

The Office for the Protection of Research Subjects (OPRS)

Institutional Review Board (IRB)
Animal Care and Use Committee
(ACUC)

OPRS

- Responsible for the administrative support and institutional oversight of:
 - the IRB
 - the ACUC (Animal Care and Use Committee)
- Processing IRB and ACUC Submissions
- Maintaining institutional policies and records for IRB and ACUC
- Training and education related to human subjects protections and animal welfare requirements

Institutional Review Board (IRB)

- An independent body constituted of medical, scientific, and non-scientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

**Guidelines for Good Clinical Practice
Code of Federal Regulations: ICH Guidelines April 1, 2004**

Who Uses the IRB ?

- Everyone performing clinical research with human subjects at NU or its affiliates
 - Affiliates include: Rehabilitation Institute of Chicago, Jesse Brown VA Medical Center, Northwestern Memorial Hospital, and Northwestern Memorial Faculty Foundation
- The IRB is responsible for reviewing all research studies to ensure adequate human subject protections, which includes ethical concerns and requires scientific validity
- No clinical research can be started or continued at NU without the IRB's approval
- Only IRB-approved consent documents and recruitment materials may be used

What Does The IRB Do ?

– The IRB is responsible for reviewing and approving many of the materials related to the study including:

- Protocols
- Amendments
- Consent form(s)
- Advertisements
- Subject handouts
- Subject payments
- Investigator brochures
- Case report forms
- Continuing (periodic) reviews
- Adverse Events Reports

The 3 Ethical Principles That Guide The IRB Review

- At Northwestern, all human subjects research is required to comply with the ethical principles elaborated in the *Belmont Report* :
 - Respect for Persons
 - Beneficence
 - Justice

Institutional Review Board (IRB)

HIPAA Compliance ✨

- The Health Insurance Portability and Accountability Act (HIPAA) has established standards for safeguarding the privacy of protected health information
- The IRB functions as the Privacy Board for research at Northwestern
- Each covered entity has its own Privacy Officer and its own HIPAA policies and procedures

Institutional Review Board (IRB)

HIPAA Compliance

- NU, Northwestern Memorial Hospital, Rehabilitation Institute of Chicago, and the Northwestern Memorial Faculty Foundation work closely to ally HIPAA policies and procedures for the research community

- For more information on HIPAA research compliance, see:

<http://www.northwestern.edu/research/OPRS/irb/hipaa/>

Ways You Can Use/Disclosure PHI for Research

- Individual HIPAA authorization
- A waiver of authorization (granted by NU IRB)
- De-identified information
- Limited Data Set with Data Use Agreement
- Research on decedents or their information
- Reviews preparatory to research (no PHI taken from medical records)

Feasibility and Recruitment Under HIPAA

- Preparatory to research provisions allow for the review of PHI in medical records in order to ascertain whether there are sufficient numbers of patients to satisfy enrollment requirements (no PHI may be taken)
- Under the Business Use Agreements with RIC, NMFF, and NMH, NU faculty and research staff may (with written permission from a treating clinician or department head and IRB approval for this recruitment strategy), initiate contact with patients for recruitment

What Forms does the IRB Need ?

- New Project Submission Form
- Expedited Review Form (if applicable)
- Radiation Dosimetry Form (if applicable)
 - <http://www.research.northwestern.edu/oprs/irb/forms/>
- Subject Recruitment Form (if applicable)
<http://www.research.northwestern.edu/oprs/irb/forms/docs/subjectrecruitmentmaterial.doc>
- HIPAA Forms
www.northwestern.edu/research/OPRS/irb/hipaa/

eIRB Submission

NU eIRB is here!

Register to begin submitting your studies electronically.



<http://www.research.northwestern.edu/oprs/irb/eirb/>

Required Training for Researchers

- CITI Human Subjects Training Completion dates for all personnel listed on the Authorized Research Personnel List (ARPL)
- Training information available at:
<http://www.research.northwestern.edu/oprs/irb/education/>

Signatures Required on the NPSF

- The principal investigator
- The section chief
- The department chair
- For studies conducted at RIC, NMH, the Cancer Center, the appropriate official for that institution must also sign
- Only original signatures are accepted

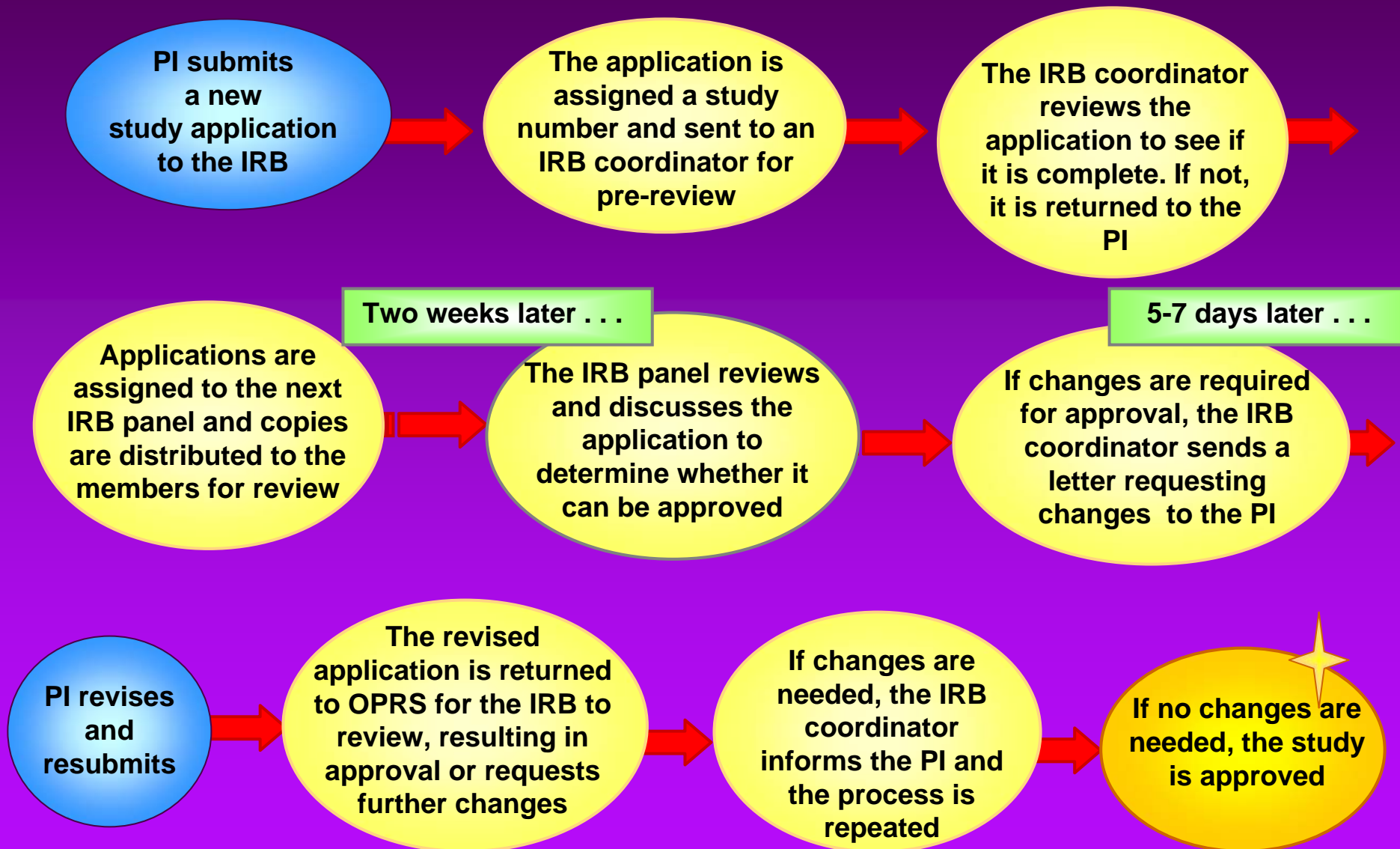
Where to Submit IRB Forms

- The complete packet should be submitted to the front desk of OPRS
7th floor, Rubloff Building
750 N. Lake Shore Drive
- Documents can be mailed via campus mail, but hand delivery is recommended

What Happens to My Application Once it is Submitted to the IRB?

- New submissions are logged into the database
- The NPSF is sent to the pre-review coordinator to verify completeness
- If complete, the project is sent to the next available IRB Panel meeting for review (4 biomedical panels – meet monthly)
- The IRB communicates the results of the review to the investigator:
 - Approval
 - Pending Modifications
 - Deferred
 - No Action
 - Rejected
- If changes are requested by the IRB, the investigator must submit these to OPRS within 45 days

What Happens to Your Application in IRB



How Long Does it Take for the IRB to Approve a New Study?

- The average approval time for a COMPLETE initial application takes 4 to 5 weeks
- The IRB Coordinator notifies the PI the application has been received and is either COMPLETE or INCOMPLETE
- If COMPLETE, submissions are reviewed by an IRB Panel approximately 2 weeks after date of submission
- The IRB coordinator informs the PI of the IRB Panel's determination and/or requests within 1-2 business days after the meeting
- Minor revisions can be approved within 5-7 days after resubmission; major revisions have to wait for a Panel meeting

IRB FAQ's

- Where do I get forms and information regarding the IRB process?
<http://www.research.northwestern.edu/oprs/irb/>
- Download forms directly from the IRB website each time you need them, since the forms are changed or updated regularly. Outdated forms will not be accepted.

Institutional Review Board (IRB)

- Who do I call for questions?
 - Call the main IRB office number at 312-503-9338, and your call will be routed to the correct person
 - You can also ask about the status of a study or submission by emailing the IRB at irb@northwestern.edu
 - Always include the study's IRB number, if you have it.
- IRB Staff Directory
<http://www.research.northwestern.edu/oprs/irb/contact/index.html>

Do you want to serve on the IRB?

The Office of Research is soliciting nominations for faculty service on one of the four biomedical Institutional Review Boards. New members are appointed for three-year terms and meet once per month throughout the year. Nominees should have a record of research experience involving human subjects, and an informed viewpoint on the ethical and humane treatment of human subjects in research.

Nominations should include a brief letter and a curriculum vitae and be sent to:

Dr. Lewis Smith, Associate Vice President for Research

You may also submit your nomination via email to Yvette Freeman at y-freeman@northwestern.edu

If you have any questions, please contact Yvette Freeman - Program Coordinator at (312) 503-2615.