Institutional Review Board Orientation
& IRB Submission Process

Kevin Nellis, MS

Executive Director, Human Research Protections and Quality Assurance

Institutional Review Board (IRB) & Privacy Board

- Protects the rights and welfare of Research Participants (Human Subjects).

- Empowered to approve, require modifications, or disapprove Human Research.

- Ensures Human (Subjects) Research is scientifically/scholastically valid, ethical, and in compliance with all requirements.

- Ensures compliance through oversight functions.

- Serves as a Privacy Board to ensure HIPAA compliance.

Key Events Change the IRB Landscape

1937	1946 - 47	1950 - 60's	1972 - 91	2010's - 20's
Sulfanilamide Elixir Incident	**Nuremberg Trials**	**Thalidomide Tragedy**	**Tuskegee Syphilis Study Exposé**	**Government aims to accelerate research and reduce regulatory burden**
Food, Drug, and Cosmetic Act ('38)	*Nuremburg Code ('47)*	*Drug Amendments added to F,D&C Act ('62)*	*National Research Act ('74)*	*21st Century Cure's Act ('16)*
		FDA Informed consent regulations ('63)	*The Belmont Report ('79)*	*NIH Single IRB Rule (Effective '18)*
			Common Rule ('81)	*Revised Common Rule (Effective '19)*
			Revised CR ('91)	*Single IRB oversight of multi-site studies (Effective '20)*

Q1: Is it Research? (Under the Common Rule)

- A Research Activity is BOTH:

  - A **systematic investigation** (including research development, testing, and evaluation) (i.e., activity that is planned, orderly, methodical, and uses data collection to answer a question)
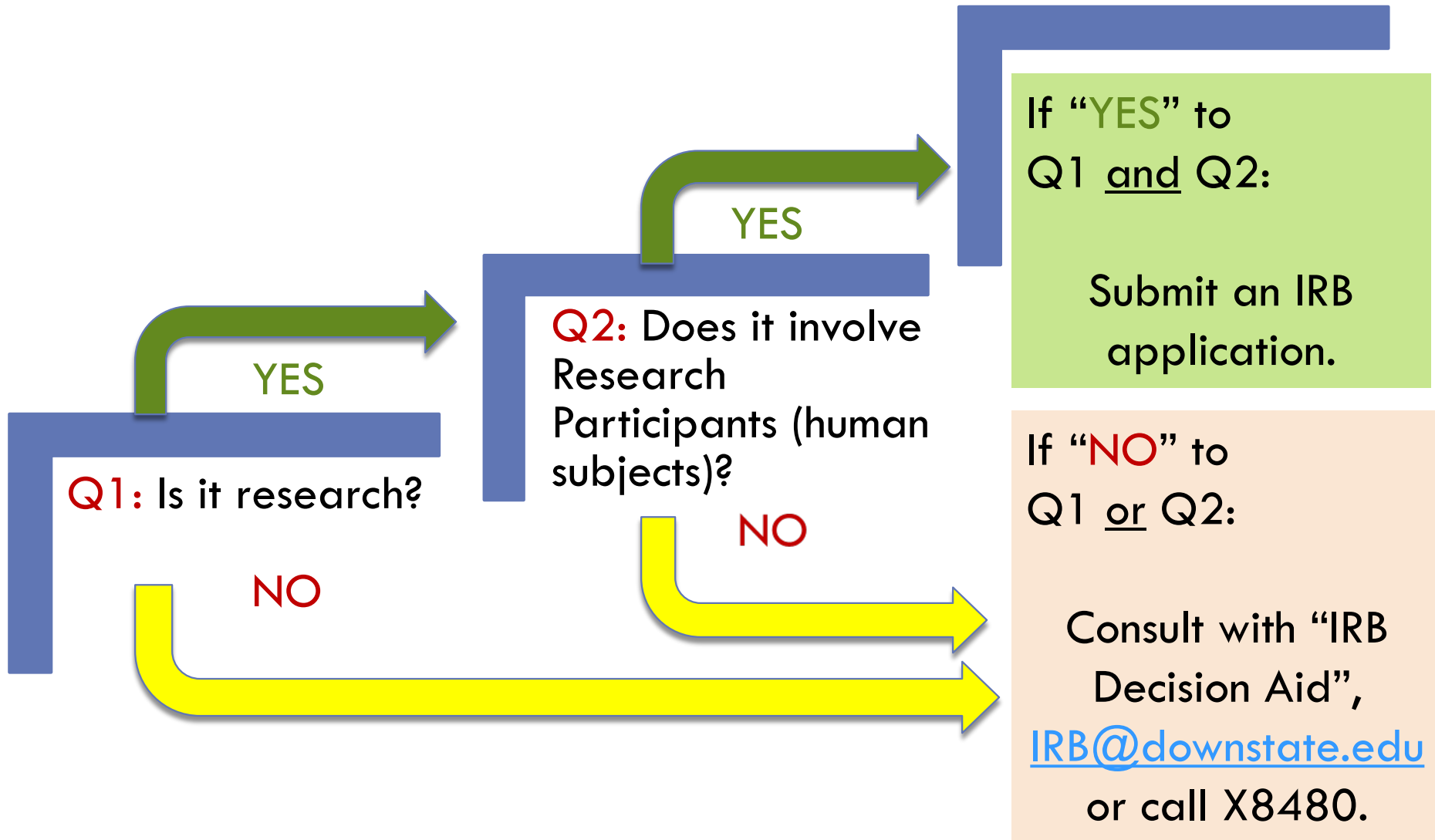
-AND-

  - Designed to develop or contribute to **generalizable knowledge** (i.e., knowledge gained from a study may be applied to populations outside of the specific study population).

Q2: Does it Involve Research Participants (Human Subjects)? (Under the Common Rule)

☐ In order for <u>research</u> to be considered <u>human research</u> (and thus requiring IRB approval before the study begins), the research must involve **living individuals** about whom an investigator (whether professional or student) conducting research either

  ▫ obtains **information or biospecimens** through **intervention or interaction** with the individual, and uses, studies, or analyzes the information or biospecimens; or

  ▫ obtains, uses, studies, analyzes, or generates **identifiable private information <u>or</u> identifiable biospecimens**.

Is IRB Approval Required?

Q1: Is it research?

YES →

Q2: Does it involve Research Participants (human subjects)?

YES →

NO →

NO →

If "YES" to Q1 <u>and</u> Q2:

Submit an IRB application.

If "NO" to Q1 <u>or</u> Q2:

Consult with "IRB Decision Aid", IRB@downstate.edu or call X8480.

Is IRB Approval Required for Performance Improvement Activities?

☐ Does the activity meet the definition of research, including the invent to develop or contribute to generalizable knowledge*?

- If YES, IRB approval is required, if there is an intervention/interaction or it involves identifiable private information or identifiable biospecimens.

- If NO, IRB approval is NOT required

Intent to publish is an insufficient criterion for determining whether a quality improvement activity involves research. Planning to publish an account of a quality improvement project does not necessarily mean that the project fits the definition of research; people seek to publish descriptions of nonresearch activities for a variety of reasons, if they believe others may be interested in learning about those activities. Conversely, a quality improvement project may involve research even if there is no intent to publish the results.

Is IRB Approval Required for Performance Improvement Activities?

Example:

- A Downstate clinic develops a patient satisfaction survey for the intent of improving the quality of their service

- Identifiable patient information is collected

- <u>Without changing intent</u>, clinic staff could
  - Share the results at a conference
  - Publish the results

- Recommend obtaining IRB determination letter stating IRB approval is not required.

Is IRB Approval Required for Case Reports or Case Series?

- Case Reports/Series of up to three (3) individuals <u>do not</u> need IRB approval
  - Such limited activities are generally not considered to be both systematic and generalizable
- Examples:
  - Review records of 3 patients
  - Review records of one patient and ask questions of 2 family members
- May request an IRB Determination letter (may be required by journal or conference)
- Some journals require informed consent/HIPAA Authorization

SUNY DOWNSTATE
Health Sciences University

Search: [   ] Go   Advanced Search
Phone Directory

Office of Research Administration

Administration
ORA Administration

Sponsored Programs
Administration

Finance and
Administration

Clinical Trials

Institutional Review Board

The Institutional Animal
Care and Use Committee
(IACUC)

Office of Technology
Commercialization

Resources
Compliance

SUNY Downstate Health Sciences University
Office of Research Administration

IRB Electronic Submission Process:

Below is a step by step process for preparing and submitting an IRB application along with all related materials to the IRB for approval of human research activities.

The order of these steps is designed for a new investigator and are not meant to be prescriptive and many of the steps can take place in parallel to save time. A more experienced investigator or coordinator who has a good grasp on the IRB process may wish to carry out the steps in a different order.

Note: For more information on whether an activity requires IRB approval, please refer to the Downstate IRB FAQs. To request an IRB determination letter for activities which do not require IRB approval, skip to step 11 (below) and review the information on the IRB Decision Aid form.

> Click here if you looking for a for a specific form, template, policy or guidance document within the steps below...

> STEP 1: Review the Downstate IRB website, policies, and guidance.

> STEP 2: Plan the project.

> STEP 3: Identify a Principal Investigator with "PI Status".

> STEP 4: Determine whether investigators are members of the Downstate workforce.

> STEP 5: Determine which IRB to use and establish any required agreements.

> STEP 6: Complete training and submit conflict of interest disclosures.

> STEP 7: Develop the research protocol.

> STEP 8: Develop consent materials or applicable waivers.

> STEP 9: Develop Short Forms, if applicable.

> STEP 10: Determine if any additional materials are required.

> STEP 11: Determine which IRB Application Form to use for initial review.

> STEP 12: Upload all application materials.

> STEP 13: Obtain Scientific/Scholarly Review, when required.

> STEP 14: Obtain ancillary reviews, when required.

> STEP 15: Obtain Downstate Department Chair or Dean Approval.

> STEP 16: Submit final application in IRBNet.

> STEP 17: Respond to IRB within deadlines.

> STEP 18: Complete requirements for external sites.

> STEP 19: Complete Post-IRB Requirements Before Starting the Research.

> STEP 20: Submit required updates after IRB approval.

IRB menu

Overview

Policies & Guidance

Training & Conflict of Interest

Members and Staff

Full Board Meetings and Deadlines

IRB Electronic Submission Process

Resources

FAQs

IRB Net & CITI Program links

Create IRBNet Account

IRB Net »

Create CITI Account

CITI Investigator Education Certification »

STEP 1: Review the Downstate IRB website, policies, and guidance.

- Review the Downstate IRB website for instructions and details on how to submit an IRB application.

  - https://research.downstate.edu/irb/electronic-submission.html

- Refer to the Policy and Guidance webpage to understand Downstate Policy IRB-01 and other applicable policies and IRB guidance.

  - https://research.downstate.edu/irb/policies.html

STEP 2: Plan the project.

- Start early!

- Conduct a literature search and keep a bibliography of references to include with the protocol.

- Consult with a mentor and other experts in the field, as needed.

- Consult with a biostatistician, as needed.

- More tips available on IRB website.

STEP 3: Identify a Principal Investigator with "PI Status".

- Seasoned investigator with a field-specific terminal degree who is a Faculty Member at Downstate

- Clinician with clinical privileges at NYC H + H, Kings County

- Faculty member under recruitment to Downstate with written approval by a Dean

- Individual approved to be a PI by written memo or e-mail from the Downstate Institutional Official

- Individual who qualifies to be a PI at an external site, when the research makes Downstate engaged. Downstate becomes engaged when:

  - Federal funding or support is provided to Downstate

  - Co-investigators or key personnel on the study are members of the Downstate workforce

STEP 4: Determine whether investigators are members of the Downstate workforce

☐ Understanding whether an Investigator (or Key Personnel) is a member of the "Downstate workforce" will help determine:

- ❏ IRB Training Requirements of Investigators and Key Personnel & Conflict of Interest (COI) Requirements for "Investigators for the Purposes of COI,

- ❏ Whether IRB Reliance Agreement(s) or Individual Investigator Agreement(s) are required, and

- ❏ Which IRB to use.

The Downstate IRB has Oversight of the Downstate Workforce:

- Faculty members, employees, and staff who are paid by Downstate,
- Employees, staff, or contractors paid by the Research Foundation for SUNY, working on behalf of Downstate,
- Individuals with a Downstate Voluntary Faculty appointment <u>with</u> medical privileges (credentialed by University Hospital SUNY Downstate),
- Retired Downstate faculty member with emeritus status (approved by IO & Dean/Department Chair),
- Residents, Fellows, or Medical Students who are sponsored by Downstate
- Students in a Downstate academic program,
- Temporary Employees or SUNY contractors working on behalf of Downstate, or
- Downstate Volunteers (officially approved by the Downstate Volunteer Office).

Individuals who are <u>not</u> members of the Downstate Workforce

- External consultants (e.g., those paid by sponsors or other entities outside of Downstate),

- Individuals with Voluntary Faculty appointments at Downstate <u>without</u> medical privileges, and

- Employees or agents of institutions that are not listed as components of the Downstate's FWA including:
  - University Physicians of Brooklyn (UPB),
  - NYC Health + Hospital, Kings County Hospital,
  - Companies within the Downstate Biotech Park,
  - Other institutions, or
  - Private practices.

STEP 5: Determine which IRB to use …

- Downstate IRB

- External IRBs:

  - Single IRB (sIRB): Federally Funded multi-site research

  - Commercial IRB: Sponsored research

  - NCI Central IRB: Oncology group trials

  - Main site IRB: Institutional IRB

  - Tribal IRB: When required by (tribal) law, typically for research with a focus on American Indians, Alaskan Natives tribes, or indigenous people.

STEP 5: …and establish required agreements, as applicable to the research

- External IRB Reliance Agreement (IRA) -request their form

- SUNY Downstate IRA if external site relies on Downstate IRB
  - This is already in place for UHP, NYC H+H, NYC and some Downstate Incubator Tenants

- Individual Investigator Agreement (IIA) for each external investigator who is not covered by:
  - SUNY Downstate IRA
  - PHS COI management process or training program

- Data Use Agreement (DUA) for limited data sets, when applicable

- Business Use Agreement (BAA) for activities with business associates

- Confidentiality Agreements

- Clinical Trial Agreement or Facilities Use Agreement

STEP 6: Complete training …

- Summary of training requirements:
  - CITI training (Group 1 or Group 2)
  - HIPAA compliance training
  - If applicable:
    - COI & research misconduct training (if PI or other investigator for COI purposes)
    - Dangerous Goods Shipping certification (if involved with shipping specimens, infectious substances, biological or hazardous substances
    - GCP training (if conducting NIH clinical trial or when required by sponsor)
    - Department of Defense training is required (if receiving DoD funding)

STEP 6: … and submit conflict of interest disclosures.

- ☐ Investigators who are determined by the PI to be if investigator for COI purposes, must submit Annual COI disclosures and Transactional Questionnaires for each study.

- ☐ Update their Annual COI disclosure within 30 days of any new significant financial interest (SFI).

- ☐ Management Plans must be established for any SFI.

- ☐ Investigators who are not members of the Downstate workforce must follow their COI disclosure process at their institution and submit their COI adjudication (determination) with the IRB submission or establish IIA.

STEP 7: Develop the research protocol.

- Options:
  - Use the protocol provided by the sponsor.
  - Use template available on Downstate IRB website.
  - Develop your own.

- Caution:
  - Must meet Downstate Data Security requirements.
  - Must be consistent with the funding documents.

STEP 8: Develop consent materials or applicable waivers.

- Review guidance for [Obtaining Legally Effective Informed Consent and HIPAA Research Authorization](#).

- Develop the informed consent templates and related materials or request a waiver, when applicable.

- HIPAA authorizations (or waivers) apply to exempt research involving PHI.

- Include SUNY RF Payment Consent, if:
  - Compensation is $\geq$$600 / calendar year
  - Compensation is over $100 per study visit (unless waived for indirect payments, such as cash, gift/pre-paid cards)

STEP 9: Develop Short Forms, if applicable.

- Review guidance for [Obtaining Legally Effective Informed Consent and HIPAA Research Authorization](#) to determine if Short Forms should be used for the study.

- Short Forms and certificates of translations are available on IRB website

- Written translation of the long form is expected when the research anticipates the enrollment of five or more research participants with limited English proficiency of the same language (e.g., 6 Spanish speaking participants), for: research:

  - Phase 0, 1,1/2, 2, 2a, 2b, or 2/3 Clinical trials which are determined to be greater than minimal risk without any anticipated therapeutic benefit for the research participants

  - Studies which are determined to be a minor increase over minimal risk, when there is no direct benefit to the research participant;

  - Complex clinical trials; or

  - When required by the sponsor.

- Interpreter and Witness signs long & short forms

STEP 10: Determine if any additional materials are required.

- Recruitment Materials, Questionnaires, Surveys, Data Collection Tools
- IND study: Investigator Brochure, FDA Form 1572, IND letter
- IDE study: Package Insert, IDE Letter, SR/NSR determination
- For trials following GCP, or when requested: CV/Biosketch
- When requested, credentials of study staff performing clinical interventions
- When requested: Contract with Sponsor
  - IRB may need to confirm consistency of informed consent language regarding compensation for injuries, additional costs, GDPR disclosures, data security requirements, or other information.
- HIPAA Preparatory to Research Certification Form.

STEP 11: Determine which IRB Application Form to use for initial review.

- IRB Application Forms are posted in IRB Website

- Website includes guidance on which form to use

- IRB is in the process of converting to PDF fillable forms

  - Download Adobe Reader DC, if needed

  - Update your software, if needed

Types of IRB Applications

- Most Common:
  - Exempt
  - Expedited or Full Board
  - External IRB Oversight
  - IRB Decision Aid
- Other Types:
  - Clinical Use of a Humanitarian Use Device (HUD)
  - Expanded Access (Investigational Drug/Biologic for Treatment Use)
  - Honest Broker Agreement (used with other applications)

Exemption Categories
(Revision effective January 2019)

1) Normal educational practices in established educational settings

2) Educational tests, surveys, interviews, or observation of public behavior

3) Benign behavioral interventions with adults with prospective agreement

4) Secondary research for which consent is not required (includes retrospective chart reviews with HIPAA waiver)

5) Federal research and demonstration projects

6) Taste and food quality evaluation and consumer acceptance studies

Expedited Review of Some Studies That Are No Greater Than Minimal Risk

- Clinical studies of drugs and medical devices only under specific conditions (no IND or IDE)
- Chart reviews (Consider Exemption #4, if PHI involved)
- Survey research (Consider Exemption #2)
- Collection of blood samples
- Biological specimens obtained by non-invasive means
- Collection of data through non-invasive means
- Materials collected solely for non-research purposes (Consider Exemption #4)
- Collection of data from voice, video, etc. (Consider Exemption #2 and/or #3)
- Research employing surveys, focus groups, etc. (Consider Exemption #2)

Examples of Full Board Review

- Studies involving greater than minimal risk

- Clinical Trials involving IND, IDE, or HUD

- Humanitarian Use Device (HUD) for clinical purpose

- Expanded Access (Drug/Biologic for Treatment Use)

- Initial review of research that meets the criteria for "expedited review" category #1 or #2:

  - If it involves biomedical interventions with children, pregnant women, neonates, prisoners, or cognitively impaired adults, or

  - If referred by the expedited reviewer

General External IRB Oversight Process

STEP 1: Initiate Reliance Request:

- On file: BRANY IRB, NCI CIRB, & SMART IRB Network (711 sites)

- Others with approval of Downstate IO

- Downstate IRB clarifies local research requirements for the external IRB

STEP 2 (Optional): Pre-Activation/Pre-Review of materials by Downstate IRB

STEP 3: Obtain External IRB approval of Downstate workforce

STEP 4: Activation by Downstate IRB:

- Confirms all local research requirements are met

- Acknowledges External IRB approval

- Downstate reserves the right to request amendments or make recommendations

STEP 5: Follow all applicable policies

IRB Decision Aid – Application for a Determination that IRB Approval is Not required

- Use FORM A when <u>Downstate is not engaged</u> in human research.
- Use FORM A when there is <u>no intention of developing or creating generalizable knowledge</u>, and the proposed activity is limited to one of the following:
  - Health care operations activity (e.g., performance improvement),
  - Case report or case series (up to three individuals)
  - Operational activity,
  - Pilot activity, feasibility activity, or evidence-based practice activity,
  - Training or educational activity, or

IRB Decision Aid – Application for a Determination that IRB Approval is Not required

- Use FORMB B for <u>any</u> request, such as:
  - Any activity described for Form 4A above, particularly if the activity also includes other activities like those listed below,
  - Secondary data or materials (data collected for another purpose) which has been de-identified,
  - Use of data or specimens from deceased individuals
  - Specimens or commercial cell lines that cannot be linked to an individual by the investigator,
  - De-identified or coded materials,
  - Use of a limited data set under a Data Use Agreement,
  - Preparatory to research activities,
  - Referring others from Downstate to a new study,
  - Pilot activity, feasibility activity, or evidence-based practice that does not involve human research as defined in Policy IRB-01, or
  - Training or educational activity that does not involve human research as defined in Policy IRB-01.

STEP 12: Upload all application materials.

☐ Create Username and Password to use IRBNet

☐ Refer to IRB guidance on how to create a new project in IRBNet

☐ Add all documents to the package

☐ Complete the IRBNet registration form (Start Wizard)

☐ OPTIONAL: If desired, share with IRB Administrator to request Pre-Review for any additional feedback

IRBNet™

Submission Manager
Agendas and Minutes
My Projects
Create New Project
🚩 My Reminders (16045)

Other Tools
Track Training (41) (337)
Forms and Templates
Library Manager

Project Information

Create a New Project

To create a new project, first provide the basic project information below. Once your project is created you may attach project documentation and share the project with other users.

Research Institution: * SUNY Downstate Medical Center, Brooklyn, NY ⌄

Title: * IRB Demo

Local Principal Investigator:
First Name:* Kevin
Last Name:* Nellis   **Degree(s):** MS

Keywords: Onclogy Treatment XYZ Phase 2b

Sponsor: ABC Inc

You may specify an internal account number, billing identifier or reference number for this project.

Internal Reference Number: ABC Inc XYZ123

[Continue]   [Cancel]

* required fields

IRBNet™

Designer

Welcome to IRBNet Kevin Nellis

Submission Manager
Agendas and Minutes
My Projects
Create New Project

🏳 My Reminders (16046)

Project Administration

Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Project History

🔔 Messages & Alerts

Other Tools

Track Training (41) (337)
Forms and Templates
Library Manager

[1566379] IRB Demo

Package: ▼ 1566379-1   Work in progress (Not submitted)

| 📝 | *Click to add a package description or notes.* |

Step 1: | Hide Form Libraries |

Download blank forms, document templates and reference materials to assist you in assembling your document package.

Select a Library: SUNY Downstate Medical Center IRB Office, Brooklyn, NY ⌄

Select a Document: IRB Update Memo 2.11.2020.pdf ⌄   Download

Step 2:

Assemble your document package here. You can add new project documents, revise existing project documents while maintaining version history, and link your project team's Training & Credentials to your package. | Learn more |

Documents in this Package:

Document Type ▲	Description	Last Modified	
▼ Consent Form	TEMPLATE Informed Consent All-in-One Version 07.10.2019.docx	02/14/2020 04:36 PM	📄 🗐 ✏ ✖
▼ Application Form	ApplicationforExternalIRBOversight 11.25.2019 fillable.pdf	02/14/2020 04:35 PM	📄 🗐 ✏ ✖

There are no Training & Credentials records linked to this package. | Link / Un-Link Training Records |

Start a Wizard   OR   Attach New Document   (When should I do this?)

STEP 13: Obtain Scientific/Scholarly Review when required.

- Scientific/Scholarly Review (SR) is required prior to IRB approval of the following types of research projects:
  - Downstate Full Board Applications, and
  - Downstate Expedited Review Applications that qualify for research reviewed under categories (1A) or (1B) (e.g., studies involving a drug, biologic, or medical device).
- Share the submission and request electronic signature in IRBNet

STEP 14: Obtain ancillary reviews, when required.

- □ UHB Pathology Laboratories Services

- □ Institutional Biosafety Committee (IBC)

- □ NIH Novel and Exceptional Technology and Research Advisory Committee (NExTRAC)

- □ Downstate Research Pharmacy

- □ Others, if requested by IRB

STEP 15: Obtain Downstate Department Chair or Dean Approval.

- Department Chair of Dean must approve application

  - Each area needs to approve the study

  - Share the submission and request electronic signature in IRBNet

- Chair/Dean may delegate to another person via "Delegation of e-Signature Form"

STEP 16: Submit final application in IRBNet.

USER PROFILE   LOGOUT

IRBNet™

Welcome to IRBNet
Kevin Nellis

Submission Manager
Agendas and Minutes
My Projects
Create New Project
🚩 My Reminders (16057)

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Project History
🔔 Messages & Alerts

Other Tools
Track Training (41) (339)
Forms and Templates
Library Manager

Submit Package

[1566379-1] IRB Demo

IRBNet supports multiple models of review. Using the "Submit" feature, you may electronically submit this document package to either a single Board, or to multiple Boards. Each Board you submit to will be notified of your submission and given access to view your electronic documents. Each Board will also be permitted to electronically record their review decision, which will be stored as a permanent part of your project record. You will be automatically notified when the review decision is electronically recorded.

Please select a Board:

Search for an Organization	[ ]	Search	Clear

☑ Only show My Default Boards

Select a Board *

SUNY Downstate Medical Center IRB Office, Brooklyn, NY

Continue   Cancel

* required fields

STEP 17: Respond to IRB Within Deadlines.

- "Unlocked" package in IRBNet by IRB:

  - Revise materials when requested

  - Lock package and mark revisions complete

- "Modifications Letter" published by IRB:

  - Submit follow-up package in IRBNet

  - Include point by point response cover letter

- CAUTION: Automatically withdrawn by IRB if response is not timely; however, PI may request more time if needed.

STEP 18: Complete requirements for external sites.

- NYC H+H, Kings County:
  - Follow policies of NYC H+H and Downstate
  - Submit IRB approval in System to Track and Approve Research (STAR).
  - Site Principal Investigator must be a full-time, part-time or voluntary physician who is a member of the Medical Staff at Kings County and who has appropriate clinical privileges
- Other external sites:
  - Follow policies of both the external site and Downstate
  - Follow requirements of IRA and/or IIA

STEP 19: Complete Post-IRB Requirements Before Starting the Research

- Upon approval by the IRB, the study team should do the following:
  - Review the IRB approval letter for accuracy and appropriate determinations.
  - Check the approval date and expiration date in letter and approved documents (consent, recruitment materials, etc.). An expiration date is NOT needed for recruitment materials
  - Contact the IRB if there are any discrepancies, errors, or questions.
  - Share applicable documents with sponsor.
  - File documents in study binder.
  - Ensure the study meets Applicable Clinical Trial Requirements of the FDA, within the required deadlines.
  - Understand and ensure the requirements of sponsor.
  - Understand reporting requirements to the IRB, sponsor, and FDA.
  - Do not use laboratory reports from research laboratories for diagnosis, treatment and prevention of disease, unless the research laboratory is properly certified or accredited.
- Finalize clinical trail agreements, facilities use agreements, with Sponsored Programs Administration, as applicable for the study
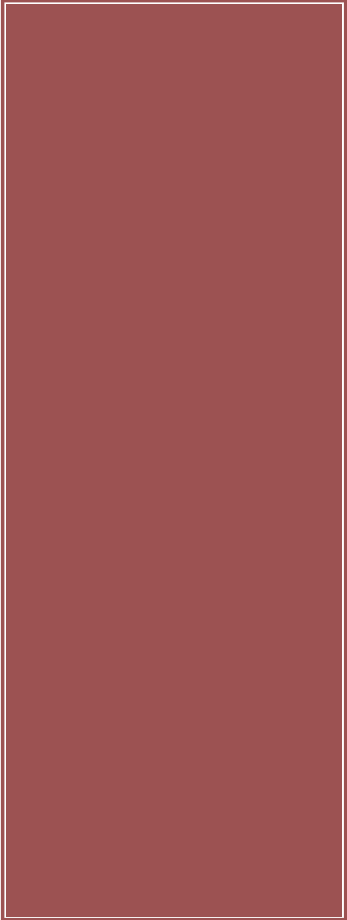- Complete any required ancillary reviews that are still pending approval.

STEP 20: Submit required updates after IRB approval.

- Acknowledgement

- Reportable Events

- Amendment (2 TYPES)

    - Staff Changes Only

    - All other changes

- Continuing Review (3 OPTIONS)

    - Abbreviated forms for External IRB or HUD for Clinical Use

- Check-In Report (for studies with 3 year approval periods)

- Final Report (Study Closure)

Reportable Events

- Government Inspections (or audit)
- Privacy or Information (Data) Security Violation (Breach)
- Incarceration of a research participant
- Any FDA Action or Changes to HUD
- Unanticipated Serious Adverse Event
- Research related Injury involving provision of healthcare
- Apparent non-compliance (including serious or continuing non-compliance)
- New information that indicates a change to the risks or potential benefits of the project
- Significant new finding
- Changes to eliminate an apparent immediate hazard

- Termination or suspension
- Administrative or enrollment hold
- Local unanticipated problem involving risks to participants or others
- Unexpected Adverse Event
- Audit or Monitor activities
- Unanticipated adverse device effect
- Interim Analysis report or DSMB report
- Adverse Event, external event, or other sponsored required reporting

Summary

- Submit IRB applications online using IRBNet

  - Initial IRB approvals

  - Required updates

- Follow instructions, policies, and guidance on IRB website

- Call or visit the IRB Office for help

IRB Contacts

Clinton Brown, MD, IRB Chair	(718) 270-1729
Stanley Friedman, MD, Vice Chair	(718) 270-1335
Jeannette Jakus, MD, Vice Chair	(718) 270-1229
Kevin L. Nellis, MS, CIP, Executive Director, Human Research Protection & Quality Assurance	(718) 613-8461
Diann Johnson, MPH, Associate IRB Administrator	(718) 270-4341
Nikol Celestine, BA, CIP, IRB Management Analyst	(718) 270-4411
Nakih Gonzales, IRB Assistant	(718) 270-4372
IRB Office (BSB 3-26) IRB@downstate.edu Appointments recommended; walk-ins welcome	(718) 613-8480

Additional Contacts

[Office of Compliance and Audit Services](#) (Privacy Officer, HIPAA, Compliance Training, Audits, Internal Controls, Clinical Reimbursements, Financial Conflict of Interest Committee)	(718) 270-4033
[Igor Gorelik](#), Information Security Officer	(718) 613-8593 (929) 359-0401
[Sponsored Programs Administration](#) (Contracts, Grant Review, Submission, and Management)	(718) 270-2680
[Finance and Administration](#) (Financial Analysis, HR, Payroll, Purchasing)	(718) 270-3027
[Technology Commercialization](#) (Commercialization and IP)	(718) 613-8514
[Michele Follen](#), MD, PhD, MBA, Director of Research and Chair, Facility Research Review Committee (KC)	(718) 613-8401
[Bryce Petty](#), CCRC, Facility Research Coordinator (KC)/STAR contact	(718) 613-8185