DEPARTMENT OF PEDIATRICS
RESEARCH GUIDE

Last updated on: 1/18/2022

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REVISIONS & UPDATES

This guide was originally published on September 15, 2019. Subsequent revisions are summarized below:

- 1/18/2022
- 12/3/2019
- 1/23/2020
- 3/11/2020

WELCOME

Welcome to Pediatric Research!

Lifespan

All aspects of research conducted in the Department of Pediatrics are overseen by the
Lifespan Office of Research (LOR) and the Lifespan Research Protection Office (RPO). Lifespan and the Department's research
policies and processes are described in this guide.

Orientation

Begin with these steps:

> Review this guide for a general
> overview of
> Pediatrics Department
> research processes

> Contact the Pediatrics
> Research Administrator
> **(KBennett5@lifespan.org)**
> to discuss your specific needs
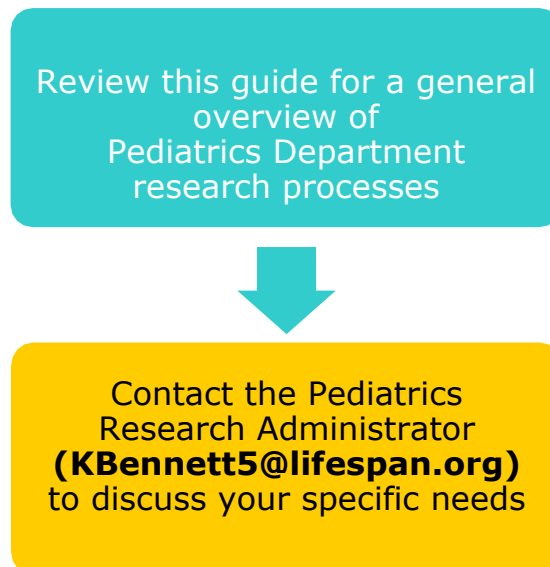
Transfers

Pediatric investigators transferring from another institution should meet with Department Research Administrators as soon as
possible to coordinate the transfer of research funds, contracts, IRBs, and other active project components.

Meet the Team!

PEDIATRICS RESEARCH LEADERSHIP

Pediatrician-in-Chief

Phyllis A. Dennery, MD

phyllis_dennery@brown.edu

Vice Chair of Research
Director of Pediatric Mentoring Program
Daphne Koinis Mitchell, PhD
dkoinismitchell@lifespan.org

Vice Chair of Education
Katherine Mason, MD
(401) 444-9328
Katherine_mason@brown.edu

Director of Fellowship Program
Mark Zonfrillo, MD
Brown Pediatrics
zonfrillo@brown.edu

RESEARCH CABINET MEMBERS

Dr. Phyllis Dennery
Dr. Jennifer Friedman
Dr. Philip Gruppuso
Dr. Daphne Koinis Mitchell
Dr. Jill Maron
Dr. Katherine Mason
Dr. Jennifer Sanders

RESEARCH ADMINISTRATION

(Hasbro 124)

Sr. Departmental Research Administrator
Kaitlin Bennett, MS
(401) 444-9328
KBennett5@Lifespan.org

PEDIATRICS CLINICAL RESEARCH STAFF
(MPH 1)

Research Nurse Supervisor
Barbara Bancroft, MSN
(401) 444-2884
BBancroft@lifespan.org

DESIGNING A STUDY

Discuss Your Idea with Colleagues

To obtain guidance and recommendations from experienced investigators, you are encouraged to present your research idea to a Pediatrics Research Cabinet member. A Cabinet member can help you identify potential road blocks early on and suggest pertinent resources you may not have been aware of. See Cabinet Member listing with contact information below.

Research Cabinet Members & Areas of Expertise

Phyllis Dennery, MD
Phyllis_Dennery@brown.edu
Basic/Transitional

Katherine Mason, MD
Katherine.Mason@lifespan.org
Educational

Jennifer Friedman, MD
Jennifer_Friedman@brown.edu
Clinical Epidemiology/International Health

Philip Gruppuso, MD
Philip_Gruppuso@brown.edu
Basic/Transitional

Jennifer Sanders, PhD
Jennifer_Sanders@brown.edu
Basic/Transitional

Daphne Koinis Mitchell, PhD
DKoinisMitchell@lifespan.org
Behavior/Clinical/Transitional

Mark Zonfrillo, MD
Zonfrillo@brown.edu
Bioepidemiology

Jill Maron, MD
JMaron@wihri.org
Basic/Translational

Consult with Experts

Dr. Philip Gruppuso, a Pediatric faculty member, research scientist, is a wonderful resource for Pediatric faculty, fellows, and residents right here in our own department. Dr. Gruppuso is available to assist Pediatric investigators with development of statistical and research design, research plans for grant applications, and development of manuscripts.

Contact Dr. Gruppuso to set up an appointment:
Philip Gruppuso, MD
Professor, Pediatric Endocrinology
Philip_gruppuso@brown.edu

Ray Tanzer, PhD and **Phin Has, MA** offer Biostatistical Support to Pediatric Faculty, Fellows and Residents. Their contact information is:
JTanzer@lifespan.org
PHas1@lifespan.org

Please fill out the **link** with any requests for biostatistical support.

The Lifespan Clinical Research Center (LCRC) offers many research services, facilities, and resources. The LCRC's Biostatistics Core provides centralized consultation services to investigators in study design, analytics, and the clear communication of scientific results. Our department provides funding to the Biostatistics Core to ensure these resources are available to our investigators. To learn more, contact:

Jason Machan, PhD
Director of Lifespan Biostatistics Core
jmachan@lifespan.org

Advance Clinical and Translational Research (Advance-CTR) is a partnership between Brown, URI, CNE, Lifespan, VA Medical Center and the RIQI to support and educate clinical and translational researchers in Rhode Island. Advance-CTR offers research services, resources, and training in biomedical informatics, research design, epidemiology, biostatistics, and clinical research to Rhode Island-based clinical and translational research faculty. Click here to request a service.

For information on research training and workshops, see CONFLICTS OF INTEREST IN RESEARCH

Pediatrics investigators with a *perceived* Conflict of Interest should first discuss with Departmental Research

Administrators.

 See Lifespan's Research Conflicts of Interest Policy

Lifespan's policy on Research Conflicts of Interest (COIs) applies to the PI and anyone else who is **responsible** for the design, conduct or reporting of the research that is conducted under the auspices of Lifespan (usually co-investigators and other senior/key personnel affiliated with Lifespan).

Anyone who falls under this policy must:

- be familiar with the policy

- complete Lifespan's mandatory CITI training course on COIs no less than every 4 years

    o Download the CITI Training Instructions handout

- disclose COIs to Lifespan prior to submitting any application for funding

    o Your departmental research administrator will send you a Lifespan COI disclosure form to complete just prior to proposal submission

- disclose COIs to Lifespan within 30 days of discovering or acquiring a new COI

    o Download the Lifespan COI disclosure form

- comply with any COI management plan issued by Lifespan

- retain all documentation that demonstrates compliance

When a COI is disclosed, the Lifespan Research Conflict of Interest Committee (LRCOIC) will determine if an actual financial conflict of interest exists and if it can be managed, reduced or eliminated. If the investigator involved in the financial COI proposes to use human subjects in research related to the disclosed conflict, the IRB shall review the COI management plan. The IRB will have the opportunity to suggest changes, approve, or disapprove the plan. The IRB will communicate the decision to the LRCOIC.

Training Requirements

CITI Training (mandatory)

All research personnel are required to complete Lifespan's CITI online training courses *prior to conducting any research activity*. Download the CITI Training Instructions handout.

Epic LifeChart Training (mandatory)

Pediatrics research staff who need to access LifeChart must complete online training courses in NetLearning. The required courses will be assigned to the user's NetLearning account and instructions will be sent to the user.

There are two levels of LifeChart access for research staff:

- Research Coordinator: allows the user to associate patients, appointments, and orders to studies, place orders and route them to appropriate individuals to be signed, and review billing

- Research Read-Only (for Research Assistants and Students): allows the user to read the medical record, but not document in the record itself

IRBnet Training (optional)

Download IRBnet training materials and guides

IRB Approval

Do I need to submit my project to the IRB?

Research Projects

All research projects **involving human subjects** must be submitted to the Lifespan IRB for review. An approval or exemption letter from the IRB is required *prior to* conducting any research activity.

QA/QI Projects

Quality assurance/quality improvement (QA/QI) projects do not require IRB review. However, investigators should consider whether **there is the possibility that the resulting data will be worthy of publication or presentation** and thereby contribute to generalizable knowledge. If so, Lifespan IRB approval must be sought *prior to* initiating the project. Should a QA/QI project provide interesting results that the investigator would like to publish, IRB approval cannot be given retroactively.

Unsure?

If you are not sure whether an activity falls into clinical practice, QA/QI or research, you should request an IRB opinion before initiating the activity. A request for opinion can be sent to:

RPO@lifespan.org

Should I submit my project to the Lifespan IRB or Brown IRB?

All research projects must be approved by the Lifespan IRB.

When is a study exempt from IRB review?

Upon submission of your application, the IRB will determine whether your study is exempt from IRB review based on criteria set by federal regulations, and will issue approval to begin the project in the form of an Exempt Determination Letter. An exempt project does not need to submit progress reports or revisions to the IRB, as long as the project maintains the properties that make it exempt.

Is my study greater than minimal risk?

Upon submission of your application, the IRB will make a determination regarding the risks associated with the research based on criteria set by federal regulations. 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. Studies that involve minimal risk to human subjects are reviewed on an expedited/rolling basis and do not have to be submitted by the established IRB deadlines.

When is the IRB submission deadline?

Download the IRB Submission Deadlines, which can be found on IRBnet. You'll notice there are three IRB committees. Refer to the deadlines for **RIH1**.

What is the difference between Lifespan's three IRB committees?

Lifespan has three IRB committees (RIH1, RIH2, and TMH) that meet once per month to review applications. When you submit your application, you will select Rhode Island Hospital and your application will automatically be sent to RIH1. An IRB assistant will review your application and may forward it to RIH2 or TMH when appropriate. Each committee specializes in different populations. For example, applications that include pediatric participants will be forwarded to RIH1 or RIH2. Applications that plan to collect data from prisoners or the deceased will be forwarded to TMH. If your application is forwarded to a different committee, you will receive an e-mail notification.

How early should I submit my IRB application?

Non-exempt studies with greater than minimal risk should be submitted **2 – 3 months prior to the anticipated project start date**.

Studies that are minimal risk or exempt will undergo an expedited review process and can be submitted 1 – 2 months prior to the anticipated project start date.

If your study is awaiting federal funding, a good time to submit the IRB application is: (1) following peer review and notification of impact score/percentile *if it appears to be in a fundable range*; or (2) after you receive a Just in Time (JIT) request. Note: The IRB approval letter <u>does not</u> have to be filed by the JIT deadline. IRB approval may be filed *at any time* before the award is made. If an IRB approval letter is not sent to the sponsor prior to the award's start date, rest assured that funds will not be withheld or delayed. However, research activities will not be allowed to begin until the IRB approval letter has been filed.

How long does IRB review take?

It depends!

Your application will first be reviewed by an IRB coordinator for errors or missing information. If modifications are required, the IRB coordinator will unlock your application and allow you to make the requested changes. Once the IRB coordinator deems your application to be complete, it will be forwarded for review. Studies that are minimal risk or exempt will be sent to a single reviewer (this is called Expedited Review). Studies that are greater than minimal risk will be placed on the agenda for an upcoming Full Board Review meeting. If the reviewer/board decides your application does not meet approval criteria, a request for revisions or clarifications letter will be sent and a response needs to be submitted addressing each concern. When the reviewer/board decides your application is clear, complete, and consistent with all regulations, an approval letter will be issued. Each time you submit information to the IRB, allow up to 10 business days to receive a response, action, or decision.

The length of review really depends on which IRB meeting date your application will be ready for and how many revisions / clarifications the reviewer will request. For this reason, it is recommended to submit your application 2 - 3 months in advance of your anticipated project start date.

Is there an administrator who can facilitate my IRB application?

Who should request IRB administrative support?
Our Regulatory Coordinator, Barbara Bancroft, is available to help submit and manage IRB applications and to serve as a liaison between the PI and the IRB. However, due to the high volume of IRB applications within the department, plan ahead as much as possible as this process can be long and arduous.

If your request is approved:
The PI is ultimately responsible for the IRB application. The PI must remain in regular contact with the Regulatory Coordinator and must respond to all requests and inquiries in a timely manner. The Regulatory Coordinator will request a copy of all study documents from the PI. She will then send the PI the required application forms to complete. The Regulatory Coordinator will upload the completed application forms and study documents to IRBnet and route for signatures. Once submitted, the Regulatory Coordinator will keep the PI informed of the approval status. The PI will be expected to attend the IRB review meeting. The Regulatory Coordinator *cannot* attend the IRB review meeting in place of the PI. Once approved, the Regulatory Coordinator will remind the PI when the annual progress report is due and will send the PI the required forms to complete. The PI must immediately inform the Regulatory Coordinator of all protocol revisions, personnel changes, adverse events, protocol deviations, and when to close the project. If the study will utilize the departmental RAs, they may assist with completing IRB forms.

Does receiving IRB approval mean that I can start my study?

An **unfunded** research project may begin when an IRB approval or exemption letter has been received.

A **funded** research project or **industry trial** can only begin if the IRB approval letter contains the following statement:

This notification CONSTITUTES AUTHORITY FOR ACTIVATION of this application.

If the IRB approval letter states… This notification DOES NOT CONSTITUTE AUTHORITY FOR ACTIVATION of this application. An activation notice will be sent, when appropriate, by a separate memo. No activity in this project is permitted until an activation notice is received. …this means the project may not begin until funding has been activated ("activated" means a cost center has been created). At this point, you should check with your Department Research Administrator on the status of your cost center activation. When you receive a cost center activation notice/memo, you will need to add the cost center number to the funding section of your IRB application. See How do I update funding information on my IRB application?

Ensure all study personnel receive a copy of the IRB-approved (i.e. stamped) versions of all study documents. If the protocol or other study documents were revised during the review process, ensure all study staff have a copy of the current, clean, and approved version. See Where can I find my IRB letter and IRB-stamped documents?

Once I have IRB approval, what do I need to report to the IRB ?

Changes to the approved protocol, forms, or study documents

Throughout the course of your study, any change to the approved protocol or other study documents must be approved by the IRB before the change is implemented. When revising a study document, make sure all changes are tracked.

See How do I notify the IRB of changes to my project?

Changes to study personnel

New study staff (or changes to an existing staff member's role and responsibilities) must be added to your IRB application and approved by the IRB *before* the staff member begins working on the study. Additionally, study staff who are no longer working on the project should be removed from your IRB application. You can wait until you submit a continuing review / progress report to remove all former staff.

See How do I add or remove study staff from my IRB application?

Changes to funding sources

Additional funding sources, a funding source that has changed from pending to unfunded, or a funding source that has changed from pending to active, must be immediately submitted as a revision to your IRB application.

See How do I update funding information on my IRB application?

Adverse events and protocol deviations

Adverse events and protocol deviations must be reported to the IRB within 5 days of awareness. Adverse events only need to be reported if they are unanticipated, serious, related to the research study, and place subjects or others at greater risk of harm than was previously known or recognized. These events routinely warrant substantive changes to protocol, ICD/Process, or other corrective actions to protect the safety, welfare or rights of subjects.

See How do I notify the IRB of an adverse event or protocol deviation?

Termination of the project

If you stop your project prematurely, you must terminate your IRB application. Normally, you would terminate your IRB application when (1) enrollment has ended, (2) data collection has ended, (3) all interactions & follow-up with subjects has ended, and (4) analysis of identifiable data has ended. Data analysis may continue after the IRB application has been terminated as along as all data has been de-identified.

See How do I close / terminate my IRB application?

Does IRB approval expire?

IRB approval will expire in 1 year (sometimes sooner). The expiration date will be stated in the IRB approval letter and posted in IRBnet. Note: Studies which are exempt from IRB review do not have an expiration date.

> See Where can I find the project's expiration date?

A continuing review (i.e. progress) report must be submitted 60 days prior to the project's expiration date to continue the project without a lapse in approval.

> See How do I renew my IRB application / submit a continuing review report?

What happens if IRB approval expires before the project has ended?

On the project's expiration date, all research activity must stop until the project has been renewed (see How do I renew my IRB application / submit a continuing review report?).

A continuing review (i.e. progress) report should have been submitted 60 days prior to the project's expiration date to avoid this lapse in approval. If the continuing review report is not received within 30 days of the project's expiration date, the project will be administratively closed. A project that has been administratively closed cannot be re-opened or renewed. If you wish to continue the project, it will need to be submitted as a new IRB application and undergo the full review and approval process (see How do I submit a new IRB application?).

When can I close / terminate my IRB application?

You may terminate your IRB application when (1) enrollment has ended, (2) data collection has ended, (3) all interactions & follow-up with subjects has ended, and (4) analysis of identifiable data has ended. Data analysis may continue after the IRB application has been terminated as along as all data has been de-identified.

What is Lifespan's single IRB policy?

NIH-funded research and **NIH funding proposals** must adhere to the new Single IRB Policy. NIH now requires multi-site, non-exempt, human subjects research projects to use a single IRB to conduct IRB review and approval for all domestic sites. This requirement does not apply to foreign sites or career (K), training (T), or fellowship (F) funded projects.

If you are at the proposal stage:

See What information should be included in an NIH proposal to meet the new single IRB requirements?

If the grant is funded (or you anticipate funding):

In general, single IRB review will involve a few steps:

1. Each participating site's IRB will need to establish a Reliance Agreement with the single IRB of record for the project. Contact the Lifespan IRB Director, Janice Muratori (jmuratori@lifespan.org), to begin this process. Many institutions (including Lifespan) have signed a generic Master Reliance Agreement called the "SMART IRB Agreement," which eliminates the need for study-specific agreements. Institutions using this agreement will have a streamlined start-up process.

2. The lead site will submit the generic protocol and consent forms to the single IRB for approval

3. The lead site will gather site-specific information to submit to the single IRB for approval. This may include investigator qualifications, site-specific recruitment and consent information, and other local context information (e.g. state and local regulations that apply to the research). Send any requests for Lifespan-specific or RI-specific information to the Lifespan IRB Director, Janice Muratori (jmuratori@lifespan.org), for assistance in gathering this information.

Contact the Lifespan IRB Director, Janice Muratori (jmuratori@lifespan.org) with any questions.

Using IRBnet for IRB Submissions

How do I create a Lifespan IRBnet account?

1. Go to www.irbnet.org
2. Click on New User Registration, select Lifespan as your organization
   a. If you already have an IRBnet account, log in to www.irbnet.org, go to User Profile (top left), click on Add an Additional Affiliation, select Lifespan

How do I search for projects in IRBnet? I can't find a project.

Click on My Projects to view all projects that you have created or that have been shared with you. Use the arrows ▶ ▶| to advance to the next page if you have more than 10 projects. To see a project that you did not create, the PI (or someone else with full access to the project) will need to log in, click on Share this Project, search for your name and give you access. Projects that have been shared with you will automatically appear in your My Projects list. If you still cannot find a project, click on Show Archived Projects to see if it may have landed in your archive folder.

How do I submit a new IRB application?

1. Log in to www.irbnet.org
2. Go to Forms and Templates, Select a Library: choose Rhode Island Hospital
3. Download the Application Checklist
4. Download and complete all required forms listed in the checklist

   Note: Before you complete a form, make sure to download and save it to your desktop, open it from your desktop, and then complete it. Do not complete a form while it is open in a web browser as your answers may be lost when you close the form.

5. Go to Create a New Project and enter the project information
6. Go to Designer to upload all required forms and documents listed in the checklist

   - To find the Core Form, click on Start a Wizard, then select: Lifespan - Research Application Part 1- Human Subject Studies

7. Go to Share this Project and grant access to the following people:

   - PI: Full Access
   - Barbara Bancroft: Read Only
   - Phyllis Dennery: Read Only
   - Other study personnel may be given full or read access as needed

8. Go to Sign this Package, select PI, then click Sign
9. Send an e-mail to Dr. Phyllis Dennery (phyllis_dennery@brown.edu) requesting she sign and approve your IRB submission

   Note: It is an IRB policy that all <u>new</u> IRB applications must be signed by the Department Chair. Go to Submit this Package, select Rhode Island Hospital, and follow the prompts to submit.

Where can I find a staff member's HSP training completion date?

A record of everyone who has completed the Lifespan CITI Human Subjects Protection (HSP) course and their completion date is posted in IRBnet:

1. Log in to www.irbnet.org
2. Go to Forms and Templates, select a Library: choose Rhode Island Hospital
3. Download the file called: CITI HSP Training Dates ##-##-#### thru ##-##-####

Contact Barbara Bancroft (Bbancroft@lifespan.org) if you're having trouble locating a CITI date or certificate.

Where can I find my study's cost center?

Funded studies: The cost center (###-####) will be listed on the funding activation notice from LOR.

Pending funds: On the first line, enter '701-7909' as the cost center and 'Department of Pediatrics as the sponsor. On separate lines, enter any pending grant applications you've submitted for this project, including the Sponsor name and 'pending' as the cost center.

Unfunded studies: Enter '701-7909' as the cost center and 'Department of Pediatrics as the sponsor.

If you have questions regarding your cost center, contact Barbara Bancroft (bbancroft@lifespan.org)

Where can I find my IRB letter and IRB-stamped documents?

1. Log in to www.irbnet.org
2. Click on the project title to open the project
3. Click on Reviews
4. Download, save, and review each attachment listed under Board Documents
5. Follow all instructions provided in the IRB letter

How do I notify the IRB of changes to my project?

1. Log in to www.irbnet.org
2. Go to Forms and Templates, select a Library: choose Rhode Island Hospital
3. Download the Revision Request Form
4. Follow all instructions on the Revision Request Form
5. Go to My Projects to open the project
6. Go to Designer to upload the Revision Request Form and all revised documents (you must upload two versions of each revised document, one showing tracked changes, and one clean version with all changes accepted).
7. Go to Sign this Package, select PI, then click Sign
8. Go to Submit this Package, select Rhode Island Hospital, and follow the prompts to submit.

How do I add or remove study staff from my IRB application?

1. Log in to www.irbnet.org
2. Go to Forms and Templates, Select a Library: choose Rhode Island Hospital
3. Download the Revision Request Form
4. Follow all instructions on the Revision Request Form
5. Go to My Projects to open the project
6. Go to Designer to upload the Revision Request Form
7. In Designer, locate the Lifespan - Research Application Part 1 – Human Subject Studies Form and click on the pencil icon next to it
    a. Under Jump To, select Study Personnel Information, then click Jump
    b. At the very bottom of the page, select Add Another Individual
    c. Complete all fields:
        i. Faculty: select Employed by Affiliate Practice
        ii. Brown Resident/Fellow/Medical Student: select yes to GME question
        iii. Students and other individuals: select yes to Volunteer Office question if the person has a Lifespan ID badge. For questions, contact Barbara Bancroft (bbancroft@lifespan.org)
        iv. HSP Training Complete Date: see Where can I find a staff member's HSP training completion date?
    d. When finished, click on Save and Exit
8. Go to Sign this Package, select PI, then click Sign
9. Go to Submit this Package, select Rhode Island Hospital, and follow the prompts to submit.

How do I update funding information on my IRB application?

1. Log in to www.irbnet.org
2. Go to Forms and Templates, Select a Library: choose Rhode Island Hospital
3. Download the Revision Request Form
4. Follow all instructions on the Revision Request Form
5. Go to My Projects to open the project
6. Go to Designer to upload the Revision Request Form
7. In Designer, locate the Lifespan - Research Application Part 1 – Human Subject Studies Form and click on the pencil icon next to it
    a. Under Jump To, select Project Funding Information, then click Jump
    b. Add the cost center # for any active funding
    c. Delete any pending funding that was not received
    d. When finished, click on Save and Exit
8. Go to Sign this Package, select PI, then click Sign
9. Go to Submit this Package, select Rhode Island Hospital, and follow the prompts to submit.

How do I notify the IRB of an adverse event or protocol deviation?

1. Log in to www.irbnet.org
2. Go to Forms and Templates, Select a Library: choose Rhode Island Hospital
3. Download the Unanticipated Event Form (for adverse events) <u>or</u> the Deviation-Exception Report Form (for protocol deviations)
4. Complete the form
5. Go to My Projects to open the project
6. Go to Designer to upload the form
7. Go to Sign this Package, select PI, then click Sign
8. Go to Submit this Package, select Rhode Island Hospital, and follow the prompts to submit.

How do I renew my IRB application / submit a continuing review report?

1. Log in to www.irbnet.org
2. Go to Forms and Templates, select a Library: choose Rhode Island Hospital
3. Download the Continuing Review Report Checklist
4. Download and complete all the required forms listed in the checklist.
5. Go to My Projects to open the project
6. Go to Designer to upload all the required forms and documents listed in the checklist
7. Go to Sign this Package, select PI, then click Sign
8. Go to Submit this Package, select Rhode Island Hospital, and follow the prompts to submit.

Where can I find the project's expiration date?

1. Log in to www.irbnet.org
2. Click on the project title to open the project
3. Click on Project Overview

See Once I have IRB approval, what do I need to report to the IRB?

How do I close / terminate my IRB application?

1. Log in to www.irbnet.org
2. Go to Forms and Templates, select a Library: choose Rhode Island Hospital
3. Download the Termination Report Form
4. Complete the form
5. Go to My Projects to open the project
6. Go to Designer to upload the form
7. Go to Sign this Package, select PI, then click Sign
8. Go to Submit this Package, select Rhode Island Hospital, and follow the prompts to submit.

See When can I close / terminate my IRB application?

Who do I contact if I have an IRB question?

IRB E-mail Messages

If you need clarification regarding an IRB e-mail, contact the IRB staff member who sent the e-mail.

IRBnet Technical Support
Barbara Bancroft
bbancroft@lifespan.org

IRB Policy Questions
RPO@lifespan.org

Lifespan IRB Website
IRB, IACUC, IBC

Good Clinical Practice

The International Conference on Harmonisation (ICH)'s Good Clinical Practice (GCP) guidelines set the standard for the design, conduct, monitoring, and reporting of clinical research to assure that human subjects are adequately protected and that the data is accurate and credible. To ensure GCP guidelines are met for all studies, all investigators must (1) comply with Lifespan's Policy and Procedure Manual and (2) comply with standard operating procedures established by the department (described below). For questions, contact Barbara Bancroft (bbancroft@lifespan.org)

Project start date

An IRB approval (or exemption) letter is mandatory prior to commencing any research activity. However, not all approval letters grant authority to begin the project. Read the approval letter carefully for stipulations. See Where can I find my IRB letter and IRB-stamped documents?

An **unfunded** research project may begin when an IRB approval or exemption letter has been received.

A **funded** research project or **industry trial** can only begin if the IRB approval letter contains the following statement:

This notification CONSTITUTES AUTHORITY FOR ACTIVATION of this application.

If the IRB approval letter states… This notification DOES NOT CONSTITUTE AUTHORITY FOR ACTIVATION of this application. An activation notice will be sent, when appropriate, by a separate memo. No activity in this project is permitted until an activation notice is received. …this means the project may not begin until funding has been activated ("activated" means a cost center has been created). At this point, you should check with the Department Research Administrators on the status of your cost center activation. When you receive a cost center activation notice/memo, you will need to add the cost center number to the funding section of your IRB application. See How do I update funding information on my IRB application?

Project startup checklist

- ☐ If funded, I have received a cost center activation notice from Lifespan

- ☐ I have received IRB approval from Lifespan to begin the project

- ☐ I have set up a Regulatory study binder / Essential documents binder (EDB)

- ☐ All study staff have undergone the appropriate training to conduct study procedures and have copies of the IRB-approved (i.e. stamped) versions of all study documents

- ☐ If funded, I have completed all start-up requirements of the sponsor

Regulatory Study Binder/Essential Documents Binder (EDB)

What it is
All studies that have an active IRB application must have a physical regulatory binder. Maintaining a study binder allows the research team to easily reference information, and provides access to essential documents by trial monitor, auditor, IRB, or regulatory authorities (e.g. OHRP, FDA). The study binder provides a complete and thorough history from study start-up to completion.

What to include
The most common sections needed in a regulatory binder are listed below. Items with an asterisk may or may not be applicable to your study. Many of these documents can be downloaded from your IRB application. As a rule of thumb, all documentation *submitted to* the IRB as well as *received from* the IRB should be included in the binder. Whenever you make an IRB transaction, remember to print the associated documents and add them to your binder. *Documents containing PHI (e.g. signed consent forms, lab results, and completed case report forms) should be maintained separately in a participant file.*

- PI's CV or biosketch
- Key Personnel List
- Training and Licensure Certificates (as applicable to the study, including CITI certificates)
- Staff Signature Log
- Enrollment/Screening Log
- Sponsor Contact Information, Sponsor Agreement, and copies of all formal sponsor correspondence*
- Laboratory Documentation/Normal Lab Values/CLIA certificate*
- Randomization Instructions*
- Emergency un-blinding procedures*
- Protocol (all IRB-stamped versions)
- Recruitment Materials (all IRB-stamped Ads, Flyers, Brochures, etc.)
- Consent/Assent Forms (all IRB-stamped versions)
- HIPAA Waiver of Authorization, Prep to Research* (IRB-stamped versions)

IRB Documentation (Original Application, Continuing Review Reports, Revisions Forms, and all IRB Letters)
- Data Collection Tools
- NIH Grant and Award*
- DSMB charter and reports*
- Unanticipated Problems / Adverse Events / Deviations Reports
- Standard Operating Procedures
- Notes to File (informal memos to study staff)
- FDA 1571/1572*
- Financial Disclosure*
- IND / IDE*
- Investigator Brochure / Package Insert / Device Manual*
- Drug / Device Accountability*
- Download templates

How to organize it
The binder should be divided into sections/tabs and each section should be organized in chronological order. All documents should have a date or version #. The most recent version of a document should always be placed on top of older versions. Older versions of documents should not be removed from the binder. It is customary to draw a large "X" over older versions of documents that are no longer in use. As the binder grows, it may be necessary to create a second binder. The regulatory binder should be stored in a place where it is accessible to all study staff and clearly labelled. The binder cover should be labelled with the following information:

- IRB committee number
- Study Title
- PI
- Sponsor
- Institution and location
- Binder # (if there are multiple; e.g. binder #1 of 3)

The PI is ultimately responsible for creation and upkeep of the binder but may delegate the task to a study staff member.

For questions, contact Barbara Bancroft (bbancroft@lifespan.org)

Accounting of disclosures

The following policy applies when a Preparatory to Research, Waiver of HIPAA Authorization or Decedent Data Collection approval has been granted by the IRB (i.e. you have been authorized to access medical records for research purposes without, or prior to, obtaining the patient's consent). Only members of the Lifespan workforce are authorized to access PHI/medical records for research purposes. Foundation-employed physicians (and foundation staff) are not considered members of the Lifespan workforce, and therefore must account for (i.e. maintain a list of) all PHI accessed *for research purposes*. Before accessing any medical records, download and review the Accounting of Disclosure instructions:

1. Log in to www.irbnet.org
2. Go to Forms and Templates, Select a Library: choose Rhode Island Hospital
3. Download HIPAA Accounting of Disclosure Instructions

To minimize the number of disclosures: Have someone within the Lifespan workforce (research staff, residents, interns, volunteers) search the medical records for the criteria specified and whittle down the # of records that may need to be viewed by a foundation-employed physician (or foundation staff). This will decrease the volume of records that need to be accounted for.

To eliminate the need for accounting of disclosures: Have someone within the Lifespan workforce (research staff, residents, interns, volunteers) review and *de-identify* the medical records before showing them to a foundation-employed physician (or foundation staff).

Remember, anyone reviewing Lifespan records for a research project must be listed under the study personnel section of the IRB application. See How do I add or remove study staff from my IRB application?

Screening and recruiting in Pediatrics

Only those personnel listed in the approved IRB application are authorized to review PHI and screen for potential subjects. It is the PI's responsibility to ensure study staff are properly trained in a study's applicable eligibility criteria.

Pediatrics Research staff responsible for screening and recruiting subjects in Pediatrics should meet with Barbara Bancroft (bbancroft@lifespan.org) to review Pediatric recruitment procedures.

Consenting and enrolling in Pediatrics

Only those personnel listed in the approved IRB application are authorized to consent and enroll subjects. It is the PI's responsibility to ensure study staff are properly trained in the study's consent and enrollment procedures.

Pediatrics research staff responsible for consenting and enrolling subjects in Pediatrics should meet with Barbara Bancroft (bbancroft@lifespan.org) to review Pediatrics consenting procedures.

Compensating study participants

The following methods are acceptable ways to pay human subjects for research study participation. Pediatrics investigators should the contact Department Research Administrators for processing.

- Cash advance (preferred): A check is made out to the PI (or a designee) to be used to pay participants. The cash advance must be settled within 6 months. Receipts must be provided monthly.

- Gift Cards (preferred): Gift cards should be purchased using a Cash advance (see above). Care should be taken to ensure that all gift cards are disbursed within 6 months. The vendor/store receipt where the gift cards were purchased must be provided. A gift card disbursement log must be provided monthly.

- Check request: A check is mailed directly to the participant. The participant's name, address, and SSN are required (i.e. participants will not be anonymous). Payments of $100 or more must utilize this method.

- Petty cash voucher: The participant can present a voucher to the Lifespan Cashier's Office to collect their participation fee. Participants can remain anonymous. There is a limit of $75 per voucher.

Disclosures:
The participant must be made aware that payment is considered taxable income. The participant must be made aware if identifiable information will be required to obtain payment (e.g. for a Check Request). With any of the above methods, *except for a Check Request*, the participant's study ID is sufficient for vouchers, receipts, and payments logs (i.e. identifiable information is not required to obtain payment).

Documentation:
For audit purposes, the PI must maintain a log of each payment made to participants including participant study ID, date, payment method, amount, and voucher# / receipt# / gift card#. Contact Department Research Administrators for a log template.

Unsettled advances:
Unsettled prior advances will result in the termination of advances to the PI (or designee) to whom the advance was made. The outstanding amount will be charged to the PI or the department and will be considered taxable income. Unsettled gift cards, however, may be used for another study.

Storage:
Study payments should be clearly labelled and kept in a locked cabinet in a locked office where they are easily accessible to study staff during recruitment.

Study oversight and monitoring

If you witness or are made aware of study personnel not following consenting guidelines, you should notify the PI, who will be responsible for addressing the issue. If the personnel involved are Pediatrics departmental staff, Barbara Bancroft (bbancroft@lifespan.org) should be notified, and she will address the issue.

Once enrollment for the study begins, the assigned research coordinator and/or delegated staff will assist the PI in monitoring the study's progress. This will be done by conferring with each other as well as with the enrolling research assistants and researchers. Rate of enrollment, reasons for patients declining to consent, and ease of study procedures will be reviewed by the study team on an ongoing basis.

Documentation for the study will continuously be reviewed by the assigned research coordinator and/or delegated staff to ensure adherence to GCP guidelines and readiness for audits. Screening and enrollment logs will be reviewed, as well as completed data sheets/case report forms and signed consents. All study documentation must be made available to the assigned research coordinator as needed.

If a study is sponsored by an outside entity, an outside monitor will often need to meet with the PI and study personnel to ensure the study is being run according to protocol. If the study utilizes department resources, the research coordinator will be responsible for helping to ensure that such monitoring visits are planned and conducted appropriately. They will ensure that all documentation needed by the monitor is made available and will schedule contact with the PI or pharmacy if required. They will also ensure proper follow-up to such visits with assistance from the regulatory coordinator.

The IRB and other regulating agencies may choose to audit a study for cause or at random. The PI should be prepared to oversee such audits. If the study utilizes department resources, the assigned research coordinator and regulatory coordinator will assist the PI with preparing for such audits, ensuring that the auditor has access to the materials they needs, and managing the audit and any follow-up requirements.

Storing study documents and data

The following documents should be stored behind two locks (e.g. in a locked filing cabinet in a locked office) in a place that is accessible only to the PI and study staff:

- The regulatory study binder
- Participant compensation (e.g. gift cards)
- A study-specific file for each participant (completed consent forms, data sheets, logs)

Lifespan requires investigators to maintain research records for a minimum of **6 years** after completion of the research study. This requirement is based on the following state and federal laws and regulations:

- RI state law to maintain research records for 5 years after completion of the research study
- FDA requires maintaining records for 2 years after approval of the investigational product
- OHRP requires 3 years after termination of the study
- HIPAA states a patient should have access to their records for a minimum of 6 years (including research records)

Studies that utilize the Pediatrics departmental research assistants and coordinators:
Documentation for these studies will be stored in a locked office. Study documents will be stored in locked file cabinets, in accordance with Lifespan policies and federal regulations. This process will be overseen by Barbara Bancroft (bbancroft@lifespan.org) the assigned research coordinators and research assistants. Once a study has been terminated with the IRB, files will be sent to long term storage where they will be stored according to Lifespan, FDA, and sponsor requirements.

Storing electronic study documents and data

Research data should only be stored on a Lifespan password-protected device.

Under no circumstances should data be stored on a personally owned and managed device.

We can create a Lifespan share folder for your study to which access can be shared with the study team. Pediatrics investigators should contact Department Research Administrators to request a new Lifespan share folder or to share access with a team member.

Storing and shipping biospecimens

Pediatrics research staff responsible for the storage or shipment of biospecimens should meet with Barbara Bancroft (bbancroft@lifespan.org) to review standard operating procedures.

Clinical Research Space / Facilities

We occupy the following space in Hasbro Children's Hospital:

Hasbro Room 124: Pediatrics Research Office - Departmental Research Administrators
Multiphasic Building, 1st floor: Pediatrics Research Office - Barbara Bancroft

Pediatrics investigators should contact Barbara Bancroft (bbancroft@lifespan.org) if freezer storage is needed.

Pediatrics investigators should contact Barbara Bancroft (bbancroft@lifespan.org) for suggested space for study procedures. Consent and enrollment should take place in the patient's treating room.

Departmental Research Assistants, Coordinators, and Research Nurse

How do I request to use the departmental RAs for my study?

Requests for assistance must be made at least 1 month in advance of the anticipated study start date. in a timely manner and we will make every effort to accommodate as many requests as possible. Please note, staff utilization is subject to available resources. Priority will be given to studies with funds allocated to RA or coordinator support. The departmental RA is mainly used for studies that can be enrolled for any time of day. If your study requires dedicated screening blocks, you should hire your own dedicated RA. If we cannot accommodate a study, we will help you identify other appropriate resources (e.g. grant opportunities, student volunteers, etc.).

If your request is approved, the PI will schedule a time to meet with the entire team to review the study protocol and prepare the RAs for study launch. Unless other arrangements are agreed upon, the PI will make monthly appearances at departmental staff meetings to address any study complications.

CONDUCTING INDUSTRY-SPONSORED CLINICAL TRIALS

Pediatrics investigators who have been contacted to conduct an industry-sponsored trial and would like to take part in the trial, should contact Barbara Bancroft. She will assess resource allocation and will assist with all study start-up tasks.

Barbara will assist you in gathering all documentation that must be reviewed and approved by the Lifespan Clinical Trials Office, including:

- Lifespan's consent form template completed with the sponsor's informed consent language
- Lifespan's Qualifying Clinical Trial form
- Study budget as accepted/negotiated by site & sponsor
- Lifespan's clinical trial budget form
- Coverage analysis
- Budgets from other departments, where necessary (ex: Pharmacy)
- Study Protocol
- Draft of Clinical Trial Agreement (CTA) provided by sponsor
- Signed Lifespan Conflict of Interest (COI) Forms
- Completed and signed Lifespan Business Forms

Once the informed consent language has been approved by the Lifespan Clinical Trials Office, the study can be submitted to the Lifespan IRB. Further budget and CTA negotiations can take part while IRB review is pending. See How do I submit a new IRB application?

The sponsor will likely want to visit the site for a site qualification visit to meet the investigator and research team, and to review the protocol.

Enrollment can begin once:
(1) IRB approval has been received from Lifespan
(2) A cost center activation noticed has been received from Lifespan
(3) The sponsor has given permission

All industry research should be governed by Good Clinical Practice guidelines and should adhere to specific requirements of the sponsor (such as screening/enrollment log set up, staff communication, enrollment milestones, etc.).

Research Administrators will invoice the sponsor on a quarterly basis.

CONDUCTING ANIMAL RESEARCH

Pediatric investigators who wish to conduct animal research should first discuss with Jennifer Sanders.

CITI Training (mandatory)

All research personnel are required to complete Lifespan's CITI online training courses *prior to conducting any research activity*.

Policies

The Lifespan Institutional Animal Care and Use Committee (IACUC), otherwise known as the Animal Welfare Committee, oversees animal research conducted by the Department of Pediatrics. Please review policies or contact a committee member.

IACUC Approval

Lifespan IACUC review and approval is required before any project using animals is initiated. Download the IACUC Submission Deadlines on IRBnet.

How to submit a new IACUC application:

1. Log in to www.irbnet.org
2. Go to Forms and Templates, Select a Library: choose Lifespan IACUC
3. Download the file named: **New Application? READ ME FIRST, and follow all instructions within this document
4. Go to Create a New Project and enter the project information
5. Go to Designer to upload all required forms and documents
   - To find the Core Form, click on Start a Wizard, then select: Lifespan - Animal Care and Use Protocol Part 1
6. Go to Share this Project and grant access to the following people:
   - PI: Full Access
   - Department Research Administrator: Read Only
   - Dr. Dennery: Read Only
   - Other study personnel may be given full or read access as needed
7. Go to Sign this Package, select PI, then click Sign
8. Send an e-mail to Dr. Dennery requesting she sign and approve your IACUC submission

   Note: It is an IACUC policy that all <u>new</u> IACUC applications must be signed by the Department Chair.

9. Go to Submit this Package, select Lifespan IACUC, and follow the prompts to submit.

CONDUCTING OTHER LABORATORY RESEARCH

CITI Training (mandatory)

All research personnel are required to complete Lifespan's CITI online training courses *prior to conducting any research activity*.

Policies

The Lifespan Institutional Biosafety Committee (IBC) oversees research involving the use of biological hazards, chemical hazards, and recombinant and synthetic nucleic acids conducted by the Department of Pediatrics. Review policies or contact a committee member.

IBC Approval

Lifespan IBC review and approval is required before any project is initiated. Download the IBC Submission Deadlines

on IRBnet. How to submit a new IBC application:

1. Log in to www.irbnet.org
2. Go to Forms and Templates, Select a Library: choose Lifespan Institutional Biosafety Committee
3. Download and complete the Biological and Chemical Hazards Application Form
4. Go to Create a New Project and enter the project information
5. Go to Designer to upload all required forms and documents
6. Go to Share this Project and grant access to the following people:
    *   PI: Full Access
    *   Department Research Administrator: Read Only
    *   Dr. Dennery: Read Only
    *   Other study personnel may be given full or read access as needed
7. Go to Sign this Package, select PI, then click Sign
8. Send an e-mail to Dr. Dennery requesting she sign and approve your IBC submission

    Note: It is an IBC policy that all <u>new</u> IBC applications must be signed by the Department Chair.

9. Go to Submit this Package, select Lifespan Institutional Biosafety Committee, and follow the prompts to submit.

DATA COLLECTION & ANALYSIS

Statistical support

Ray Tanzer, PhD, and Phin Has, MA, are wonderful resources for Pediatrics faculty, fellows, and trainees right here in our own department. They are available to assist investigators with development of statistical and research design, development of research plans for grant applications, and development of manuscripts. Please complete the brief Pediatrics Service Request Form and a member of the team will be in touch to schedule a meeting.

Ray Tanzer, PhD
RTanzer@lifespan.org

Phin Has, MA
PHas1@lifespan.org

Additionally, the Lifespan Clinical Research Center (LCRC) offers many research services, facilities, and resources. The LCRC's Biostatistics Core provides centralized biostatistics consultation services to investigators in study design, analytics, and the clear communication of scientific results.

REDCap

Data can be collected and managed using the REDCap electronic data capture tools hosted by Lifespan. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies. REDCap is free to all members of the department. Click here to learn more about REDCap.

To request a REDCap account, go to www.LifespanREDcap.org, and scroll down to 'Request an Account' at the very bottom of the page.

GRANTS & FUNDING

Submitting a Grant

What is the grant submission policy?

All applications for external funding originating from the Department of Pediatrics (including subawards) must be reviewed and approved by (1) Department Research Administrators, (2) Dr. Dennery, and (3) the Lifespan Office of Research (LOR) prior to submission. Please note that grants sponsored by Brown University are considered *external* funding. Applications must be complete and routed for approval **10 business days (or 2 weeks) prior to the sponsor's deadline**. A Department Research Administrator will assist you in preparing your application, route your application through the chain of approval, and submit your application.

When and how do I start a grant submission ?

The process and timeline for a grant submission is as follows:

≥ 8 weeks prior to the sponsor's deadline	Give the Department Research Administrators (DRA) a heads up! E-mail the funding opportunity name, website, and deadline.
	Your DRA will send you a grant checklist, deadlines, and templates. If your application will include subcontracts, the DRA will contact each site to obtain the required documentation.
	You will write each section of the application, consulting your DRA for guidance as needed.
≥ 3 weeks prior to the sponsor's deadline	The final versions of each section of the application are due to the DRA. The DRA will review each section for adherence to guidelines and will fix formatting as needed. The DRA will complete the application face pages, table of contents, assemble attachments, and send you a final preview of the application.
≥ 10 business days prior to the sponsor's deadline	Your DRA will route the final application through the chain of approval: (1) Department Research Administrators, (2) Dr. Dennery, and (3) the Lifespan Office of Research (LOR).
≥ 1 week prior to the sponsor's deadline	Your application will be submitted by LOR.

I am participating on someone else's proposal under a subcontract / subaward, how do I obtain the required documentation and approval for a subaward request ?

If you will be participating on a proposal being submitted by another institution, you will most likely receive an e-mail from the PI's administrator requesting a subaward budget, letter, and other documentation. All of this needs to be reviewed and approved by (1) Department Research Administrators, (2) Dr. Dennery, and (3) the Lifespan Office of Research (LOR) prior to submission. Subaward documentation must be complete and routed for approval **10 business days (or 2 weeks) prior to the deadline provided by the prime institution**. A Department Research Administrator will work with you and the administrator at the prime institution to prepare your subaward documentation and route it through the chain of approval.

The process and timeline for a subaward request is as follows:

Immediately	As soon as you are aware that you will be participating as a subaward on a proposal, please give the Department Research Administrators a heads up!
	Forward the e-mail requesting subaward documentation to the Department Research Administrator.
	Your DRA will review the sub budget and budget justification, will gather or prepare all other requested materials, and send all final versions to you for approval.
≥ 2 weeks prior to the prime institution's deadline	Your DRA will route the subaward documentation through the chain of approval: (1) Department Research Administrator, (2) Dr. Dennery, and (3) the Lifespan Office of Research (LOR).
≥ 1 week prior to the prime institution's deadline	Your DRA will submit the final and approved subaward documentation to the prime institution's administrator.

Preparing a Grant Application

What is my applicant organization / primary site?

The applicant organization and primary site for all Pediatric grant proposals is:

Rhode Island Hospital
593 Eddy Street
Providence, RI 02903-4923

In the narrative of the grant proposal you may mention your affiliation with Brown, however you must make it clear that the applicant organization and primary site of the project is the Department of Pediatrics *at Rhode Island Hospital* and that you work as a Pediatrician at Rhode Island Hospital. It's also important to list your position at Rhode Island Hospital in your biosketch. *For pediatric studies*, you can change 'Rhode Island Hospital' to 'Rhode Island Hospital / Hasbro Children's Hospital.'

Who should I list as the Primary Grant Contact Person / Grant Administrator?

This will be someone from the Lifespan Office of Research (LOR). This person can change from time to time, so it's best ask the Department Research Administrators who our *current* grants contact person is.

Who should I list as the Authorizing Official / Signing Official?

This will be someone from the Lifespan Office of Research (LOR). This person can change from time to time, so it's best ask the Department Research Administrators who our *current* grants signing official is.

Where can I find grant forms and templates?

Download grant forms and templates. Contact the Department Research Administrators with any questions.

Who do I contact to get salary information for a grant budget?

Contact the Department Research Administrators.

Should I request the maximum amount of the award?

You can and should request the maximum amount of the award if you can reasonably justify how the funds will be used. There is no competitive advantage to requesting *less than* the maximum amount of the award.

How do I calculate % effort ?

% effort = # hrs/wk necessary for you to conduct the project divided by total # hrs/wk in a typical work week

E.g. 2 hrs/wk in a 40-hr work week = 5% effort, 4 hrs/wk in a 40-hr work week = 10% effort, etc.

In grant terms, effort is the amount of time spent on a sponsored project. It reflects the % of your professional time you will spend working on the sponsored project, for which salary will be directly charged to the grant. Note: Professional time does not include activities such as consulting that are conducted outside the terms of employment. Effort should always be calculated based on your typical work week (generally, 40 hrs/wk for staff, but likely more for faculty).

On grant proposal budgets, the amount of effort that you specify should be the full amount necessary for you to conduct your role & responsibilities on the project. Make a list of the work you'll have to do (specific activities, time you'll spend collaborating with other investigators, training your team, and building your infrastructure) and how much time each task will take. This information will need to be included in your budget justification for reviewers to understand why you need the time you request. Calculating effort isn't an exact science and is not set in stone, but you need to make an appropriate estimate based on your actual needs in order to budget for the appropriate amount of salary. The PI will have to determine the % effort necessary for each person working on the project.

Reviewers use this figure to assess whether you can reasonably complete the research with the amount of effort you plan to commit to the proposed project. Reviewers may accept lower levels of effort from well-established, high-performing PIs who have demonstrated stellar research performance over an extended period of time. For new investigators who don't yet have a comparable track record, reviewers will likely raise concerns over a low level of effort.

If you spend less time on the project than you specified:
- The unspent salary can be re-budgeted to other project expenses
- Note: NIH allows automatic carry forward of residual funds from one year to the next
- Note: On federal grants, the PI (and key personnel named in the Notice of Award) must obtain prior approval from the program officer to reduce their effort by 25% or more from the level that was approved in the budget (e.g. a reduction from 30% to 20% will require prior approval)

If you spend more time on the project than you specified:
- If there is room in the budget, you can charge the additional time to the grant
  - e.g. you (or another person on the grant) spent less time in some months resulting in residual funds
  - e.g. you spend more time in some months, with the intention of spending less time in other months to balance it out
- If there is no room in the budget, the extra time cannot be charged and will be considered voluntary

How do I calculate person months?

Calendar months = % effort multiplied by 12 months (the # of months of your appointment)

E.g. 5% effort for 12 months = 0.6 calendar months, 10% effort for 12 months = 1.2 calendar months, etc.

A "person month" is the metric some sponsors use for expressing effort. It is based on the type of appointment of the individual with the organization; e.g., calendar year (CY), academic year (AY), and/or summer months (SM); and the organization's definition of such. For instance, some institutions define the academic year as a 9-month appointment while others define it as a 10-month appointment. As a hospital, we operate on the calendar year (i.e. a 12-month appointment).

What is the difference between a subcontract, vendor, and consultant?

Subcontract

A subcontract is appropriate when:

- Substantive, programmatic work or an important or significant portion of the research program or project is being undertaken by the other entity.
- The research program or project is within the research objectives of the entity.
- The entity participates in a creative way in designing and/or conducting the research.
- The entity **retains some element of programmatic control and discretion over how the work is carried out**.
- The entity commits to a good faith effort to complete the design or conduct of the research.
- The entity makes independent decisions regarding how to implement the requested activities.
- **A principal investigator has been identified at the entity and functions as a "Co-Investigator".**
- There is the expectation that the entity will retain ownership rights in potentially patentable or copyrightable technology or products that it produces in the course of fulfilling its scope of work.
- **Publications may be created or co-authored at the entity.**
- The entity provides cost sharing or matching funds for which it is not reimbursed.
- The entity regards itself, and/or is regarded as "engaged in research" involving human subjects under the Common Rule and therefore requires approval for its interactions with human subjects.
- Source: https://osp.finance.harvard.edu/subrecipient-vs-contractor-guidance

Generally, a subcontract is required in the following circumstances:

If the budget includes salary support for:	Subcontract Required?
Pediatric employees	**No**
LPG employees	**No**
Rhode Island Hospital / Hasbro employees	**No**
The Miriam, Newport, Bradley Hospital employees	**Yes**
Brown employees or faculty (non-clinical)	**Yes**
Employees at any other institution	**Yes**

If the budget includes research expenses at:	Subcontract Required?
Rhode Island Hospital / Hasbro	**No**
The Miriam, Newport, Bradley Hospital, LPG	**Yes**
Brown University	**Yes**
Any other institution	**Yes**
A company providing a service for your project (vendor)	**No, letter only**

If a subcontract is required, you will need to develop a separate budget (and budget justification) for each sub-institution. Your Department Research Administrator will contact the sub-institution to have the budget approved and to request all required documentation to be included in the proposal (e.g. biosketches, letters of support, a Statement of Intent to Establish a Subcontract, F&A agreement, etc.).

Vendor

A vendor agreement is appropriate when:

- The entity is **providing specified services** in support of the research program.
- The entity has not significantly participated in the design of the research itself, but is implementing the research plan of the investigator.
- The entity is not directly responsible to the sponsor for the research or for determining research results.
- The entity markets its services to a range of customers, including those in non-academic fields.
- Little or no independent decision-making is involved in the design and conduct of the research work being completed.
- The agreement only specifies the type of goods/services provided and the associated costs.
- The entity commits to deliverable goods or services, which if not satisfactorily completed will result in nonpayment or requirement to redo deliverables.
- The entity **does not expect to have its employees or executives credited as co-authors** on papers that emerge from the research.
- The expectation is that the work will not result in patentable or copyrightable technology or products that would be owned by the entity.
- Source: https://osp.finance.harvard.edu/subrecipient-vs-contractor-guidance

Consultant

A consultant/contractor agreement is appropriate when:

- The person has no employment relationship with Rhode Island Hospital or its affiliated foundations.
- The work being performed for the investigator is independent of their employment. Ask yourself: *If this person lost their job, would they still be able to provide this service to me?*
- If the service they are providing is part of their standard job responsibilities, a subcontract or vendor agreement should be established with the employer.

For vendors, contractors, and consultants, a Letter of Commitment must be included in the proposal, which describes the goods/services/deliverables to be provided, the agreed upon rate ($XX/hour) and total number of hours.

If you need further clarification, contact your Department Research Administrators.

How do I determine if someone is senior/key , non-key, or other?

Personnel Category	NIH Definition	Other Definitions	Requirements
Senior/Key	Individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries or compensation are requested.	• Their absence from the project would have a significant impact on the scope, direction or conduct of the project • Dedicating a specified amount of effort, cannot be 'in kind' or 'as needed' • Typically, have a doctoral or other professional degree	• Biosketch • Letter (if not affiliated with RIH) • Must be listed in personnel section of the application • Must devote measurable effort to the project whether or not salary is requested • Prior to award, must provide Other Support information
Other Significant Contributor/ Other	Individuals who commit to contribute to the scientific development or execution of the project, but **do not commit any specified measurable effort** to the project.	• Their absence from the project would have a significant impact on the scope, direction or conduct of the project • Effort is '**in kind**' or '**as needed**' • Typically, mentors	• Biosketch • Letter (if not affiliated with RIH) • Must be listed in personnel section of the application
Non-Key	Individuals who do not meet the definitions of Senior/Key or OSC/Other.	• Their absence from the project **would not** have a significant impact on the scope, direction or conduct of the project • The role could be filled by anyone possessing the minimum qualifications • Typically, staff and post docs	• These individuals will not be listed in the personnel section of the application (but will be listed in the budget) • No other requirements

Notes:

- A consultant can fall under any category for which they meet the definition.

- On NIH grants, NIH will determine who *they consider* to be key to the project and will name those individuals in the Notice of Award. This is usually just the PI (or Multiple PIs), and sometimes another co-investigator whom they feel you cannot conduct the project without. These named individuals must obtain prior written approval from the program officer for (1) a change in status or (2) a reduction of effort by 25% or more.

I need help developing a budget

Contact the Department Research Administrators.

I need help creating a Biosketch

Contact the Department Research Administrators. Additionally, the NIH website has instructions & samples of [biosketches.](#)

I need help developing the Facilities and Other Resources section

Our department's *Environment* document for a description of our facilities, scientific, academic, and research environment and other resources, along with models of this document, can be provided by your Department Research Administrators.

I need help drafting a Letter of Support

Contact your Department Research Administrators.

I need help creating or revising a table / figure

Contact Department Research Administrators.

I need help with citation management

Contact Department Research Administrators.

I need a list of my current and pending research support

Contact Department Research Administrators.

What information should be included in an NIH proposal to meet the new single IRB requirements?

As this requirement is new and cumbersome, it is highly recommended that PI's discuss their single IRB needs with Barbara Bancrfot at least **6 weeks before the NIH proposal deadline**.

NIH funding proposals must adhere to the new Single IRB Policy. NIH now requires multi-site, non-exempt, human subjects research projects to use a single IRB to conduct IRB review and approval for all domestic sites. This requirement does not apply to foreign sites or career (K), training (T), or fellowship (F) funded projects.

If Lifespan is the lead site, you will need to:

1. Select and secure a single IRB of record for your project. Contact the IRB (RPO@lifespan.org), **5 weeks before the NIH proposal deadline** to:

   For 3 sites or less:
   - Obtain Lifespan's agreement to serve as the single IRB for your project

   For more than 3 sites:
   - Obtain Lifespan's approval to use another institution's IRB (e.g. the IRB of one of your participating sites) as the single IRB for your project; or
   - Obtain Lifespan's approval to use an external, commercial IRB as the single IRB for your project. Lifespan will recommend that you use Quorum IRB, a commercial IRB for which they have a pre-negotiated Reliance Agreement, and can help you obtain the documentation needed for your proposal.

2. Obtain a fee schedule (i.e. quote) and include those IRB fees as a *direct cost in each year* of the budget (this is not included in the indirect cost rate)
   - Single IRB fees are the responsibility of the lead site and should not be included in subaward budgets.
   - Commercial IRBs will provide you with a fee schedule specific to your project.
   - If you are using the IRB of another institution, single IRB fees will vary by institution.

3. Obtain a letter from the chosen IRB expressing their commitment to serve as the single IRB of record for the project.

4. Obtain a letter from each site (including Lifespan) affirming that their institution will rely on the chosen single IRB for the project.

5. For large multi-site studies, you may want to consider budgeting for an additional staff member to manage IRB relations (i.e. an 'IRB Liaison').

6. Include a Single IRB Plan in your proposal.

If Lifespan is a participating site (not the lead site), you will need to:

1. Contact the IRB (RPO@lifespan.org), **3 weeks before the NIH proposal deadline** to request a letter indicating that Lifespan will rely on the chosen single IRB for the project.

2. Provide this letter to the lead PI to include in the proposal.

If the proposal is funded, see What is Lifespan's single IRB policy? for next steps.

eRA Commons Account (Federal grants only)

All federal grant applicants must have an eRA commons account. One account should exist per person. Accounts can only be created by the applicant's institution.

To create a new account or transfer an existing account:

1. Contact your Department Research Administrators to request a new account or to transfer an existing account from another institution.

2. Once your account has been created/transferred, please log in and delegate access with your Department Research Administrator.

Managing your profile:

Before applying for a federal grant, check to make sure the following information is up-to-date:

1. **Institutional affiliation:** Your profile must be affiliated with Rhode Island Hospital. If it is not, contact the Department Research Administrators immediately to transfer your account.

2. **Education/degrees:** The degrees listed in your profile are used to determine your eligibility for new, early, and established investigator status. See What are the benefits of new, early, and established investigator status?

3. **E-mail address:** This should be your primary email address where you would like to receive official correspondence.

Just in Time Requests

If you receive a Just in Time request, please forward it to your Department Research Administrators right away for processing.

IRB Approval for Just in Time Requests

NIH is very clear that they require the date of <u>final</u> IRB approval; *conditional or pending* IRB approval is not sufficient and should not be filed. If final IRB approval is not submitted with the just in time request, rest assured that funds *will not* be withheld. However, NIH will restrict you from conducting human subject activities until the date of IRB approval is filed.

See How early should I submit my IRB application?

Post-award Grants Management

All research awards are managed by the Department Research Administrators.

I received correspondence regarding an award, who should I notify?

Forward all correspondence regarding your research awards and funding to the Department Research Administrators.

How is an award / cost center set up?

When the PI receives a funding award notice, the notice must be forwarded to the Department Research Administrators right away for processing. The Department Research Administrators will work with the Lifespan Office of Research (LOR) to review the award terms & conditions and formally accept the award. If there are any issues or re-budgeting / re-negotiating is necessary, Department Research Administrators will work this out with the PI.

When the funds are released, LOR will create a cost center for that award and will send a cost center activation notice/memo to the PI and to the Department Research Administrators. Funded projects may not begin until the PI receives the cost center activation notice. The PI must add the cost center # to their IRB application (see How do I update funding information on my IRB application?).

New PIs must designate who is allowed to use their cost centers by completing a Grant Signature Authority Form. Department Research Administrators will provide this form to you.

How can I see my award balance?

Contact Department Research Administrators to set up DataWatch access or for a copy of the most recent financial report from LOR.

Funding Opportunities

When searching for a funding opportunity, keep in mind the grant must cover all costs needed to conduct the project (i.e. you must be able to complete the scope of work / specific aims using the award amount and within the award dates).

Federal

Use Grants.gov to search all federal agency opportunities. Agencies that we have sent applications to include NIH, CDC, AHRQ, SAMSHA, and DoD

Foundations

Links to several foundations that fund Pediatric Research are listed below:

- Robert Wood Johnson Foundation (RWJF)
- Charles H. Hood Foundation
- The Gerber Foundation
- American Lung Association-
- National Institutes of Health-
- National Cancer Institute-
- Cystic Fibrosis Association-
- Society for Pediatric Research
- Thrasher Research Fund

Department Funding

Children's Miracle Network Annual Scholar Awards
To foster academic pursuits and collaborative engagement in the Department of Pediatrics, two awards of $25,000 each are allocated to support faculty members with projects that will help improve the lives of our pediatric patients.

Pediatrics Hasbro/Bradley Pilot Clinical Research Awards
A small fund was established to support pilot research projects focused on clinical programs at Bradley/Hasbro Hospitals. In order to encourage collaboration between different disciplines, each project must be led by two Principal Investigators: one from the Department of Pediatrics and one from Psychiatry. Each PI must have a Brown Faculty appointment. The goal is to develop innovative pediatric/behavioral health projects that will improve patient care and lead to external funding. Funding for two awards of up to $25,000 each will be available each academic year.

If you have questions about the application process for either program, please email **Kaiti Bennett (KBennett5@Lifespan.org)**.

Brown Funding Opportunities

Advance CTR Funding Opportunities

Research Budget & Accounting

The department's research budget is managed by the Department Research Administrators.

Contract Management

Subcontracts

Contact the Department Research Administrators regarding subcontract agreements and invoicing.

Consultant / vendor / professional service agreements

Contact the Department Research Administrators regarding consultant agreements and payments.

Data use agreements

Contact the Department Research Administrators regarding data use agreements.

Industry-sponsored clinical trial agreements

Contact the Department Research Administrators regarding clinical trial agreements.

Time & Effort Reporting

Each month you will have to report the actual % effort you worked on all research projects. Research time & effort (T&E) reporting is processed by Department Research Administrators. If you are required to report research effort, a Department Research Administrator will send you the following e-mail each month. Please respond promptly as <u>one</u> person's delay in responding will delay reimbursement of <u>all</u> physician salaries to Pediatric Research.

1. This e-mail will contain your T&E report, which you will need to complete and return via e-mail to your Department Research Administrators. Prompt notice of any changes to your *dedicated* effort or *active* projects for the upcoming month is requested, to generate an accurate report.

Purchasing

Advanced notice is key! Always contact Department Research Administrators *before* making a purchase that will be charged to a research account to ensure that it is allowable and/or reimbursable.

Department Research Administrators will warn you if there is a cost limit. If the vendor you are planning to use is not approved by Lifespan, Department Research Administrators can suggest other options. Non-approved vendors will require justification and more time for approval.

Note: **Amazon** is not an approved vendor. Products should be purchased directly from distributors.

To place an order: Obtain a quote from the vendor, or generate a shopping list from the vendor's website, and send it to your division's administrative assistant. Your shopping list should include the following details:

i. Vendor
ii. Product name
iii. Product ID
iv. Unit price
v. Qty
vi. Total price
vii. Product website link, if available
viii. Vendor justification, if applicable (reason you are not using an approved vendor)
ix. Study
x. Cost center

Once approved, your Department Research Administrators will instruct you on how to submit your order to the Lifespan Purchasing Department.

The following vendors should be used whenever possible:

- **WB Mason** (office supplies)

- **Dell** (desktops, laptops, monitors): This link will bring you to Lifespan's Epic-approved products. Add items to your cart to generate an eQuote. Leave the Authorized Buyer field blank and select Paul Pereira @ 167 Point Street for the Ship To.

- **Lifespan Tech Center** (mice, keyboards, monitors, Lifespan-approved flash drives, Dragon mics, Topaz signature pads, external hard drives, Fujitsu scanners, iPads, Snag It, Adobe Acrobat, Endote, Visio, Project, headsets, cables, laptop batteries, surge strips, & more). Call (401) 444-6382 or Techctr@lifespan.org for inventory and prices.

- **Lifespan Warehouse** (medical supplies): Call (401) 444-2152 for inventory, item ID, and prices.

- **Life Technologies** (life science, applied science, and clinical products)

- **Claflin** (medical and surgical products)

- **Grainger** (industrial-grade supplies and safety products)

- **Fisher Scientific** (laboratory and biotechnology products)

- **Henry Schein** (health care products)

- **Sigma Aldrich** (chemical, life science and biotechnology)

- **AirGas** (gases, welding equipment and supplies, and safety products)

Check Requests & Reimbursements

Check requests for research payments & reimbursements for research expenses are processed by Department Research Administrators.

<u>Check Requests</u>

To request a check:
1. Send the invoice (or request for payment) and cost center to the Department Research Administrators.
2. A Department Research Administrator will send you a check request form to sign.
3. Return the signed form to the Department Research Administrators.

<u>Reimbursements</u>

To request a reimbursement:
1. Contact the Department Research Administrators to ensure the expense is reimbursable. Department Research Administrators will send you the appropriate reimbursement request form.
2. Complete and sign the reimbursement request form.
3. Return the completed form and supporting documentation to your Department Research Administrator. Organize your supporting documentation to make it easy to review. Supporting documentation should include:
    a. Original itemized receipts
    b. Sign in sheet for meeting expenses
    c. Conference flyer or agenda for conference expenses
    d. If travel is included, create a summary of your travel expenses using the travel worksheet included in the reimbursement form or generate a similar report.
        i. Review the Lifespan travel policy (see below)
        ii. Gather your travel supporting documentation (see below)
        iii. International travel expenses should be converted to US dollars. Documentation showing the currency exchange conversion should be included.

Travel

Travel for research purposes (to be reimbursed from a research account) must adhere to Lifespan travel policies.

Before planning a trip:
1. Review the Lifespan travel policy below
2. Contact the Department Research Administrators to determine your reimbursement eligibility and limits
   - International travel must be approved in advance. Contact the Department Research Administrators to assist with obtaining approval.

Lifespan Travel Policy

- The following **supporting documentation** is required:
  - <u>Original</u>, detailed receipts for all expenses
    - Receipts must show proof of payment (i.e., the last 4 digits of the credit card used). If the receipt does not show proof of payment, a credit card statement or screen shot of the statement of your account must be submitted
    - The credit card slips given by restaurants are not considered detailed receipts as the expenses are not itemized, but they should be included along with the detailed receipt to show proof of added gratuity
    - Detailed receipts are required for room service charges
  - Itemized hotel statements for all lodging stays
  - Flight statements must reflect all charges and form of payment
  - The cover page of the conference program or the meeting agenda to show proof of the purpose of the trip and dates
  - For international travel, documentation showing the currency exchange conversion
- The maximum daily meal reimbursement is $90. The maximum gratuity reimbursement is 20%.
- Mileage will be reimbursed at the current IRS standard mileage rate. A schedule detailing the starting and destination points and the number of miles traveled will be required. The hospital or the employee's home should be used as the starting point. Tolls incurred will be reimbursed.
- Air travel will be reimbursed at coach rates.
- Car rentals are generally not reimbursed. Car rentals will be reimbursed when it is the only available mode of transportation available *or* if it results in a significant savings (written explanation is required). The employee must also purchase a Bodily Injury and Physical Damage Comprehensive and Collision insurance policy from the car rental agency (if not provided by the employee's credit card company). Insurance premiums paid will be reimbursed.
- Non-refundable expenses include but are not limited to:
  - Alcohol
  - Expenses incurred by a guest of the Lifespan employee
  - Entertainment including music, spectator, and sporting event costs
  - In-room movies, spa fees, and air club memberships
  - Laundry
  - Parking violations
  - Seat upgrades from coach class
- Download the full Lifespan travel policy

HIRING & ONBOARDING NEW RESEARCH STAFF

New Research Staff Checklist

Pediatrics investigators are responsible for supervising their own research staff and ensuring staff follow Lifespan policies. Any projects they work on should be assigned by you directly. Be accessible to your staff and check in frequently. The PI is responsible for ensuring that each research staff member has:

- ☐ **a Rhode Island Hospital ID badge**
  - ☐ For paid and unpaid research positions, contact the Department Research Administrators to initiate the hiring process

- ☐ **a workspace**
  - ☐ There is no available workspace in the Pediatrics Department. Workspaces must be approved by the Director of Business Affairs, Dustin Wesolowski.

- ☐ **completed CITI research training**
  - ☐ Download the CITI Training Instructions handout.
  - ☐ Employees must be paid for all training hours (i.e. an employee should not be asked to complete any form of training before their employment start date). All forms of training should be completed while the employee is badged-in.

- ☐ **received IRB approval**
  - ☐ New staff members need to be added to the IRB for each project they will be working on
  - ☐ See How do I add or remove study staff from my IRB application?

- ☐ **signed the Staff Signature Delegation Log in the regulatory study binder**
  - ☐ New staff members need to sign the signature log for each project they will be working on
  - ☐ See Regulatory study binder / Essential documents binder (EDB) for more information

- ☐ **received project-specific training**
  - ☐ New staff members should have the knowledge and training necessary to conduct study procedures according to GCP guidelines
  - ☐ See Good Clinical Practice for more information

Who do I contact to onboard a new research staff member?

For paid and unpaid research positions, contact the Department Research Administrators to initiate the hiring process. The hiring process can take up to 1 month.

Who do I contact for an access request?

Requests for Pediatric research staff to obtain a Lifespan ID, a Lifespan email address, access to a share drive, access to LifeChart or any other Lifespan application or program can be requested by going into the IS Intranet Page and completing an IAM request on behalf of new hires.

Can I recruit a student or volunteer to work on my study?

Yes, you may take on an unpaid student or volunteer at any time. Please follow the New Research Staff Checklist.

Questions regarding Pediatric research staffing should be directed to the Department Research Administrators.

PUBLISHING

Publication Fees

The cost of publication should be included in grant application budgets (including departmental, foundation and federal grants).

Managing Citations

There are multiple free options for publication and citation management. Brown faculty, fellows, residents, and staff can download Endnote for free to a personally-owned (i.e. not Lifespan-owned) workstation or laptop (PC or MAC). Additionally, the basic versions of EndNote Online, Mendeley, and Zotero are available to any user. Click here to find download and access instructions to these programs.

PRESENTING

Research Conferences

We do our best to keep you informed of upcoming conferences and presenting opportunities. Below is a list of annual conferences:

AAP (American Academy of Pediatrics)

SPR (Society for Pediatric Research)

PAS (Pediatric Academic Societies)

MDLinx is a useful resource to find conferences.

Presentations

Where can I find presentation templates?

Download PowerPoint templates, poster templates, and logos. These are not mandatory.

How do I order a poster?

The department may cover the cost of printing a research poster, for presentation at a scientific conference, if printed through Office Services at the Lifespan Print Shop. Fabric posters are <u>not</u> available. Check with your division director.

To order a poster from the Lifespan Print Shop, Pediatric investigators should email the following details to Department Research Administrators two weeks before the date the poster is needed. You will be notified when your poster is ready for pick up from the Print Shop.

- the PPT file
- orientation (landscape or portrait)
- poster size needed (landscape-style max height is 44 inches; portrait-style max width is 44 inches)
- date needed
- glossy or matte finish (fabric posters are not available)

You may print your poster elsewhere, however the Department will not *reimburse* you unless you have a grant or research funds to which the poster can be charged. Before placing an order, contact the Department Research Administrators to verify that you have funds available.

CONFLICTS OF INTEREST IN RESEARCH

Pediatric investigators with a *perceived* COI should first discuss with the Department Research Administrators.

See Lifespan's Research Conflicts of Interest Policy

Lifespan's policy on Research Conflicts of Interest (COIs) applies to the PI and anyone else who is **responsible** for the design, conduct or reporting of the research that is conducted under the auspices of Lifespan (usually co-investigators and other senior/key personnel affiliated with Lifespan).

Anyone who falls under this policy must:

- be familiar with the policy

- complete Lifespan's mandatory CITI training course on COIs no less than every 4 years

    o Download the CITI Training Instructions handout

- disclose COIs to Lifespan prior to submitting any application for funding

    o Your departmental research administrator will send you a Lifespan COI disclosure form to complete just prior to proposal submission

- disclose COIs to Lifespan within 30 days of discovering or acquiring a new COI

    o Download the Lifespan COI disclosure form

- comply with any COI management plan issued by Lifespan

- retain all documentation that demonstrates compliance

When a COI is disclosed, the Lifespan Research Conflict of Interest Committee (LRCOIC) will determine if an actual financial conflict of interest exists and if it can be managed, reduced or eliminated. If the investigator involved in the financial COI proposes to use human subjects in research related to the disclosed conflict, the IRB shall review the COI management plan. The IRB will have the opportunity to suggest changes, approve, or disapprove the plan. The IRB will communicate the decision to the LRCOIC.

RESEARCH EDUCATION

Departmental Research Lectures & Workshops
The Department of Pediatrics offers several workshops each year on various topics related to research. Dr. Daphne Koinis Mitchell is the Director of the Pediatrics Mentoring Program. Watch for announcements of upcoming workshops and lectures on the Pediatrics research webpage.

Lifespan Biostatistics Core Training Programs
The Biostatistics Core has a small lab in Grads Dorm with 4 workstations to teach small, applied classes in response to common requests. Click here to learn more.

Advance-CTR Training Programs
Advance-CTR provides a variety of research trainings including REDCap classes and workshops, clinical research training and certification programs, mentorship training, PRIM&R, GCP Live! Training, SOCRA, and more. Click here to learn more.

Advance-CTR's monthly seminar series gives pilot projects recipients, mentored research scholars and other clinical and translational researchers the opportunity to present their research (at any stage) and progress in a collaborative, interdisciplinary setting. Presentations, followed by feedback, allows presenters the opportunity to refine and strengthen their research progress. Click here to learn more.

Brown Training Programs
Qualitative Science & Methods Training Program: This program is directed by Dr. Kate M Guthrie, PhD and is intended for postdoctoral fellows or faculty investigators. The program is split into two parts: Part I is a Fundamentals Seminar (monthly from Oct – Jun). Part II is a Skills-Building Workshop (~100 hours total; 2 hours/week from Jul – Jun). To participate in the workshop, investigators must have completed Part I and have a project or proposal.

Clinical and Translational Research Master's Program: Students in this program will complete nine courses, including research methods, advanced research methods, scientific writing, biostatistics and applied data analysis, two electives, and a series of seminars, workshops, and mentoring sessions. Given the applied nature of the program, students will work closely with advisors to develop a portfolio composed of a grant proposal, first author abstract submitted to a regional, national, or international conference, and first author research manuscript. Click here to learn more.

Clinical and Translational Research Certificate Program: This program is designed for trainees who need a more structured and intensive experience than can be obtained from taking one or two courses as a special student, but do not need or are not in a position to pursue the full master's degree. Click here to learn more.

DATA AND SAFETY MONITORING BOARD

The Pediatrics Research Committee developed a Data and Safety Monitoring Board (DSMB) to fulfill the DSMB requirements of studies within the department.

If you would like the department's DSMB to serve as the DSMB of record on your study, please send your DSM plan and study protocol to Jennifer Sanders.

The DSMB meets *as needed* during the monthly Research Committee meetings. If you need to convene the DSMB (e.g. to review your data, to review an adverse event, if you have concerns about continuing your study, if you need help drafting a DSM plan, etc.) see RESEARCH COMMITTEE for upcoming meetings dates and to learn how to request time on the agenda. Each DSMB review must have a quorum of three DSMB reviewers present. The committee will ensure enough reviewers will be present on the meeting date you request, otherwise the review may need to be rescheduled to the following month.

After each review, a report will be provided to the PI summarizing the discussion and recommendations. This report should be submitted to the IRB (and to the sponsor, if requested).

INITIATING A DATA REPORTING REQUEST

Below are the standard instructions for initiating a data reporting request:

- Go to the Ivanti Self Service portal and choose "Lifespan Report Request." You will be prompted to answer several questions, dependent upon which type of request you select. **Please be sure to note the IRB approval number, the study name, and the PI**.

- The Reporting Team meets on Friday mornings to review and prioritize new requests, and your request will be assigned to a team member at that time. Marylouise Moran (mmoran1@Lifespan.org) and Jodie Vilardi (JVilardi@Lifespan.org) are the trainers.

- If you indicate on the request form that the data is needed for purposes of research, you will need to provide an IRB approval number, and the data reporting request must match what is in your protocol.

- If it's preparatory to research, that should be noted.

- If you request data for "Quality Improvement" purposes, not research, you don't need an IRB approval; but if you subsequently try to publish the QI request as research, you will run into issues. Be certain to request appropriately.

RESEARCH MISSION STATEMENT

The Mission of the Research Cabinet is to support and promote visibility, impact, and Scholarship of all members of the Department of Pediatrics.

To achieve this, the Research Cabinet of the Department of Pediatrics will continue to address the following:

- Identify and promote opportunities for pediatric faculty and trainees to undertake scholarly activities in all forms
- Provide personal, direct support to help faculty produce scholarly works
- Enhance the research infrastructure of the Department through identification of grant opportunities, facilitation of grant submissions, and advocacy on the department's behalf with the medical school and hospital systems
- Identify and foster collaboration outside and within the Department of Pediatrics
- Identify and promote faculty professional development opportunities
- Support and enhance the department's mentoring program
- Advance the hiring of academic faculty

RESIDENTS, FELLOWS, & MEDICAL STUDENTS

Conducting a Research Project as a Trainee

A research project can *generally* take 2 years (1 year for planning, approval, preparation and 1 year to conduct the study, analyze data, and publish the results). Advanced planning is key as you must be able to complete the project before graduation. It is *highly recommended* that you present your research project idea to our department's Research Cabinet early in the planning stages to receive feedback from experienced investigators. The Research Cabinet will assist you in finding a project mentor, fine-tuning your research plan, determining what resources you will need and how to obtain them, highlight policies you may not have been aware of, offer realistic timelines, and research training opportunities you may want to consider.

Finding a Project Mentor

For each research project, you will be required to designate a Pediatrics faculty member as your project mentor. Your career mentor may not be appropriate for this role. It is important to find someone who can guide you through successful completion of your research project. Ideally, this would be a Pediatrics faculty member who has been successful in the same *type* of research you are pursuing (e.g. interventions, surveys, randomized trials, qualitative research, etc.). Look for a research mentor who possesses the *skills* you need, not necessarily someone with the same research interests. You may find that you need a different project mentor for different projects.

Note: It is a Lifespan policy that Residents, Fellows or Students may not serve as Principal Investigator. They must have a Pediatrics faculty member who will serve as PI on the study. The lead resident or fellow should use the title of Principal Researcher (e.g. on the IRB application, consent forms, and any other study materials). Residents, Fellows or Students may, however, use the title of PI on grant proposals and list the Pediatrics faculty member as the Primary Mentor.

Funding Opportunities for Trainees

START HERE: What grants are appropriate for my career stage?

Applying for Funding

Pediatrics residents, fellows, and medical students must follow the department's process for Submitting a Grant. This applies to medical students who are conducting a *Pediatrics* project and/or your faculty mentor is an *Pediatrics* faculty member.

Where to Find Help

To discuss a project idea with senior Pediatrics researchers, see RESEARCH CABINET.
To discuss available resources, grants, and funding for your project, contact the Department Research Administrators.

Pediatrics Resident Research Coordinator, Deb Pratas.
Pediatric Fellowship Research Coordinator, Dr. Mark Zonfrillo.

QUICK LINKS

Websites

Brown Pediatrics Research

Lifespan Office of Research Website

Lifespan IRB

IRB Training Materials

Directions for CITI COI Training:

The CITI COI training is within the CITI Program website (www.citiprogram.org), and the completion certificate is transmitted electronically to Lifespan (be sure your Lifespan ID is part of you profile inside your CITI account). Inside your account at the CITI website, to take the CITI COI course, click on Add a Course, and go down to Question 9 to add the COI course, then you will see it in the Main Menu as a course to take. If you have problems, you should contact Jacqui Poore (JPoore@Lifespan.org).