Welcome to our March METS

- Please make sure your microphones are muted
- There will be a Q&A session after this presentation
  - Please reserve your questions until then

    OR
  - Put any/all questions in the chat and we will address them after the presentation
- This session will be recorded

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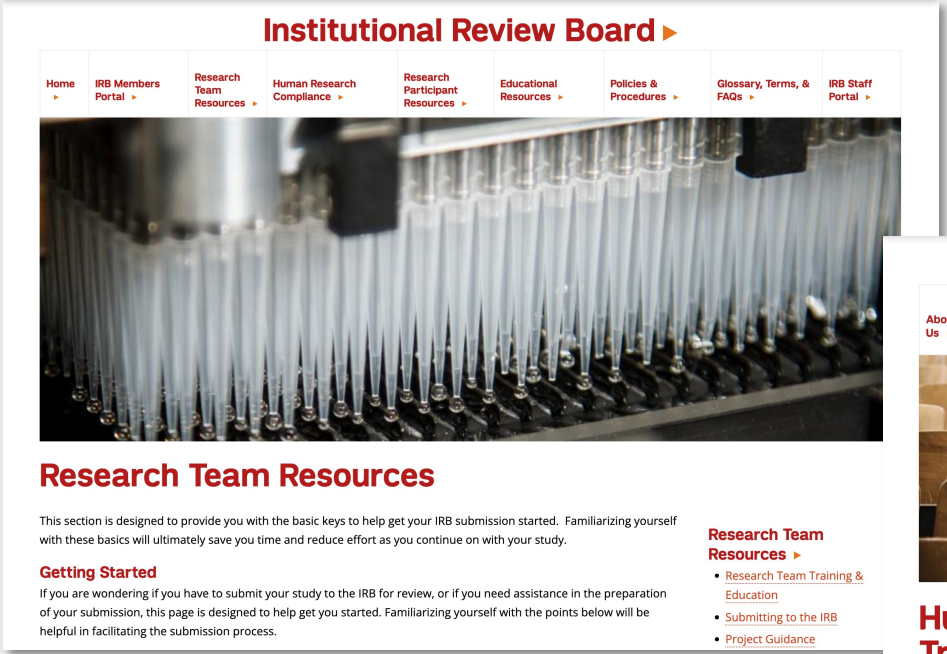
Submitting an IRB Application

A Step-by-Step Guide

Office of Human Research Compliance
Melissa Epstein, PhD, MBE, CIP *Executive Director*

https://research.weill.cornell.edu/irb



For an overview of the WCM IRB, please join us at next month's METS

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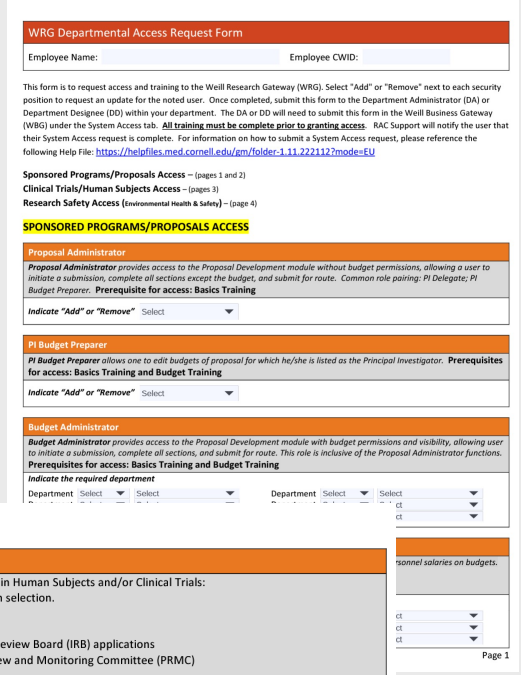
How Do I Get Started?

First Things First: Access to WRG-HS & -CT

- **<u>WRG Access Form</u> submitted by Department DA**
- **Modules to have access to:**
  - Human Subjects (HS)
  - Clinical Trials (CT)
- Select **add** for both **regulatory coordinator** and **clinical research associate**



WRG Departmental Access Request Form

Employee Name: Employee CWID:

This form is to request access and training to the Weill Research Gateway (WRG). Select "Add" or "Remove" next to each security position to request an update for the noted user. Once completed, submit this form to the Department Administrator (DA) or Department Designee (DD) within your department. The DA or DD will need to submit this form in the Weill Business Gateway (WBG) under the System Access tab. **All training must be complete prior to granting access**. RAC Support will notify the user that their System Access request is complete. For information on how to submit a System Access request, please reference the following Help File: https://helpfiles.med.cornell.edu/gm/folder-1.11.222112?mode=EU

Sponsored Programs/Proposals Access – (pages 1 and 2)
Clinical Trials/Human Subjects Access – (pages 3)
Research Safety Access (Environmental Health & Safety) – (page 4)

SPONSORED PROGRAMS/PROPOSALS ACCESS

Proposal Administrator

Proposal Administrator *provides access to the Proposal Development module without budget permissions, allowing a user to initiate a submission, complete all sections except the budget, and submit for route. Common role pairing: PI Delegate; PI Budget Preparer.* **Prerequisite for access: Basics Training**

Indicate "Add" or "Remove" Select

PI Budget Preparer

PI Budget Preparer *allows one to edit budgets of proposal for which he/she is listed as the Principal Investigator.* **Prerequisites for access: Basics Training and Budget Training**

Indicate "Add" or "Remove" Select

Budget Administrator

Budget Administrator *provides access to the Proposal Development module with budget permissions and visibility, allowing user to initiate a submission, complete all sections, and submit for route. This role is inclusive of the Proposal Administrator functions.* **Prerequisites for access: Basics Training and Budget Training**

Indicate the required department

Department Select Select Department Select Select

CLINICAL TRIALS/HUMAN SUBJECTS

Human Subjects Research Responsibilities

Select the tasks that the employee will be performing in Human Subjects and/or Clinical Trials:
(checkboxes or indicated an "add/delete" next to each selection.

<u>Regulatory Coordinator</u>
- Creating, editing or submitting Institutional Review Board (IRB) applications
- Creating, editing or submitting Protocol Review and Monitoring Committee (PRMC)

<u>Clinical Research Associate</u>
- Enrollment of participants/subjects onto studies
- Management of participant/subject data

Prerequisite for access: Study Activation and/or Subjects Enrollment Training

Indicate "Add" or "Remove"

Regulatory Coordinator Select

Clinical Research Associate: Select / Add / Remove

Page 1

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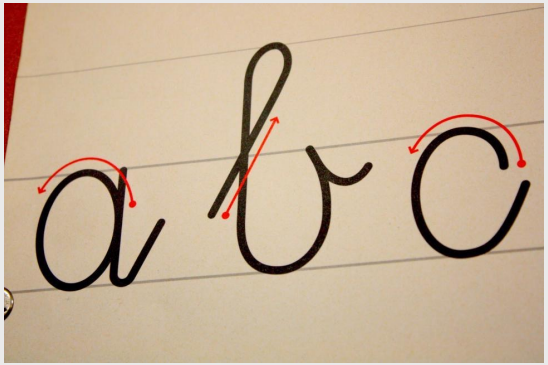
Submitting to the WCM IRB

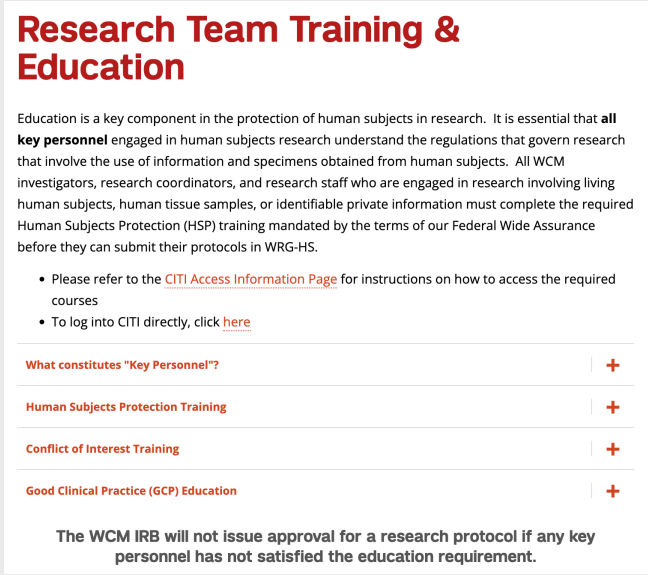
1. **Personnel training verification**
2. **Conflict of Interest (COI) certification**
3. **Submission Documents**
   - ✓ Protocol template
   - ✓ Initial Review Application
   - ✓ Supplemental Forms
   - ✓ Consent
   - ✓ Other Documents
4. **Intake form**
5. **PRMC review or its equivalent**
6. **IRB application**
7. **Personnel approval and certification**



1. Confirm Personnel Training

- **Key Personnel = Any individual engaged in research with human subjects**
- **CITI Modules:**
  - Biomedical Research Investigators and Key Personnel (3 yrs)
  - Good Clinical Practice (3 yrs)
  - Conflict of Interest (4 yrs)

See Training and Education requirements on the Research Team Training & Education page of IRB site



Research Team Training & Education

Education is a key component in the protection of human subjects in research. It is essential that **all key personnel** engaged in human subjects research understand the regulations that govern research that involve the use of information and specimens obtained from human subjects. All WCM investigators, research coordinators, and research staff who are engaged in research involving living human subjects, human tissue samples, or identifiable private information must complete the required Human Subjects Protection (HSP) training mandated by the terms of our Federal Wide Assurance before they can submit their protocols in WRG-HS.

- Please refer to the CITI Access Information Page for instructions on how to access the required courses
- To log into CITI directly, click here

What constitutes "Key Personnel"? +

Human Subjects Protection Training +

Conflict of Interest Training +

Good Clinical Practice (GCP) Education +

The WCM IRB will not issue approval for a research protocol if any key personnel has not satisfied the education requirement.

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2. Confirm COI Certifications

- **All personnel listed on the IRB application must have completed Conflicts Survey on file**
  - Including those with no interests to disclose
- **COI disclosures must be submitted when additional investigators join a study**
- **Minimum once annually**
- **Changes must be reported within 30 days**

Find the "COI Annual Disclosure Survey" button on the Conflicts of Interest website

See "Submitting your Conflicts Survey article on ITS site

3. Prepare Submission Documents

- ☑ JCTO Protocol Template, if applicable
- ☑ IRB Review Application
- ☑ Supplemental Forms
- ☑ WCM Informed Consent Form
- ☑ Other documents

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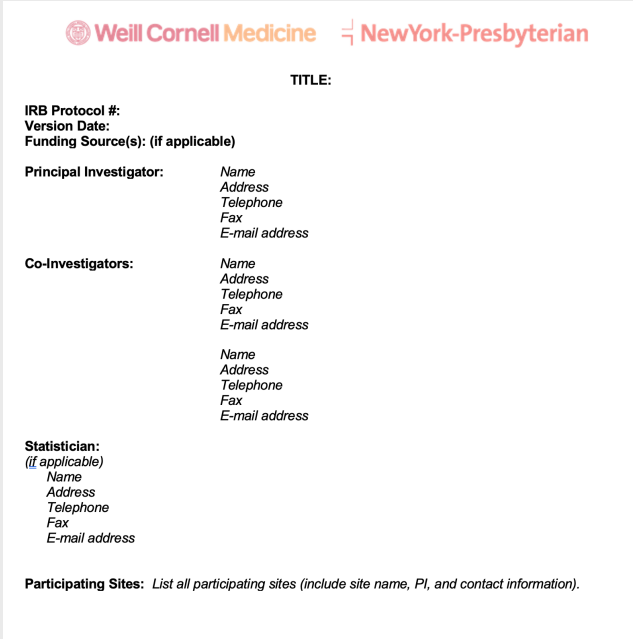
JCTO Protocol Templates



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TITLE:

IRB Protocol #:
Version Date:
Funding Source(s): (if applicable)

Principal Investigator: *Name, Address, Telephone, Fax, E-mail address*

Co-Investigators: *Name, Address, Telephone, Fax, E-mail address*

Name, Address, Telephone, Fax, E-mail address

Statistician:
(if applicable)
Name, Address, Telephone, Fax, E-mail address

Participating Sites: *List all participating sites (include site name, PI, and contact information).*

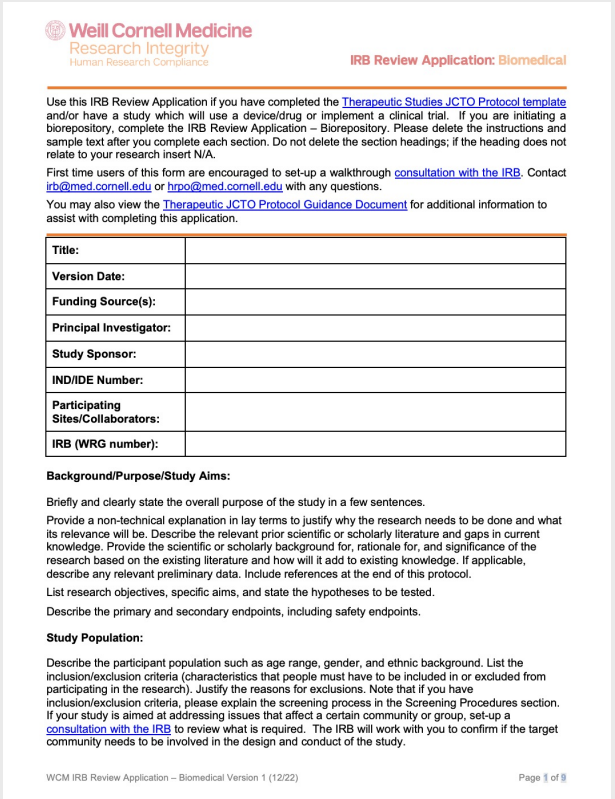
Joint Clinical Trials Office (JCTO) Protocol Templates:

- Observational Correlative Studies
- Therapeutic Studies
- Tissue Use/Chart Reviews

For questions about these templates, please contact the JCTO or visit their website: https://jcto.weill.cornell.edu/

IRB Review Application (IRA)

- **Streamlines/focuses the collection of all IRB-required ethical and regulatory information**
- **Reduces duplicative information found in previous WRG-HS application**
- **Available on WCM IRB website for easier updates with no impact in WRG**
- **Versions:**
  - Biomedical IRA
  - Biorepository IRA
  - SBER and Records IRA



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IRB Review Application: Biomedical

Use this IRB Review Application if you have completed the Therapeutic Studies JCTO Protocol template and/or have a study which will use a device/drug or implement a clinical trial. If you are initiating a biorepository, complete the IRB Review Application – Biorepository. Please delete the instructions and sample text after you complete each section. Do not delete the section headings; if the heading does not relate to your research insert N/A.

First time users of this form are encouraged to set-up a walkthrough consultation with the IRB. Contact irb@med.cornell.edu or hrpo@med.cornell.edu with any questions.

You may also view the Therapeutic JCTO Protocol Guidance Document for additional information to assist with completing this application.

Title:	
Version Date:	
Funding Source(s):	
Principal Investigator:	
Study Sponsor:	
IND/IDE Number:	
Participating Sites/Collaborators:	
IRB (WRG number):	

Background/Purpose/Study Aims:

Briefly and clearly state the overall purpose of the study in a few sentences.

Provide a non-technical explanation in lay terms to justify why the research needs to be done and what its relevance will be. Describe the relevant prior scientific or scholarly literature and gaps in current knowledge. Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge. If applicable, describe any relevant preliminary data. Include references at the end of this protocol.

List research objectives, specific aims, and state the hypotheses to be tested.

Describe the primary and secondary endpoints, including safety endpoints.

Study Population:

Describe the participant population such as age range, gender, and ethnic background. List the inclusion/exclusion criteria (characteristics that people must have to be included in or excluded from participating in the research). Justify the reasons for exclusions. Note that if you have inclusion/exclusion criteria, please explain the screening process in the Screening Procedures section. If your study is aimed at addressing issues that affect a certain community or group, set-up a consultation with the IRB to review what is required. The IRB will work with you to confirm if the target community needs to be involved in the design and conduct of the study.

WCM IRB Review Application – Biomedical Version 1 (12/22) Page 1 of 9

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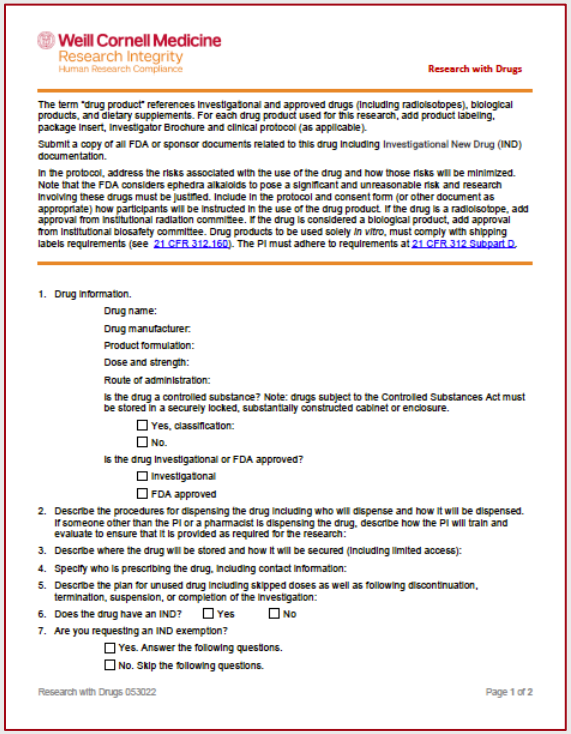
Supplemental Forms



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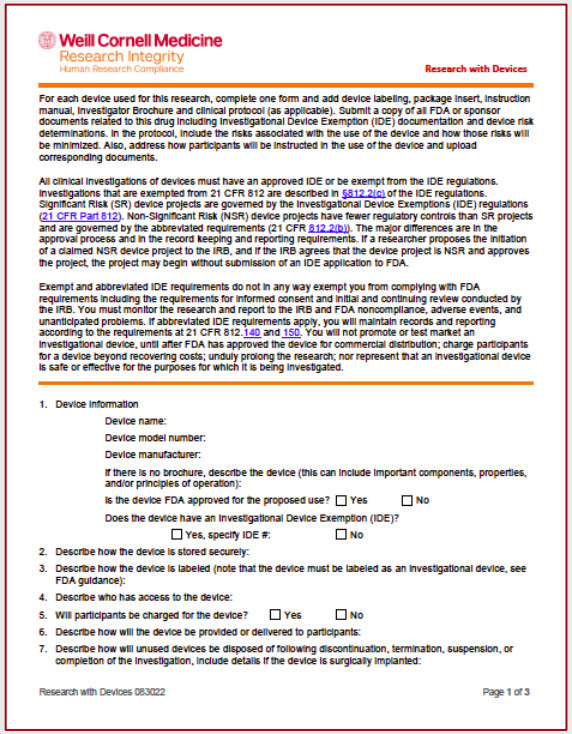
Research with Drugs

The term "drug product" references investigational and approved drugs (including radioisotopes), biological products, and dietary supplements. For each drug product used for this research, add product labeling, package insert, Investigator Brochure and clinical protocol (as applicable).

Submit a copy of all FDA or sponsor documents related to this drug including Investigational New Drug (IND) documentation.

In the protocol, address the risks associated with the use of the drug and how those risks will be minimized. Note that the FDA considers ephedra alkaloids to pose a significant and unreasonable risk and research involving these drugs must be justified. Include in the protocol and consent form (or other document as appropriate) how participants will be instructed in the use of the drug product. If the drug is a radioisotope, add approval from institutional radiation committee. If the drug is considered a biological product, add approval from institutional biosafety committee. Drug products to be used solely *in vitro*, must comply with shipping labels requirements (see 21 CFR 312.160). The PI must adhere to requirements at 21 CFR 312 Subpart D.

1. Drug information.
   - Drug name:
   - Drug manufacturer:
   - Product formulation:
   - Dose and strength:
   - Route of administration:
   - Is the drug a controlled substance? Note: drugs subject to the Controlled Substances Act must be stored in a securely locked, substantially constructed cabinet or enclosure.
     - ☐ Yes, classification:
     - ☐ No.
   - Is the drug investigational or FDA approved?
     - ☐ Investigational
     - ☐ FDA approved
2. Describe the procedures for dispensing the drug including who will dispense and how it will be dispensed. If someone other than the PI or a pharmacist is dispensing the drug, describe how the PI will train and evaluate to ensure that it is provided as required for the research:
3. Describe where the drug will be stored and how it will be secured (including limited access):
4. Specify who is prescribing the drug, including contact information:
5. Describe the plan for unused drug including skipped doses as well as following discontinuation, termination, suspension, or completion of the investigation:
6. Does the drug have an IND? ☐ Yes ☐ No
7. Are you requesting an IND exemption?
   - ☐ Yes. Answer the following questions.
   - ☐ No. Skip the following questions.



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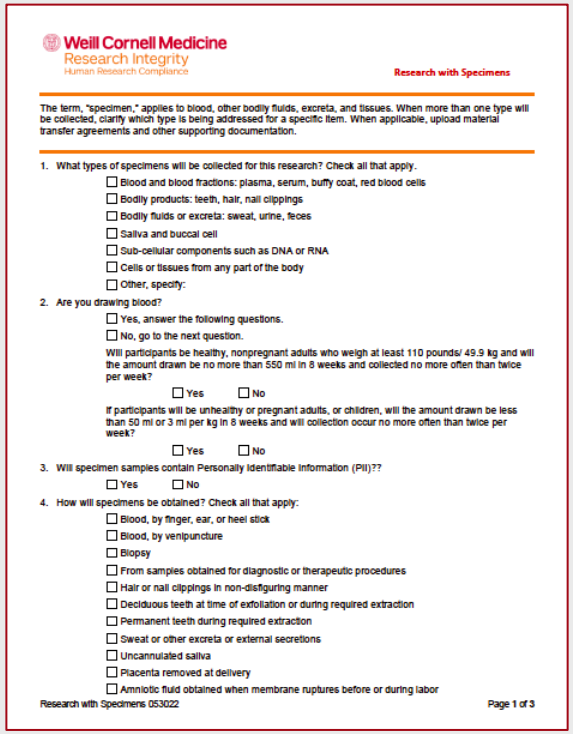
Research with Devices

For each device used for this research, complete one form and add device labeling, package insert, instruction manual, Investigator Brochure and clinical protocol (as applicable). Submit a copy of all FDA or sponsor documents related to this drug including Investigational Device Exemption (IDE) documentation and device risk determinations. In the protocol, include the risks associated with the use of the device and how those risks will be minimized. Also, address how participants will be instructed in the use of the device and upload corresponding documents.

All clinical investigations of devices must have an approved IDE or be exempt from the IDE regulations. Investigations that are exempted from 21 CFR 812 are described in §812.2(c) of the IDE regulations. Significant Risk (SR) device projects are governed by the Investigational Device Exemptions (IDE) regulations (21 CFR Part 812). Non-Significant Risk (NSR) device projects have fewer regulatory controls than SR projects and are governed by the abbreviated requirements (21 CFR 812.2(b)). The major differences are in the approval process and in the record keeping and reporting requirements. If a researcher proposes the initiation of a claimed NSR device project to the IRB, and if the IRB agrees that the device project is NSR and approves the project, the project may begin without submission of an IDE application to FDA.

Exempt and abbreviated IDE requirements do not in any way exempt you from complying with FDA requirements including the requirements for informed consent and initial and continuing review conducted by the IRB. You must monitor the research and report to the IRB and FDA noncompliance, adverse events, and unanticipated problems. If abbreviated IDE requirements apply, you will maintain records and reporting according to the requirements at 21 CFR 812.140 and 150. You will not promote or test market an investigational device, until after FDA has approved the device for commercial distribution; charge participants for a device beyond recovering costs; unduly prolong the research; nor represent that an investigational device is safe or effective for the purposes for which it is being investigated.

1. Device Information
   - Device name:
   - Device model number:
   - Device manufacturer:
   - If there is no brochure, describe the device (this can include important components, properties, and/or principles of operation):
   - Is the device FDA approved for the proposed use? ☐ Yes ☐ No
   - Does the device have an Investigational Device Exemption (IDE)?
     - ☐ Yes, specify IDE #: ☐ No
2. Describe how the device is stored securely:
3. Describe how the device is labeled (note that the device must be labeled as an investigational device, see FDA guidance):
4. Describe who has access to the device:
5. Will participants be charged for the device? ☐ Yes ☐ No
6. Describe how will the device be provided or delivered to participants:
7. Describe how will unused devices be disposed of following discontinuation, termination, suspension, or completion of the investigation, include details if the device is surgically implanted:



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Research with Specimens

The term, "specimen," applies to blood, other bodily fluids, excreta, and tissues. When more than one type will be collected, clarify which type is being addressed for a specific item. When applicable, upload material transfer agreements and other supporting documentation.

1. What types of specimens will be collected for this research? Check all that apply.
   - ☐ Blood and blood fractions: plasma, serum, buffy coat, red blood cells
   - ☐ Bodily products: teeth, hair, nail clippings
   - ☐ Bodily fluids or excreta: sweat, urine, feces
   - ☐ Saliva and buccal cell
   - ☐ Sub-cellular components such as DNA or RNA
   - ☐ Cells or tissues from any part of the body
   - ☐ Other, specify:
2. Are you drawing blood?
   - ☐ Yes, answer the following questions.
   - ☐ No, go to the next question.

   Will participants be healthy, nonpregnant adults who weigh at least 110 pounds/ 49.9 kg and will the amount drawn be no more than 550 ml in 8 weeks and collected no more often than twice per week?
   - ☐ Yes ☐ No

   If participants will be unhealthy or pregnant adults, or children, will the amount drawn be less than 50 ml or 3 ml per kg in 8 weeks and will collection occur no more often than twice per week?
   - ☐ Yes ☐ No
3. Will specimen samples contain Personally Identifiable Information (PII)??
   - ☐ Yes ☐ No
4. How will specimens be obtained? Check all that apply:
   - ☐ Blood, by finger, ear, or heel stick
   - ☐ Blood, by venipuncture
   - ☐ Biopsy
   - ☐ From samples obtained for diagnostic or therapeutic procedures
   - ☐ Hair or nail clippings in non-disfiguring manner
   - ☐ Deciduous teeth at time of exfoliation or during required extraction
   - ☐ Permanent teeth during required extraction
   - ☐ Sweat or other excreta or external secretions
   - ☐ Uncannulated saliva
   - ☐ Placenta removed at delivery
   - ☐ Amniotic fluid obtained when membrane ruptures before or during labor

How does the IRA streamline the submission process?

IRAs will now account for information about:

- General Study Design
- Retrospective and/or Prospective
- Cost, Reimbursement, or Compensation
- Risks and Risk Minimization
- Benefits
- Privacy and Confidentiality
- Informed Consent, Minor Assent, and Parental/Guardian Permission

WRG-HS's initial application will now ONLY collect:

- Personnel (WCM/NYP)
- Non-Affiliated (Non-WCM/NYP) Personnel
- Review & Approval
- Sponsors and Entities
- Attachments

Institutional Review Board

Home | IRB Members Portal | Research Team Resources | Human Research Compliance | Research Participant Resources | Educational Resources | Policies & Procedures | Glossary, Terms, & FAQs | IRB Staff Portal

Forms, Templates, & Guidance

*This page is being continually updated; please check back often!

Forms & Applications

IRB Review Application (IRA) Forms

For all **new initial applications** submitted to WRG-HS, a supplemental IRB Review Appication (IRA) must be attached. Please select and fill in the applicable IRB Review Application (IRA) linked below. Once complete, please upload it to WRG as part of your new submission.

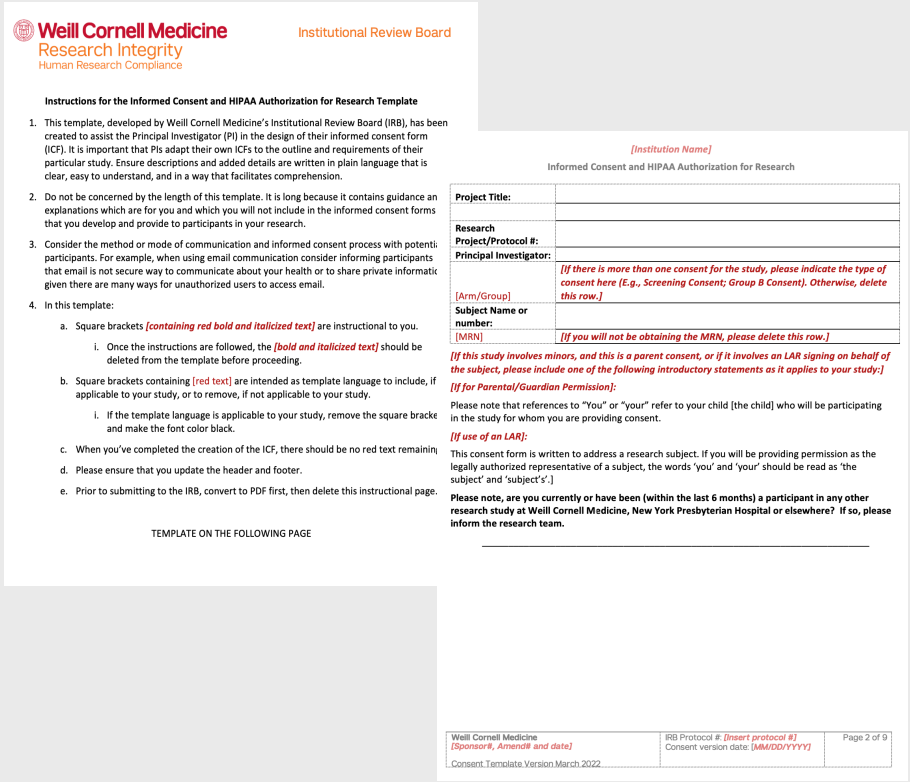
- Biomedical IRA: Use this IRB Review Application if you have completed the Therapeutic Studies JCTO Protocol template and/or have a study which will use a device/drug or implement a clinical trial.
- Biorepository IRA: This IRB Review Application template is **only** to be used for the establishment of a biorepository (storage and maintenance) for potential future use, not testing and research.
- Social-Behavioral and Educational Research (SBER) and Records IRA: Use this IRB Review Application if you have completed the Non-Therapeutic Studies or Tissue Use/Chart Review JSTO template, the Education Protocol Template and/or have a study which will use conduct social, behavioral, or educational research.

Supplemental Forms

- Drug Form: Used for any study involving drugs/dietary supplements
- Device Form: Used for any study involving medical devices (as defined by the FDA)
- Specimen Form: Used for any study collecting or using Human biological specimens for research (e.g., organ tissue, plasma, urine, feces, cells). This may include specimens collected as part of routine care for use as part of the research. This includes medical waste.

WCM Informed Consent Form

- **WCM Template**: ”*WCM Informed Consent Template* ***(with Key Information section)***”
  - available on the IRB web page: Forms, Templates, & Guidance



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Institutional Review Board

Instructions for the Informed Consent and HIPAA Authorization for Research Template

1. This template, developed by Weill Cornell Medicine's Institutional Review Board (IRB), has been created to assist the Principal Investigator (PI) in the design of their informed consent form (ICF). It is important that PIs adapt their own ICFs to the outline and requirements of their particular study. Ensure descriptions and added details are written in plain language that is clear, easy to understand, and in a way that facilitates comprehension.
2. Do not be concerned by the length of this template. It is long because it contains guidance an explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.
3. Consider the method or mode of communication and informed consent process with potenti participants. For example, when using email communication consider informing participants that email is not secure way to communicate about your health or to share private informatic given there are many ways for unauthorized users to access email.
4. In this template:
   a. Square brackets *[containing red bold and italicized text]* are instructional to you.
      i. Once the instructions are followed, the *[bold and italicized text]* should be deleted from the template before proceeding.
   b. Square brackets containing [red text] are intended as template language to include, if applicable to your study, or to remove, if not applicable to your study.
      i. If the template language is applicable to your study, remove the square bracke and make the font color black.
   c. When you've completed the creation of the ICF, there should be no red text remainin
   d. Please ensure that you update the header and footer.
   e. Prior to submitting to the IRB, convert to PDF first, then delete this instructional page.

TEMPLATE ON THE FOLLOWING PAGE

[Institution Name]

Informed Consent and HIPAA Authorization for Research

Project Title:	
Research Project/Protocol #:	
Principal Investigator:	
[Arm/Group]	*[If there is more than one consent for the study, please indicate the type of consent here (E.g., Screening Consent; Group B Consent). Otherwise, delete this row.]*
Subject Name or number:	
[MRN]	*[If you will not be obtaining the MRN, please delete this row.]*

[If this study involves minors, and this is a parent consent, or if it involves an LAR signing on behalf of the subject, please include one of the following introductory statements as it applies to your study:]

[If for Parental/Guardian Permission]:

Please note that references to "You" or "your" refer to your child [the child] who will be participating in the study for whom you are providing consent.

[If use of an LAR]:

This consent form is written to address a research subject. If you will be providing permission as the legally authorized representative of a subject, the words 'you' and 'your' should be read as 'the subject' and 'subject's'.]

Please note, are you currently or have been (within the last 6 months) a participant in any other research study at Weill Cornell Medicine, New York Presbyterian Hospital or elsewhere? If so, please inform the research team.

Weill Cornell Medicine
[Sponsor#, Amend# and date]
Consent Template Version March 2022

IRB Protocol #: *[Insert protocol #]*
Consent version date: *[MM/DD/YYYY]*

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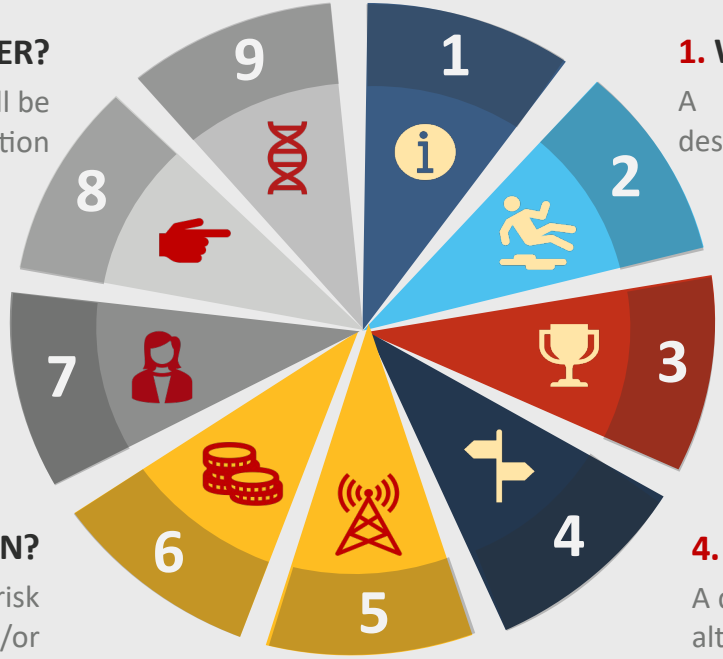
Elements of the Informed Consent Form



1. WHAT IS IT ABOUT?

A statement about, and description of, the study

2. WHAT ARE THE RISKS?

A description of risks or discomforts to the subject

3. WHAT ARE THE BENEFITS?

A description of any benefits to the subjects

4. ARE THERE ALTERNATIVES?

A disclosure of appropriate alternative procedures or courses of treatment

5. WHO WILL KNOW?

A statement describing how confidentiality will be maintained

6. IS THERE COMPENSATION?

For greater-than-minimal risk studies, compensation and/or medical treatment

7. WHO IS THE CONTACT?

Contact information for questions or more information

8. IS IT MANDATORY?

A statement that participation is voluntary

9. WHAT HAPPENS AFTER?

A statement about what will be done with collected information

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What the Key Information Section Is

- **The first thing your participant sees during the Informed Consent process**
- **Should include the most crucial information needed to decide on participation**
- **It is NOT a summary**
- **It does NOT have all elements of the Informed Consent**
- **It does NOT include exclusion criteria***
- **It does NOT have to look identical to our template**

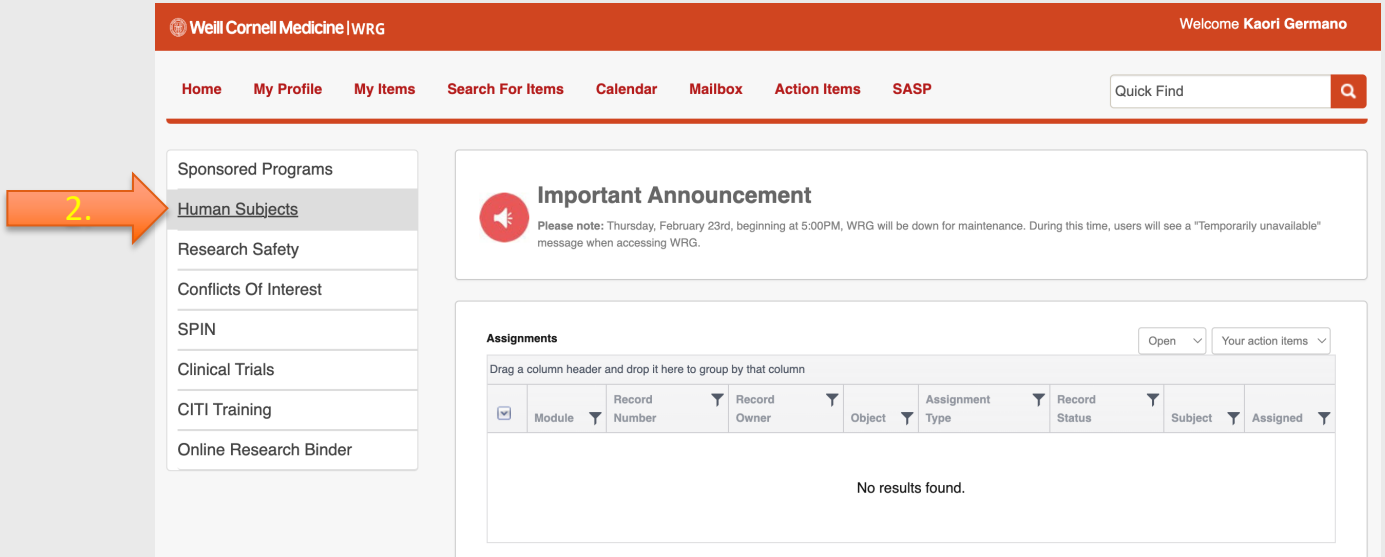
For more on Informed Consent, watch:

☑ Other Documents

- **Letters of Support**
- **Other IRB Approvals**
- **Data Transfer Agreements**
- **Certificates of Confidentiality**
- **Assent Document**
- **HIPAA Authorization**
- **Recruitment Materials**
- **Surveys/questionnaires/data collection tools/interview scripts/questions**

4. Submit an IRB Intake

1. Log in to the Weill Research Gateway with your CWID and password
2. Click the **Human Subjects** link in the left navigation menu



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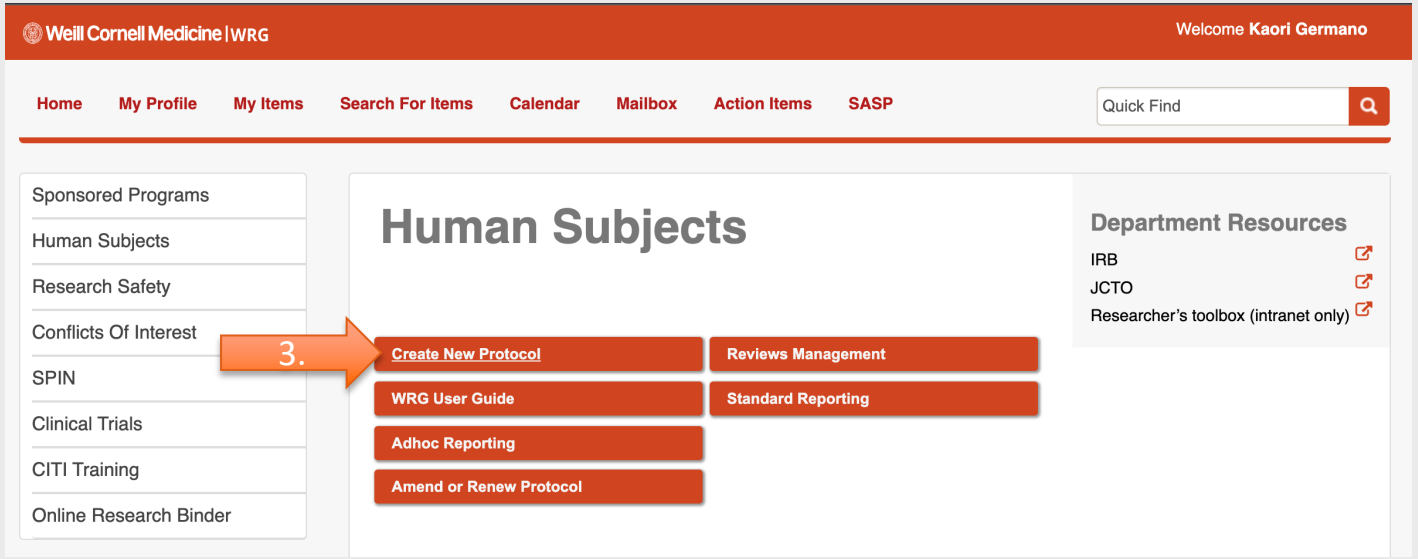
See *"HowTo: Submit an Intake Form (Study Activation)"* on ITS site

4. Submit an IRB Intake

3. Click the **Create New Protocol** button



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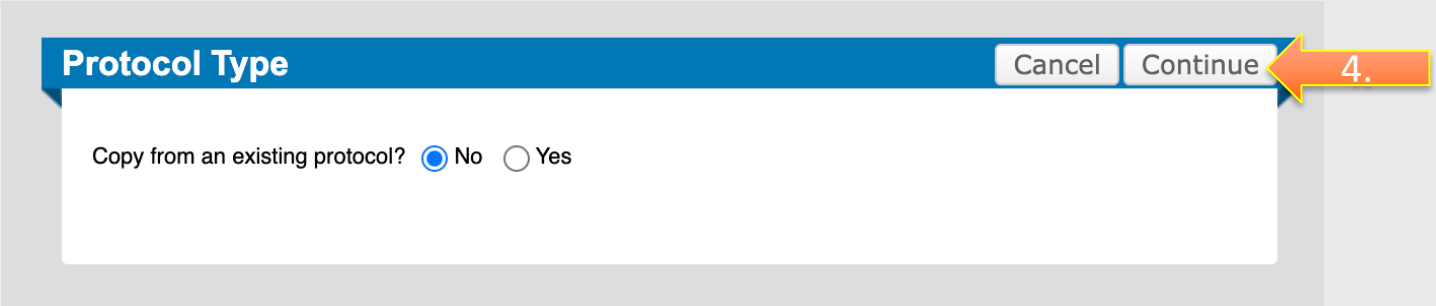
See *"HowTo: Submit an Intake Form (Study Activation)"* on ITS site

4. Submit an IRB Intake

4. Copy from Existing Protocol should default to **No.** Keep that as is and click **Continue**.



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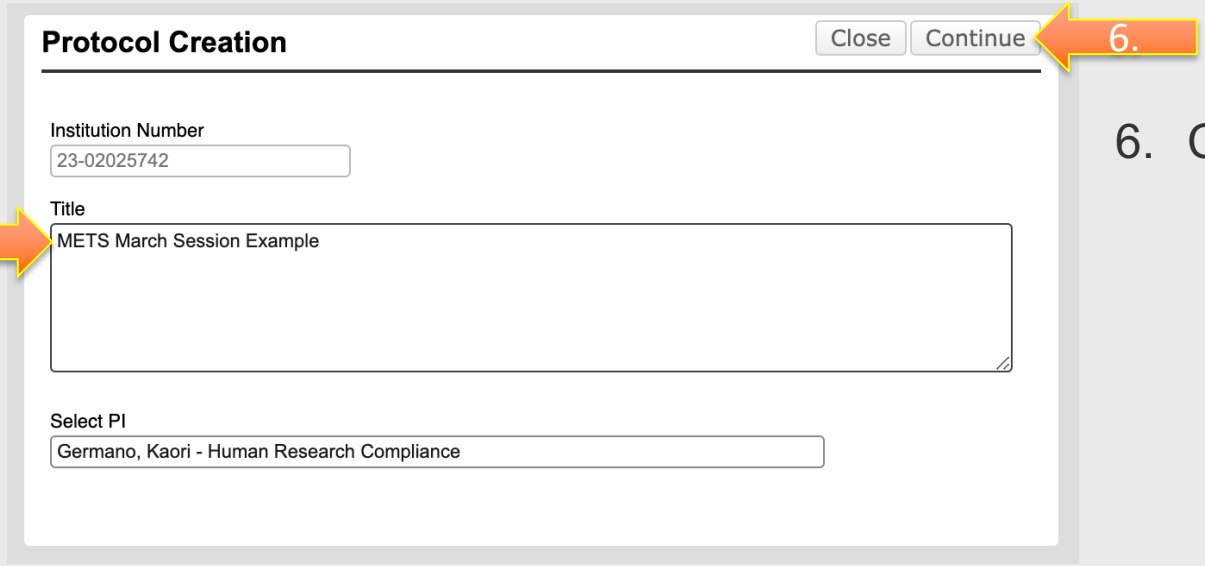
See *"HowTo: Submit an Intake Form (Study Activation)"* on ITS site

4. Submit an IRB Intake

5. Enter a **Title** for this protocol. The Title should match the name of your study.



6. Click continue.

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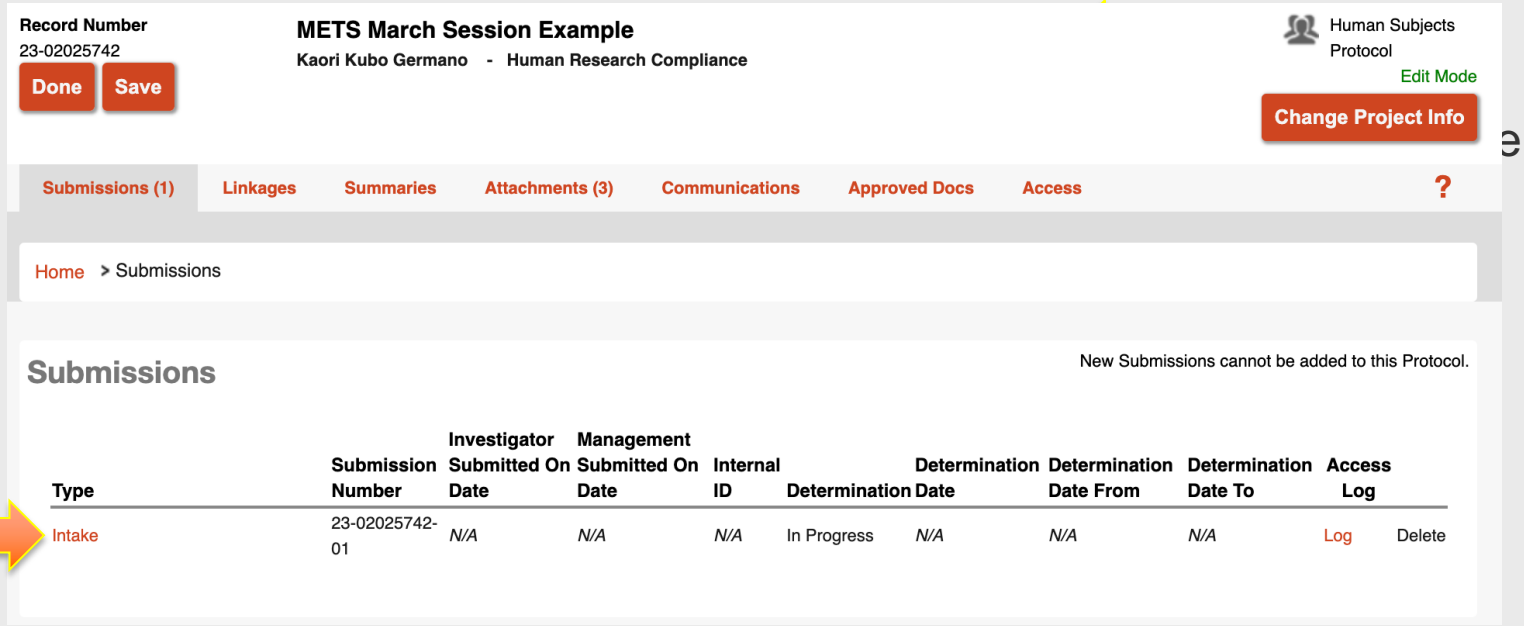
See *"HowTo: Submit an Intake Form (Study Activation)"* on ITS site

4. Submit an IRB Intake

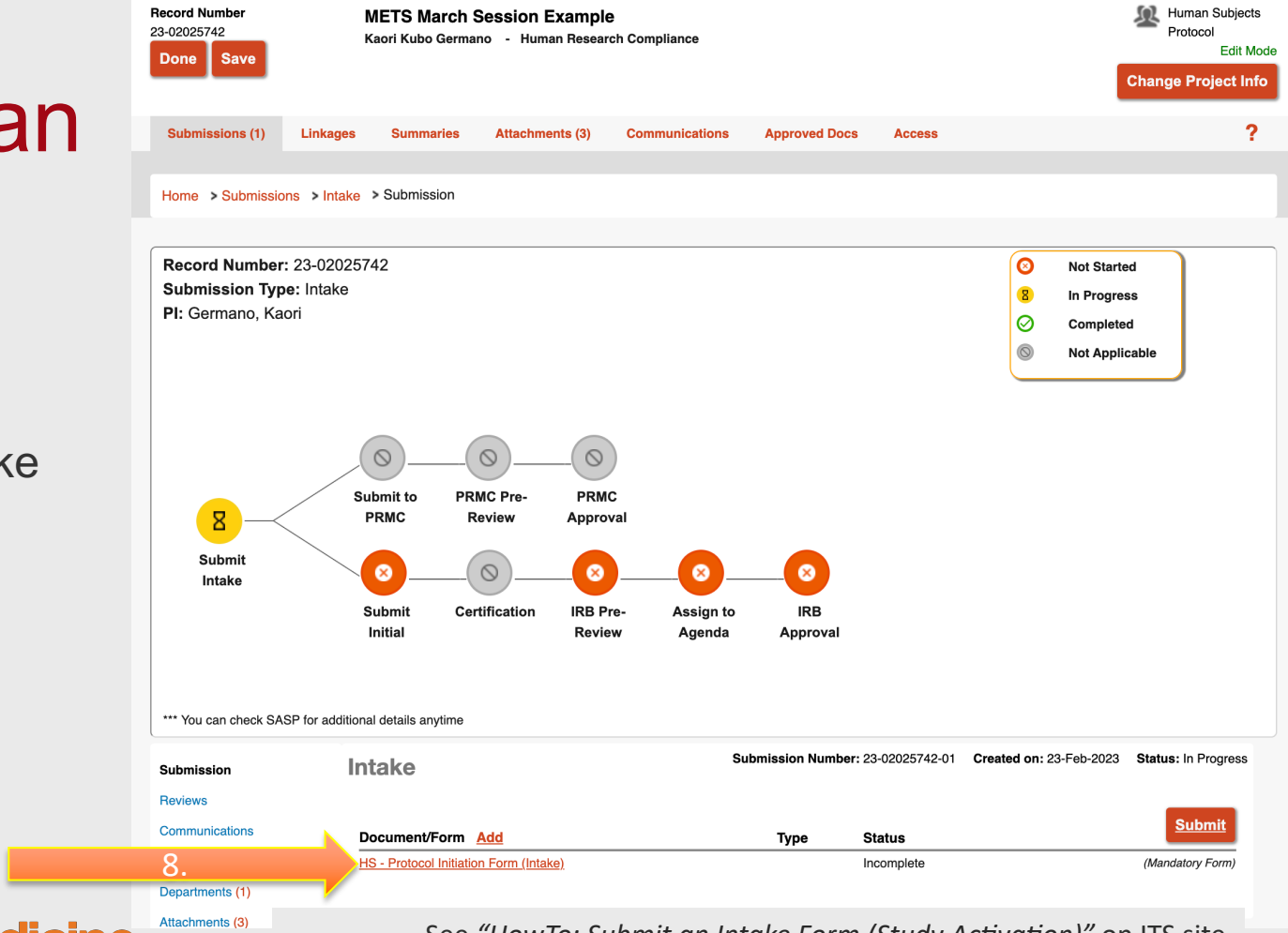
7. Click the **Intake** form



See *"HowTo: Submit an Intake Form (Study Activation)"* on ITS site

4. Submit an IRB Intake

8. Click on the Intake Form



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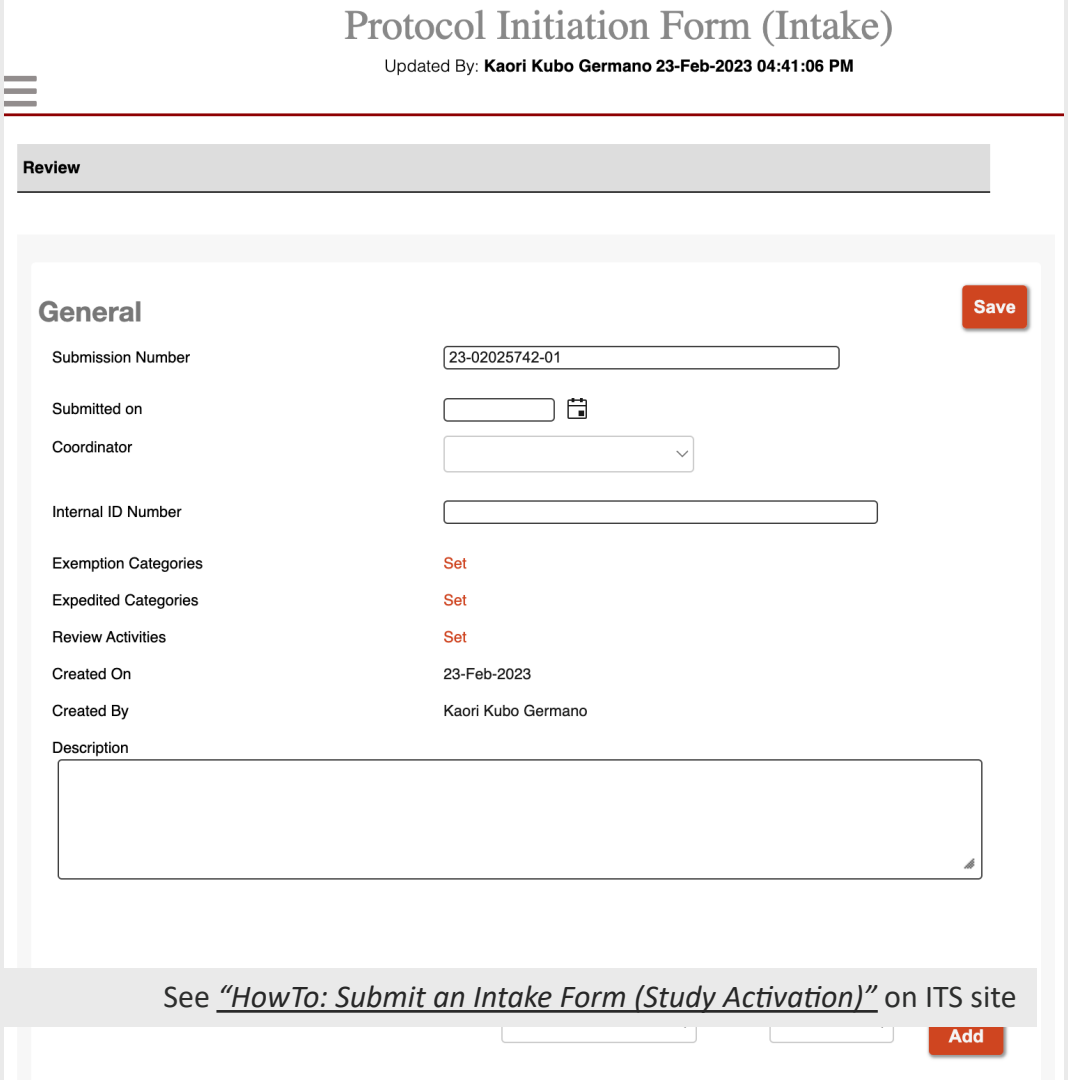
See *"HowTo: Submit an Intake Form (Study Activation)"* on ITS site

4. Submit an IRB Intake

9. Answer all questions



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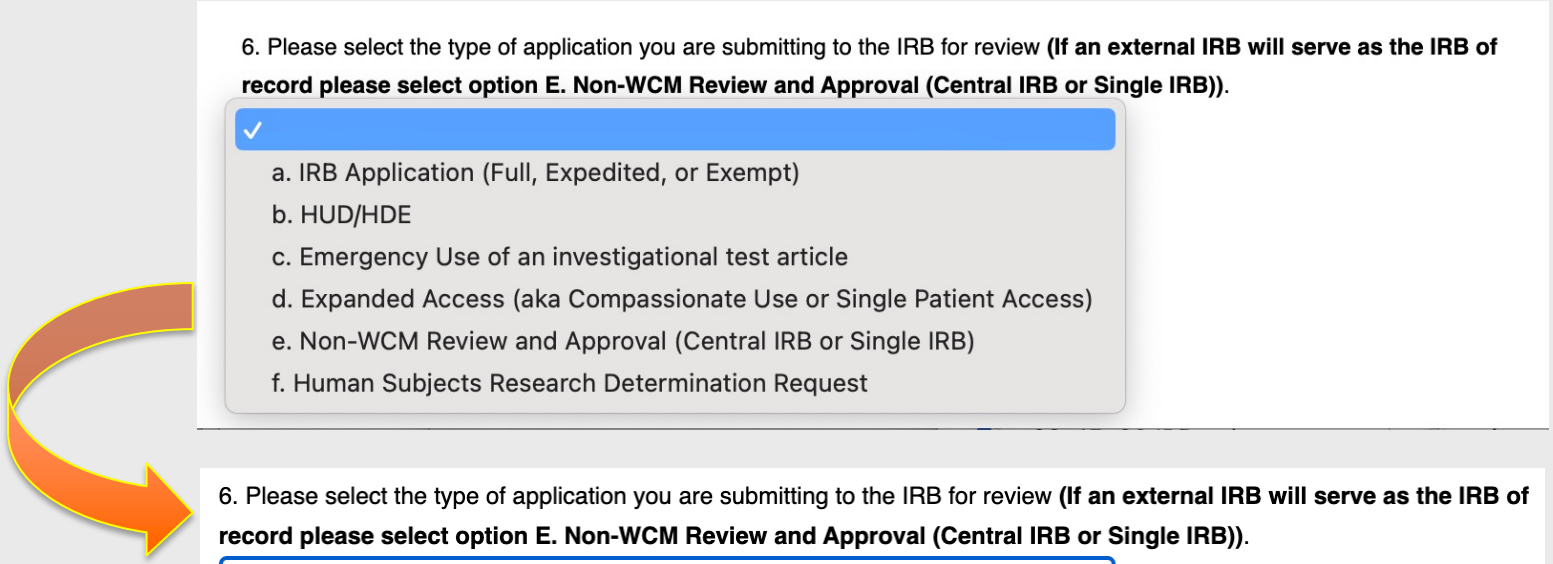
See *"HowTo: Submit an Intake Form (Study Activation)"* on ITS site

4. Submit an IRB Intake



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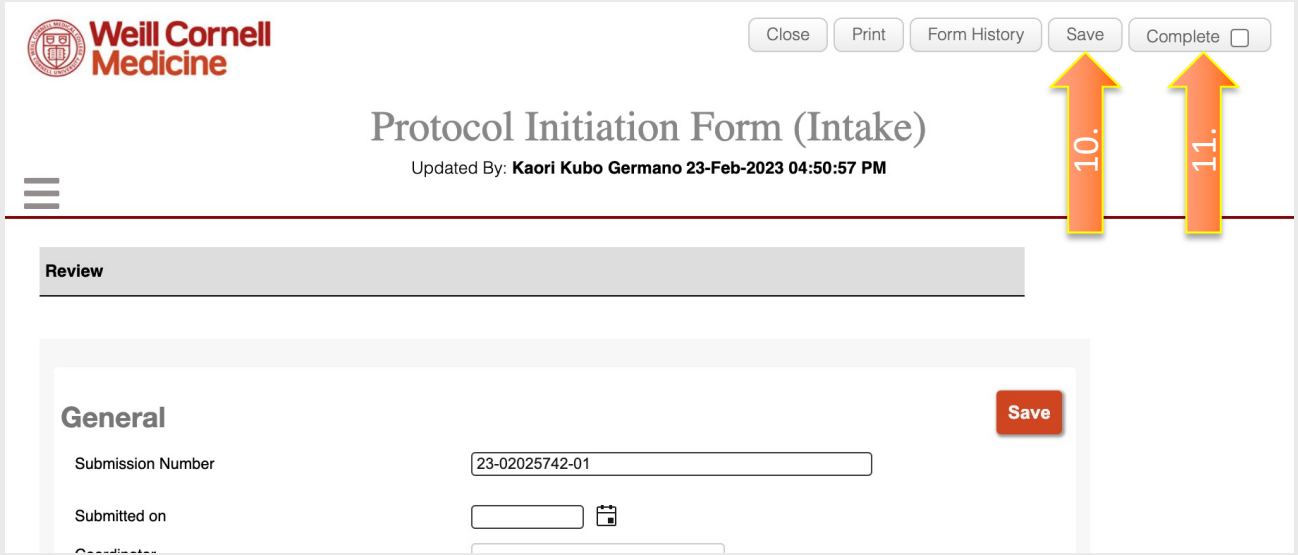
See *"HowTo: Submit an Intake Form (Study Activation)"* on ITS site

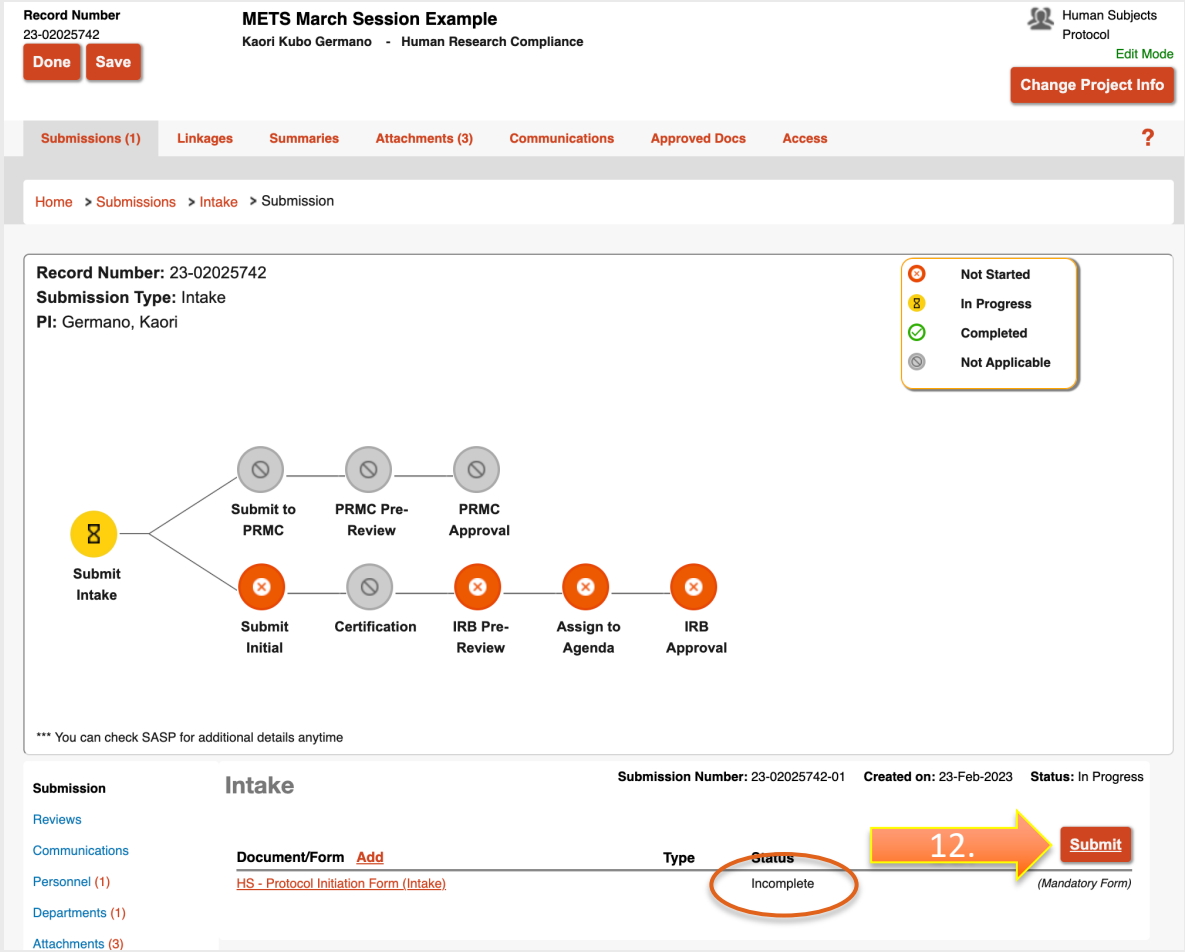
4. Submit an IRB Intake

10. When you've answered all questions, click the **Save** button
11. Then the **Complete** button, both of which are at the top of the page.



4. Submit an IRB Intake

12. Back on this page the status will now read, **Complete;** click **Submit**



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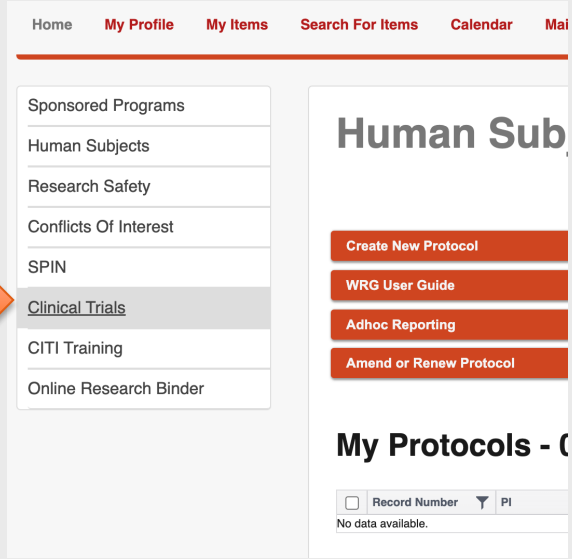
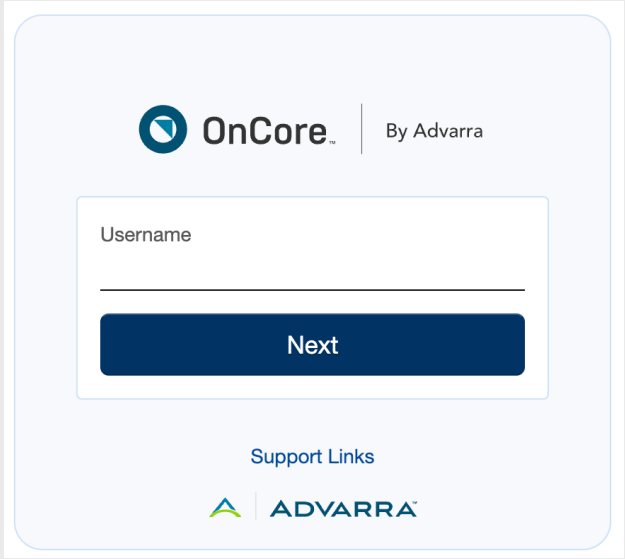
5. Submit a PRMC Application





For step-by-step instructions visit JCTO's Navigating the PRMC page

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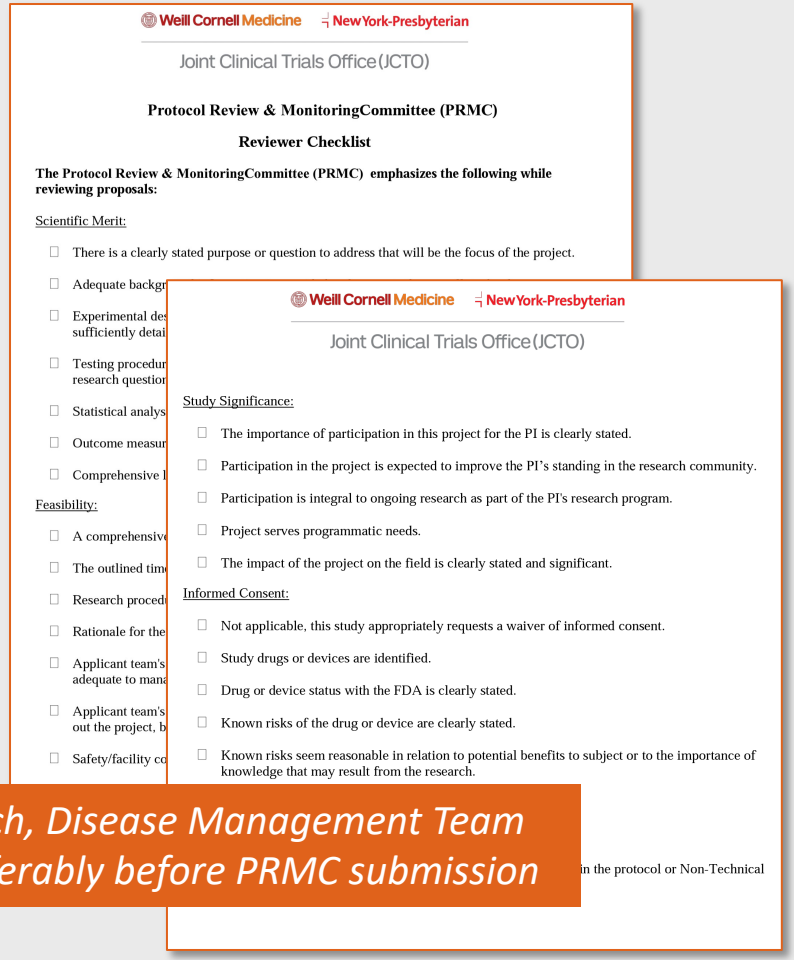
About the PRMC

- **Independent of the IRB**
  - Obtain PRMC approval *prior to* submitting to the IRB
- **For inquiries:**
  - General PRMC: generalprmc@med.cornell.edu
  - Cancer PRMC: cancerprmc@med.cornell.edu
- **90-day submission clock begins at initial intake**



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Joint Clinical Trials Office (JCTO)

Protocol Review & MonitoringCommittee (PRMC)

Reviewer Checklist

The Protocol Review & MonitoringCommittee (PRMC) emphasizes the following while reviewing proposals:

Scientific Merit:

- ☐ There is a clearly stated purpose or question to address that will be the focus of the project.
- ☐ Adequate backgr
- ☐ Experimental des sufficiently detai
- ☐ Testing procedur research questior
- ☐ Statistical analys
- ☐ Outcome measur
- ☐ Comprehensive l

Feasibility:

- ☐ A comprehensive
- ☐ The outlined tim
- ☐ Research proced
- ☐ Rationale for the
- ☐ Applicant team's adequate to mana
- ☐ Applicant team's out the project, b
- ☐ Safety/facility co

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Joint Clinical Trials Office (JCTO)

Study Significance:

- ☐ The importance of participation in this project for the PI is clearly stated.
- ☐ Participation in the project is expected to improve the PI's standing in the research community.
- ☐ Participation is integral to ongoing research as part of the PI's research program.
- ☐ Project serves programmatic needs.
- ☐ The impact of the project on the field is clearly stated and significant.

Informed Consent:

- ☐ Not applicable, this study appropriately requests a waiver of informed consent.
- ☐ Study drugs or devices are identified.
- ☐ Drug or device status with the FDA is clearly stated.
- ☐ Known risks of the drug or device are clearly stated.
- ☐ Known risks seem reasonable in relation to potential benefits to subject or to the importance of knowledge that may result from the research.

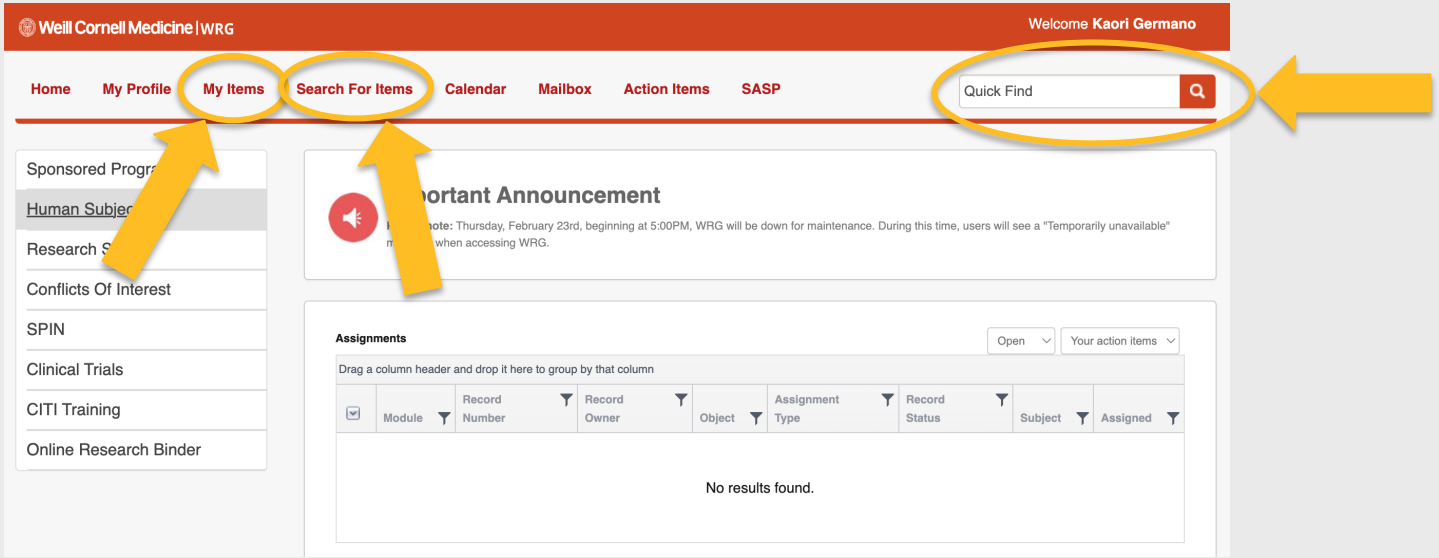
in the protocol or Non-Technical

If the study relates to cancer research, Disease Management Team (DMT) approval is also required, preferably before PRMC submission

6. Submit an Initial Application

Proceed to this step ONLY once PRMC approval has been obtained

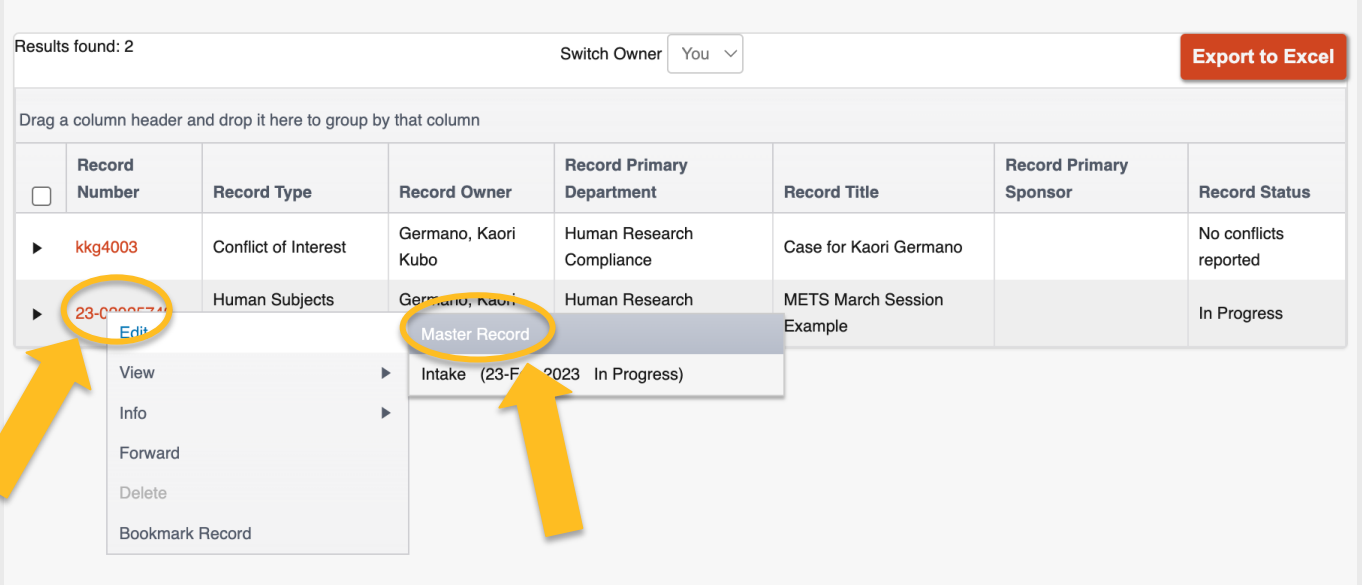
Step I: Locate your protocol



6. Submit an Initial Application

Proceed to this step ONLY once PRMC approval has been obtained

Step I: Locate your protocol



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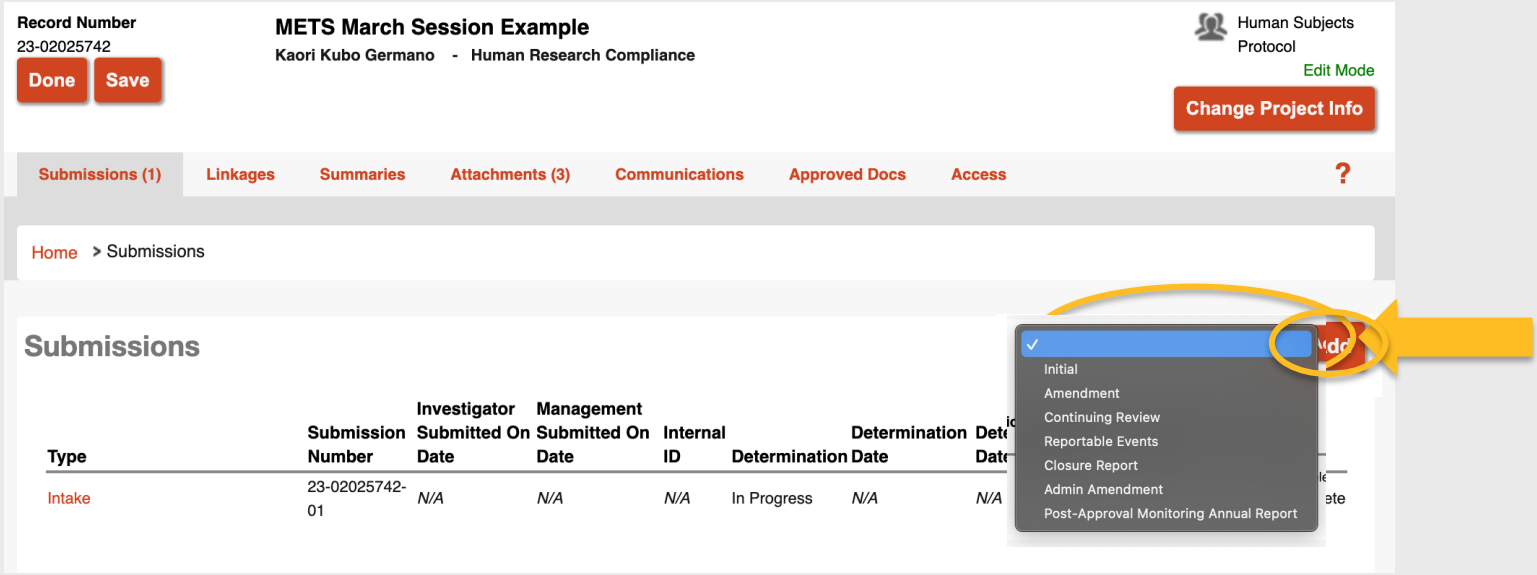
See *"HowTo: Submit Your Initial IRB Application"*** on ITS site

6. Submit an Initial Application

Step II: Add an Initial IRB Application to your Submission Package



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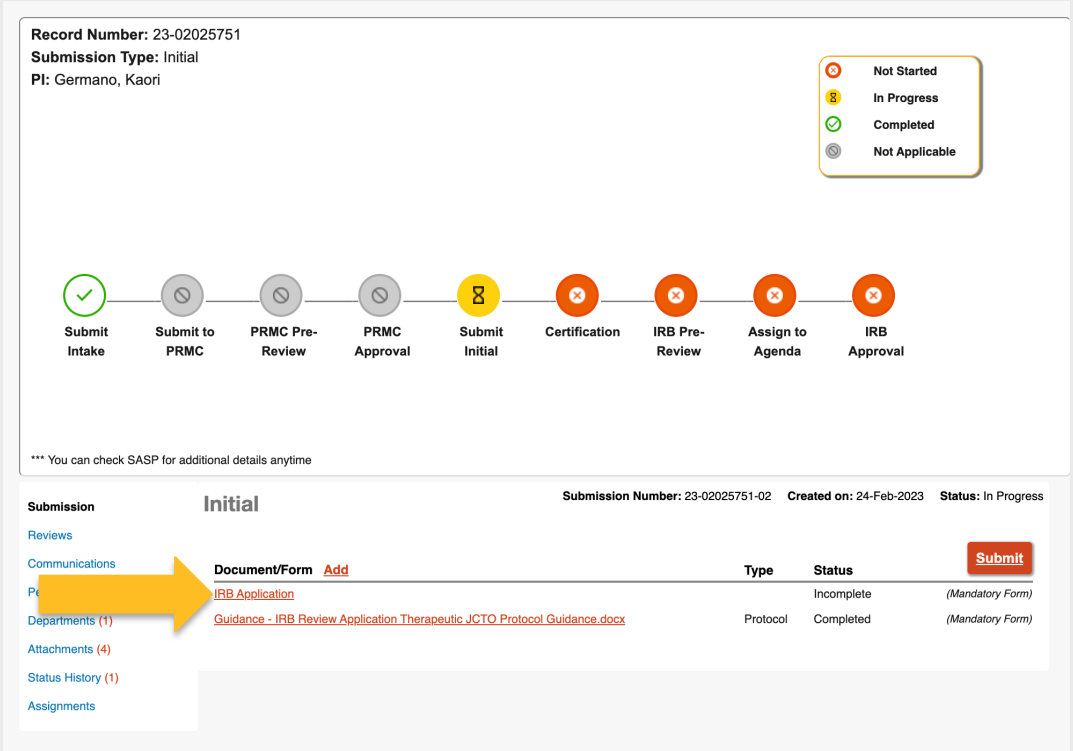
See *"HowTo: Submit Your Initial IRB Application"*** on ITS site

6. Submit an Initial Application

Step III: Fill out and submit your Initial IRB Application



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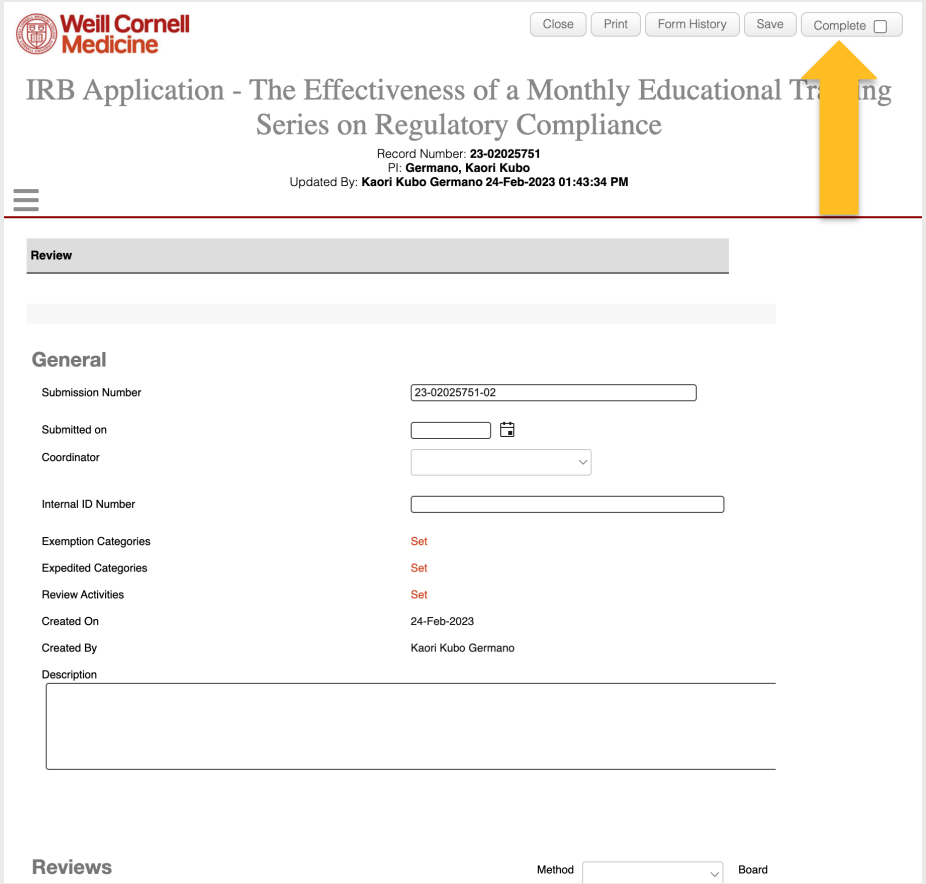

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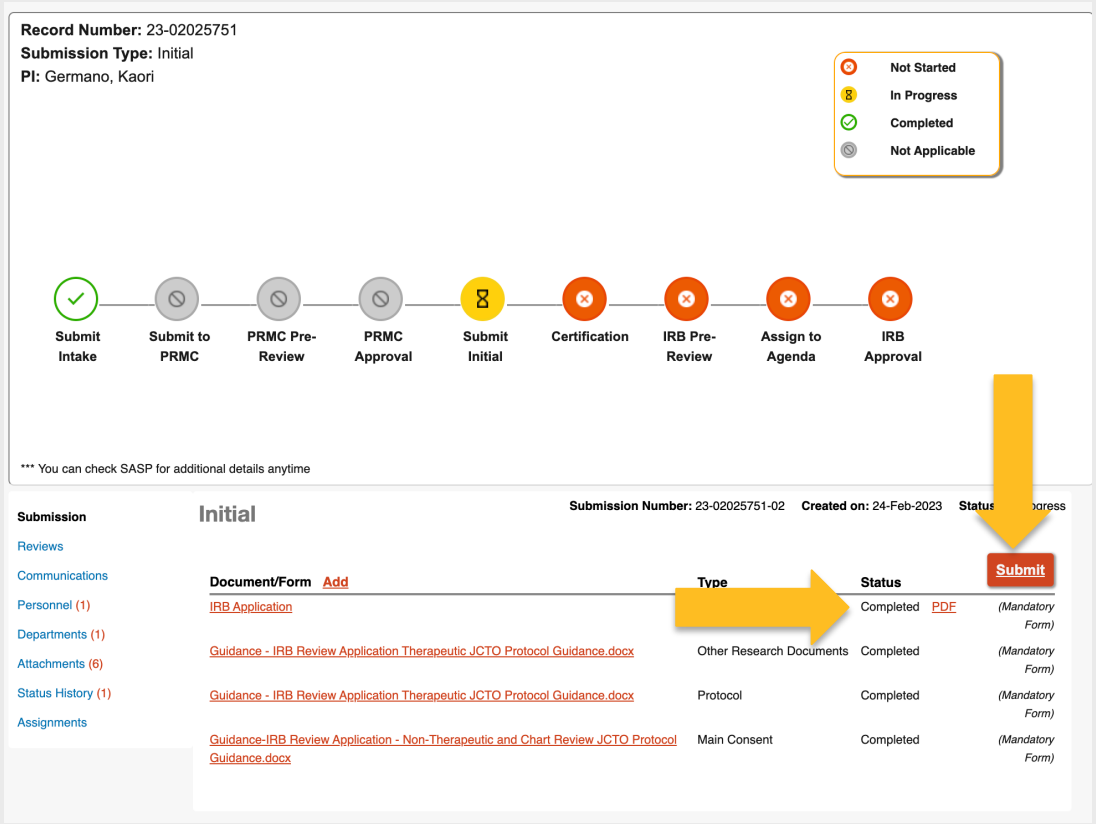

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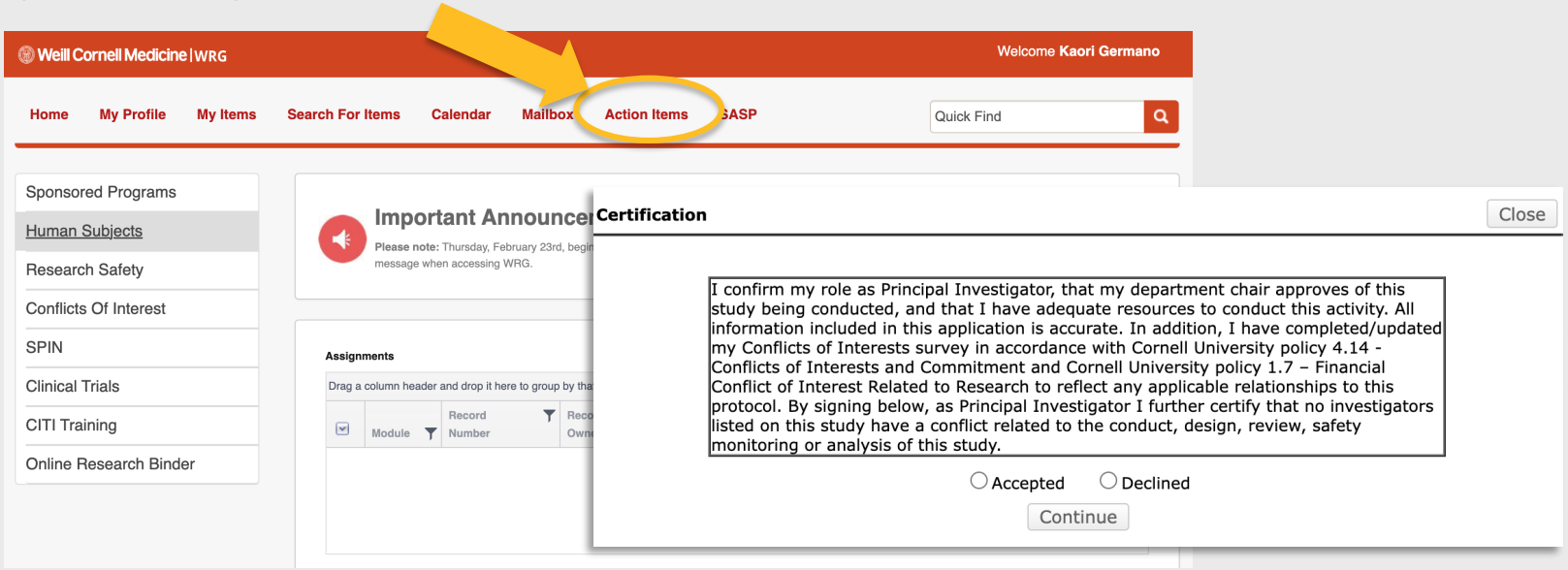
See *"HowTo: Submit Your Initial IRB Application"*** on ITS site

7. Certify Your Application

This is confirmation of the study personnel's agreement to be part of your study!



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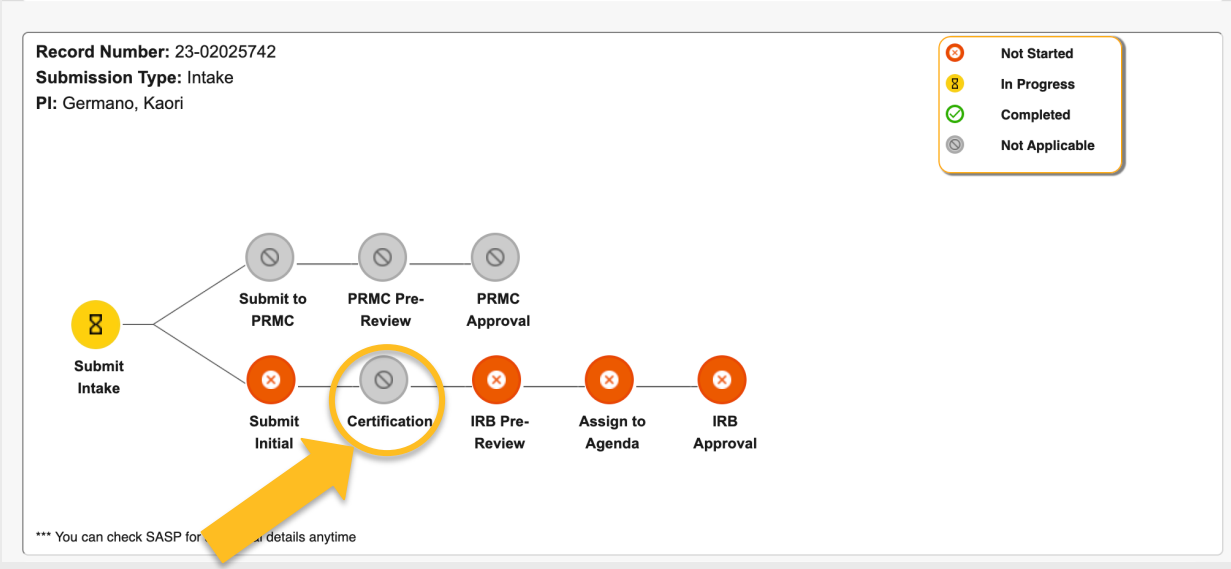
See *"HowTo: Certify on an IRB Application or Other Submission Type"* on ITS site

7. Certify Your Application

Hover over ‘Certification’ to see which certification is missing



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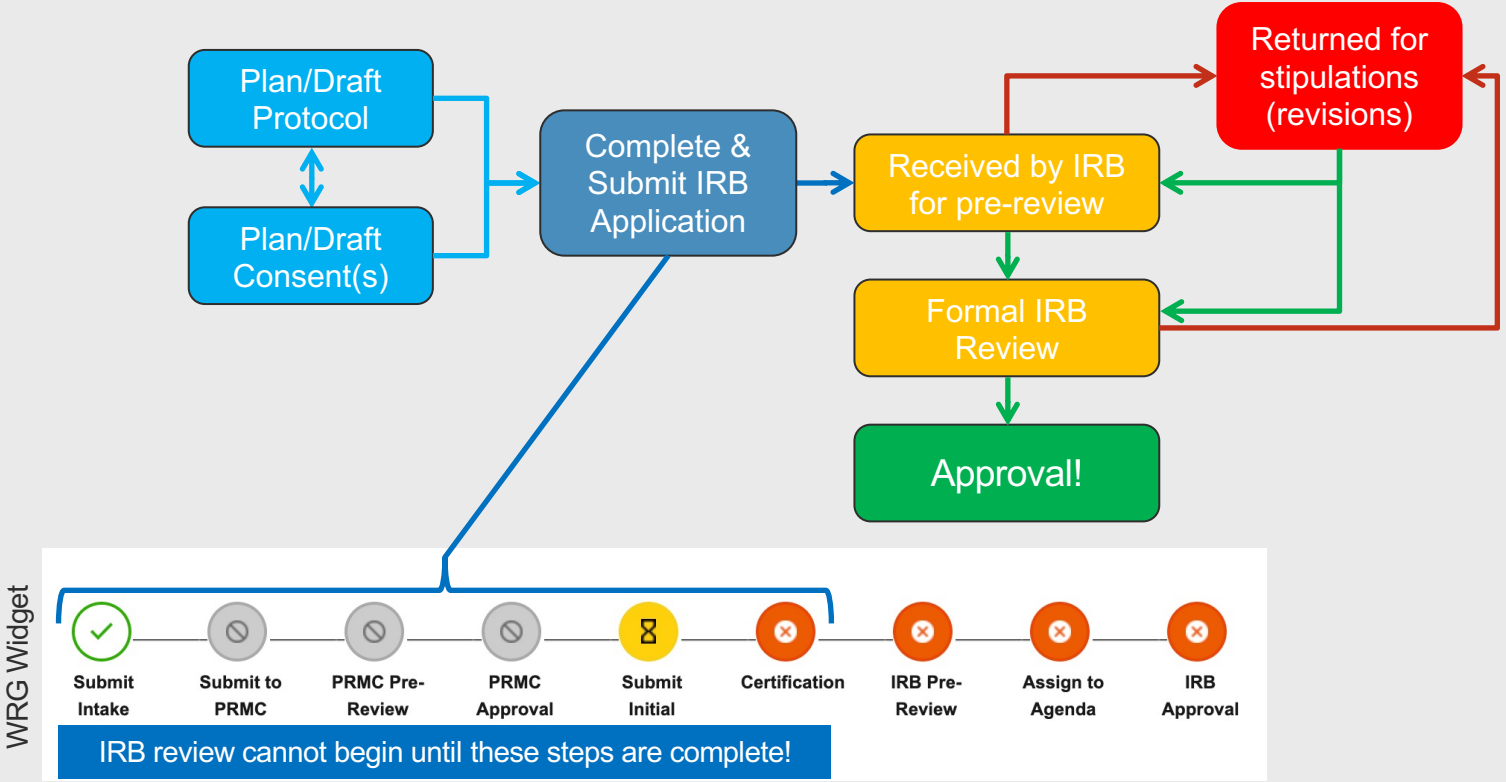
See *“HowTo: Certify on an IRB Application or Other Submission Type”* on ITS site

IRB Review and Decision



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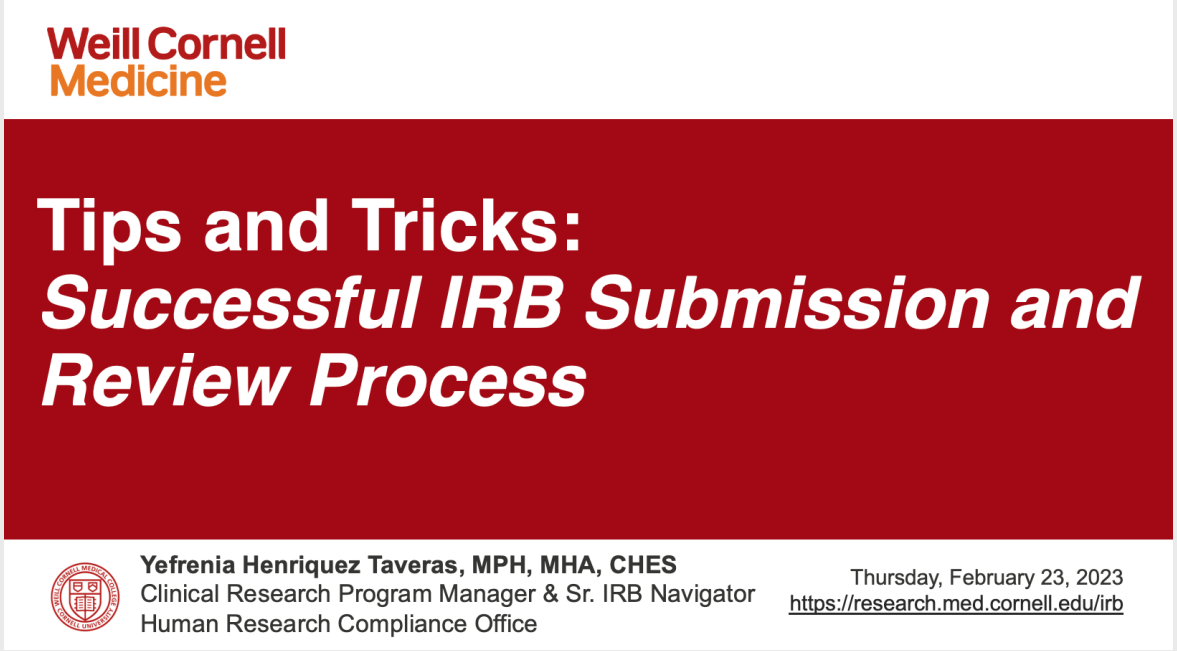
For Tips and Tricks for a Successful Submission, watch:



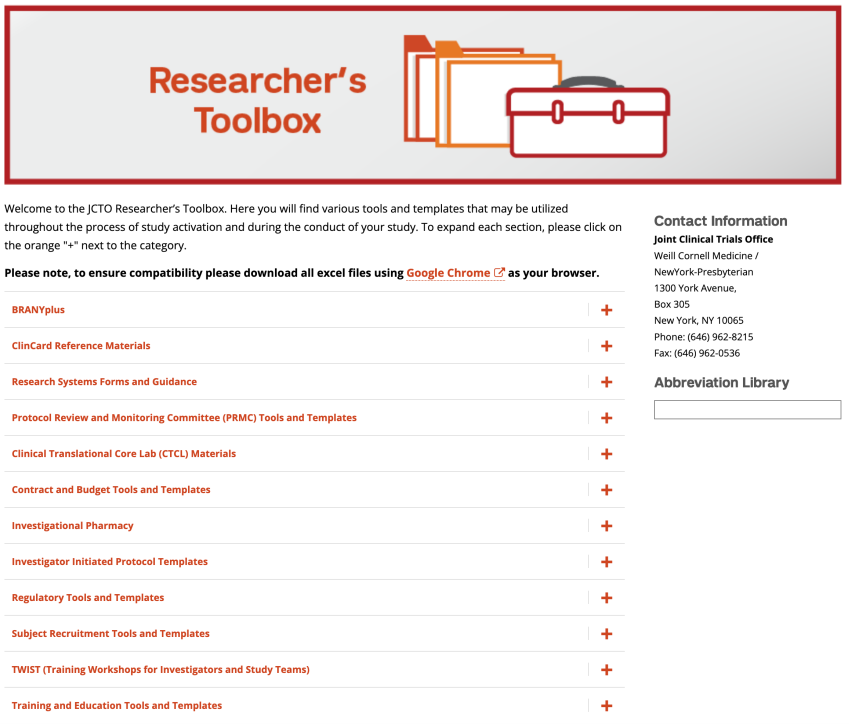
Resources

- **ITS Study Activation Guides**
- **JCTO Researcher's Toolbox**

Study Activation Guides

In order to obtain access to the Human Subjects and Clinical Trials modules, please work with your department to submit a WRG Access Request form. While a few of the videos contained in the course may appear in the articles below, you must complete the coursework in the Learning Management System (LMS) in order to be granted system access.

- Video: Study Activation Process Overview
- How To: Submit an Intake Form
- Overview: The Study Activation Status Page (SASP)
- How To: Submit your Protocol to the PRMC in ePRMS
- How To: Submit your Initial IRB Application
- How To: Approve + Certify on an IRB Application
- How To: Complete Items on your Task Lists
- How To: Submit Study Lifecycle Events (Amendments, Continuing Reviews, etc.)



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Helpful contacts

- *BRANYplus-related questions:* branyplus@med.cornell.edu
- *JCTO-related questions:* *jctooperations@med.cornell.edu*
- *PRMC-related questions*: generalprmc@med.cornell.edu *(non-cancer studies)*; cancerprmc@med.cornell.edu
- *Single IRB/reliance-related questions*: singleirb@med.cornell.edu
- *Oncore, WRG-CT-related questions:* jctoctms@med.cornell.edu
- *WRG-related issues/questions:* wrg-support@med.cornell.edu

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