

# IRB MEMBER ORIENTATION

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## 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/>

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	<div> <div>Exemption 5 (X5)</div> <ul style="list-style-type: none"> <li>Study of barriers to obtaining new Medicare benefits.</li> <li>Outcomes assessment from government-sponsored mental health services.</li> </ul> <div> Evaluation of investigator-sponsored diabetes intervention. </div> </div>	<div> <div>Exemption 6 (X6)</div> <ul style="list-style-type: none"> <li>Evaluation of wholesome food preferences.</li> <li>Study looking at approved levels of an agricultural chemical on taste of vegetables.</li> </ul> <div> Study evaluating novel food additives. </div> <ul style="list-style-type: none"> <li>Testing high doses of environmental contaminant on food taste.</li> </ul> </div>	<div> <div>Exemption 7 (X7)</div> <ul style="list-style-type: none"> <li>Creating a dataset containing identifiers from a previous study to conduct future research.</li> <li>Saving blood samples from collaborator's study for a future research question. (Broad consent obtained and limited IRB review conducted.)</li> </ul> <div> Dataset containing identifiers from prior study stored for future research, with informed consent for disease-specific research. </div> </div>	<div> <div>Exemption 8 (X8)</div> <ul style="list-style-type: none"> <li>Using dataset from prior study containing identifiers to answer subsequent research question.</li> <li>Using blood samples from collaborator's study for an additional research question. (Broad consent obtained and limited IRB review conducted.)</li> </ul> <div> Using blood drawn from subjects with study specific consent for future research questions. </div> </div>

✓ = exempt
✗ = non-exempt
Please note: these are possible examples only. Final determination of exemptions should be made in accordance with 45 CFR 46.

## 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.

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

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[illegible]

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 <p>The Research Foundation of SUNY</p>	<p>Institutional Review Board &amp; Privacy Board</p> <p>FWA# 3024 • CIPR# 04 • IRB# 1521</p>	 <p>SUNY Medical Center</p>
<p>+</p>		
<p><b>GUIDANCE FOR IRB MEMBERS:</b></p>		
<p><b>INITIAL REVIEW OF A FULL BOARD OR EXPEDITED STUDY</b></p> <ul style="list-style-type: none"> <li>✓ This protocol involves IRB or IRB expedited review of identifiable information.</li> <li>✓ An IRB member may examine and study the corresponding deidentified version.</li> <li>✓ For more information please refer to <b>IRB, DARS &amp; Compliance</b> or contact IRB at 718-441-8480 or <a href="mailto:IRB@sunysp.org">IRB@sunysp.org</a>.</li> </ul>		
<p><b>Applicable of Key Regulations</b></p>		
<p>1. Use the table below to determine which key regulations apply to a specific human research study:</p>		
Circumstances:	Key Regulations:	
<p>All research, including FDA regulated research, except for certain purposes as stated in 21 CFR 312.63</p>	<p>Follow the provisions of the July 21, 2018 Common Rule (41 CFR 46, Subpart A) as outlined in Policy 2018-01.</p>	
	<p>Common Rule IRB exemptions (categories 1-4) can apply, when applicable, except that if these exemptions cannot be applied to FDA or DOJ regulated research, then use:</p>	<p><i>None.</i></p>
	<p>Federal Expedited review categories apply, when applicable.</p>	<p><i>None. As the time of writing, DARS does not accept exemption category 1 or 4 research, as the policy is under review.</i></p>
<p>U.S. Department of Justice (DOJ) regulated research.</p>	<p>The Federal Government does not review category B, C, D, and E and therefore results are not included in official reviews of the regulations.</p>	<p>The DOJ is not subject to the July 21, 2018 Common Rule. However, they intend to become an official applicant to the Bureau. IRB staff will continue to monitor this.</p>

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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

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- 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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- 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
<b>Respect for Persons</b> <ul style="list-style-type: none"> <li>-Protects autonomy</li> <li>-Protect those with diminished autonomy</li> </ul>	-Informed Consent, Parent/Legal Guardian Permission, or Legally Authorized Representative <ul style="list-style-type: none"> <li>- Disclose all information</li> <li>- Ensure comprehension</li> <li>- Ensure voluntariness</li> </ul>
<b>Beneficence</b> <ul style="list-style-type: none"> <li>-Do no harm</li> <li>-Maximize benefits</li> <li>-Minimize risks</li> </ul>	-Risk/benefit ratio must be justified
<b>Justice</b> <ul style="list-style-type: none"> <li>-Equal distribution of benefits and risk</li> </ul>	-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
<b>Category 404</b> (45 CFR 46.404 and 21 CFR 50.51)	✓ No greater than minimal risk	✓ Permission of one parent/guardian ✓ Assent
<b>Category 405</b> (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
<b>Category 406</b> (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 <b>both</b> 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.
<b>Category 407</b> (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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- 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

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#### **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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**SUNY Downstate Medical Center Institutional Review Board**  
**WAIVER OF INFORMED CONSENT REQUIREMENTS**

IRB Number: \_\_\_\_\_  
Project Title: \_\_\_\_\_  
Principal Investigator: \_\_\_\_\_

Please check the applicable category of waiver(s) requested:

☐ Waiver of Informed Consent (waiver of the entire process of informed consent) complete Section 1.  
☐ Waiver of Required Elements of Informed Consent complete Section 1.A.2.  
☐ Waiver of Documentation of Informed Consent (waiver of signature(s)) complete Section 1.

**Section 1:**

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

Describe why the research cannot practicably be carried out without the waiver: \_\_\_\_\_

Please check either box 1 or box 2 below:

☐ (1) 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).

If box (1) is checked, when applicable, describe how the research participants will be provided with additional pertinent information after participation: \_\_\_\_\_ ☐ N/A

☐ (2) The research cannot practicably be carried out without the waiver or alteration and the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

- public benefit or service programs;
- procedures for obtaining benefits or services under those programs;
- possible changes in or alternatives to those programs or procedures; or
- possible changes in methods or levels of payment for benefits or services under those programs.

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**Section 2:**

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

Check the element(s) of informed consent for which this waiver request applies:

☐ (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the research participant's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.  
☐ (2) A description of any reasonably foreseeable risks or discomforts to the research participant.  
☐ (3) A description of any benefits to the research participant or to others which may reasonably be expected from the research.  
☐ (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the research participant.  
☐ (5) A statement describing the extent, if any, to which confidentiality of records identifying the research participant will be maintained.  
☐ (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and if so, what they consist of, or where further information may be obtained.  
☐ (7) An explanation of whom to contact for answers to participant questions about the research and research participant's rights, and whom to contact in the event of a research-related injury to the research participant; and  
☐ (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the research participant is otherwise entitled and the research participant may discontinue participation at any time without penalty or loss of benefits to which the research participant is otherwise entitled.

Provide a justification for requesting a waiver of the above checked element(s): \_\_\_\_\_

**Section 3:**

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

Provide a detailed explanation for making this request: \_\_\_\_\_

Please check either box 1, 2, or 3 to describe the criteria that justify your request for waiver of documentation of informed consent:

☐ (1) That the research presents no more than minimal risk of harm to research participants and involves no procedures for which written consent is normally required outside of the research context (e.g., drawing a blood sample, survey, collection of easily discarded data, etc.).  
☐ (2) The only record linking the research participant and the research would be the consent document and the completed form would be destroyed from a breach of confidentiality. Each document will be sealed whether the research participant wants documentation linking further with the research and further action will be taken.  
☐ (3) The research participant (or LAR/borrower) is a member of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to participants and provides there is an appropriate alternative mechanism for documenting that informed consent was obtained.  
☐ If box (2) is checked, describe how the study team will link a research participant to the research if the research participant requests such documentation: \_\_\_\_\_  
☐ (4) The research participant (or LAR/borrower) is a member of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to participants and provides there is an appropriate alternative mechanism for documenting that informed consent was obtained.  
☐ If box (2) is checked, describe how the study team will document informed consent (e.g., making a note on the informed consent document or placing a note in the research record, etc.).  
Check: Section 4 is only for research approved on or after 2/1/2018, not required by FDA or DOJ.

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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: Unchecked, 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 practically 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 practically 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 (i.e., identifiers) 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 group/study arms) in the study, please describe the population(s) (or group/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 (BIR) for which use or access is necessary for the research:

- 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: \_\_\_\_\_
- 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 (BIR) to the researcher.
- 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 (IH) will be stored, and who will have access (this list must be included, 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 (i.e., 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 case) or research justification for retaining the identifiers or describe how retention of the identifiers required by law: \_\_\_\_\_

c. The PI's signature in IRBNet affirms that PHI (BIR) 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.

A. OHRP Policy HIPAA-72: Uses and Disclosures for Research Purposes

B. HHS HIPAA-32 policy: Uses and Disclosures Regarding Patient Authorization

iii. Explain why the research cannot practically be carried out without the waiver or alteration: \_\_\_\_\_

iv. Explain why the research could not practically be conducted without access to, and use of, the PHI (BIR): \_\_\_\_\_

### IRB/PRIVACY BOARD APPROVAL

If this waiver is approved after IRB approval 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(BIR) 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 case) 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 practically be conducted without access to and use of the protected health information.

HIPAA Waiver  
Form Version 12-19-2018

## What is "Impracticable" ?

34

### 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:

35

- 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:

36

- 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 Consent (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)

38

- ☐ 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?

39

### IRB

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#### 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

41

- 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

42

- 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

43

- 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

44

- 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 ?

45

### IRB

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- 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

IRBNet Innovative Solutions for Compliance and Research Management

Login:  Username  Password

[Home](#) | [The IRBNet Difference](#) | [Demo](#) | [Contact Us](#) | [FAQ](#)

## 50

## View Submission Details

51

Welcome to IRBNet  
Lisa Franklin

**Submission Detail**

Metropolitan IRB  
[163073-2] Motivations of Research Subjects: A Mixed Methods Study

**Project Status as of: 08/23/2012** **Reviewing Board: Metropolitan IRB, Frederick, MD**

Project Status: Deferred - Modifications Required  
Project Risk Level: Minimal Risk  
Project Expiration Date:  
Initial Approval Date:

**Package Details**

IRBNet ID: 163073-2  
Title: Motivations of Research Subjects: A Mixed Methods Study  
Special Pre-  
Principal Investigator: Researcher, Trent, PhD  
Lock Status: Locked | View History |

**Submission Details**

Submission Date: 03/30/2010  
Submitted by: John Researcher  
Submission Type: Revision  
Local Board Reference Number: 10-15

**Review Details:**

Agenda	Review Type	Action	Effective Date	Expiration Date
04/16/2010 07:00 AM	EXP	Pending Review		

**New and Revised Documents in this Package:**

Document Type	Description	Last Modified
Amendment/Modification	Research Team Member Addition	03/06/2010 08:04 AM
Consent Form	Consent Form v2	03/05/2010 08:28 AM
Training/Certification	Training Certification - Murray Rogers	03/05/2010 08:02 AM

## View Submission Details (continued)

52

**Project Team Tracking:** | Show Project Team Tracking |

**This Package has been Signed By:**

Date	Signed By	Role
05/28/2015 01:38 PM	Timothy Resnick	Principal Investigator

This submission is currently shared with the following Committee Members:

User	Special Designation	Share Date	Shared By
Administrator, Tanya	Not Applicable	Not Applicable	Not Applicable
Eliot, Charles	Not Applicable	05/28/2015 02:02 PM	Administrator, Tanya
Reviewer, Trisha	Expedited Reviewer	05/28/2015 02:02 PM	Administrator, Tanya

**Committee Messages (1)** **Send Committee Mail** to Members and Administrators.

**Add comments and reviewer documents to this submission.**

Reviewer	Comment	Recommend	Last Updated	Completed Date	View
Administrator, Tanya	The pre review is complete. The consent is very confusing.		05/28/2015 01:58 PM	05/28/2015 02:00 PM	View

## Review Process

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✓ Open any submitted document by clicking the blue link.

**New and Revised Documents in this Package:**

Document Type	Description	Last Modified
Advertisement	radio jingle	05/28/2015 01:37 PM
Consent Form	Consent Form template	05/28/2015 01:23 PM
UMCP - IRB Initial Application - Part 1	IRB Application	05/28/2015 01:37 PM

There are 6 Training & Credentials records linked to this package. | [View Linked Records](#) |

\* Browse the complete list of project documents, and access historical documents, on the **Designer**.

## View Project Details

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Welcome to IRBNet  
Lisa Franklin

Submission Manager  
Agendas and Minutes  
My Reminders (1)  
Project Administration  
Project Overview  
**Designer**  
Package Signatures  
Send Project Mail  
Reviews  
Project History

Metropolitan IRB  
[163073-2] Motivations of Research Subjects: A Mixed Methods Study  
Project Status as of [03/30/2010 07:00 AM]  
Project Risk

**Package Details**

[163073-2] Motivations of Research Subjects: A Mixed Methods Study  
This package is: **Locked** | [View History](#) |

Get stamped documents, approval letters and other board documents, and track reviews for this package: [Review details](#).

**New and Revised Documents in this Package:**

Document Type	Description	Last Modified
Amendment/Modification	Research Team Member Addition	03/30/2010 08:04 AM
Consent Form	Consent Form v2	03/30/2010 08:26 AM
Training/Certification	Training Certification - Murray Rogers	03/30/2010 08:02 AM

Documents from Previous Packages:

Pkg #	Document Type	Description	Last Modified	Pkg Submission Date	Pkg Status
1	IRB Basic Application Part 1	IRB Basic Application Part 1	03/24/2010 03:03 PM	03/24/2010	Approved
1	Protocol	ASM981 C2439 Protocol.pdf	03/24/2010 03:03 PM	03/24/2010	Approved

Agenda  
2010 07:00 AM EXP Pending Review

Revised Documents in this Package:

Document Type	Description	Last Modified
Amendment/Modification	Research Team Member Addition	03/30/2010 08:04 AM

✓ **Designer:** review all documents submitted in previous packages.

✓ **Reviews:** view historical review details for all packages, decision letters, and other board documents.

✓ **Project History:** view the complete submission history.

## Add Reviewer Comments & Documents

55

This Package has been Signed By:

Date	Signed By	Role
05/28/2015 01:38 PM	Timothy Resnick	Principal Investigator

This submission is currently shared with the following Committee Members and Administrators:

User	Special Designation	Share Date
Administrator, Tanya	Not Applicable	Not Applicable
Elliott, Charles	05/28/2015 02:02 PM	Administrator, Tanya
Reviewer, Trisha	Expedited Reviewer	05/28/2015 02:02 PM

Committee Messages (1) [Send Committee Mail to Members and Administrators.](#)

✓ Click "Add" to record reviewer comments

Add comments and reviewer documents to this submission.

Reviewer	Comment	Recommend	Last Updated	Completed Date	
✓ Administrator, Tanya	The pre review is complete. The consent is very confusing.		05/28/2015 01:58 PM	05/28/2015 02:00 PM	<a href="#">View</a>

✓ View comments by administrators and other members.

Note: Administrator / reviewer comments are private and may not be accessed by researchers.

## Add Reviewer Comments & Documents

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✓ Record your comments in the rich text editor. You may also use the editor tools to cut/paste.

✓ Be sure to save your comments first before doing anything else.

✓ You may attach completed reviewer worksheets, edited consent forms and other documents here.

Reviewer Comments:

I have reviewed the study and support approval as well. See the attached reviewer worksheet.

The consent form is very clear. Only a few grammatical edits. See attached.

Recommendation:

Last Updated: 03/30/2010 10:37 AM

☐ Mark my personal review as complete.

Completed Date:

[Save & Exit](#) [Save](#) [Cancel](#)

Reviewer Documents:

There are no reviewer documents attached.

[Add New Document](#)

[Return to Submission Detail.](#)

## Complete Your Review

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Project Administration  
Project Overview  
Designer  
Sign this Package  
Send Project Mail

I have reviewed the study and support approval as well. See reviewer worksheet.

The consent form is very clear. Only a few grammatical errors.

Note: Accomplishing steps 1, 2, and 3 verifies you have completed your review.

Recommendation: Approve

Last Updated: 03/30/2010 10:37 AM

☒ Mark my personal review as complete.

Completed Date:

Save & Exit Save Cancel

Reviewer Documents:

Document Type	Description	Last Modified	View	Update	Delete
Other	CF - Minor edits	03/30/2010 10:38 AM		<a href="#">Update</a>	<a href="#">Delete</a>
Reviewer Worksheet	Reviewer Checklist	03/30/2010 10:38 AM		<a href="#">Update</a>	<a href="#">Delete</a>

[Add New Document](#)

✓ Step 1: Record your recommendation for this submission here.

✓ Step 2: When your review is complete, be sure to check this box.

✓ Step 3: Save and exit when finished.

## Track Your Progress

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IRBNet

Welcome to IRBNet  
Lisa Franklin

Submission Manager  
Agendas and Minutes  
My Reminders

Other Tools  
Forms and Templates

USER PROFILE LOGOUT

Submission Manager

Submissions for: Metropolitan IRB

The following submissions are available for your submission and to access project documents:

✓ The filter tool hides your completed reviews.

Agenda: 04/15/2010 07:00 AM

☐ Only show submissions awaiting Board Action

☒ Only show submissions not marked Review: Completed

Search:

Search By Tag: ▼

Search Clear

[Show Agenda Item Numbers](#)

IRBNet ID	Project Title	Principal Investigator	Submission Type	Review Type	Action	Ref #	Submitting Date
164073-3	✓ Motivations of Research Subjects: A Mixed Met.	Researcher	Revision	EXP	Pending Review	10-15	03/30/2010
164813-1	✓ ECG 8897: Phase B Comparison of Adjunct C...	Wilson	New Project	FULL	Pending Review	10-19	03/30/2010

Agenda, Minutes and other Administrative Documents for this Meeting

[Agenda](#) [Educational](#)

✓ "Check mark" indicates you have completed your review.

## View “My Reminders”

Welcome to IRBNet  
Lisa Franklin

Submission Manager  
Agendas and Minutes  
▼ My Reminders (1)  
Other Tools  
Forms and Templates

**My Reminders**

An IRBNet personal reminder is automatically activated for you each time you receive a new message or alert. You can also set additional reminders for yourself on the Messages & Alerts page. Other IRBNet users do not see your personal reminders. You can turn on or silence a personal reminder without affecting other IRBNet users. You can also choose to view recently silenced reminders (within the past 30 days) in addition to your active reminders.

Show Silenced Reminders | Silence All Reminders |

IRBNet ID	Project Title	Message Type	Date
163073-2	Motivations of Research Subjects: A Mixed Met...	Reviewer Access Granted	03/30/2010 08:10 AM

1 - 1 of 1 | 10

✓ Indicates an active Reminder.

✓ Click the Project Title to go to the Submission Detail page.

✓ Click here to view the message.

## Manage Work Queue

Welcome to IRBNet  
Lisa Franklin

Submission Manager  
Agendas and Minutes  
▼ My Reminders (1)  
Other Tools  
Forms and Templates

**Submission Manager**

Submissions for: Metropolitan IRB

The following submissions are available for your review. Click on the project title to view more information about the submission and to access project documents.

Search All: [ ] Search All

Agenda: 04/16/2010 07:00 AM

Search: [ ] Search By Tag: [ ]

☐ Only show submissions awaiting Board Action.  
☒ Only show submissions not marked Review Completed

Search Clear

Show Agenda Item Numbers |

IRBNet ID	Project Title	Principal Investigator	Submission Type	Review Type	Action	Ref #	Submission Date
163073-2	Motivations of Research Subjects: A Mixed Met...	Researcher	Revision	EXP	Pending Review	10-15	03/30/2010

1 - 1 of 1 | 10

✓ The flag indicates an active reminder, which may be read in the My Reminders page.

✓ One Star indicates you are the primary reviewer.

✓ Coordinator-defined Tags allow custom organization of submissions. Clicking the Tag will display all submissions with that Tag.

Agenda, Minutes and other Admin

Agenda

## Manage Work Queue

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IRBNet ID: 163073-2

USER PROFILE LOGOUT

Welcome to IRBNet  
Lisa Franklin

Submission Manager  
Appendices and Minutes  
**My Reminders (1)**  
Back to Submission Detail

Project Administration  
Project Overview  
Designer  
Sign this Package  
Send Project Mail  
Reviews  
Project History  
Messages & Alerts

[163073-2] Motivations of Research Subjects: A Mixed Methods Study

The following reminder on IRBNet users viewed in the

✓ The red number will decrease every time a message is "silenced."

posted for this submission. You can set an IRBNet personal turn on or silence a personal reminder without affecting other communications between the project team and the board can be

Silence All Reminders

IRBNet ID	Project Title	Message Type	Date
163073-2	Motivations of Research Subjects: A Mixed Methods Study	Reviewer Access Granted	03/30/2015 08:10 AM

✓ Click the red flag and "silence" the message as an easy way to keep track of completed reviews.

## IRB Contacts



Clinton Brown, MD, IRB Chair	(718) 270-1729
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Stanley Friedman, MD, Vice Chair	(718) 270-1335
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IRB Office (BSB 3-26) <a href="mailto:IRB@downstate.edu">IRB@downstate.edu</a>	(718) 613-8480

## 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