IRB MEMBER ORIENTATION

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Executive Director, Human Research Protections and Quality Assurance

Objectives

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1) Understand criteria and considerations for IRB approval of human research activities.
2) Conduct reviews and manage workload in IRBNet.
3) Know where to find additional resources.

Types of IRB Applications

General Types of IRB Applications

http://research.downstate.edu/irb/irb-electronic-submissions.html

There are two (2) versions of the IRB Exempt application. Use the DOJ/DIJ version for research funded by DOJ/DIJ.
NOTE: The applicable exemption categories are described on each form.

A. **NEW** Application for Exempt Review **(version 12.17.2018)** • This form includes new expanded exemption categories under the revised Common Rule, effective 1.21.2019.	**A.NEW:** "Application for Exempt Review." **(version 12.17.2018)**
B. DOJ/DIJ Application for Exempt Review - DOJ/DIJ Funded Research Only **(version 12.21.2018)** • Use this form now for DOJ funded research now. DOJ has not a signatory to the revised Common Rule.	**B. DOJ/DIJ:** "Application for Exempt Review - DOJ/DIJ Funded Research Only." **(version 12.21.2018)**
Expedited Review or Convened (Full) IRB Review ***Note: The criteria for expedited review can be viewed on the OHRP web site, by clicking here.*** • There is just one form for both types of review. • The IRB will make the final determination as to the type of review performed. • Submit Full Board studies by designated deadline for the meeting.	"Application for Expedited or Full Review" **(Posted 12.17.2018)**
External IRB Review (some multi-site research)	"Application for External IRB Oversight" **(Posted 12.17.2018)** ***Note: Please share the following with the External IRB:*** *Guidance: Local Research Context for External IRB.* **(Updated 12.21.2018)**
Use of a Humanitarian Use Device (HUD) for clinical purposes **(Including external IRB review of a multi-site activity)**	"Application for HUD for Clinical Purposes" **(Posted 12.19.2018)**
Expanded Access to Investigational Drug/Biologic For Treatment Use **(Including external IRB review of a multi-site activity)**	"Application for IRB Approval of Expanded Access to Investigational Drug/Biologic for Treatment Use" **(Posted 12.17.2018)**

Considerations for IRB Approval of Exempt Studies

Exemption Categories*

1) Normal educational practices in established educational settings

2)** Educational tests, surveys, interviews, or observation of public behavior – unless identified & sensitive

3) Benign behavioral interventions

4) Secondary research uses of data or specimens

5) Evaluation of public service programs

6) Taste and food quality evaluation and consumer acceptance studies

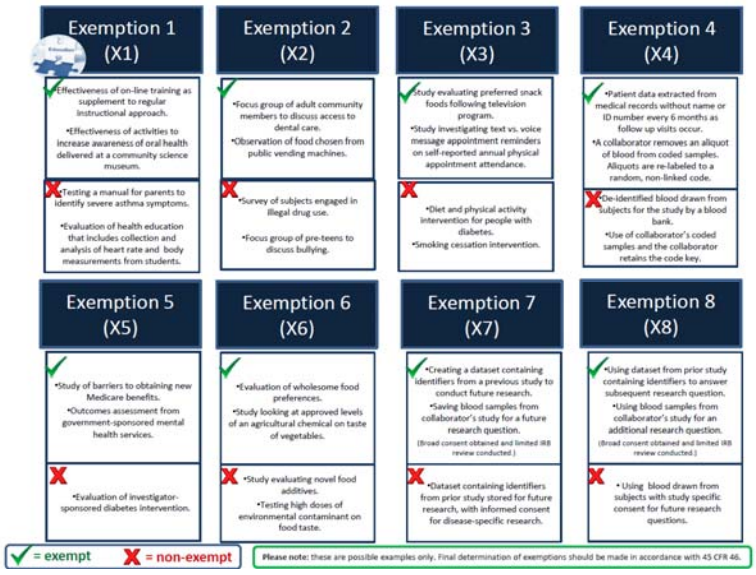
7 & 8) N/A at Downstate

* May include populations that might only incidentally include prisoners.

** Limited applicability with children.

NIH Infographic for Exemptions

NIH guidance: https://nexus.od.nih.gov/all/2019/01/07/nih-implementation-of-the-final-rule-on-the-federal-policy-for-the-protection-of-human-subjects-common-rule/



Exempt Review Considerations

- Studies which are Exempt from Federal Regulations must still meet the requirements of Policy IRB-01.
- HIPAA regulations apply to research involving Protected Health Information (PHI).
  - May need HIPAA waiver or HIPAA Authorization, or another HIPAA instrument, such as BAA or DUA.
- IRB may require information sheet for vulnerable populations.

Criteria and Considerations for IRB Approval of Non-Exempt Studies

IRB Review Checklist & Guidance

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

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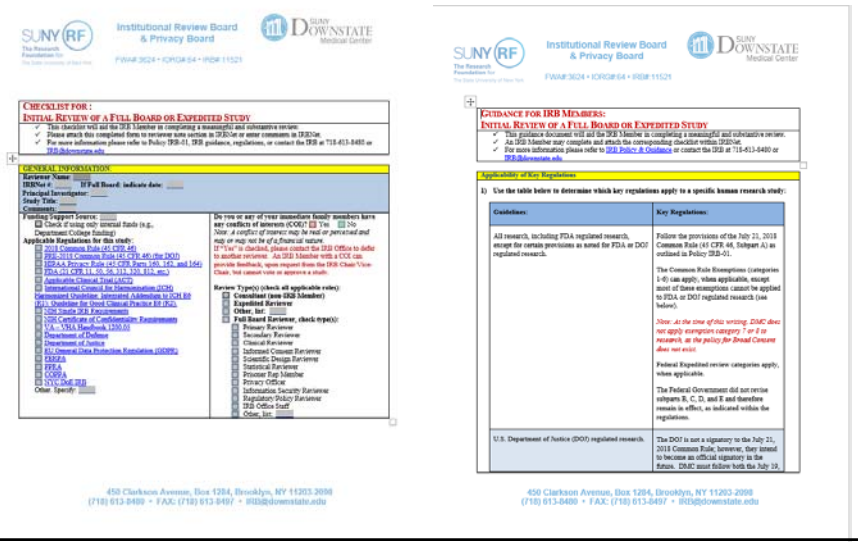

Risk Assessment

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- **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
  - Calibrated to the life of normal, healthy individuals and daily life to be those activities to which most individuals are exposed.
  - IRB may determine some risks constitute greater than minimal risk for populations that are vulnerable by virtue of their condition or circumstances.

Which studies are greater than minimal risk? Why?

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IRB CHALLENGE

A. Survey for individuals with traumatic experiences.
B. A cardiologist enrolls diabetic patients into an exercise study using a weight supported treadmill.
C. A study giving vitamin D3 to children that are scheduled to undergo routine hematopoietic stem cell transplants for AML or ALL. The outcome measures are incidence of GVHD, infection rates, and overall survival.
D. A study for adults includes collecting 2 mls of blood for genetic testing and taking a single chest x-ray.

Examples of Minimal Risk Research Under Expedited Review

- Clinical studies of drugs and medical devices only under specific conditions (IND and IDE not required)
- Chart reviews
- Survey research which is sensitive **and** includes identifiable information
- 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
- Collection of data from voice, video, etc.
- Research employing surveys, focus groups, etc.
- Continuing review under specific conditions
- See: http://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html

Which of the following studies can be reviewed via expedited review? Why?

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IRB CHALLENGE

A. Clinical study that compares the outcomes of thrombotic cardiovascular events when the following FDA approved regimens are used during course of usual care: 1)'Baby aspirin' vs. 2) 'Clopidogrel + aspirin' vs. 3) 'Brilanta + aspirin'.
B. Retrospective chart review of Afro-Caribbean patients with cardiac disease.
C. DNA testing of specimens that currently exist in the pathology clinical archives.
D. Additional special stains performed on bone marrow aspirates that will be obtained in the course of usual care.

Belmont Principles

Principle	Application
Respect for Persons -Protects autonomy -Protect those with diminished autonomy	-Informed Consent, Parent/Legal Guardian Permission, or Legally Authorized Representative - Disclose all information - Ensure comprehension - Ensure voluntariness
Beneficence -Do no harm -Maximize benefits -Minimize risks	-Risk/benefit ratio must be justified
Justice -Equal distribution of benefits and risk	-Equitable selection -Consider recruitment of those with limited English proficiency when there is a therapeutic benefit

Criteria for IRB Approval of (Non-Exempt) Research (111 Findings)

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- Risks to research participants are minimized:
  - By using procedures consistent with sound research design and which do not unnecessarily expose research participants to risk, and
  - When appropriate, use procedures already being performed for diagnostic or treatment purposes
- Risks to the research participants are reasonable in relation to anticipated benefits, if any, to the research participants, and the importance of the knowledge that may reasonably be expected to result from the research

Criteria for IRB Approval of (Non-Exempt) Research (111 Findings)

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- Selection of research participants is equitable;
- Informed consent will be sought (unless waived) from each prospective research participant or their legally authorized representative, and appropriately documented (unless waived);
- Where appropriate, the research plan adequately provides for monitoring the data collected to ensure the safety of research participants;

Criteria for IRB Approval of (Non-Exempt) Research (111 Findings)

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- Where appropriate, there are adequate provisions to protect the privacy of research participants and to maintain the confidentiality of data;
- When some or all of the research participants are vulnerable to coercion or undue influence, additional protections are put in place to protect them;
- Where the study involves vulnerable populations, the research complies with applicable research requirements (subpart findings).

Additional Criteria and Considerations for IRB Approval of (Non-Exempt) Research

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- Follow IRB Guidance or Policy IRB-01, for an extensive list of criteria and considerations.
- When vulnerable populations are included, the IRB must also ensure the research is in compliance with regulations to the extent required by 45 CFR 46, subpart B, C, and D.
- For FDA regulated clinical investigations involving children, ensure compliance with 21 CFR 50, subpart D.
- Each Federal Agency has additional requirements.
- For clinical trials which follow ICH-GCP requirements, the IRB must ensure additional requirements are met. See IRB Guidance for more details.

Categories of Permissible Research Involving Children (see pp 6-7 Review Guidance)

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Categories of permissible research for children	Evaluation	Requirements
Category 404 (45 CFR 46.404 and 21 CFR 50.51)	✓ No greater than minimal risk	✓ Permission of one parent/guardian ✓ Assent
Category 405 (45 CFR 46.405 and 21 CFR 50.52)	✓ Greater than minimal risk ✓ Presents prospect of direct benefit to the individual research participants ✓ The risk is justified by the anticipated benefit to the participants; and ✓ The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.	✓ Same as 404
Category 406 (45 CFR 46.406 and 21 CFR 50.53)	✓ Greater than minimal risk ✓ Minor increase over minimal risk ✓ No prospect of direct benefit to the individual research participants ✓ Likely to yield generalizable knowledge about the research participants' disorder or condition ✓ Intervention/procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations	✓ Permission must be obtained by **both parents (or guardians)**, unless one is deceased, unknown, incompetent or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child ✓ Assent ✓ If children are wards of the state or any other agency, institution, or entity are included, additional requirements of 45 CFR 46.409 must also be met.
Category 407 (45 CFR 46.407 and 21 CFR 50.54)	✓ Research is not otherwise in category 404, 405, or 406, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.	✓ Includes 406 requirements ✓ **OHRP (or by the FDA, if FDA regulated) must also approve the research**

Which category of permissible research applies to each of the following studies?

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IRB CHALLENGE

A. Survey on middle school homework performance
B. Clinical trial to determine best standard of care (SOC) for Super-Refractory Status Epilepticus, where there are three treatment (SOC) arms using FDA approved drugs.
C. Clinical trial to test bioavailability and safety of a new route for an anti-seizure medication. Study is a cross-over study comparing rectal gel to an investigational nasal spray. All subjects have refractory epilepsy, but one cohort does require recent multiple seizures. Thus, some participants might get medication they do not need.
D. Safety and efficacy of pediatric smallpox vaccine in response to the September 11th terrorist attack.

Clinical Trials with Investigational Drug or Biological

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- In general, an IND is required for clinical trials with:
  - Investigational drugs or biologics
  - FDA approved drug/biologic, unless exempt from IND
  - Some studies using endogenous compounds, live organisms, cosmetics dietary supplements, food, food-derived products, spices, herbs, or electronic cigarettes

References:

- FDA Draft Guidance on INDs – Determining Whether Human research Studies Can Be Conducted Without an IND
- FAQs - Clinical Studies Involving Electronic Cigarettes and INDs

*Criteria for IND Exemption

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- Not intended to be reported to FDA;
- Not to support change advertising of FDA approved product;
- Does not involve change in route, dosage, patient population, or other factor that significantly increases the risks of FDA approved drug; and,
- IRB approves study and informed consent

*See full text for IND exemption criteria at 21 CFR 312.2(b)(2)(ii)

Clinical Trials with Investigational Drug or Biological

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- IRB application requirements for studies with IND:
  - IND Letter from FDA or Sponsor
  - FDA Statement of Investigator (Form 1572)
  - Investigator's Brochure

IRB Evaluation of Clinical Investigation with an IND may require… (IRB-01: p 54)

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- Published literature about the chemistry, manufacturing, and control of the drug substance and product;
- A summary of previous human experience with the drug product;
- Sufficient information regarding the source, purity, quality, and method of preparation and delivery of the drug used in the research; and
- Information regarding the pharmacology and toxicity of the drug product in animals.

FDA Reference:
https://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/UCM133768.pdf

Medical Device Studies

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- If study evaluates safety and effectiveness of a medical device, determine first if it meets criteria for IDE exemption at 21 CFR 812.2(c).
  - If no, determine if study is Significant (SR) or Non-Significant (NSR) device study.
  - If SR, an IDE is needed from FDA
- Reference:
  https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126418.pdf

*Criteria for IDE Exemption for a Diagnostic Device

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- Is noninvasive,
- Does not require an invasive sampling procedure that presents significant risk,
- Does not by design or intention introduce energy into a research participant, and
- Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

*See full text for IDE exemption criteria at 21 CFR 812.2(c).

What is a SR Device Study?

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- Medical device is an implant;
- Presents a potential for serious risk to the health, safety, or welfare of a research participant;
- Supports or sustains life;
- Substantially important in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health; or
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a research participant.

Reference: FDA Guidance for SR & NSR Medical Device Studies

What is a NSR Device Study?

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- Medical device study that is not a SR study

Reference: FDA Guidance for SR & NSR Medical Device Studies

Is the following study a SR or NSR study?

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IRB CHALLENGE

Prostatic Artery Embolization (PAE) for Treatment of Benign Prostatic Hyperplasia (BPH)

- Investigational microsphere particles are injected in arteries to block blood supply, leading to death of the prostate
- Risks: Accidental injection of beads into other organs, leading to their death; bleeding; infection; death
- PI is an Interventional Radiologist, who will perform procedure with real time imaging and has done similar standard of care procedures.
- PI claims this is a Non Significant Risk (NSR) Device Study and therefore an IDE is not required from the FDA

Criteria for Informed Consent and/or HIPAA Authorization

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- Informed consent is a "process" not just a form.
- Basic elements required, unless waived.
- Additional elements required when applicable.
- Verify appropriate lines are on form for Names, Signatures, and Dates.
- Review other considerations and recommendations outlined in the IRB Guidance and Policy IRB-01.

Waiver of Informed Consent Requirements (see handout)

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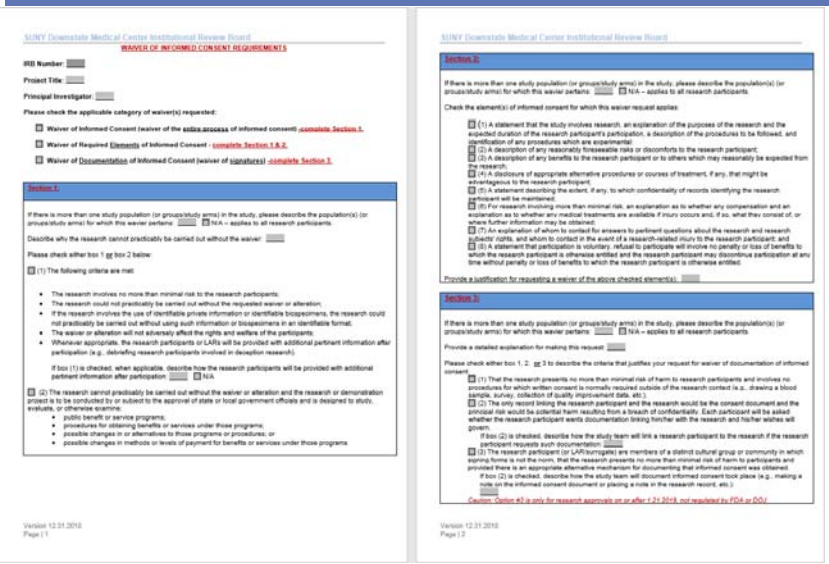

HIPAA Waivers

(see handout)

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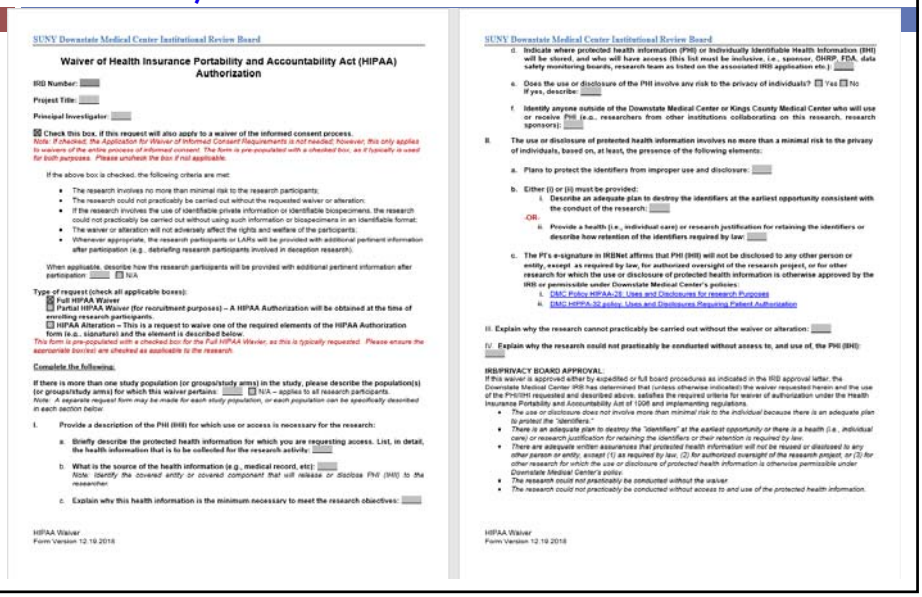

SUNY Downstate Medical Center Institutional Review Board

Waiver of Health Insurance Portability and Accountability Act (HIPAA) Authorization

IRB Number:

Project Title:

Principal Investigator:

☒ Check this box, if this request will also apply to a waiver of the informed consent process.

Note: If checked, the Application for Waiver of Informed Consent Requirements is not needed; however, this only applies to waivers of the entire process of informed consent. The form is pre-populated with a checked box, as it typically is used for both purposes. Please uncheck the box if not applicable.

If the above box is checked, the following criteria are met:

- The research involves no more than minimal risk to the research participants;
- The research could not practicably be carried out without the requested waiver or alteration;
- If the research involves the use of identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the participants;
- Whenever appropriate, the research participants or LARs will be provided with additional pertinent information after participation (e.g., debriefing research participants involved in deception research).

When applicable, describe how the research participants will be provided with additional pertinent information after participation: ☐ N/A

Type of request (check all applicable boxes):

☒ Full HIPAA Waiver

☐ Partial HIPAA Waiver (for recruitment purposes) – A HIPAA Authorization will be obtained at the time of enrolling research participants.

☐ HIPAA Alteration – This is a request to waive one of the required elements of the HIPAA Authorization form (e.g., signature) and the element is described below.

This form is pre-populated with a checked box for the Full HIPAA Waiver, as this is typically requested. Please ensure the appropriate box(es) are checked as applicable to the research.

Complete the following:

If there is more than one study population (or groups/study arms) in the study, please describe the population(s) (or groups/study arms) for which this waiver pertains: ☐ N/A – applies to all research participants.

Note: A separate request form may be made for each study population, or each population can be specifically described in each section below.

I. Provide a description of the PHI (IHI) for which use or access is necessary for the research:

a. Briefly describe the protected health information for which you are requesting access. List, in detail, the health information that is to be collected for the research activity:

b. What is the source of the health information (e.g., medical record, etc):
Note: Identify the covered entity or covered component that will release or disclose PHI (IHI) to the researcher.

c. Explain why this health information is the minimum necessary to meet the research objectives:

HIPAA Waiver
Form Version 12.19.2018

SUNY Downstate Medical Center Institutional Review Board

d. Indicate where protected health information (PHI) or Individually Identifiable Health Information (IHI) will be stored, and who will have access (this list must be inclusive, i.e., sponsor, OHRP, FDA, data safety monitoring boards, research team as listed on the associated IRB application etc.):

e. Does the use or disclosure of the PHI involve any risk to the privacy of individuals? ☐ Yes ☐ No
If yes, describe:

f. Identify anyone outside of the Downstate Medical Center or Kings County Medical Center who will use or receive PHI (e.g., researchers from other institutions collaborating on this research, research sponsors):

II. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

a. Plans to protect the identifiers from improper use and disclosure:

b. Either (i) or (ii) must be provided:

i. Describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research:

OR

ii. Provide a health (i.e., individual care) or research justification for retaining the identifiers or describe how retention of the identifiers required by law:

c. The PI's e-signature in IRBNet affirms that PHI (IHI) will not be disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information is otherwise approved by the IRB or permissible under Downstate Medical Center's policies:

i. DMC Policy HIPAA-28: Uses and Disclosures for research Purposes

ii. DMC HIPPA-32 policy: Uses and Disclosures Requiring Patient Authorization

III. Explain why the research cannot practicably be carried out without the waiver or alteration:

IV. Explain why the research could not practicably be conducted without access to, and use of, the PHI (IHI):

IRB/PRIVACY BOARD APPROVAL:

If this waiver is approved either by expedited or full board procedures as indicated in the IRB approval letter, the Downstate Medical Center IRB has determined that (unless otherwise indicated) the waiver requested herein and the use of the PHI/IHI requested and described above, satisfies the required criteria for waiver of authorization under the Health Insurance Portability and Accountability Act of 1996 and implementing regulations.

- *The use or disclosure does not involve more than minimal risk to the individual because there is an adequate plan to protect the "identifiers."*
- *There is an adequate plan to destroy the "identifiers" at the earliest opportunity or there is a health (i.e., individual care) or research justification for retaining the identifiers or their retention is required by law.*
- *There are adequate written assurances that protected health information will not be reused or disclosed to any other person or entity, except (1) as required by law, (2) for authorized oversight of the research project, or (3) for other research for which the use or disclosure of protected health information is otherwise permissible under Downstate Medical Center's policy.*
- *The research could not practicably be conducted without the waiver*
- *The research could not practicably be conducted without access to and use of the protected health information.*

HIPAA Waiver
Form Version 12.19.2018

What is "Impracticable" ?

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- Common definitions of "Practicable":
  - Feasible;
  - Capable of being effected, done or put into practice; and that may be practiced or performed;
  - Capable of being done or accomplished with available means or resources.
- The emphasis being that it is impracticable to perform the research, and not just impracticable to obtain consent.

Reference: https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-january-31-letter/index.html

Concepts that may help determine whether it is impracticable to obtain consent:

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- Scientific validity would be compromised if consent was required. Examples of this might include the following:
  - The sample size required is so large (e.g., population-based studies, epidemiology trials) that including only those samples/records/data for which consent can be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed.
  - The subjects for whom records would be reviewed are no longer followed and may be lost to follow-up. For example the proportion of individuals likely to have relocated or died may be a significant percentage of the subject population and the research results may not be meaningful and lose statistical power.
  - The disclosure of the study purpose as part of the consent process would bias the research subjects so that the results will not be meaningful.

Concepts that may help determine whether it is impracticable to obtain consent:

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- Ethical concerns would be raised if consent were required. For example:
  - There is a risk of creating additional threats to privacy by having to link otherwise de-identified data with nominal identifiers in order to contact individuals to seek consent.
  - There is a risk of inflicting psychological, social or other harm by contacting individuals or families.
- There is a scientifically and ethically justifiable rationale why the research could not be conducted with a population from whom consent can be obtained.
- Practicability should not be determined solely by considerations of convenience, cost, or speed.

Additional Considerations
(Consult Policy IRB-01 and Reviewer Guidance)

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- Exception From Informed Consult (EFIC) for Planned Emergency Research or Clinical Trials
- Recruitment of Students, Residents, Fellows, Employees, or Volunteers as Research Participants
- Investigator Qualifications
- Adequacy of Research Site(s)
- Data and Safety Monitoring
- Data Security
- Recruitment, Referral, Screening, Advertising, and Incentives

Additional Considerations
(Consult Policy IRB-01 and Reviewer Guidance)

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- Study Population
- Enrolling Participants with Limited English Proficiency (LEP)
- Long Form vs. Short Form
- Study Design & Statistical Considerations
- Ethical considerations
- Approval Periods

Should the IRB Approve the use of a Short Form Informed Consent Process?

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IRB CHALLENGE

Phase 4 Clinical Trial of SS-XYZ in Children with Sickle-Cell Disease:

- IND is in place for SS-XYZ biological agent.
- Recruitment criteria: Children with Sickle-Cell, ages 6-17, with no HIV or Hepatitis, with no upcoming surgeries.
- PI wishes to recruit a single patient: 7 year old boy who is fluent in English and Haitian Creole
- Both parents prefer Haitian Creole, but can read some English
- Biologic is reconstituted with saline and infused at home.
- Study uses an e-diary to track symptoms and quality of life.
- Consent form is 32 pages, due to the complexity of trial
- This is a "Qualifying Clinical Trial" under CMS regulations: Study bills insurance for the infusions of the study drug.

Types of IRB Approval

IRB Actions

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- Approve
- Approve with conditions
  - Response reviewed by expedited review
- Require modifications to secure approval
  - Response reviewed by Full Board, if initial review was required by Full Board
- Disapprove

Conditional Approval

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- Specific changes are required (usually minor)
- IRB notifies the PI in writing of the changes that are required.
- The IRB may approve research with conditions if:
  - Given the scope and nature of the required conditions, the IRB is able to make all of the determinations required for approval

  -AND-
  - IRB assumes the conditions will be satisfied
- Federal Guidance:
  - OHRP Guidance
  - FDA Guidance

Examples of Conditional Approval

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- Confirmation of specific assumptions or understandings on the part of the IRB regarding how the research will be conducted (e.g., confirmation that the research excludes children);
- Submission of additional documentation (e.g., certificate of CITI training);
- Precise language changes to protocol or informed consent documents; or
- Substantive changes to protocol or informed consent documents along with clearly stated parameters that the changes must satisfy.

Circumstances that Preclude IRB from Approving Research

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- IRB cannot make one or more of the determinations required for approval (e.g., 111 findings or subpart findings)
- ***Example:***
  - IRB is unable to make the required determinations about risks and benefits, adequacy of privacy and confidentiality protections, or adequacy of informed consent because insufficient information is provided

  -AND-

  - the IRB is unable to specify changes that would allow the IRB to make these determinations.

Which circumstances preclude the IRB from granting conditional approval ?

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IRB CHALLENGE

A. Justification for using a placebo or withholding available treatment for a serious medical condition
B. Providing a justification for enrolling children and how regulatory requirements are met
C. Revising a study hypothesis
D. Providing a description of procedures that the control group will undergo
E. Clarifying information regarding risks
F. Clarifying timing or circumstances for seeking informed consent
G. Providing additional monitoring plans

IRB Can Approve Some Components of a Proposed Research Study and Defer Taking Action of Others

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Example:

- A full board study includes enrolling participants ages 12-65 years, including pregnant women
- Investigator does not provide sufficient information for the IRB to make findings under Subpart B & D; however, the study meets all other requirements for approval under 45 CFR 46.111.
- ACTION: IRB approves research for one year only for involvement of non-pregnant adults.
  - Required modifications need to be submitted to FULL IRB to include children and pregnant women before final approval can be granted.

Conditional Approvals at the Time of Continuing Review

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- IRB should carefully specify whether any conditions need to be satisfied before an investigator can continue the research
- ***Example:***
  - IRB specifies changes for screening process of the prospective participants; research for currently enrolled participants may continue, but no new participants may be enrolled
  - IRB requires changes within 30 days to the informed consent document to describe a newly identified risk and a plan for informing currently enrolled participants;
    - research for currently enrolled participants may continue, but no new participants may be enrolled
    - alternatively, the IRB may specify that no further activities may take place, including currently enrolled participants

Navigating IRBNet

Refer to:

- IRB Guidance: IRBNet (IRB Application and Reporting System)
  - Available at: http://research.downstate.edu/irb/irb-policies.html
- IRBNet Instructional Resources:
  - Available at: http://www.irbnetresources.org/tresources/member-training.html
    User Name / password: downstate / training1

Log into IRBNet at www.irbnet.org

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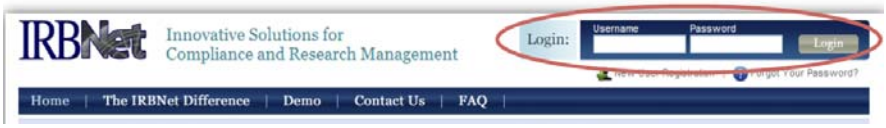

Access Submission Manager

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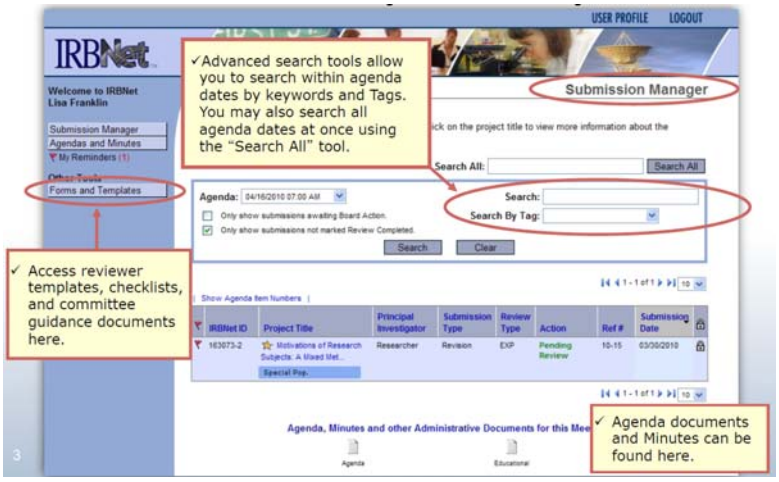

View Submission Details

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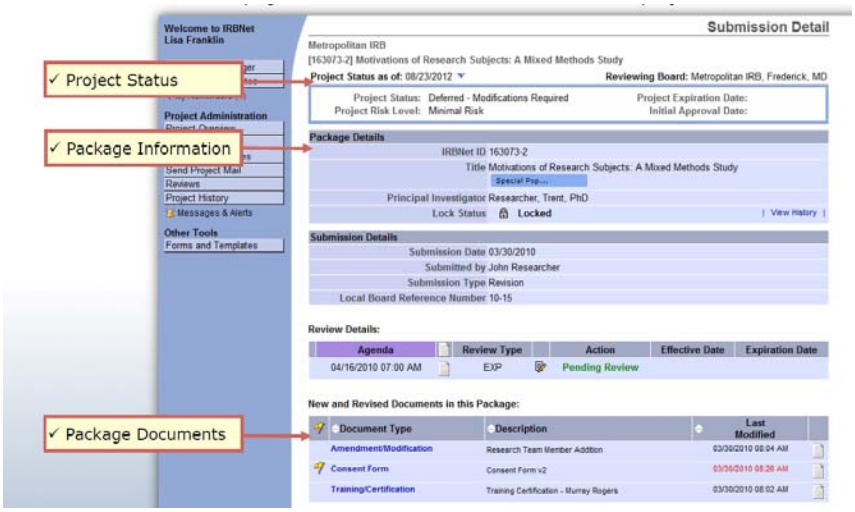

View Submission Details (continued)

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Review Process

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View Project Details

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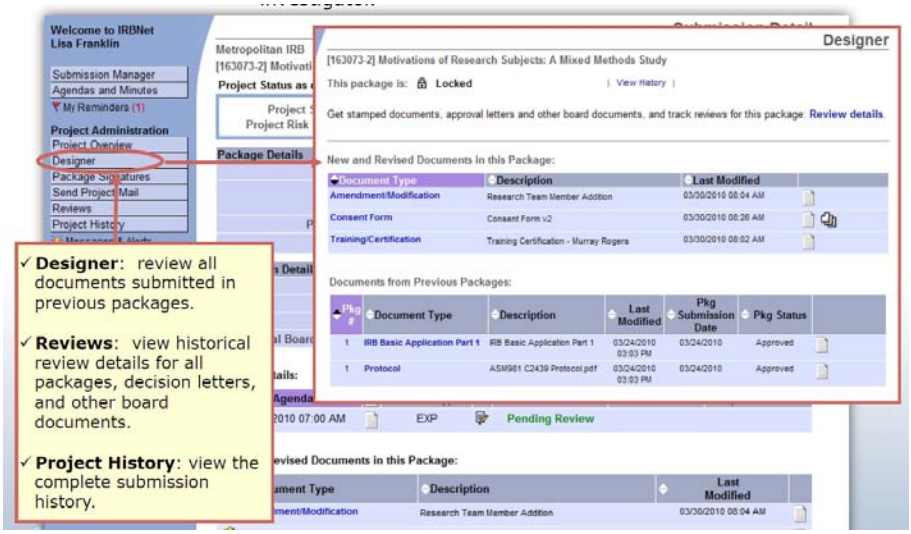
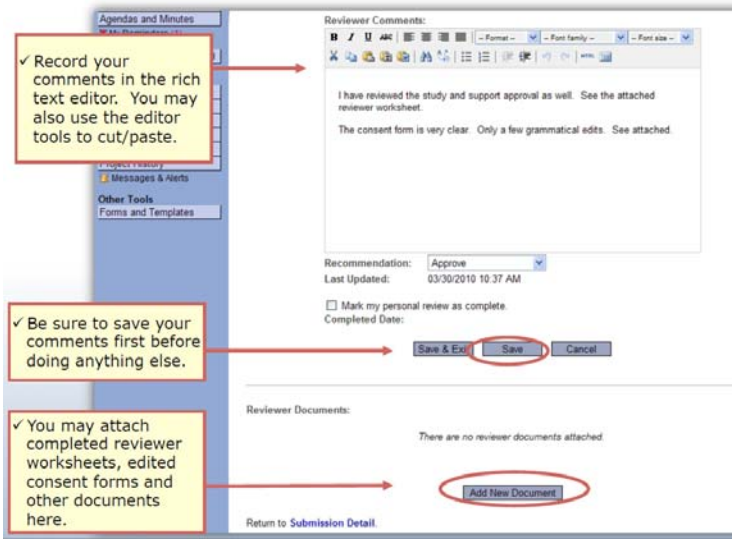


Add Reviewer Comments & Documents

55

Add Reviewer Comments & Documents

56



Complete Your Review

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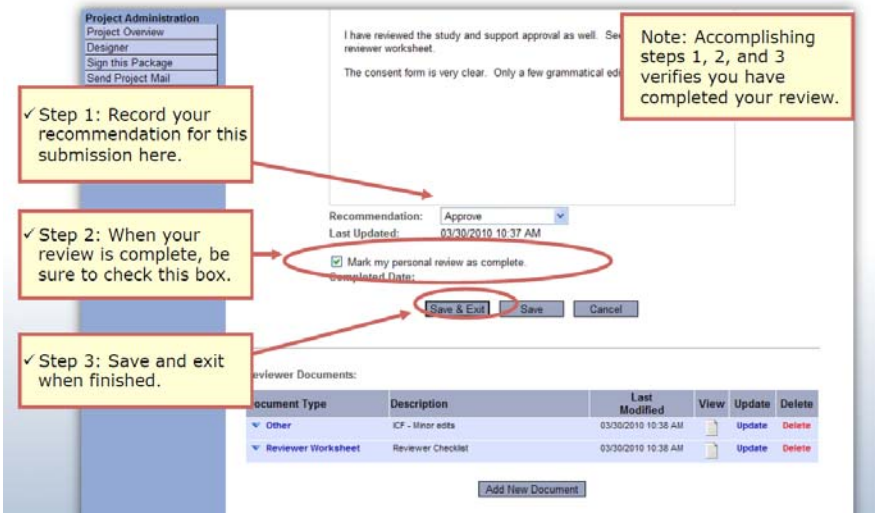

Track Your Progress

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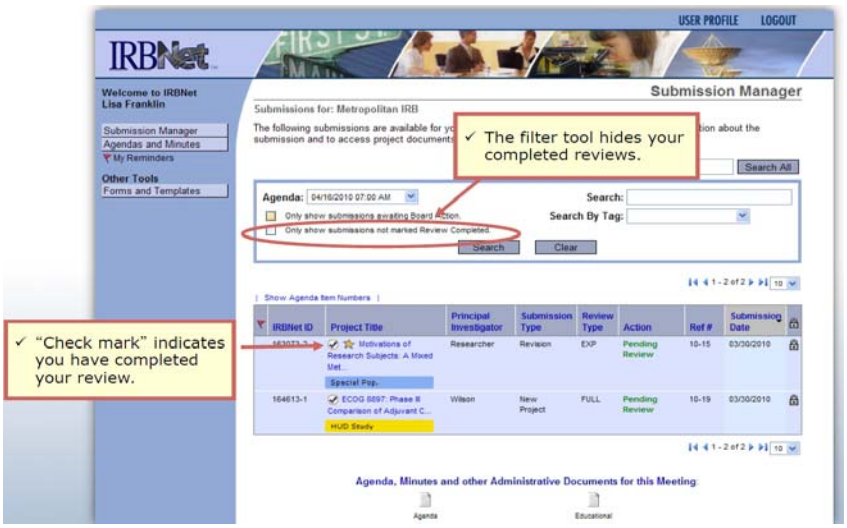
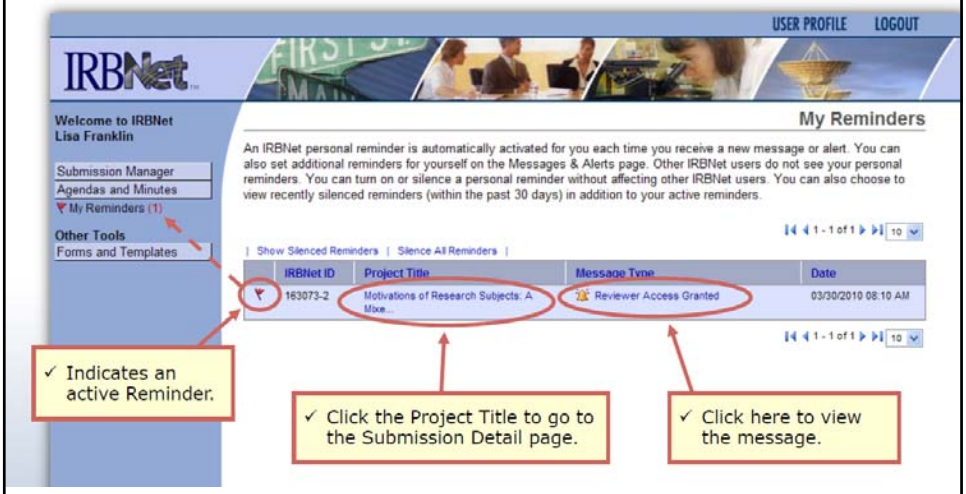
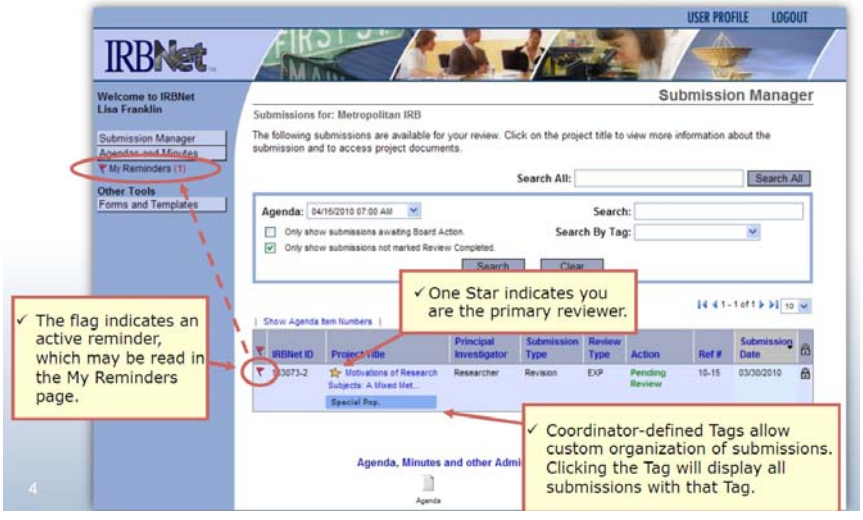


View "My Reminders"

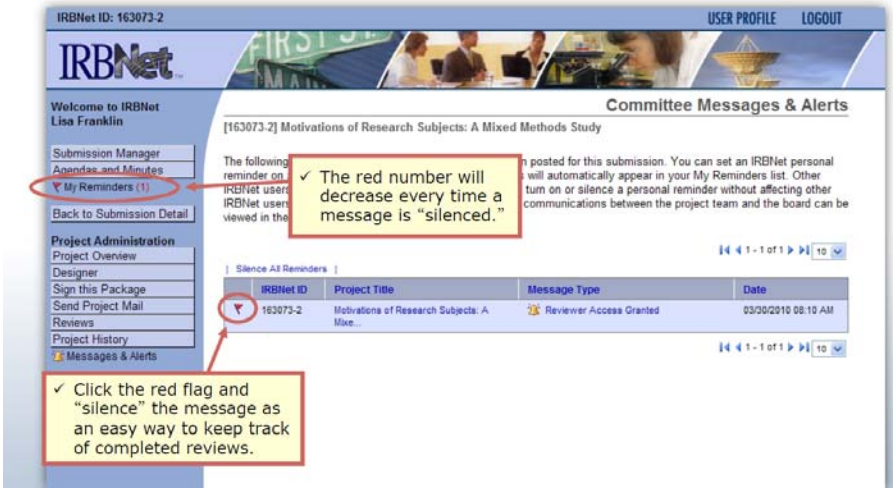


Manage Work Queue



Manage Work Queue

61



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Summary

- Review research based on IRB approval criteria and other considerations
- Manage reviews in IRBNet
- Refer to policy and guidance
- Call the IRB office for help