Lurie Children’s Panel #2

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What is Panel #2?

- Joint IRB Panel
  - 50% Lurie Children’s personnel; 50% NU personnel
- Monthly meetings
- Typical turnaround time: reviews or approvals issued within 4 days of IRB meeting
- Reviews studies involving Lurie Children’s and Northwestern University (NU) or an affiliate (NMH, CDH, RIC, etc.)
  - Panel #2 can serve as IRB of record for these studies
  - NU IRB can accept reliance upon review in eIRB+
    - Abbreviated application completed for eIRB+
    - Applies to all types of studies (Full Board and Expedited)
Both institutions agreed that:

• NU may rely on Lurie Children’s Panel #2 for review and continuing oversight of its human subject research in these situations:
  • Any study that involves research activity at both Lurie Children’s and NU; and/or
  • Any study with funding through NU but research activity at LCH.

• Both institutions will make reasonable efforts to identify studies at the time of continuing review and transition them to Lurie Children’s IRB Panel #2.

- Lurie Children’s Responsibilities:
  - Serve as the IRB of record for studies involving both institutions
  - Lurie Children’s Panel #2 will review the entire study, including research activity that involves both adults and children taking place outside Lurie Children’s
    - IRB expertise is made up of both pediatric and adult specialties (i.e., maternal-fetal medicine, neonatology, dermatology, etc.)
  - Lurie Children’s Panel #2 will have oversight authority to correct non-compliance and/or suspend research

NU’s Responsibilities:

• Ensure NU researchers comply with University policies and procedures regarding the conduct of human subject research.

• Conduct post-approval monitoring of research activities within NU or its affiliated entities.

• Report any non-compliance or conflict of interest to Lurie Children’s IRB Panel #2.

• Attend Lurie Children’s IRB Panel #2 meetings.
Consideration #1: Location
- Which site(s) will be involved?
  - My study will be conducted at NU (and NU affiliates) only.
  - My study will be conducted at LCH only.
  - My study will be conducted at NU and LCH.

Consideration #2: Funding
- Determine where your grants and/or contracts are processed.
  - My funding is processed through NU OSR.
  - My funding is processed through LCH OSP.
**Consideration #3: Where to Submit**

- If your research activity will involve only Lurie Children’s and the funding is processed through the Lurie Children’s OSP, contact the Lurie IRB to submit your study in Cayuse. No submission to NU is necessary.

- If your study will be conducted only at NU (or an NU affiliate) and the funding is processed through the NU OSR, contact the NU IRB to submit your study solely in eIRB+.

- If your study involves research activity at both Lurie Children’s and NU and/or has funding through NU but research activity at LCH, your study may be reviewed by the Lurie Children’s Panel #2. This will require an abbreviated CIRB submission in NU eIRB+ and a full submission in LCH Cayuse.
When is NU engaged?

- **Examples of when NU is engaged:**
  - Participants will have study visits/activity at an NU site
  - Identified data and/or samples will be sent to investigators at NU
  - Non-Lurie Children’s NU faculty or staff will be engaged in some aspect of the research
  - Some or all of the funding will be coming through the NU Office of Sponsored Research

- **Examples of when NU is involved, but not engaged:**
  - Data will be collected or stored using RedCAP
  - Sharing de-identified data/specimens only
  - Providing standard of care services only (e.g. radiation therapy that is only being done for standard of care)
  - Performing commercial service (e.g. statistical analysis, lab analysis, etc.)
Cayuse IRB Questions

2 Study Settings

A Multi-Institutional Research

* A.1 Is this a multi-center protocol?
  - Yes
  - No

* A.1a Is another site serving as the lead site (that is not Lurie Children’s)?
  - Yes
  - No, Lurie Children’s will be the lead site.
  - N/A, there is no lead site

* A.2 Does this study involve activity, personnel or funding of Northwestern University (NU) or an NU Affiliate (NMH, CDH, RIC, etc.)? Check all of the following that apply:
  - Participants will have study visits/activity at an NU site
  - Identified data and/or samples will be sent to investigators at NU
  - Non-Lurie Children’s NU faculty or staff will be engaged in some aspect of the research
  - Some or all of the funding will be coming through the NU Office of Sponsored Research
  - Data will be collected or stored using RedCAP
  - Sharing de-identified data/specimens only
  - Providing standard of care services only (e.g., radiation therapy that is only being done for standard of care)
  - Performing commercial service (e.g., statistical analysis, lab analysis, etc.)
  - Other:
    - No, NU or an NU Affiliate is not involved in this research study

Note: this study may be reviewed by Lurie Children’s IRB Panel #2. If the PI wishes Lurie Children’s to serve as the IRB of Record for both institutions, the PI must also enter the study into NU’s eIRB+ system and upload the Lurie Children’s IRB approval documents to NU as soon as they are available. The NU Center for Clinical Research (CCR) is available to assist in this process. CCR can be contacted at centerforclinicalresearch@northwestern.edu or at 312-503-9999.

* A.3 Is the PI requesting that Lurie Children’s serve as the IRB of Record for one or more other study sites participating in this study?
  - Yes, this study involves activity at Lurie Children’s and Northwestern University or its affiliates
  - Yes, Lurie Children’s will serve as the IRB of Record for another site other than NU or an NU affiliate
  - No, each institution will conduct its own IRB review
Lurie Children's Review Process

- Submission received via Cayuse IRB
- IRB staff conduct pre-review
  - Identify major issues
  - Note what type of review is required (convened, expedited)
  - If convened, study is routed to IRB Chair for comments
- Submission returned to PI for response to pre-review comments
- Response to pre-review reviewed by same coordinator who conducted pre-review
  - If convened, routed to Panel #2 for review
  - If expedited, route to Vice Chair for review
- Issues remain, routed back to PI for response
- Approved, documents sent to PI
PI Submits Study, Modification or Renewal for Study involving Lurie Children’s & NU or affiliate

To Lurie Children’s IRB Indicating Involvement with NU or affiliate

Study Undergoes Pre-Review per Lurie Children’s P &P

Study Reviewed by Lurie Children’s Panel #2

Once approved Principal Investigator provides Lurie Children’s approval documents to NU IRB

To NU IRB (abbreviated application) indicating Reliance on Lurie Children’s

NU or affiliates verifies
- Investigator/Staff are qualified and have met human subjects education requirement
- Confirm NU/affiliate has facilities to perform study/department approvals
- Forward any pertinent COI management plans to Lurie Children’s Panel #2

NU determines if reliance is appropriate
Lurie Children’s- Types of Submissions

• New studies
  • Can request reliance between the institutions upon initial review

• Renewals (Continuing Reviews)
  • Studies identified to have NU or an affiliate engagement in the research routed through Panel #2 for review
  • PI can request NU’s reliance on Lurie Children’s upon submission of renewal to eIRB+ (This requires a MOD/CR submission.)

• Modifications (Amendments)
  • Modifications adding NU or an affiliate as a study site is routed through Panel #2 for review
Submission requirements for studies reviewed under Panel #2 follow Lurie Children’s policies and procedures:

- Complete Cayuse IRB submission
  - Typically completed prior to submitting study to eIRB+ (unless NU involvement including funding, then simultaneous submissions are acceptable)
- Letters of Support and Organizational Approval for Lurie Children’s only
- Joint Panel Informed Consent documents
NU - Types of Submissions & Requirements

- **New studies**
  - Include the identifier “(CIRB)” at the beginning of the study title
  - Indicate in Basic Information Question #7 that an external IRB will serve as the IRB of record
  - Enter the Lurie Children’s Panel #2 expiration date

- **Updates (Continuing Reviews)**
  - Upload a copy of:
    - the approval letter from Lurie Children’s,
    - the most recently approved protocol, and
    - the most recently approved consent/assent documents (if applicable).

- **Modifications (Amendments)**
  - Necessary only if the IRB responsibility needs to be changed

- **Reportable New Information (RNIs)**
  - Anytime participants at NU are involved, follow guidance on IRB website.
Update External IRB Status

1. External IRB:
   - CopenHHS Group IRB

2. Approval letter from external IRB:
   - Upload Revision
   - Delete

3. Initial approval date by external IRB:
   - 7/7/2015

4. Last date of the approval period:
   - 2/2/2016

5. Supporting documents:

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6. Has the external IRB closed the study? (If so, the study will be closed here)
   - [ ] Yes
   - [ ] No

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*Funding & Study Personnel*

*AT INITIAL SUBMISSION ONLY*
Why do I get a letter sometimes and not others?!

- Still working out converting active studies

- The submission fields were not an exact match in eIRB+

- This is an evolving process
Dr. Knee, a Lurie Children’s physician, has a greater than minimal risk study being conducted at the Lurie Children’s pediatric orthopaedic clinic. Dr. Knee also has privileges at NU, and his funding for this study was received through the NU Office of Sponsored Research. No research procedures are occurring at NU.

Which panel at Lurie Children’s should review this study?

Is NU IRB review required?
Case #1 Answers

Which panel at Lurie Children’s should review this study?

Lurie Children’s Panel #2

Is NU IRB reliance required?

Yes
Dr. Baby is conducting a study in the Prentice NICU and Lurie Children’s PICU. Both Lurie Children’s and NU staff are research personnel, and will perform study procedures. The study population includes mothers and their newborn infants being seen in the NICU.

Which panel at Lurie Children’s should review this study?

Is NU IRB reliance required?
Case #2 Answers

Which panel at Lurie Children’s should review this study?

Lurie Children’s Panel #2

Is NU IRB reliance required?

Yes
Dr. Head is a neurologist at Lurie Children’s, and has a study where all the research activity is occurring at Lurie Children’s. NU’s involvement is limited to data being stored in REDCap.

Which panel at Lurie Children’s should review this study?

Is NU IRB review required?
Case #3 Answers

Which panel at Lurie Children’s should review this study?

Lurie Children’s Panel #1

Is NU IRB reliance required?

No
Cayuse IRB Access

- To request Cayuse IRB access:
  - Complete the Cayuse Backbone form
    - Available on the ORIC website or from ORIC staff
  - Complete Human Subjects Protection Education
    - CITI or NIH course acceptable
  - Send both to IRB@luriechildrens.org
eIRB+ Access

NU Biomedical IRB Information:
You may either call 312/503.9338 or send an e-mail to: irb@northwestern.edu

Instructions on how to submit your study can be found on the NU IRB website: http://irb.northwestern.edu
Panel #2 Meeting Schedule

Panel #2
For studies with NU involvement and/or submissions that have completed the pre-review process by noon 10 days prior to the meeting as the agenda permits.

- August 31, 2015
- October 5, 2015
- November 2, 2015
- December 7, 2015
Questions?