IRB MEMBER ORIENTATION

Kevin L. Nellis, MS, CIP
Executive Director, Human Research Protections and Quality Assurance

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>
</tr>
</thead>
<tbody>
<tr>
<td>Determination Letter &lt;br&gt; (indicates IRB review is NOT required)</td>
<td>“IRB Decision Aid - Application for a Determination Letter to State IRB Approval is NOT Required”</td>
</tr>
<tr>
<td>Exempt Review</td>
<td>“Application for Exempt Review.” &lt;br&gt; NOTE: The exemption categories are described on the form.</td>
</tr>
<tr>
<td>Expedited Review</td>
<td>“Application for Expedited or Full Review” &lt;br&gt; Note: The criteria for expedited review can be viewed on the OHRP website, by clicking here.</td>
</tr>
<tr>
<td>Convened (Full) IRB Review</td>
<td>“Application for Expedited or Full Review”</td>
</tr>
<tr>
<td>Use of a Humanitarian Use Device (HUD) for clinical purposes</td>
<td>“Application for HUD for Clinical Purposes”</td>
</tr>
<tr>
<td>External IRB Review &lt;br&gt; (some multi-site research)</td>
<td>“Application for External IRB Oversight” &lt;br&gt; Note: To share additional guidance with the External IRB, please see the Guidance: Local Research Context for External IRB.</td>
</tr>
</tbody>
</table>
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.
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?

IRB CHALLENGE

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

Examples of Minimal Risk Research Under Expedited Review

- Clinical studies of drugs and medical devices only under specific conditions (IND and IDE not required)
- Chart reviews
- Survey research which is sensitive and includes identifiable information
- Collection of blood samples
- Biological specimens obtained by non-invasive means
- Collection of data through non-invasive means
- Materials collected solely for non-research purposes
- Collection of data from voice, video, etc.
- Research employing surveys, focus groups, etc.
- Continuing review under specific conditions
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;

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

- 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>
</tr>
</thead>
<tbody>
<tr>
<td>Category 404 (45 CFR 46.404 and 21 CFR 50.51)</td>
<td>✓ No greater than minimal risk ✓ Permission of one parent/guardian ✓ Assent</td>
<td>✓ Same as 404</td>
</tr>
<tr>
<td>Category 405 (45 CFR 46.405 and 21 CFR 50.52)</td>
<td>✓ 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.</td>
<td>✓ Same as 404</td>
</tr>
</tbody>
</table>
### Categories of Permissible Research Involving Children

<table>
<thead>
<tr>
<th>Category</th>
<th>Evaluation</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Category 406</strong>&lt;br&gt;(45 CFR 46.406 and 21 CFR 50.53)</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>
</tr>
</tbody>
</table>

### Categories of Permissible Research Involving Children

<table>
<thead>
<tr>
<th>Category</th>
<th>Evaluation</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Category 407</strong>&lt;br&gt;(45 CFR 46.407 and 21 CFR 50.54)</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.
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

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


---

**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)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm).*

---

**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.

What is a **NSR** Device Study?

- Medical device study that is not a SR study


---

**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)
HIPAA Waivers (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.

- 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?

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

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

- 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

IRB Actions
## 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.

- Access reviewer templates, checklists, and committee guidance documents here.

- 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.

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

- "Check 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.

Manage Work Queue

- 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.
Additional Resources

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Phone Number</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)</td>
<td><a href="mailto:IRB@downstate.edu">IRB@downstate.edu</a></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