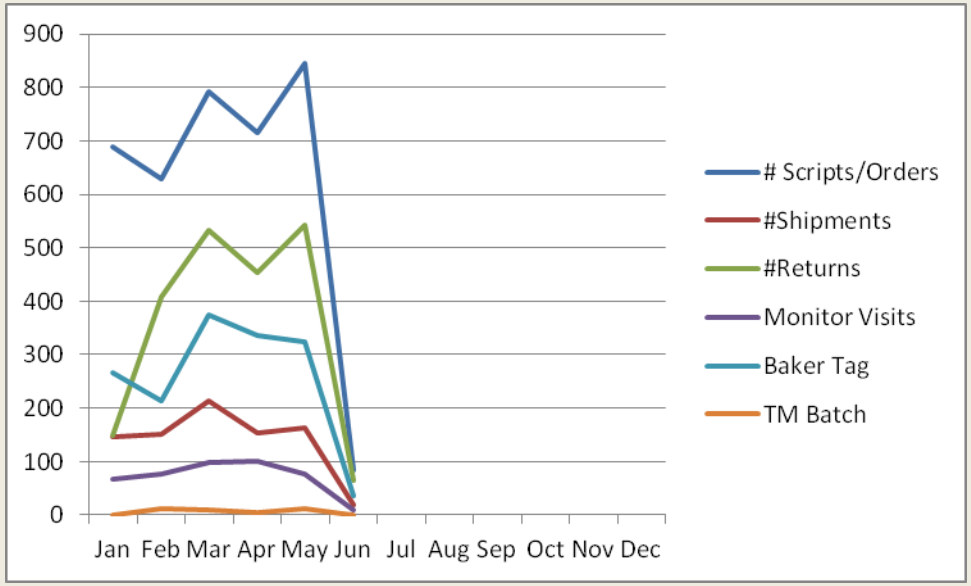
# Site Initiation Visits & IDS

## Key Points:

- Contact IDS directly via list-serv to schedule
- An approved Section I Form is required for SIV scheduling
- All study documents should be sent to IDS electronically prior to the SIV
- IDS cannot accept IP prior to the SIV
- IDS maintains and can provide the following SOPs during/prior to the SIV:
  - SOP for Disposal of Investigational Products
  - SOP for Accountability and Vestigo
  - SOP for Delegation of Authority, Training and Credentials (in conjunction w/ JCTO)

# Jan – Jun 2016 Data

| DATE 2016 | # Scripts/Orders | #Shipments | #Returns | Monitor Visits | Baker Tag | TM Batch |
|---|---|---|---|---|---|---|
| Jan | 688 | 145 | 148 | 68 | 265 | 0 |
| Feb | 630 | 150 | 408 | 76 | 213 | 12 |
| Mar | 793 | 213 | 533 | 97 | 375 | 10 |
| Apr | 716 | 154 | 453 | 100 | 335 | 5 |
| May | 846 | 164 | 543 | 76 | 324 | 12 |
| Jun | 83 | 19 | 65 | 9 | 35 | 0 |
| TOTAL | 3756 | 845 | 2150 | 426 | 1547 | 39 |




We manage close to 400 active protocols

. . . . . .

And the number is growing by the day!!

# Thank you!

Questions?

Starr3-ids-pharm@nyp.org

212-746-2533

Fo6-ids-pharm@nyp.org

212-746-0743

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# Updates to Immediate Reporting Policy

Rosemary Kraemer, Ph.D., C.I.P.
Director, Human Research Protections Program

TWIST Round Table

June 20, 2016

# Immediate Reporting Policy

- **Effective date of new policy as of June 1, 2016**
- **Broadcast email announcing new policy was sent June 7, 2016**
- **Major change regarded the reporting of adverse events from external sites in multisite studies.**

# Previous Adverse Event Reporting Policy: Immediate report

**Immediately report any harm experienced by a participant or other individual, whether occurring to a subject enrolled at WCMC or elsewhere, including Investigational New Drug (IND) reports and MedWatch reports, related to the human research procedure(s), intervention(s), and/or device(s) when ALL of the following three (3) conditions are met:**

**1. 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**

**2. 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**

**3. 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**

# New AE reporting policy: Immediate Reporting Policy

- **Reporting for WCMC AEs did not change**
- **Reporting for AE from external sites now reads:**

**If this is a multi-site study, the Adverse Event & IND Safety Reporting Cumulative Table must include individual adverse events from all external sites that meet all of the following criteria and must be submitted as an immediate report, as described in part A:**

**1. The harm is "unexpected" when its specificity and severity are not accurately reflected in the WCM consent document, Investigator's Brochure (if applicable), or package insert (if applicable); AND**

**2. 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**

**3. Necessitates changes in the conduct of the study, i.e., requires a significant, usually safety-related, change in the protocol. This may include, but are not limited to, revising the inclusion/exclusion criteria, monitoring requirements, informed consent form, or investigator's brochure.**

# Previous Reporting Policy: At continuing review (Cumulative Table)

**At the time of IRB Continuing Review, an Adverse Event & IND Safety Reporting Cumulative Table must be submitted listing adverse events from the WCMC site and any external sites that are both expected and unexpected and for which ANY of the following apply:**

**1. Severe or medically significant, but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care activities of daily living**

**(Grade 3)***

**2. Life-threatening consequences; urgent intervention indicated (Grade 4)**

**3. Death related AE (Grade 5)**

# New Reporting Policy: Cumulative Table

**At the time of IRB Continuing Review, an Adverse Event & IND Safety Reporting Cumulative Table must be submitted listing adverse events from the WCM site that are both expected and unexpected and for which ANY of the following apply:**

**1. Severe or medically significant, but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care activities of daily living (Grade 3)***

**2. Life-threatening consequences; urgent intervention indicated (Grade 4)**

**3. Death related AE (Grade 5)**

- **Adverse events from external sites that do not meet the WCM immediate reporting policy no longer have to be submitted by sponsors and no longer have to be listed on the cumulative table at the time of continuing review and do not have to be sent to the IRB office for acknowledgment.**
- **The Cumulative table should list all AEs from subjects enrolled at WCMC that are both expected and unexpected.**
- **Only AEs from external sites that meet the WCMC immediate reporting policy should be listed on the cumulative table.**

# Reasons for this change

- **The listing of all adverse events from external sites on the cumulative table, regardless of whether they were expected or unexpected, was considered to be large administrative burden, both to the research team and the IRB administrative team (request to acknowledge)**
- **In consultation with IRB leadership and the IRBs, it was determined that this information was not necessary to determine the if the overall risk level of the protocol has changed since the last review and whether the continuing review could be approved**

# Previous Protocol Deviation Policy

**Immediately report if ANY of the following conditions are met:**

**A. Protocol deviation that harmed participants or others or that indicates participants or others might be at increased risk of harm; OR**

**B. 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); OR**

**C. Protocol deviation that was made in order to eliminate an apparent immediate hazard to participant(s). (Submit an Immediate Report within 24 hours) OR**

**D. Breach of Confidentiality (Submit within 24 hours)**

# New Protocol Deviation Policy

**Immediately report if ANY of the following conditions are met:**

**A. Protocol deviation that was made in order to eliminate an apparent immediate hazard to participant(s). (Submit an Immediate Report within 24 hours) OR**

**B. Breach of Confidentiality (Submit within 24 hours) OR**

**C. Protocol deviation that represents a failure to follow the IRB approved 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), which meet BOTH of the following conditions:**

**a. The deviation has the potential to negatively impact subject safety or integrity of study data (ability to draw conclusions from the study data), or affect the subject's willingness to participate in the study AND**

**b. The deviation places WCM subjects at greater risk of harm (including physical, psychological, economic or social harm).**

- **Deviations that do not meet the any of the above conditions must be recorded by the PI on a protocol-specific Deviation Log and submitted to the IRB at the time of continuing review. The Deviation Log should include all deviations, including those that are immediately reportable. A Deviation Log template and guidance document for reporting protocol deviations are available in the Researcher's Toolbox on the JCTO website (jcto.weill.cornell.edu)**
- **It is the responsibility of the PI to determine whether a deviation from the IRB approved protocol is immediately reportable to the IRB as outlined above. The PI is responsible for reviewing the Deviation Log periodically to ensure timely and appropriate reporting to the IRB. If a deviation that is not immediately reportable occurs repeatedly, this pattern should be immediately reported to the IRB.**

# Examples of Immediately Reportable Protocol deviations

- **Changes necessary to eliminate apparent immediate hazards to the subject**
- **Failure to obtain informed consent or obtaining consent after the initiation of study procedures**
- **Enrollment of an ineligible subject (did not meet all inclusion/exclusion criteria)**
- **Performing study procedure not approved by the IRB**
- **Failure to report a serious adverse event (SAE) to the IRB and/or sponsor**
- **Failure to perform a required lab test that, in the opinion of the PI, may affect subject safety or data integrity**
- **Dispensing or dosing error of an Investigational Product (IP)**
- **Study visit conducted outside of required timeframe that, in the opinion of the PI, may affect subject safety**
- **Failure to follow safety monitoring plan**
- **Enrollment of subjects after IRB-approval has expired**

# Examples of Protocol Deviations that can be listed in the Deviation Log

- **Inappropriate documentation of informed consent, including**
- **Use of outdated/expired consent form that contains all required information and elements of informed consent**
- **Study procedure conducted out of sequence**
- **Omitting an approved procedure of the protocol**
- **Failure to perform a required lab test**
- **Missing lab results**
- **Failure of subject to return study medication**
- **Over-enrollment**
- **Failure to submit continuing review application to the IRB before study expiration**

**The new policy can be found on the following websites:**

**The IRB Policies and Procedures website:**

**http://researchintegrity.weill.cornell.edu/institutional_review_board/irb_policies_and_procedures.html**

**The Immediate Reporting Policy Page:**

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

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

- **Please send all questions to irb@med.cornell.edu**

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# When should a study be closed? (i.e. Should I submit a continuing review or close the protocol)

- **If Industry sponsored protocol, the study can be closed once the sponsor indicates as such.**
- **If a consortium trial, the study should not be closed, even if there is no further activity on the study at WCMC, until the consortium says the study can be closed.**
- **The study should remain open**
  - **If continuing to analyze data (Even if de-identified)**
  - **Manuscript has been submitted and are waiting to hear back for the journal**

## Guidance from OHPR: http://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html

**Conversely, OHRP considers private information or specimens not to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. For example, OHRP does not consider research involving only coded private information or specimens to involve human subjects as defined under 45 CFR 46.102(f) if the following conditions are both met:**

- **the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and**
- **the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain.**

**If there were multiple investigators on the study, and all activity at WCMC has finished (data analysis only), then remove all investigators that are no longer involved in the study, even if only the PI of the study is the only investigator that remains.**

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# New Decision Tools for Expedited and Exempt Research

- **The aim of the tools is to provide further guidance regarding regulatory criteria and institutional requirements for the Exempt and Expedited categories, as well as to provide guidance regarding the information needed to submit a successful application of each type.**
- **The tools do not replace any part of the formal determination process, and cannot guarantee that the application type selected will be correct.**
- **These tools are should be used in the developmental stages of research projects, and can contribute to a smooth application process.**

# New Decision Tools for Expedited and Exempt Research

**The ORI has created new tools to assist researchers in determining whether the protocols will qualify for Expedited or Exempt review:**

**Expedited:**

**http://researchintegrity.weill.cornell.edu/institutional_review_board/expedited_category/index.html**

**Exempt:**

**http://researchintegrity.weill.cornell.edu/institutional_review_board/exempt_category/index.html**

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## Monday, June 20th 2016

with presentations by

**Taylor Mazac, MPH**

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**Nicolette Andolfo, Pharm D**

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**Rosemary Kraemer, PhD, CIP**