IRB MEMBER ORIENTATION

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Objectives

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

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

<table>
<thead>
<tr>
<th>TYPE OF REVIEW</th>
<th>REQUIRED FORM</th>
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</thead>
<tbody>
<tr>
<td>Determination Letter (indicates IRB review is NOT required)</td>
<td>“IRB Decision Aid - Application for a Determination Letter to State IRB Approval is NOT Required”</td>
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</tbody>
</table>
| Exempt Review | “Application for Exempt Review.”  
**NOTE:** The exemption categories are described on the form. |
| Expedited Review | “Application for Expedited or Full Review”  
**Note:** The criteria for expedited review can be viewed on the OHRP website, by clicking here. |
| Convened (Full) IRB Review | “Application for Expedited or Full Review” |
| Use of a Humanitarian Use Device (HUD) for clinical purposes | “Application for HUD for Clinical Purposes” |
| External IRB Review (some multi-site research) | “Application for External IRB Oversight”  
**Note:** To share additional guidance with the External IRB, please see the [Guidance: Local Research Context for External IRB](http://research.downstate.edu/irb/irb-electronic-submissions.html) |
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) Research on elected or appointed officials or candidates for public office
4) Research on existing data, if publically available or recorded without identifiers
5) Evaluation of public service programs
6) Taste and food quality evaluation and consumer acceptance studies

* Does not apply to research with prisoners.
** Does not apply to research with children.
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
Risk Assessment

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

### 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

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

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.

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

- 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)

- 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;

- 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

- 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

<table>
<thead>
<tr>
<th>Category</th>
<th>Evaluation</th>
<th>Requirements</th>
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<tbody>
<tr>
<td>Category 404 (45 CFR 46.404 and 21 CFR 50.51)</td>
<td>✓ No greater than minimal risk</td>
<td>✓ Permission of one parent/guardian &lt;br&gt; ✓ Assent</td>
</tr>
<tr>
<td>Category 405 (45 CFR 46.405 and 21 CFR 50.52)</td>
<td>✓ Greater than minimal risk &lt;br&gt; ✓ Presents prospect of direct benefit to the individual research participants &lt;br&gt; ✓ The risk is justified by the anticipated benefit to the participants; and &lt;br&gt; ✓ The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.</td>
<td>✓ Same as 404</td>
</tr>
<tr>
<td>Category</td>
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<tr>
<td><strong>Category 406</strong>&lt;br&gt;<strong>(45 CFR 46.406 and 21 CFR 50.53)</strong></td>
<td>✓ Greater than minimal risk&lt;br&gt;✓ Minor increase over minimal risk&lt;br&gt;✓ No prospect of direct benefit to the individual research participants&lt;br&gt;✓ Likely to yield generalizable knowledge about the research participants’ disorder or condition&lt;br&gt;✓ 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</td>
<td>✓ 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&lt;br&gt;✓ Assent&lt;br&gt;✓ 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.</td>
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<td><strong>Category 407</strong>&lt;br&gt;<strong>(45 CFR 46.407 and 21 CFR 50.54)</strong></td>
<td>✓ 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.</td>
<td>✓ Includes 406 requirements&lt;br&gt;✓ OHRP (or by the FDA, if FDA regulated) must also approve the research</td>
</tr>
</tbody>
</table>
Which category of permissible research applies to each of the following studies?

A. Study involving a survey on middle school homework performance
B. Clinical trial to determine standard of care for Super-Refractory Status Epilepticus, where there is both a placebo and treatment arm for weaning subjects of third-line agents.
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. Pediatric smallpox vaccine trials evaluating safety in response to the Sept. 11 attack.

Research Involving Prisoners

- Only certain research is permitted:
  - Four (4) categories of permissible research, outlined in IRB guidance, or
  - Epidemiological study that meets the criteria for an HHS waiver
  - All federally funded prisoner research must be certified by Office for Human Research Protections (OHRP)
- If research participant becomes incarcerated during the research, the research must stop or the IRB must review the study to ensure all Subpart C criteria are met.
Clinical Trials with Investigational Drug or Biological

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

Clinical Trials with Investigational Drug or Biological

IRB application requirements for studies with IND:
- IND Letter from FDA or Sponsor
- FDA Statement of Investigator (Form 1572)
- Investigator’s Brochure (ICH-GCP trials)
*Criteria for IND Exemption*

- 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


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**Medical Device Studies**

  - If no, determine if study is Significant (SR) or Non-Significant (NSR) device study.
  - If SR, an IDE is needed from FDA

*Reference:*

*Criteria for IDE Exemption for a Diagnostic Device

- 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?

- 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?

- Medical device study that is not a SR study


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Is the following study a SR or NSR study?

**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

- Informed consent is a “process” not just a form.
- Specific requirements are needed for federally funded or supported research.
- 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)
What is “Impracticable”?  

- 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.

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

- 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:

- 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.
Should the IRB approve these waivers?

- Review sample handout on waiver of documentation of informed consent
- Review sample handout on HIPAA waiver

Exception From Informed Consult (EFIC) for Planned Emergency Research or Clinical Trials

- Emergency research refers to the study of acute, life-threatening clinical situations.
- Often, informed consent from the participants is not feasible because the participant lacks the capacity to provide their own consent (e.g., unconscious) and/or there is insufficient time because treatment must be promptly administered.
- Consult Policy IRB-01 (pages 53-56), for EFIC regulations and policies.
Recruitment of Students, Residents, Fellows, Employees, or Volunteers as Research Participants

- Have investigators sufficiently minimized coercion and undue influence?
- Is privacy adequately protected?
- Does the research need to comply with Family Educational Rights and Privacy Act (FERPA), Protection of Pupil Rights Amendment (PPRA), or Children’s Online Privacy Protection Act (COPPA)?
- Must the research be approved by the NYC Department of Education IRB?
- Consult IRB Guidance: Students, Residents, Fellows, Employees, or Volunteers as Research Participants.

Investigator Qualifications

- Is the PI qualified to conduct and oversee the research?
- Does the PI need to submit a CV?
- Does the PI have the required PI Status?
- Should other investigators be added to the study?
- If multiple PIs are used in this project, are there any concerns with the roles, responsibilities or relationship to the primary PI?
Adequacy of Research Site(s):

- Are the sites adequate to conduct the research?
- Are the facility’s staff and medical equipment adequate?
- Are emergency or specialized care, adequate if the need arises?
- Does the IRB require additional information on facility, staffing, resources, etc.?

Data and Safety Monitoring

- Is it appropriate for this research to include a plan to monitor the data collected to ensure the safety of research participants?
- Has the sponsor or other entity established a Data and Safety Monitoring Board (DSMB)?
  - If no DSMB, is the Data and Safety Monitoring Plan appropriate?
- Is an external or independent committee required?
- Is the proposed composition appropriate?
  - If no, what composition is recommended?
Data Security

- Are all information security requirements met?
- Are physical safeguards adequate?
- Are protocol specific safeguards adequate?
- Are technical safeguards adequate?
- Are data stored behind the Downstate firewall?
- Are encrypted lap top and thumb drives used?
- Are employee controls adequate?
- Are records backed-up?

For more information, see IRB guidance on Data Security.

Recruitment, Referral, Screening, Advertising, and Incentives

- Are the methods for participant recruitment clearly outlined in the protocol?
- Is voluntariness of participation ensured?
- Are privacy protections in place?
- Is the process for making referrals appropriate?
- Are recruitment materials and advertising acceptable?
- Have efforts been made to minimize undue influence and coercion?
- Are recruitment incentives (compensation, reimbursements) appropriate?
Study Population

- Is the study population defined, including inclusion/exclusion criteria?
- Is there appropriate justification for the inclusion/exclusion of populations as outlined in the application materials?
- Are adequate provisions made for recruiting those with Limited English Proficiency (LEP), when appropriate (i.e., when the study holds the prospect of direct therapeutic benefit), unless there are risks or barriers that prohibit the enrollment of those with LEP.

Enrolling Participants with Limited English Proficiency (LEP)

- Information given to the research participant or LAR shall be in their preferred language.
- Unless waived, the consent form may be either:
  - A written informed consent document that meets all of the IRB requirements.
  - A short form written informed consent form stating that the elements of informed consent have been presented orally to the participant or the participant's LAR.
Long Form vs. Short Form

- Written translation of the long forms is generally expected if anticipating enrollment of five or more research participants with LEP, for the following types of 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.

What informed consent process should the IRB require to approve this study?

**Phase 4 Clinical Trial of SS-XYZ in Children with Sickle-Cell Disease:**
- IDE 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
- Qualifying Clinical Trial: Study bills insurance for the infusions, and study drug.
Approval Period

- Maximum of 1 year
- Shorter review period may be required
- Can specify a maximum number of research participants that can be enrolled before next IRB review
- Factors for shorter approval periods are outlined in Policy IRB-01 (pages 73-74)

Conflict of Interest Disclosures and Training Requirements

- Conflict of Interest Disclosures required for “Investigators for the purposes of COI,” as determined by PI.
  - Investigators who are considered to be essential to work performance or responsible for design, conduct, or reporting of research.
  - The PI does not need to include transient staff and trainees, such as medical students, residents and fellows who merely implement a protocol developed by an Investigator or enter data into an electronic data capturing system.
- All CITI and other training requirements must be completed
- See IRB Guidance: [http://research.downstate.edu/irb/irb-training.html](http://research.downstate.edu/irb/irb-training.html)
Electronic Signature Requirements

- PI
- Scientific Review Committee (and SRC form)
- Department Chair
- Pathology Services, when applicable
- Pharmacy, when drug or biologic is involved
- Paper Signatures (when applicable):
  - IBC Approval Letter

Federal Grant Congruency

- IRB must confirm application materials are consistent with any Federal Grant
- This requirement may disappear when the new Common Rule (45 CFR 46) is implemented by HHS and other Federal agencies
  - Date TBD: Possibly by July 2018 or January 2019
Study Design & Statistical Considerations

- Were there any concerns from the scientific reviewer?
- Is the protocol methodology scientifically sound and adequately designed?
- Are the hypotheses, clinical objectives and planned analyses clearly stated?
- Are the planned interventions and their timing clearly stated?
- For drug trials, are dosages, changes in dosages, and duration of administration clearly stated?

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Study Design & Statistical Considerations

- Are the primary and secondary outcome measures defined?
- Is the sample size projected on the basis of statistical calculation?
- Are the statistical analyses of outcome measures appropriate?
- Is the randomization method described and appropriate (if applicable)?
Ethical Considerations

- Is the research guided by the ethical principles set forth in the Belmont Report?
- Are there any other concerns related to other applicable principles of professional conduct or ethical codes (e.g. Downstate Code of Ethics, Nuremberg Code, Declaration of Helsinki)?

*NOTE: The Declaration of Helsinki is followed in Clinical Trials which follow ICH-GCP Standards.*

### Apply the Belmont Principles

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

- IRB applications for Clinical Use Only:
  - Clinical Use of Humanitarian Use Device (HDE).
  - Expanded Access of Investigational Drug or Biologic for Treatment Use (IND).
- COI & Training requirements do not apply.
- IRB can place limitations on clinical use.
- If no time for IRB review, clinician follows Emergency Use policy and reports use of agent within 5 days.
Types of IRB Approval

IRB Actions

- 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

- 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

- 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

- 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?

- 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

**Example:**
- 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 changes are submitted to FULL IRB to include children and pregnant women before final approval can be granted

Conditional Approvals at the Time of Continuing Review

- 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
Access Submission Manager

- Advanced search tools allow you to search within agenda dates by keywords and tags. You may also search all agenda dates at once using the "Search All" tool.
- Agenda documents and Minutes can be found here.

View Submission Details

- Project Status
- Package Information
- Package Documents
View Submission Details (continued)

- Electronic Signatures
- Committee / Admin access list
- Reviewer comments.
- The check indicates the user has completed their review.

Click here to send a message to any member with whom the submission has been shared.

Review Process

- Open any submitted document by clicking the blue link.
View Project Details

- **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

- **Click “Add” to record reviewer comments**
- **View comments by administrators and other members.**

*Note: Administrator / reviewer comments are private and may not be accessed by researchers.*
Add Reviewer Comments & Documents

- 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.

Complete Your Review

- 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.

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

- Click mark indicates you have completed your review.
- The filter tool hides your completed reviews.

View “My Reminders”

- Indicates an active Reminder.
- Click the Project Title to go to the Submission Detail page.
- Click here to view the message.
Manage Work Queue

- 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.

- The red number will decrease every time a message is "silenced."
- Click the red flag and "silence" the message as an easy way to keep track of completed reviews.
IRB Website

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

Policies:

1. Select SUNY Downstate Medical Center Policies:
   - IRB-01: SUNY Downstate Medical Center Human Research Protections Program (HRPP) (FDC)
   - IRB-02: IRB Diana: Research Conflict of Interest Policy
   - IRB-04: Investigational Drug/Device and Utilization
   - SUNY Downstate Office of Compliance and Audit Services
   - SUNY Downstate Medical Center Information Services Policies and Procedures
   - SUNY Downstate Medical Center - Language Services to Patients with Limited English Proficiency
   - SUNY Downstate: HIPAA (Health Insurance Portability and Accountability Act) Policies and Forms
     - Select HIPAA policies and forms:
       - Research Certification for Personnel Preparatory to Research
       - HIPAA Template Policy (HIPAA 3)
       - HIPAA De-identification of Information (HIPAA 3)
       - Minimum Necessary Guidelines (HIPAA 15)
       - Use of Limited Data Sets (HIPAA 17)
       - Stays and Disclosures for Research Purposes (HIPAA 28)

2. Select SUNY Policies:
   - SUNY RF: Policies A to Z
   - SUNY RF: Acceptable Use and Security of RF Data and Information Technology
   - SUNY RF: Human Subject Payments
   - SUNY RF: Remote Access Policy
   - SUNY RF: Records Management Policy
   - SUNY RF: Record Retention: Agency/Institutional Records
   - SUNY RF: Record Retention: Personal-Related Records
   - SUNY RF: Project Administration Records

3. Select NYC Health: Kings County Policies:
   - NYC HHC: Kings County Clinical Research Office Menu
   - NYC HHC: Kings County Human Subject Research Protections Program
   - NYC HHC: Kings County System to Track and Appraise Research (KSTAR)
   - IRB NY HCC
   - IRB Control HCC

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

Investigator Guidance:
1. Acronyms and Definitions
2. Accrual Reviews
3. Applicable Clinical Trial (ACT) Checklist
4. Data Security
5. FDA Guidance
6. Fees for Industry Sponsored Studies
7. Genome-Wide Association Studies (GWAS-NH)
   - GWAS PAFs (NH)
8. ICH GCP (Blueskin) 2086
9. IRBnet (IRB Application and Reporting System)
10. Lay-Person Summary
11. Local Research Conduct for External IRB
12. Material Transfer Agreements
13. Military Health Systems Research Regulatory Oversight Office
15. Office for Human Research Guide (Alphabetical List)
16. Qualification Tip Sheet
17. Recruitment, Referred, Screening, Advertising, and Incentives
18. REDCap: Research Data Capture and Analysis System
19. Respondibilities
20. Reportable Events
21. Submission Requirements for IRB Review
22. Students, Residents, Fellows, Volunteers, or Employees as Research Participants
23. Training and Conflict of Interest Disclosure
24. Veterans Affairs Office of Research and Development
25. Applicable Clinical Trial (ACT) Checklist

IRB Member Reviewer Guidance:
1. IRB Member Role and Goal
2. IRB Checklist for Full or Expedited Review
3. Guidance for IRB Members Full or Expedited Review
4. IRB Member Training Eligibility for IRBNet

IRB Office Guidance:
1. IRB Records and Distributions
2. Records Management Certificate of Distribution
3. Records Management Certificate of Distribution - Supplement Form A

IRB Updates:
1. May 2018
2. January 2019
3. October 2017
4. May 2017
5. December 2019
## IRB Contacts

<table>
<thead>
<tr>
<th>Name</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinton Brown, MD, IRB Chair</td>
<td>(718) 270-1729</td>
</tr>
<tr>
<td>Daniel Cukor, PhD, Vice Chair</td>
<td>(718) 270-2077</td>
</tr>
<tr>
<td>Stanley Friedman, MD, Vice Chair</td>
<td>(718) 270-1335</td>
</tr>
<tr>
<td>Kevin L. Nellis, MS, CIP, Executive Director, Human Research Protection &amp; Quality Assurance</td>
<td>(718) 613-8461</td>
</tr>
<tr>
<td>Diann Johnson, MPH, Associate IRB Administrator</td>
<td>(718) 270-4341</td>
</tr>
<tr>
<td>Danielle Lewis, MD, MPH, IRB Management Analyst</td>
<td>(718) 270-4454</td>
</tr>
<tr>
<td>Nikol Celestine, BA, CIP, IRB Management Analyst</td>
<td>(718) 270-4411</td>
</tr>
<tr>
<td>Nakih Gonzales, IRB Assistant</td>
<td>(718) 270-4372</td>
</tr>
<tr>
<td>IRB Office (BSB 3-26) <a href="mailto:IRB@downstate.edu">IRB@downstate.edu</a></td>
<td>(718) 613-8480</td>
</tr>
</tbody>
</table>

## 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
Contact Information

Kevin L. Nellis, MS, CIP
Executive Director, Human Research Protections and Quality Assurance
Research Foundation for SUNY - Downstate Medical Center
Office of Research Administration - Institutional Review Board
450 Clarkson Avenue, Box 1284 (BSB 3-27)
Brooklyn, NY 11203-2098
(718) 613-8461
kevin.nellis@downstate.edu
http://research.downstate.edu/irb/irb.html
IRB MEMBER CHECKLIST
FOR INITIAL REVIEW
OF A FULL BOARD
OR EXPEDITED STUDY

Respect for Persons ♦ Beneficence ♦ Justice ♦

This checklist will aid the IRB Member in completing a meaningful and substantive review.

Please attach this completed form to reviewer note section in IRBNet OR simply just enter all comments in IRBNet.

For more information please refer to Policy IRB-01, IRB guidance, regulations, or contact the IRB at 718-613-8480 or IRB@downstate.edu

GENERAL INFORMATION:

<table>
<thead>
<tr>
<th>Reviewer Name:</th>
<th></th>
<th>IRBNet #:</th>
<th>If Full Board: indicate date:</th>
<th>and committee:</th>
<th>A</th>
<th>B</th>
<th>E</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator:</td>
<td></td>
<td>Study Title:</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Funding/Support Source: ______
- □ Check if using only Department Funds

Applicable Regulations for this study:
- Research involving protected health information:
  - □ HIPAA Privacy Rule (45 CFR Parts 160, 162, and 164)
- General regulations:
  - □ Common Rule (45 CFR 46)
  - □ FDA (21 CFR 11, 50, 56, 32, 812, etc.)
  - □ Applicable Clinical Trial (ACT)
  - □ International Council for Harmonisation (ICH)
  - □ Harmonized Guideline: Integrated Addendum to ICH E6 (R1); Guideline for Good Clinical Practice E6 (R2)
- Federal Regulations, when applicable:
  - □ NIH Single IRB Requirements
  - □ NIH Certificate of Confidentiality Requirements
  - □ VA – VHA Handbook 1200.05
  - □ Department of Defense
  - □ Department of Justice

Regulations involving children and/or students:
- □ FERPA
- □ PPRA
- □ COPPA
- □ NYC DoE IRB

Do you or your immediate family members have any conflicts of interests (COI)? □ Yes □ No

Note: A conflict of interest may be real or perceived and may or may not be of a financial nature.

If “Yes” is checked, please contact the IRB Office to defer to another reviewer. An IRB Member with a COI can provide feedback, upon request from the IRB Chair/Vice-Chair, but cannot vote or approve a study.

Review Type(s) (check all applicable roles):
- □ Expedited Reviewer

Full Board Reviewer, check type(s):
- □ Primary Reviewer
- □ Secondary Reviewer

- □ Clinical Reviewer
- □ Informed Consent Reviewer
- □ Scientific Design Reviewer
- □ Statistical Reviewer
- □ Prisoner Rep Member
- □ Privacy Officer
- □ Information Security Reviewer
- □ Regulatory/Policy Reviewer
- □ IRB Office Staff
- □ Other, list: ______
REVIEW:

Are the IRB application materials congruent with the federal grant?
☐ N/A (no federal grant) ☐ Yes ☐ No, explain: 1)

Category of permissible research in children:
☐ N/A ☐ 404 ☐ 405 ☐ 406 ☐ 407

Category of permissible research in prisoners:
☐ N/A ☐ Category #1 ☐ Category #2 ☐ Category #3 ☐ Category #4 ☐ Epidemiological Waiver

Overall risk assessment? (Choose one):
☐ No greater than minimal
☐ Greater than minimal risk (>MR)

If >MR and the research involves children, check below:
☐ N/A (No Children involved)
☐ Minor increase over minimal risk for children (research is approvable under Category 406).
☐ Greater than just a minor increase over minimal risk for children (research is NOT approvable under Category 406).

Medical device study risk assessment, if applicable:
☐ N/A ☐ Non-Significant Risk (NSR) ☐ Significant Risk (SR); IDE required.

All risks to research participants reasonable in relation to anticipated benefit:
☐ N/A or No anticipated benefit ☐ Yes ☐ No, explain: 1) If no is checked, please request changes below.

Check the eligible expedited review category/categories:
☐ N/A ☐ #1A ☐ #1B ☐ #2A ☐ #2B ☐ #3 ☐ #4 ☐ #5 ☐ #6 ☐ #7

Check if any of the following are missing, when required:
☐ N/A ☐ IND Letter ☐ FDA Form 1572 ☐ Investigator Brochure (IB)

Indicate type(s) of waivers requested for this submission:
☐ N/A
☐ Waiver of the entire informed consent process
☐ Waiver of documentation (signatures) of informed consent
( NOTE: an information sheet or telephone script will most likely be required for the study)
☐ Waiver of an element of informed consent
☐ Exception form informed consent (EFIC) requirements for emergency research
☐ Health Insurance Portability and Accountability Act (HIPAA) Waiver
☐ Partial HIPAA Waiver (e.g., for recruitment purposes, with follow-up authorization)
☐ HIPAA Alteration (e.g., removal of signature or other required element)

Criteria are met to grant a waiver of informed consent and/or HIPAA Waiver:
Note: The criteria to approve the waivers are included on the request forms.
☐ N/A ☐ Yes ☐ NO: Changes requested below.
☐ Waiver(s) missing, specify: 1)

Informed consent and/or HIPAA Research Authorization requirements met (except as otherwise waived above):
☐ N/A ☐ Yes ☐ NO: Changes requested below.

To enroll participants with Limited English Proficiency, the following translated forms can be used:
☐ N/A ☐ Short Form(s) ☐ Long Form(s) (E.g., amendment needed for translated written consent document, information sheet, etc)
All IRB application materials are congruent with one another:
☐ N/A  ☐ Yes  ☐ NO: Changes requested below.

Marked-up copy of the consent document/information sheet attached:
☐ N/A  ☐ Yes  ☐ NO: Changes requested below.

Criteria met for IRB approval:
☐ N/A  ☐ Yes  ☐ NO: Changes requested below.

**CHANGES REQUESTED:**

Specific Changes needed for Conditional Approval:
(PLEASE BE AS SPECIFIC AS POSSIBLE)
1)
2)

General Modifications Required:
1)
2)

Recommendations (optional/not required):
1)
2)

Comments:
1)
2)

**Approval Decision:**

For Expedited Reviews:
☐ Approval. Approval as submitted, no changes required.
☐ Conditional Approval or Modifications Required. The revised submission returned for review by an expedited reviewer.
☐ Refer for additional review by IRB member with the following area of expertise: ____
☐ Refer to IRB Chair. IRB Chair to resolve controverted issue(s) with PI.
☐ Refer to Full Board. PI not willing or not able to make requested changes.

For Full Board Reviews:
☐ Approval. Approval as submitted, no changes required.
☐ Conditional Approval. Approval is subject to verification of specific requested revisions required to meet all approval criteria. Revisions submitted back to an expedited reviewer before final approval granted.
☐ Modifications Required. General changes submitted back to the full board).
☐ Disapproval (the submission is not approvable).

Approval Period:

Based on the assessed degree of risk and other factors outlined in Policy IRB-01 (page 73-74), specify the approval period for this study:
☐ 12 months. If not 12 months, list the number of months (not to exceed 12): ____
   If less than 12 months, please explain: 1)

**Reviewer Certification:**

Sign and date if not attached to review notes in IRBNet:
X _____________________________  ____/____/18
GUIDANCE FOR IRB MEMBERS:

INITIAL REVIEW OF A FULL BOARD OR EXPEDITED STUDY

♦ Respect for Persons  ♦ Beneficence  ♦ Justice  ♦

✓ This guidance document will aid the IRB Member in completing a meaningful and substantive review.
✓ Please either attach a completed “IRB Member Checklist for Initial Review of a Full Board or Expedited Study” form OR enter all comments to the reviewer note section in IRBNet.
✓ For more information please refer to regulations, Policy IRB-01, guidance, or contact the IRB at 718-613-8480 or IRB@downstate.edu

Risk Assessment:

Minimal risk in research involving individuals who are not prisoners and who are not involved in DoD funded research 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.

The IRB interprets minimal risk to be calibrated to the life of normal, healthy individuals and daily life to be those activities to which most individuals are exposed. The IRB may determine that procedures that are considered minimal risk for normal healthy individuals constitute greater than minimal risk for populations that are vulnerable by virtue of their condition or circumstances.

Minimal risk in research involving prisoners is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

When following Department of Defense (DoD) regulations, the definition of minimal risk based on the phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests” shall not be interpreted to include the inherent risks certain categories of research participant’s face in their everyday life. For example, the risks imposed in research involving research participants focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

For further guidance, here is the link to The Secretary’s Advisory Committee on Human Research Protections (SACHRP) Attachment A: Recommended Guidance on Minimal Risk Research and Informed Consent: https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2015-september-28-attachment-a/index.html

Drug and Biologic studies:

Questions for consideration, if applicable:

1. If investigational drugs or biologics are used, is there an IND Letter from the sponsor or FDA?
2. If an FDA approved drug is used in an unapproved way, is there an IND number or is it exempt from IND requirements?
3. If an IND exemption is requested, does the protocol meet the criteria for an IND exemption?
   Note: IND exemption criteria are listed at 21 CFR 312.2(b)(2)(ii).
4. Should the IRB request the PI provide confirmation from the FDA?
5. Does the IRB application include the FDA Form 1572?
6. Is the Investigators Brochure (IB) present? (Required for ICH-GCP trial)
**Medical device studies:**

Questions for consideration, if applicable:

1. Does this study evaluate the safety and effectiveness of a “medical device” study?
2. **If yes to (1), does the study meet the criteria for IDE Exemption** [21 CFR 812.2(c)]?
3. **If no to (2), is this a Significant Risk (SR) or Non-Significant Risk (NSR) device study?**
   - *If NSR, the study will be under an abbreviated IDE by the IRB (no IDE needed from FDA).*
   - *If SR, an IDE is needed from the FDA.*
4. Does the IRB need to see a De-

**Criteria for IRB approval of (Non-Exempt) Research:**

The following requirements must be satisfied to approve non-exempt human research:

1) Risks to research participants are minimized:
   a) by using procedures which are consistent with sound research design and which do not unnecessarily expose research participants to risk, and
   b) whenever appropriate, by using procedures already being performed for diagnostic or treatment purposes.
2) Risks to research participants are reasonable in relation to anticipated benefits, if any, to research participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies research participants would receive even if not participating in the research). The IRB does not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3) Selection of research participants is equitable. In making this assessment the IRB takes into account the purposes of the research, the adequacy of inclusion and exclusion criteria, and the setting in which the research will be conducted. The IRB is particularly cognizant of the special problems of research that involves a category of research participants who are vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, and handicapped individuals.
4) Informed consent (and HIPAA research authorization, when applicable) will be sought from each prospective research participant or his/her legally authorized representative (LAR), in accordance with, and to the extent required by the federal regulations and will be appropriately documented, unless waived.
   a) The IRB members review the informed consent document to ensure all required elements and appropriate additional elements are provided to the research participant at the time of initial review.
   b) At the time of continuing review, the IRB must also review the informed consent document to determine if any additional changes are required.
5) Informed consent (and HIPAA research authorization, when applicable) will be appropriately documented or waived in accordance with Policy IRB-01.
6) When appropriate, the research plan must make adequate provision for monitoring the data collected to ensure the safety of research participants.
7) When appropriate, there are adequate provisions to protect the privacy of research participants and to maintain the confidentiality of data.
8) When some or all of the research participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, or handicapped individuals the IRB must evaluate whether additional safeguards have been included in the study to protect the rights and welfare of these research participants based on the IRB application materials. The IRB may require additional safeguards, if needed.
9) In order to approve research involving some or all research participants that include vulnerable populations, 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.
10) In order to approve FDA regulated clinical investigations involving some or all research participants that include children, the IRB must also ensure the research is in compliance with regulations to the extent required by 21 CFR 50, subpart D.
11) FDA requires the sponsor or the sponsor-investigator to determine whether an IND or IDE is required for a particular study. The IRB may request the basis for the determination or request supporting documentation from the FDA. If the IRB is unable to resolve the issue, it will be considered a controverted issue and cannot approve the study until the matter is resolved.

Guidance for IRB Members: Initial Review of a Full Broad or Expedited Study (03.29.2018)
12) For investigational device studies, the IRB’s determination that a device study is significant risk (SR) or non-significant risk (NSR) can be made at a convened meeting. A SR device study must have an IDE from the FDA before the IRB can approve the investigation.

13) Additional criteria must be met for the following vulnerable populations, as indicated in the links below:
   a) Children
   b) Children who are Wards
   c) Children in Clinical Investigations
   d) Children who are Wards in Clinical Investigations
   e) Pregnant women or fetuses or neonates
   f) Research Involving Placenta, Dead Fetus, or Fetal Material
   g) Prisoners

14) Additional criteria must be met when a study is funded or conducted by
   a) NIH
      i) Single IRB Review for multi-site studies
      ii) Certificate of Confidentiality
   b) VA VHA Handbook 1200.05
   c) Department of Defense
   d) Department of Justice

15) For clinical trials which follow ICH-GCP requirements, the following IRB review requirements must be met:
   a) An IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects. Special attention should be paid to trials that may include vulnerable subjects. (3.1.1)
   b) The IRB/IEC should obtain the following documents: trial protocol(s)/amendment(s), written informed consent form(s) and consent form updates that the investigator proposes for use in the trial, subject recruitment procedures (e.g., advertisements), written information to be provided to subjects, Investigator's Brochure (IB), available safety information, information about payments and compensation available to subjects, the investigator’s current curriculum vitae and/or other documentation evidencing qualifications, and any other documents that the IRB/IEC may need to fulfill its responsibilities. (3.1.2)
   c) The IRB/IEC should consider the qualifications of the investigator for the proposed trial, as documented by a current curriculum vitae and/or by any other relevant documentation the IRB/IEC requests. (3.1.3)
   d) The IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human subjects, but at least once per year. (3.1.4)
   e) The IRB/IEC may request more information than is outlined in paragraph 4.8.10 be given to subjects when, in the judgement of the IRB/IEC, the additional information would add meaningfully to the protection of the rights, safety and/or well-being of the subjects. (3.1.5)
   f) When a non-therapeutic trial is to be carried out with the consent of the subject’s legally acceptable representative (see 4.8.12, 4.8.14), the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials. (3.1.6)
   g) Where the protocol indicates that prior consent of the trial subject or the subject’s legally acceptable representative is not possible (see 4.8.15), the IRB/IEC should determine that the proposed protocol and/or other document(s) adequately addresses relevant ethical concerns and meets applicable regulatory requirements for such trials (i.e., in emergency situations). (3.1.7)
   h) The IRB/IEC should review both the amount and method of payment to subjects to assure that neither presents problems of coercion or undue influence on the trial subjects. Payments to a subject should be prorated and not wholly contingent on completion of the trial by the subject. (3.1.8)
   i) The IRB/IEC should ensure that information regarding payment to subjects, including the methods, amounts, and schedule of payment to trial subjects, is set forth in the written informed consent form and any other written information to be provided to subjects. The way payment will be prorated should be specified. (3.1.9)

<table>
<thead>
<tr>
<th>Categories of permissible research for children</th>
<th>Evaluation</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 404 (45 CFR 46.404 and 21 CFR 50.51)</td>
<td>✓ No greater than minimal risk</td>
<td>✓ Permission of one parent/guardian</td>
</tr>
</tbody>
</table>
Guidance for IRB Members: Initial Review of a Full Broad or Expedited Study (03.29.2018)

| Category 405  | ✓ 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 |
| (45 CFR 46.405 and 21 CFR 50.52) |

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

Categories of permissible research for prisoners:

**Note:** For reference, see 45 CFR 46.306(a)(2).

**Category #1:** Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the research participants;

**Category #2:** Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the research participants;

**Category #3:** Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after OHRP has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his/her intent to approve such research; or

**Category #4:** Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the research participants. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after OHRP has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.

This is an epidemiological study that meets the criteria for a waiver as described below:

Health and Human Services has waived the applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain research conducted or supported by HHS that involves epidemiological studies that meet the following criteria:

1. In which the sole purposes are:
a. To describe the prevalence or incidence of a disease by identifying all cases, or
b. To study potential risk factor associations for a disease, and
2. Where the IRB has approved the research and has fulfilled its duties under 45 CFR 46.305(a)(2)–(7) and determined and documented that the following conditions are met:
   a. The research presents no more than minimal risk and no more than inconvenience to the research participants, and
   b. Prisoners are not a particular focus of the research.
3. The specific type of epidemiological research subject to the waiver involves no more than minimal risk and no more than inconvenience to the research participants. The waiver would allow the conduct of minimal risk research that does not now fall within the categories set out in 45 CFR 46.306(a)(2).
4. The range of studies to which the waiver would apply includes epidemiological research related to chronic diseases, injuries, and environmental health. This type of research uses epidemiologic methods (such as interviews and collection of biologic specimens) that generally entail no more than minimal risk to the research participants.

In order for a study to be approved under this waiver, the IRB would need to ensure that, among other things, there are adequate provisions to protect the privacy of research participants and to maintain the confidentiality of the data.

**Recruitment of students, residents, fellows, employees, or volunteers as research participants:**

Questions for consideration, if applicable:
1. Have investigators sufficiently minimized coercion and undue influence?
2. Is privacy adequately protected?
3. Does the research need to comply with Family Educational Rights and Privacy Act (FERPA)?
4. Does the research need to comply with Protection of Pupil Rights Amendment (PPRA)?
5. Does the research need to comply with Children’s Online Privacy Protection Act (COPPA)?
6. Must the research be approved by the NYC Department of Education IRB?

For more information, consult with the IRB Guidance: Students, Residents, Fellows, Employees, or Volunteers as Research Participants.

**Adequacy of research site(s):**

Questions for consideration, if applicable:
1. Is (are) the site(s) adequate to conduct the research?
2. Are the facility’s staff and medical equipment adequate?
3. Are emergency or specialized care, adequate if the need arises?
4. Does the IRB need a statement from an external research site regarding adequacy?
5. Does the IRB require additional information regarding any of the following:
   a. Description of the facility where the research will take place
   b. More information on staffing
   c. More information on resources

**IRB application materials**

Are there any concerns with any of the applicable application materials?
1. IRBNet Registration Form
2. IRB Application
3. Protocol
4. Informed Consent Form (with HIPAA Authorization)
5. Information Sheet
6. Information Sheet/HIPAA Authorization
7. Pregnancy Follow-Up Consent Form
8. Consent Form Addendum for NCI CIRB Approved Clinical Trials
9. Assent Form
10. Short Form(s)
11. Phone Script
12. HIPAA Preparatory to Research Certification
13. HIPAA Waiver
14. Waiver of Informed Consent Requirements
15. Subject Recruitment Authorization Form – Internal
Guidance for IRB Members: Initial Review of a Full Broad or Expedited Study (03.29.2018)

Page 6

16. Subject Recruitment Authorization Form – External
17. Recruitment Materials
18. Questionnaires or Surveys
19. Data Collection Tools
20. FDA Form 1572
21. IND Letter
22. Investigator Brochure
23. IDE Letter
24. Package Insert for IDE Study
25. Scientific Review Committee Worksheet
26. Other

Study design/statistical considerations:
Questions for consideration, if applicable:
1. Were there any concerns from the scientific reviewer?
2. Is the protocol methodology scientifically sound and adequately designed?
3. Are the hypotheses, clinical objectives and planned analyses clearly stated?
4. Are the planned interventions and their timing clearly stated?
5. For drug trials, are dosages, changes in dosages, and duration of administration clearly stated?
6. Are the primary and secondary outcome measures defined?
7. Is the sample size projected on the basis of statistical calculation?
8. Are the statistical analyses of outcome measures appropriate?
9. Is the randomization method described and appropriate (if applicable)?

Data security
For more information, see IRB guidance on Data Security.
Questions for consideration, if applicable:
1. Are all information security requirements met?
2. Are physical safeguards adequate?
3. Are protocol specific safeguards adequate?
4. Are technical safeguards adequate?
5. Are data stored behind the Downstate firewall?
6. Are encrypted laptop and thumb drives used?
7. Are employee controls adequate?

Study population:
Questions for consideration, if applicable:
1. Is the study population defined, including inclusion/exclusion criteria?
2. Is there appropriate justification for the inclusion/exclusion of populations as outlined in the application materials?
3. Are adequate provisions made for recruiting those with Limited English Proficiency (LEP), when appropriate (i.e., when the study holds the prospect of direct therapeutic benefit), unless there are risks or barriers that prohibit the enrollment of those with LEP.

Informed consent requirements:
For more information, see IRB guidance: Obtaining Legally Effective Informed Consent and HIPAA Research Authorization

1) Process requirements:
a) Except as provided elsewhere in POLICY IRB-01, an investigator may not involve a participant in research covered by this policy, unless the investigator has obtained the legally effective informed consent of the research participant or his/her legally authorized representative (LAR).
b) An investigator shall seek such consent only under circumstances that provide the prospective participant or the LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence. 

   c) The prospective research participant or LAR should be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. 

   d) The information that is given to the participant or the LAR shall be in language understandable to the participant or the representative. 

   e) No informed consent may include any exculpatory language through which the participant or the LAR is made to waive or appear to waive any of the participant’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

2) **The following is required for federally funded or supported research; however, recommended for all studies:** 

   a) Informed consent should begin with a concise and focused presentation of the key information that is most likely to assist a prospective research participant or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

   b) Informed consent as a whole should present information in sufficient detail related to the research, and should be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective research participant’s or LAR’s understanding of the reasons why one might or might not want to participate.

3) **When seeking informed consent, the following basic elements of informed consent shall be provided to each prospective participant (unless waived by the IRB):**

   a) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant’s participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

   b) A description of any reasonably foreseeable risks or discomforts to the participant;

   c) A description of any benefits to the research participants or to others that may reasonably be expected from the research;

   d) A disclosure of appropriate alternative procedures or courses of treatment, if any alternatives are available, that might be advantageous to the research participant;

   e) A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records (if the research is FDA regulated);

   f) For research involving more than minimal risk, an explanation as to whether there is any compensation for potential study-related injury 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;

   g) An explanation of whom to contact for answers to pertinent questions about the research and research participants’ rights, and whom to contact in the event of a research related injury to the participant;

   h) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

   i) For research which is federally supported or conducted or when otherwise applicable to the research or when required by the IRB, one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens should be included:

      i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the research participant or LAR, if this might be a possibility; or

      ii) A statement that the research participant’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

   j) When seeking informed consent for an “Applicable Clinical Trial” (see checklist), as defined FDA Amendments Act of 2007 (FDAAA); the following statement must be included in the informed consent documents and should be included in the information sheet, when documentation of informed consent is waived by the IRB: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

Guidance for IRB Members: Initial Review of a Full Broad or Expedited Study (03.29.2018)
When Individually Identifiable Health Information (IIHI) or Protected Health Information (PHI) and/or identifiable biospecimens are involved in the study, the required HIPAA authorization language must be included with the informed consent to cover the uses and disclosures of IIHI (or PHI). This language is included in the templates in the IRB Application and Reporting System. For additional information see:

i) DMC IRB Informed Consent Template or Information Sheet with HIPAA Authorizations
ii) DMC HIPAA-28 Policy: Uses and Disclosures for Research Purposes

4) When appropriate, one or more of the following additional elements of information must be provided to each research participant or the LAR:
   a) A statement that the particular treatment or procedure may involve risks that are currently unforeseeable to the participant (or to the embryo or fetus, if the participant is or may become pregnant);
   b) Anticipated circumstances under which participation in the research may be terminated by the investigator without regard to the research participant’s or LAR’s consent;
   c) Any additional costs to the participant that may result from participation in the research;
   d) The consequences of a participant’s decision to withdraw from the research and procedures for orderly termination of participation;
   e) A statement that significant new findings developed during the course of the research that may relate to the participant’s willingness to continue participation will be provided to the participant;
   f) The number of participants (approved by the IRB) to be involved in the study. For multi-site studies, it is best to indicate both the number that will be enrolled at the local site and all sites.
   g) For research which is federally supported or conducted or when otherwise applicable to the research or when required by the IRB, the following elements are recommended:
      i) A statement that the research participant’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the research participant will or will not share in this commercial profit;
      ii) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to research participants, and if so, under what conditions; or
      iii) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
   h) Any requirements of any applicable federal, state, or local law.
   i) Any requirements of any applicable tribal law passed by the official governing body of an American Indian or Alaska Native tribe
   j) Include applicable Downstate template language regarding HIV-related information.
   k) When the study involves genetic testing for CLINICAL PURPOSES, include all the required statements described for NYS 79-L. Note: See informed consent template for details. When genetics testing is done only for research purposes, NYS 79-L does not apply; however, some statements in the ICF template may be helpful to inform the participants.
   l) Certificate of Confidentiality (COC) language must be added to all NIH studies, or whenever a COC is required or requested.

5) Informed consent must be obtained for federally funded or conducted research involving Newborn Screening Spots.

6) Lines should be added for the Names of the following individuals:
   a) Child under 13
   b) Cognitively impaired adult

7) Lines should be added for the Names, Signatures, and Dates, as indicated below:
   a) Child providing assent. In general, can be added to consent for assent ages 13-17; otherwise an assent document should be used for ages 7-12
   b) Parent or Legal Guardian. Required when enrolling a child, under the age of 18.
   c) 2nd Parent or Legal Guardian (if applicable). Required for category 406 & 407 research.
   d) Emancipated Minor. An emancipated minor is defined as either a person who is 16 years or older and living independently from his/ her parents or a minor who is a parent him/herself.
   e) Married Minor.
a) To the extent possible, technical, medical, legalese, and scientific concepts should be explained in lay terms (i.e. understandable to the people being asked to participate), especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits. Typically, the consent should be understandable to someone who is educated to the 6th to 8th grade level. Avoid long sentences and medical/technical jargon and define any technical terms clearly whenever they are used. If the definitions of technical terms are lengthy, describe in separate sentences.

b) The IRB should review the adequacy and appropriateness of all wording in the consent materials, as well as the overall length and presentation of information. Consent forms that are long, complex, legalistic, and have a high reading level may overwhelm potential subjects and may inhibit reading of the full document and understanding of the relevant information.

c) Pictures or diagrams may be used to improve understanding of medical terms or how an investigational product functions. IRBs may wish to evaluate, through subject interviews, how well the consent materials communicate critical information.

d) DO NOT Use the first-person tense (e.g., "I understand that..."). As it can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a subject.

e) Provide the names of the sponsor(s) and the institution(s) that support the study (Downstate Medical Center and/or NYC H+H, Kings County) is provided.

f) Description of the standard of care options that would be offered, if the participant does not wish to participate.

g) Description of prohibited materials (medications, supplements, biologics, devices)

h) Description of exclusion criteria.

i) Information about pregnancy testing and/or birth control requirements.

j) Information about pregnancy follow-up studies.

k) Description of the consequences of withdrawing from the study.

l) Description of financial relationships or interests or conflict of interest management plans.

m) Description of specimens or information may be stored for future studies.

n) Include a tiered consent for optional research.

o) Include permission to collect contact information for a personal representative. **NOTE: A waiver of informed consent is needed to collect this information.**

p) Include option to provide contact information of the research participant or legally authorized representative.

q) The amount and schedule of all payments to the participant.

r) Include language regarding any **anticipatable** incidental finding. For more information see Downstate Guidance on Legally Effective Informed Consent or the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) report: **Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Public Health Context.**
Guidance for IRB Members: Initial Review of a Full Broad or Expedited Study (03.29.2018)

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Investigator Qualifications:

Questions for consideration, if applicable:
1. Is the PI qualified to conduct and oversee the research?
   *Note: Review CV if not familiar with the investigator.*
2. Does the PI need to submit a CV?
3. Does the PI have the required PI Status?
4. Should other investigators be added to the study?
5. If multiple PIs are used in this project, are there any concerns with the roles, responsibilities or relationship to the primary PI?

Check the following websites when applicable or concerned:
- Compliance and enforcement lists posted on FDA’s website
- Clinical Investigator Status (Biologics)
- Inspection Classification Database Search
- Clinical Investigators - Disqualification Proceedings
- Inspections, Compliance, Enforcement, and Criminal Investigations

Data and Safety Monitoring Plan:

Questions for consideration, if applicable:
1. Is it appropriate for this research to include a plan to monitor the data collected to ensure the safety of research participants?
2. Has the sponsor or other entity established a Data and Safety Monitoring Board (DSMB)?
3. If no DSMB, is the Data and Safety Monitoring Plan appropriate?
4. Is an external or independent committee required?
5. Is the proposed composition appropriate?
6. If no, what composition is recommended?

Considerations for Recruitment, Referral, Screening, Advertising, & Incentives:

For more information, see IRB Guidance on "Recruitment, Referral, Screening, Advertising, and Incentives."

Questions for consideration, if applicable:
1. Are the methods for participant recruitment clearly outlined in the protocol?
2. Is voluntariness of participation ensured?
3. Is voluntariness of participation ensured?
4. Are privacy protections in place?
5. Is the process for making referrals appropriate?
6. Are recruitment materials and advertising acceptable?
7. Have efforts been made to minimize undue influence and coercion?
8. Are recruitment incentives (compensation, reimbursements) appropriate?

Ancillary Reviews:

Consider whether ancillary reviews are needed for:
- UHB Pathology
- Institutional Biosafety Committee (IBC)
- NIH Recombinant DNA Advisory Committee (RAC)
- Pharmacy
- Radiology
- Radiation Safety
- Other Department Chair(s)
**Conflict of Interest Disclosures**

Consider the following regarding conflict of interest disclosures:

1. Are all required Annual and Transactional reviewers complete?
   
   *Note: The IRB Office checks these and usually places a copy of the check list in the reviewer notes under office workspace, so they may not be visible to other IRB members.*

2. Are Management Plans in place for any Significant Financial Interests?
   
   *Note: A study is flagged by IRB Office if there is a SFI reported. A copy of the COI Management Plan that is in place is attached to the submission in the reviewer notes of an IRB Office member.*

3. Are appropriate disclosures included in the informed consent document?
   
   (See COI Management Plan for requirements; however, IRB may be more stringent)

**Training Requirements**

Consider whether all required trainings are complete?

(IRB Office checks – see checklist)

**Ethical Considerations:**

Questions for consideration, if applicable:

1. Is the research guided by the ethical principles set forth in the Belmont Report?

2. Are there any other concerns related to other applicable principles of professional conduct or ethical codes (e.g. Downstate Code of Ethics, Nuremberg Code, Declaration of Helsinki)?

   *NOTE: The Declaration of Helsinki is followed in Clinical Trials which follow ICH-GCP Standards.*

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**NOTICE OF GCP COPYRIGHT:** Information regarding GCP requirements is taken from the: International Council for Harmonisation (ICH) Harmonized Guideline: *Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2).*
Categories of Research That May Be Reviewed by the
Institutional Review Board (IRB) through an
Expedited Review Procedure

Applicability

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects= financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncanulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electrotetinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and height of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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1 An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

2 Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

WAIVER OF INFORMED CONSENT REQUIREMENTS

IRB Number: SAMPLE #1
Project Title: REDACTED
Principal Investigator: REDACTED

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 & 2.
- ☒ Waiver of Documentation of Informed Consent (waiver of signatures) - complete Section 3.

Section 1:

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.

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 is federally supported or conducted and 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 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.

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 pertinent questions about the research and research subjects’ 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.

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

**Section 3:**

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.

Provide a detailed explanation for making this request: Data comes via participation in an online survey. Participants will be given an information sheet delineating informed consent as the first screen after they have clicked the survey link and they will have to click a button at the bottom that will say "I agree" to participate in the survey. Clicking the button is their consent. This is because it is an anonymous survey and will not ask names or identifying information beyond certain optional demographic information. The documentation is not something that can be linked to anyone taking the survey as even the information that may aid in identifying them such as specialty, age, gender, etc, is optional on their behalf.

Please check either box 1 or box 2 to describe the criteria that justifies 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 quality improvement data, etc.).
2. ☐️ The only record linking the research participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the research participant wants documentation linking him/her with the research and his/her wishes will govern.

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

IRB Number: SAMPLE #2

Project Title: REDACTED

Principal Investigator: REDACTED

☑ 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.

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 is federally supported or conducted and 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.

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 (IHII) 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: We will collect the following information: date of birth, age, sex, race, primary language, insurance, date of clinic visit at which screening test ordered, no of clinic visits in past 2 years, date of most recent ordered HIV testing.

b. What is the source of the health information (e.g., medical record, etc): Electronic medical record

Note: Identify the covered entity or covered component that will release or disclose PHI (IHII) to the researcher.

c. Explain why this health information is the minimum necessary to meet the research objectives: Access to the health information is necessary in order to obtain the initial data set of patient demographics

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and tests ordered from the outpatient clinic electronic medical record. Someone from the clinic that is not associated with this study will create the initial data set. The investigators will not record any identifiers because we are seeking exemption approval.

d. Indicate where protected health information (PHI) or Individually Identifiable Health Information (IIHI) 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.): Only de-identified information will be recorded by investigators. All patient identifiable information will remain in the medical record at UHB, which is subject to privacy and security regulations, policies and procedures. The researchers have been educated on HIPAA regulations and will use password-protected access to medical records. No identifiable information will be used on any of the data worksheets. Any patient lists created will be destroyed at the earliest opportunity consistent with the conduct of the research. Only the research team as listed on the IRB application will have access to the patient list and data.

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): N/A

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: From the original list, we will cross out the names of each patient as we conduct the query of each patient. Only de-identified information will be recorded by investigators. All patient identifiable information will remain in the medical record at UHB, which is subject to privacy and security regulations, policies and procedures. The researchers have been educated on HIPAA regulations and will use password-protected access to medical records. No identifiable information will be used on any of the data worksheets. Only the research team as listed on the IRB application will have access to the patient list and data. The original list will be kept in a locked drawer.

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: We will destroy the original patient list after all names are crossed off the list by shredding it in a Shred-IT box, located in the Department. We will maintain the de-identified dataset for at least 3 years in a secure location after the study is closed, as required by regulations and policy before it is destroyed.
   -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: N/A

c. The PI's e-signature in IRBNet affirms that PHI (IIHI) 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: The scientific validity would be compromised if consent was required. The sample size required is so large that including only those
records for which consent can be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed. Many of the subjects for whom records would be reviewed also are no longer followed.

IV. Explain why the research could not practicably be conducted without access to, and use of, the PHI (IIHI): It would be impossible to investigate the hypothesis presented in the research without access to and use of the PHI due to the nature of the study.

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/IIHI 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.