# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>REVISIONS &amp; UPDATES</td>
<td>7</td>
</tr>
<tr>
<td>WELCOME</td>
<td>8</td>
</tr>
<tr>
<td>Orientation</td>
<td>8</td>
</tr>
<tr>
<td>Research Staff Directory</td>
<td>9</td>
</tr>
<tr>
<td>Research Assistants</td>
<td>10</td>
</tr>
<tr>
<td>How do I request to use the RAs for my study?</td>
<td>10</td>
</tr>
<tr>
<td>Research Space and Facilities</td>
<td>11</td>
</tr>
<tr>
<td>Clinical</td>
<td>11</td>
</tr>
<tr>
<td>Basic</td>
<td>11</td>
</tr>
<tr>
<td>Simulation</td>
<td>11</td>
</tr>
<tr>
<td>RESIDENTS, FELLOWS, &amp; MEDICAL STUDENTS</td>
<td>12</td>
</tr>
<tr>
<td>Conducting a Research Project as a Trainee</td>
<td>12</td>
</tr>
<tr>
<td>Finding a Research Project Mentor</td>
<td>12</td>
</tr>
<tr>
<td>Applying for Research Funding</td>
<td>12</td>
</tr>
<tr>
<td>Funding Opportunities for Trainees</td>
<td>12</td>
</tr>
<tr>
<td>Where to Find Help</td>
<td>12</td>
</tr>
<tr>
<td>DESIGNING A STUDY</td>
<td>13</td>
</tr>
<tr>
<td>Discuss your idea with colleagues</td>
<td>13</td>
</tr>
<tr>
<td>Consult with experts</td>
<td>13</td>
</tr>
<tr>
<td>CONDUCTING HUMAN SUBJECTS RESEARCH</td>
<td>14</td>
</tr>
<tr>
<td>Training Requirements</td>
<td>14</td>
</tr>
<tr>
<td>CITI Training (mandatory)</td>
<td>14</td>
</tr>
<tr>
<td>Epic LifeChart Training (mandatory)</td>
<td>14</td>
</tr>
<tr>
<td>IRBnet Training (optional)</td>
<td>14</td>
</tr>
<tr>
<td>IRB Approval</td>
<td>15</td>
</tr>
<tr>
<td>Do I need to submit my project to the IRB?</td>
<td>15</td>
</tr>
<tr>
<td>Should I submit my project to the Lifespan IRB or Brown IRB?</td>
<td>15</td>
</tr>
<tr>
<td>Where can I find Lifespan’s IRB policies?</td>
<td>15</td>
</tr>
<tr>
<td>What is the difference between Lifespan’s three IRB committees?</td>
<td>15</td>
</tr>
<tr>
<td>What is the difference between full, expedited, and exempt review?</td>
<td>16</td>
</tr>
<tr>
<td>Does my study qualify for a waiver of informed consent?</td>
<td>17</td>
</tr>
<tr>
<td>What is exception from informed consent (EFIC)?</td>
<td>17</td>
</tr>
<tr>
<td>How do I submit an application to the IRB?</td>
<td>18</td>
</tr>
<tr>
<td>When is the IRB application deadline?</td>
<td>18</td>
</tr>
<tr>
<td>How early should I submit my IRB application?</td>
<td>18</td>
</tr>
<tr>
<td>How long IRB review take?</td>
<td>18</td>
</tr>
<tr>
<td>Does receiving IRB approval mean that I can start my study?</td>
<td>18</td>
</tr>
<tr>
<td>Once I have IRB approval, what do I need to report to the IRB?</td>
<td>19</td>
</tr>
<tr>
<td>Does IRB approval expire?</td>
<td>20</td>
</tr>
<tr>
<td>What documentation is required to renew / continue a project?</td>
<td>20</td>
</tr>
<tr>
<td>What happens if IRB approval expires before the project has ended?</td>
<td>20</td>
</tr>
<tr>
<td>When can I close / terminate my IRB application?</td>
<td>20</td>
</tr>
<tr>
<td>Is there a departmental administrator who can facilitate my IRB application?</td>
<td>21</td>
</tr>
<tr>
<td>IRB changes coming in 2019</td>
<td>21</td>
</tr>
<tr>
<td>IRB changes coming in 2020</td>
<td>22</td>
</tr>
<tr>
<td>Questions?</td>
<td>23</td>
</tr>
</tbody>
</table>
Using a Single IRB

<table>
<thead>
<tr>
<th>Question</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the federal single IRB policy?</td>
<td>24</td>
</tr>
<tr>
<td>What is Lifespan’s single IRB policy?</td>
<td>24</td>
</tr>
<tr>
<td>How is single IRB review conducted?</td>
<td>24</td>
</tr>
<tr>
<td>Using IRBnet</td>
<td>25</td>
</tr>
<tr>
<td>How do I create a Lifespan IRBnet account?</td>
<td>25</td>
</tr>
<tr>
<td>How do I search for projects in IRBnet?</td>
<td>25</td>
</tr>
<tr>
<td>How do I submit a new IRB application?</td>
<td>25</td>
</tr>
<tr>
<td>Where can I find a staff member’s HSP training completion date?</td>
<td>26</td>
</tr>
<tr>
<td>Where can I find my study’s cost center?</td>
<td>26</td>
</tr>
<tr>
<td>How do I share a project with / grant access to a team member?</td>
<td>26</td>
</tr>
<tr>
<td>Where can I find my IRB letter and IRB-stamped documents?</td>
<td>26</td>
</tr>
<tr>
<td>How do I notify the IRB of changes to my project?</td>
<td>27</td>
</tr>
<tr>
<td>How do I add or remove study staff from my IRB application?</td>
<td>27</td>
</tr>
<tr>
<td>How do I update funding information on my IRB application?</td>
<td>27</td>
</tr>
<tr>
<td>How do I notify the IRB of an adverse event or protocol deviation?</td>
<td>28</td>
</tr>
<tr>
<td>How do I submit a continuing review?</td>
<td>28</td>
</tr>
<tr>
<td>How do I submit an annual update?</td>
<td>28</td>
</tr>
<tr>
<td>Where can I find the project’s expiration date?</td>
<td>29</td>
</tr>
<tr>
<td>How do I close / terminate my IRB application?</td>
<td>29</td>
</tr>
<tr>
<td>Questions?</td>
<td>29</td>
</tr>
</tbody>
</table>

Good Clinical Practice

<table>
<thead>
<tr>
<th>Topic</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project start date</td>
<td>30</td>
</tr>
<tr>
<td>Project startup checklist</td>
<td>30</td>
</tr>
<tr>
<td>Regulatory study binder / Essential documents binder (EDB)</td>
<td>31</td>
</tr>
<tr>
<td>Accounting of disclosures</td>
<td>32</td>
</tr>
<tr>
<td>Screening and recruiting in the ED</td>
<td>32</td>
</tr>
<tr>
<td>Consenting and enrolling in the ED</td>
<td>32</td>
</tr>
<tr>
<td>Compensating study participants</td>
<td>33</td>
</tr>
<tr>
<td>ClinicalTrials.Gov reporting requirement</td>
<td>33</td>
</tr>
<tr>
<td>Data and safety monitoring</td>
<td>34</td>
</tr>
<tr>
<td>Study oversight and monitoring</td>
<td>34</td>
</tr>
<tr>
<td>Storing study documents and data</td>
<td>35</td>
</tr>
<tr>
<td>Storing electronic study documents and data</td>
<td>35</td>
</tr>
<tr>
<td>Storing and shipping biospecimens</td>
<td>35</td>
</tr>
<tr>
<td>Questions?</td>
<td>35</td>
</tr>
</tbody>
</table>

CONDUCTING INDUSTRY-SPONSORED CLINICAL TRIALS

<table>
<thead>
<tr>
<th>Question</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>I’ve been contacted to conduct an industry-sponsored trial; how should I proceed?</td>
<td>36</td>
</tr>
<tr>
<td>What is the process for establishing an industry-sponsored trial agreement?</td>
<td>36</td>
</tr>
<tr>
<td>What is the process for invoicing an industry trial sponsor?</td>
<td>37</td>
</tr>
<tr>
<td>What is the ClinicalTrials.Gov reporting requirement?</td>
<td>37</td>
</tr>
<tr>
<td>Questions?</td>
<td>37</td>
</tr>
</tbody>
</table>

CONDUCTING DRUG / DEVICE CLINICAL TRIALS

<table>
<thead>
<tr>
<th>Question</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coming soon!</td>
<td>38</td>
</tr>
</tbody>
</table>

CONDUCTING ANIMAL RESEARCH

<table>
<thead>
<tr>
<th>Question</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>CITI Training (mandatory)</td>
<td>39</td>
</tr>
<tr>
<td>Policies</td>
<td>39</td>
</tr>
<tr>
<td>IACUC Approval</td>
<td>39</td>
</tr>
<tr>
<td>Questions?</td>
<td>39</td>
</tr>
</tbody>
</table>
CONDUCTING OTHER LABORATORY RESEARCH ................................................................................................................. 40
CITI Training (mandatory) ........................................................................................................................................................ 40
Policies ...................................................................................................................................................................................... 40
IBC Approval .............................................................................................................................................................................. 40
Questions? .............................................................................................................................................................................. 40
DATA COLLECTION & ANALYSIS ......................................................................................................................................... 41
REDCap ................................................................................................................................................................................ 41
Statistical support .................................................................................................................................................................. 41
Questions? .............................................................................................................................................................................. 41
GRANTS & FUNDING .............................................................................................................................................................. 42
Submitting a Grant .................................................................................................................................................................. 42
What is the grant submission policy? ................................................................................................................................... 42
When and how do I start a grant submission? .......................................................................................................................... 42
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? ................................................................................. 43
Questions? .............................................................................................................................................................................. 43
Preparing a Grant Application ............................................................................................................................................. 44
What is my applicant organization / primary site? .......................................................................................................................... 44
Who should I list as the Primary Grant Contact Person / Grant Administrator? ................................................................. 44
Who should I list as the Authorizing Official / Signing Official? ............................................................................................ 44
Where can I find grant forms and templates? ............................................................................................................................ 44
How do I contact to get salary information for a grant budget? ............................................................................................... 44
Should I request the maximum amount of the award? ............................................................................................................... 44
How do I calculate % effort? ....................................................................................................................................................... 45
How do I calculate person months? ........................................................................................................................................ 45
What is the difference between a subcontract, vendor, and consultant? .................................................................................... 46
How do I determine if someone is senior/key, non-key, or other? .......................................................................................... 48
I need help developing a budget ............................................................................................................................................... 49
I need help creating a Biosketch ............................................................................................................................................... 49
I need help developing the Facilities and Other Resources section .......................................................................................... 49
I need help drafting a Letter of Support .................................................................................................................................. 49
I need help creating or revising a table / figure .......................................................................................................................... 49
I need help with citation management .................................................................................................................................. 49
I need a list of my current and pending research support ...................................................................................................... 49
What is a business form? .......................................................................................................................................................... 49
What information should be included in a federal proposal to meet the single IRB requirement? ........................................... 50
eRA Commons Account (required for Federal grants only) ...................................................................................................... 51
Just in Time Requests ............................................................................................................................................................. 52
IRB Approval for Just in Time Requests .................................................................................................................................. 52
Post-award Grants Management ........................................................................................................................................... 53
I received correspondence regarding an award, who should I notify? .......................................................................................... 53
How is an award / cost center set up? ...................................................................................................................................... 53
How can I see my award balance? ......................................................................................................................................... 53
How do I submit progress and final reports? ............................................................................................................................ 53
What are the ClinicalTrials.Gov reporting requirements? ...................................................................................................... 54
Questions? .............................................................................................................................................................................. 54
Contract Management ............................................................................................................................................................... 55
Subcontract agreements ............................................................................................................................................................ 55
Consultant / vendor / professional service agreements .......................................................................................................... 55
This guide was originally published on December 1, 2018. Subsequent revisions will be summarized here.

December 20, 2018:

- Section added: IRB changes coming in 2019
- Section added: IRB changes coming in 2020
- Section added: Using a Single IRB
- Section added: What information should be included in a federal proposal to meet the single IRB requirement?
Welcome to EM Research!

Lifespan

All aspects of research conducted in the Department of Emergency Medicine are overseen by the Lifespan Office of Research Administration (ORA) and the Lifespan Research Protection Office (RPO). Lifespan’s and the Department of Emergency Medicine’s research policies and processes are described in this guide.

Orientation

Begin with these steps:

Review this guide for an overview of EM research processes

Contact the EM Research Program Manager, Suzanne Araujo (saraujo@lifespan.org), to discuss your specific needs

Transfers

Investigators transferring to the Department of Emergency Medicine from another institution should meet with the EM Research Program Manager, Suzanne Araujo (saraujo@lifespan.org), as soon as possible to coordinate the transfer of research funds, contracts, IRBs, and other active project components.
Research Staff Directory

Meet the team!

EM RESEARCH LEADERSHIP

Vice Chair for Research
Gregory Jay, MD, PhD
Coro West Suite 106
(401) 444-6656
gjay@lifespan.org

Director of Clinical Research
Francesca Beaudoin, MD, PhD
Claverick 211
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francesca.beaudoin@brownphysicians.org

Associate Director of Clinical Research for Pediatric EM
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Claverick 246
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thomas.chun@brownphysicians.org

Research Program Manager
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Claverick 266
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saraujo@lifespan.org

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(CLAVERICK 237)

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amichaluk@lifespan.org

Research Administrator
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(401) 444-3374
jheraldines.paulino@lifespan.org

Clinical Research Coordinator
Aderonke Ilegbusi
(401) 444-6619
aderonke.ilegbusi@lifespan.org

Clinical Research Assistants
(401) 444-3813 Office
(401) 350-3700 Pager

Download the EM Research Organizational Chart
Research Assistants

The Department of Emergency Medicine has a team of clinical research assistants at the Anderson ED (24/7 coverage), Hasbro ED (24/7 coverage), and The Miriam ED (7a – 9p). The clinical research assistants are managed by the Research Program Administrator, Erin Ryan (erin.ryan@lifespan.org), and the Director of Clinical Research, Dr. Francesca Beaudoin (francesca.beaudoin@brownphysicians.org).

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

To request to use the departmental RAs to screen & enroll for your study, EM investigators should complete the Research Assistant Request Form.

Requests must be made at least 1 month in advance of the anticipated study start date. Requests will be reviewed and approved by Erin Ryan (erin.ryan@lifespan.org) and Dr. Francesca Beaudoin (francesca.beaudoin@brownphysicians.org) 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 RAs are mainly used for studies that can be enrolled for at 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.
Research Space and Facilities

Clinical

The Department of Emergency Medicine conducts clinical research at the Rhode Island Hospital Anderson ED, the Hasbro Children’s Hospital ED, and The Miriam Hospital ED.

The EM clinical research team occupies the following space in the Anderson ED:
- **Davol 158**: EM Research Office (clinical research assistants)
- **Davol 159**: EM Research Office (clinical research coordinators)
- **Bridge 1.094**: -80-degree freezer, fridge for specimen storage, misc. lab & study equipment

EM investigators should contact Erin Ryan (erin.ryan@lifespan.org) if freezer storage is needed. EM investigators should contact Erin Ryan (erin.ryan@lifespan.org) for suggested space for study procedures. Consent and enrollment should take place in the patient’s treating room. If additional space is needed to complete study procedures or follow up, you may consider using the ED family room.

Basic

The Department of Emergency Medicine maintains the following research labs in the Coro Building:
- **Dr. Jay’s Lab**: musculoskeletal trauma and bio-engineering research
- **Dr. Chodobski’s Lab**: neurotrauma and brain barriers research

Simulation

The Department of Emergency Medicine oversees the Lifespan Medical Simulation Center in the Coro Building where simulated provider training and patient safety research is conducted.
Conducting a Research Project as a Trainee

Start early! Research planning, approval, and start up will take longer than you anticipate. It is highly recommended for EM trainees to present your research project idea to the EM Research Committee early in the planning stages of your project. The EM Research Committee 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. See RESEARCH COMMITTEE for upcoming meeting dates and times.

Lifespan policy: Residents, fellows or students cannot serve as Principal Investigator (PI). Residents, fellows or students leading a project will serve as the Principal Researcher (e.g. on the IRB application, consent forms, and any other study materials) and must designate a faculty member to serve as the Principal Investigator (PI). Residents, fellows or students may, however, serve as PI on funding proposals (if they meet the PI qualifications required by the sponsor) and must list a faculty member as their Project Mentor.

Finding a Research Project Mentor

For each research project, EM trainees will be required to designate an EM 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 an EM 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 mentor who possesses the skills you need, not necessarily someone with the same interests. You may find that you need a different project mentor for different projects.

Applying for Research Funding

EM residents and fellows must follow the Department of Emergency Medicine’s process for Submitting a Grant. This also applies to medical students who are submitting a proposal for an Emergency Medicine project and/or your project mentor on the proposal is an Emergency Medicine faculty member.

Funding Opportunities for Trainees

External: What EM grants are appropriate for my career stage?
Departmental: Download the Department of Emergency Medicine’s list of departmental grants

Where to Find Help

To discuss a project idea with senior EM researchers, see RESEARCH COMMITTEE
To discuss available EM resources for your project, contact Dr. Francesca Beaudoin (francesca.beaudoin@brownphysicians.org)
To discuss EM grants and funding, contact Suzanne Araujo (saraajo@lifespan.org)
To find research learning opportunities, see RESEARCH EDUCATION & TRAINING
DESIGNING A STUDY

Discuss your idea with colleagues

To obtain guidance and recommendations from experienced EM investigators, members of the Department of Emergency Medicine are encouraged to present their research idea to the EM Research Committee. The EM Research Committee can help you identify potential roadblocks early on and suggest pertinent resources you may not have been aware of. See RESEARCH COMMITTEE for upcoming meeting dates.

Consult with experts

Dr. Janette Baird, an EM faculty member, research scientist and biostatistician, is a wonderful resource for members of the Department of Emergency Medicine. Dr. Baird is available to assist EM investigators with development of statistical and research design, development of research plans for grant applications, and development of manuscripts. EM investigators may contact Dr. Baird to set up an appointment.

Janette Baird, PhD
Associate Professor of Emergency Medicine (Research)
Research Scientist
Departmental Biostatistician
(401) 444-4976
jbaird@lifespan.org

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. The Department of Emergency Medicine provides funding to the Biostatistics Core to ensure these resources are available to EM investigators. Click here to schedule an appointment. To learn more, contact:

Jason Machan, PhD
Director of Lifespan Biostatistics Core
(401) 444-1493
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 RESEARCH EDUCATION & TRAINING
CONDUCTING HUMAN SUBJECTS RESEARCH

Training Requirements

CITI Training (mandatory)

All researchers and research personnel are required to complete Lifespan’s CITI online training courses prior to conducting any research activity.

Download the CITI Training Instructions

Epic LifeChart Training (mandatory)

Lifespan research staff (employees and interns) can request access to review charts for research purposes. You must first obtain approval and then complete a set of online training courses in NetLearning. Once approved, a member of the Epic team will send training instructions to the user.

There are two levels of LifeChart access for research personnel:

- 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

EM research staff should contact Amy Michaluk (amichaluk@lifespan.org) to request approval.

IRBnet Training (optional)

The Lifespan IRB conducts training sessions at Coro for researchers and support staff. Contact IRB Coordinator, Adrienne McParlin (amcparkin@lifespan.org) to schedule a training session.

Download IRBnet training materials and guides
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. Contact the Lifespan Research Protection Office Director, Janice Muratori (jmuratori@lifespan.org) to request an opinion.

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

All research conducted by members of the Department of Emergency Medicine must be approved by the Lifespan IRB.

Where can I find Lifespan’s IRB policies?

Click here for Lifespan’s IRB and human subject research policies manual.

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.
What is the difference between full, expedited, and exempt review?

Upon submission of your application, the IRB will determine which level of review is appropriate for your project based on criteria set by federal regulations.

**Full Board Review**

Studies that involve greater than minimal risk to human subjects (e.g. involve vulnerable subjects, FDA-regulated drug/device, collecting biospecimens) will undergo review by the Full Board of IRB members. Full Board Review meetings are held once per month. Applications must be submitted 3 weeks in advance of the intended Full Board Review meeting date. Download the list of upcoming IRB submission deadlines and meeting dates.

**Vulnerable Subjects:** children (under 18), pregnant women, fetuses, neonates, cognitively / decisionally impaired, prisoners, students, employees, or economically or educationally disadvantaged persons

**Expedited Review**

Studies that involve minimal risk to human subjects (e.g. chart reviews, surveys, collecting data via routine non-invasive procedures) are generally reviewed by a single IRB member and not the Full Board. These types of applications do not have to be submitted by the established IRB deadlines. Your application will be forwarded to an IRB member for review on a rolling basis.

**Minimal Risk:** 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.

**Exempt Determination**

Click here to review the types of projects that are eligible for exemption from IRB review. Although a project may be eligible for exemption, the PI is required to submit an application to the IRB and the IRB must issue approval to begin the project in the form of an Exempt Determination Letter. After receiving an Exempt Determination Letter, the PI will not be required to submit anything further to the IRB (e.g. annual progress reports, deviations, revisions), as long as the project maintains the properties that make it exempt.

**Exempt Determination with Limited IRB Review**

For exemption eligible projects that will collect sensitive and identifiable information, an IRB member will need to review the project’s privacy and confidentiality protections before issuing an Exempt Determination Letter.
Does my study qualify for a waiver of informed consent?

Full Waiver of Consent (or PartialWaiver of Consent Elements)

Generally, the Lifespan IRB will not consider issuing a waiver of informed consent for any research intervention performed while the subject is a patient of a Lifespan hospital. If the subject is not currently a patient, the IRB may consider granting a full or partial waiver of informed consent if:

- The research involves no more than minimal risk to the subjects
- The waiver will not adversely affect the rights and welfare of the subjects
- The research could not practically be carried out without the waiver

Waiver of the Consent Form

The IRB may consider granting a waiver of documentation of informed consent (i.e. waiving the requirement for a signed consent form) if:

- The research involves no more than minimal risk to the subjects
- The research involves no procedures for which written consent is normally required (outside of the research context)
- The only record linking the subject and the research would be the consent form, and there is a risk of potential harm resulting from a breach in confidentiality (e.g. anonymous surveys)
- The research is not FDA-regulated

Waiver of Authorization to Use or Disclose PHI

Subjects must grant authorization to the researcher to use/disclose their PHI for the purposes of the study. This language is included within the consent form. Under the following conditions, however, the IRB may allow a researcher to use or disclose PHI without obtaining authorization from the subject:

- The use or disclosure of PHI involves no more than minimal risk to the subjects
- There is an adequate plan to protect and destroy the PHI and identifiers
- The research could not practically be conducted without the waiver and without access to and use of the PHI

Researchers may request permission to use/disclose PHI for screening purposes (prior to obtaining the subject’s full consent).

Researchers may request permission to use/disclose PHI prior to IRB submission and approval of the project for the purpose of preparing a research protocol (i.e. to determine feasibility).

Researchers may request permission to use/disclose the PHI of a decedent for research purposes. Identifiable health information continues to be treated as PHI for 50 years after a person’s death.

What is exception from informed consent (EFIC)?

FDA and DHHS regulations allow the IRB to grant an Exception from Informed Consent (EFIC) (i.e. informed consent is not required of all subjects prior to initiating the research intervention) for Planned Emergency Research. Research that involves subjects who, because of their condition (e.g. unconsciousness) are in a life-threatening situation that makes intervention necessary, are unable to give informed consent, and to be effective, the intervention must be administered before obtaining informed consent from the subject’s legally authorized representative is reasonably possible.

The Lifespan Research Protection Office recommends PIs who are planning emergency research contact the RPO Director, Janice Muratori (jmuratori@lifespan.org), for assistance at least 4-5 months prior to the planned start date. The requirements are very complex and include consultation within the institution, the FDA, the DHHS, and community outreach initiatives.
How do I submit an application to the IRB?

IRB applications are submitted in IRBnet (an electronic submission system). Once the application is submitted, all correspondence regarding the project will be conducted within IRBnet. See Using IRBnet for detailed instructions.

When is the IRB application deadline?

Download the list of upcoming IRB submission deadlines. Refer to the deadlines for RIH1.

How early should I submit my IRB application?

If you anticipate your study will require Full Board Review, you should submit the IRB application 2 – 3 months prior to the anticipated project start date. If you anticipate your study will be exempt or qualify for expedited review, you should submit the IRB application 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 typically does not have to be filed by the JIT deadline (unless otherwise stated in the JIT request). 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.

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 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). When you receive a cost center activation notice, 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?

EM investigators may contact Suzanne Araujo (saraujo@lifespan.org) to check on the status of a cost center activation.
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 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**

You should 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 long as all data has been de-identified.

You should terminate your IRB application immediately if you stop the project prematurely.

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. See Where can I find the project’s expiration date? The IRB will send reminders to the PI when the expiration date is approaching and will ask the PI to submit the documentation needed to continue the project without a lapse in approval.

What documentation is required to renew / continue a project?

Depending on the project, renewal documentation may be requested in the following manners:

**Continuing Review**

For a continuing review, the PI will need to complete the continuing review application form, update the Research Application Part I form, submit all study documents that will be used for the upcoming year, and submit any study monitoring reports. Depending on the project, the IRB may need to review these materials in a Full Board Meeting or an expedited review may suffice. The IRB will re-stamp each study document and issue a Continuing Review Approval Letter indicating that the project may continue. Continuing review materials must be submitted at least 60 days prior to the project’s expiration date to ensure that a Continuing Review Approval Letter is received before the project expires. If you do not receive a Continuing Review Approval Letter before the project’s expiration date, all research activity must stop until the continuing review is approved. See How do I submit a continuing review?

**Annual Update**

Some projects may not require a continuing review, but will need to submit an annual update. For the annual update, the PI will need to complete the one-page annual update form and update the Research Application Part I form. See How do I submit an annual update?

Note: Exempt projects do not have an expiration date.

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. If the documents required for renewal (see What documentation is required to renew / continue a project?) are 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 re-submitted as a new IRB application.

When can I close / terminate my IRB application?

You should 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. You should terminate your IRB application immediately if you stop the project prematurely. See How do I close / terminate my IRB application?
Is there a departmental administrator who can facilitate my IRB application?

Who should request IRB administrative support
Our EM Regulatory Coordinator, Jhery Paulino (jheraldines.paulino@lifespan.org), is available to submit and manage Emergency Medicine IRB applications and to serve as a liaison between the PI and the IRB. However, due to the high volume of IRB applications within our department, this level of support is generally reserved for large, funded clinical studies. IRB applications for unfunded projects, exempt projects, chart reviews, resident/fellow projects should be submitted and managed by the PI. If the project has a dedicated RA, the RA can assist with the IRB application.

How to request IRB administrative support
To request IRB administrative support, EM investigators should complete the IRB Admin Support Request Form. Requests should be made 2-3 months before the project’s anticipated start date. Requests for support will be reviewed and approved by Dr. Francesca Beaudoin (francesca.beaudoin@brownphysicians.org), Erin Ryan (erin.ryan@lifespan.org) and Jhery Paulino (jheraldines.paulino@lifespan.org).

If your request is approved
The PI is ultimately responsible for the IRB application. The PI must remain in regular contact with Jhery and must respond to all requests and inquiries in a timely manner. Jhery will request a copy of all study documents from the PI. She will then send the PI the required application forms to complete. Jhery will upload the completed application forms and study documents to IRBnet and route for signatures. Once submitted, Jhery will keep the PI informed of the approval status. The PI will be expected to attend the IRB Full Board Review meeting. Jhery cannot attend the IRB Full Board Review meeting in place of the PI. Once approved, Jhery 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 Jhery 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.

IRB changes coming in 2019
As a result of the 2018 Revised Common Rule (the Federal Policy for the Protection of Human Subjects), the IRB must implement the following changes for projects approved on or after January 21, 2019.

Changes to informed consent:

- For all studies:
  - **Approved on or after January 21, 2019:**
    - Additional elements/language will be required on informed consent forms. New consent form templates will be added to the Forms & Templates Library in IRBnet.
    - A separate consent form for specimen banking will be required and a new template will be added to the Forms & Templates Library in IRBnet.
    - Initialing every page of the consent form will no longer be a requirement.
    - For federally-sponsored clinical trials, the awardee/PI must post a copy of one IRB-approved version of the consent form that was used for enrollment to ClinicalTrials.gov within 60 days after the trial is closed for recruitment.
  - **Approved before January 21, 2019:**
    - These projects are considered "grandfathered" and will not be required to comply with the new consent rules
EMERGENCY MEDICINE | RESEARCH GUIDE

Changes to continuing reviews:

- There will be a new process for renewing a minimal risk study or a study that is closed to enrollment – called an Annual Study Update. The Annual Study Update will simply include a one-page form summarizing enrollment progress.
- For minimal risk studies:
  - Approved on or after January 21, 2019: An Annual Study Update will replace the full Continuing Review (unless the IRB determines that a full Continuing Review is necessary). Consent forms will not have an expiration date and will not need to be renewed at the time of the Annual Study Update.
  - Approved before January 21, 2019: A full Continuing Review will be required for 2019. An Annual Study Update will replace the full Continuing Review starting in 2020. Also starting in 2020, consent forms will not have an expiration date and will not need to be renewed at the time of the Annual Study Update.
- For greater than minimal risk studies:
  - Approved on or after January 21, 2019: At the time of continuing review if the study is closed to enrollment with no study intervention being done, an Annual Study Update will be required instead of a full Continuing Review.
  - Approved before January 21, 2019: A full Continuing Review will be required for 2019. Beginning in 2020, at the time of continuing review if the study is closed to enrollment with no study intervention being done, an Annual Study Update will be required instead of a full Continuing Review.

Changes to categories of review:

- A new category will be added called “Exempt with Limited IRB Review.” For exemption eligible projects that will collect sensitive and identifiable information, an IRB member will need to review the project’s privacy and confidentiality protections before issuing an Exempt Determination Letter.

IRB changes coming in 2020

As a result of the 2018 Revised Common Rule (the Federal Policy for the Protection of Human Subjects), investigators and institutions must comply with the following rule by January 20, 2020.

Single IRB requirement for cooperative research:

- All US institutions engaged in federally funded cooperative research (i.e. studies that involve multiple sites conducting the same protocol) must rely on a single IRB as the reviewing IRB for that study. This requirement will not apply to:
  - (1) cooperative research for which more than single IRB review is required by law; or
  - (2) cooperative research for which the supporting federal department/agency determines and documents that the use of a single IRB is not appropriate for the study.
- NIH already implemented a single IRB policy in 2018. The process and rules for this new provision will be very similar to that of NIH, but will expand to all fifteen DHHS federal agencies under the Common Rule.
- See Using a Single IRB for more information.
Questions?

EM investigators seeking clarification on matters pertaining to the IRB may contact Dr. Jim Linakis (jlinakis@Lifespan.org) or bring your question before the EM Research Committee (see RESEARCH COMMITTEE).

Lifespan Research Protection Office (RPO)

Janice Muratori, MSN, RNP, CIP
Lifespan RPO Director
jmuratori@lifespan.org

S. Candace (Candy) Frater, MD, MHA
Lifespan RPO Manager
sfrater@lifespan.org

Lifespan RPO Website
https://www.lifespan.org/office-research-administration/institutional-review-board-irb
Using a Single IRB

What is the federal single IRB policy?

As of 1/25/18, the NIH requires that NIH proposals for cooperative research (i.e. multiple sites conducting the same protocol) rely on a single IRB as the reviewing IRB for that study. Click here to review the NIH Single IRB Policy. As of 1/20/20, all US institutions conducting federally funded cooperative research must rely on a single IRB. Click here to review this policy. In some cases, the single IRB will be chosen by the federal sponsoring agency. In most cases, however, the applicant (i.e. the lead institution) will be asked to choose the single IRB for the study at the time of proposal submission. Single IRB costs (i.e. fees imposed by the single IRB) are the responsibility of the lead institution and should be included in the proposal budget as a direct cost to the project. Single IRB costs are not included in your institution’s indirect cost rate.

See What information should be included in a federal proposal to meet the single IRB requirement?

What is Lifespan’s single IRB policy?

The Lifespan IRB will serve as the single IRB for projects involving 2 sites (inclusive of Lifespan as one of the 2 sites). Projects with 3 or more sites will need to partner with an external single IRB of your choice. You may partner with the IRB of one of your participating sites. In cases where no other IRB is agreeable, you will need to work with a commercial IRB. Lifespan has an agreement in place with Quorum IRB. However, there are several other commercial options available, such as Western IRB. The process for partnering with an external single IRB is overseen by the Lifespan Research Protection Office (RPO). Contact the Lifespan RPO Manager, S. Candy Frater (sfrater@lifespan.org) for assistance.

EM investigators are highly encouraged to have a discussion with Dr. Gregory Jay (gjay@lifespan.org) when searching for an external single IRB. EM investigators have been creative and successful in finding no-cost options.

How is single IRB review conducted?

Single IRB review will generally 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. 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. Contact the Lifespan RPO Manager, S. Candy Frater (sfrater@lifespan.org), to obtain a Reliance Agreement for Lifespan sites.

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. 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 local context review to the Lifespan RPO Manager, S. Candy Frater (sfrater@lifespan.org), for assistance in gathering this information.
Using IRBnet

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. Before you complete a form, make sure to download and save it to your desktop, and then open it from your desktop. Do not complete a form while it is open in a web browser as your answers will not save.
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 PI, the Dept Chair, and others as needed.

   EM investigators must grant access to the following people:
   • PI: Full Access
   • Suzanne Araujo: Read Only
   • Gregory Jay: Read Only
   • Any staff member assisting with the IRB application: Full Access

8. Go to Sign this Package, select PI, then click Sign
9. Ask your Dept Chair to sign the package

   EM investigators should send an e-mail to Dr. Gregory Jay (gjay@lifespan.org) requesting he sign the package. Although Lifespan policy states that new IRB applications must be signed by the Dept Chair, Dr. Gregory Jay (Vice Chair for EM Research) fulfills this role in the Department of Emergency Medicine.

10. 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 ##-###-####

EM investigators may contact Amy Michaluk (amichaluk@lifespan.org) for assistance locating a CITI date or certificate.

Where can I find my study’s cost center?

A cost center (###-#####) must be listed in the funding section of every IRB application. Do not leave this section blank.

**Funded projects:** The cost center will be listed on the cost center activation notice from Lifespan. EM investigators may contact Suzanne Araujo (saraujo@lifespan.org) with questions regarding your cost center.

**Pending funds:** If funds are pending, ask your Department which research cost center you can list as a placeholder. You should list the Dept. cost center as the first source of funding (enter the Dept name in the Sponsor field). You should list the pending funds as the second source of funding (enter the Sponsor name and ‘pending’ in the cost center field). EM projects may use the cost center ‘701-7909’ and enter ‘Department of Emergency Medicine’ in the sponsor field.

**Unfunded projects:** Your Department is your sponsor. Ask your Department which research cost center you should list (enter the Dept name in the Sponsor field). EM projects may use the cost center ‘701-7909’ and enter ‘Department of Emergency Medicine’ in the sponsor field.

How do I share a project with / grant access to a team member?

1. Log in to www.irbnet.org
2. Click on the project title to open the project
3. Click on Share this Project and follow the prompts

   - **Read access** = read only, cannot upload or submit documents; IMPORTANT: the user will not be cc’d on IRB e-mail notifications regarding the project
   - **Write access** = can read, upload, and submit documents, but cannot share the project with others or delete the project; the user will be cc’d on all IRB e-mail notifications regarding this project
   - **Full access** = no limitations; the user will be cc’d on all IRB e-mail notifications regarding this project

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

4. Log in to www.irbnet.org
5. Click on the project title to open the project
6. Click on Reviews
7. Download, save, and review each attachment listed under Board Documents
8. 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 and complete all fields
   c. 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. Complete all fields (see Where can I find my study’s cost center?)
   c. 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) or 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 submit a continuing review?

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 of the required forms listed in the checklist.
5. Go to My Projects to open the project
6. Go to Designer to upload all of the required forms and documents listed in the checklist
7. In Designer, locate the Lifespan - Research Application Part 1 – Human Subject Studies Form and click on the pencil icon next to it
   a. Click jump to review each page and make sure all information is up to date
   b. When finished, click on Save and Exit
   c. If you made any revisions to the form, you must document these changes in a Revision Request Form
      i. Go to Forms and Templates, Select a Library: choose Rhode Island Hospital
      ii. Download and complete the Revision Request Form
      iii. Go to Designer to upload the Revision Request Form
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 submit an annual update?

1. Log in to www.irbnet.org
2. Go to Forms and Templates, Select a Library: choose Rhode Island Hospital
3. Download and complete the Annual Update Form
4. Go to My Projects to open the project
5. Go to Designer to upload the Annual Update Form
6. In Designer, locate the Lifespan - Research Application Part 1 – Human Subject Studies Form and click on the pencil icon next to it
   a. Click jump to review each page and make sure all information is up to date
   b. When finished, click on Save and Exit
   c. If you made any revisions to the form, you must document these changes in a Revision Request Form
      i. Go to Forms and Templates, Select a Library: choose Rhode Island Hospital
      ii. Download and complete the Revision Request Form
      iii. Go to Designer to upload the Revision Request 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.
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

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?

Questions?

EM investigators may contact the EM Regulatory Coordinator, Jhery Paulino (jheraldines.paulino@lifespan.org) with IRBnet questions.

**IRBnet 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**

Sara Spangenberger
Lifespan IRB Assistant
sspangenberger@lifespan.org

Betty Pisaturo
Lifespan IRB Assistant
elizabeth.pisaturo@lifespan.org
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, Lifespan investigators must (1) comply with Lifespan’s Policy and Procedure Manual and (2) comply with standard operating procedures established by your Department.

The Department of Emergency Medicine’s standard operating procedures for conducting human subjects research are described below.

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 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). When you receive a cost center activation notice, 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 study binder (see 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
- If applicable, the trial has been registered with ClinicalTrials.Gov (see ClinicalTrials.Gov reporting requirement)
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.

EM investigators may contact Jhery Paulino (jheraldines.paulino@lifespan.org) with questions.
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 the ED

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.

EM research staff responsible for screening and recruiting subjects in the ED should meet with Erin Ryan (erin.ryan@lifespan.org) or Jhery Paulino (jheraldines.paulino@lifespan.org) to review ED recruitment procedures.

Download screening log templates

Consenting and enrolling in the ED

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.

EM research staff responsible for consenting and enrolling subjects in the ED should meet with Erin Ryan (erin.ryan@lifespan.org) or Jhery Paulino (jheraldines.paulino@lifespan.org) to review ED consenting procedures.

Download enrollment log templates
Compensating study participants

The following methods are acceptable ways to pay human subjects for research study participation.

- **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#.

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 (e.g. the EM Research Office) where they are easily accessible to study staff during recruitment.

EM investigators should contact Suzanne Araujo (saraajo@lifespan.org) to process any of these payment methods.

ClinicalTrials.Gov reporting requirement

Click here to determine if your clinical trial is subject to the reporting requirements of the FDA. *All clinical trials funded by NIH must register and report the results of their trial in Clinicaltrials.gov (regardless of whether they are subject to the FDA regulation). Click here for more information on this NIH policy.*

If applicable, the PI must ensure the study is reported to ClinicalTrials.Gov no later than 21 days after enrollment of the first participant.
Data and safety monitoring

All clinical trials require a data and safety monitoring (DSM) plan to assure the safety and welfare of the research subjects. There is no one standard DSM plan. The IRB and study sponsor will have specific requirements for the method and degree of monitoring commensurate with the risks, size and complexity of the study. Monitoring may be conducted in various ways or by various individuals or groups. The monitoring function may be performed by the PI (in most cases), or by a study monitor assigned by the PI, or by an independent data and safety monitoring board (DSMB) organized by the PI. Click here to review the Data and Safety Monitoring expectations of the NIH and its institutes/centers.

EM investigators are encouraged to consult with the Emergency Medicine Research Committee if you need assistance in preparing a DSM plan. See RESEARCH COMMITTEE for meeting dates and times. EM investigators are welcome to use the Emergency Medicine Research Committee as their Data and Safety Monitoring Board (DSMB). If interested, see DATA AND SAFETY MONITORING BOARD.

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.

Once enrollment for the study begins, the study team 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 study team 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 by the PI to the study team.

If a study is sponsored by an outside entity, an outside monitor will often need to meet with the PI and study team to ensure the study is being run according to protocol. The PI may assign a study team member to be responsible for monitoring visit preparation, ensuring that they are planned and conducted appropriately. S/he will ensure that all documentation needed by the monitor is made available, and will schedule contact with the PI or pharmacy if required. S/he will also ensure proper follow-up to such visits.

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. The PI may assign a study team member to be responsible for audit preparation, ensuring that the auditor has access to the materials s/he needs, and managing the audit and any follow-up requirements.

If the issue involves EM clinical research staff, Erin Ryan (erin.ryan@lifespan.org) should be notified, and she will address the issue.
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, cash, vouchers)
- 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 EM clinical research assistants and coordinators:**
Documentation for these studies will be stored in the EM Research Offices (Bridge Room 1.094, Davol 158, Davol 159). These rooms are accessible by code, which is only available to EM research staff. Study documents will be stored in locked file cabinets in these rooms, in accordance with Lifespan policies and federal regulations. This process will be overseen by Erin Ryan (erin.ryan@lifespan.org), the assigned research assistants and coordinators. The PI will be notified of the exact location of the study's files and materials. Once a study has closed to enrollment, participant files will be moved to a storage closet in Davol 159. 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. Any materials that were utilized during patient recruitment should be moved out of the EM Research Office as soon as enrollment ends. If materials are not moved within 3 months of enrollment closure or if a storage plan has not been agreed upon with Erin Ryan (erin.ryan@lifespan.org), materials may be discarded.

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.** You may open an LIAM ticket to request a Lifespan share folder be created for your study to which access can be shared with the study team. Follow your department’s process for submitting LIAM tickets. EM investigators should contact Amy Michaluk (amichaluk@lifespan.org) to open an LIAM ticket for (1) a new Lifespan share folder, or (2) to share access to an existing folder with a team member.

Storing and shipping biospecimens

EM research staff responsible for the storage or shipment of biospecimens should meet with Erin Ryan (erin.ryan@lifespan.org) or Kristen Basso (kristin.basso@lifespan.org) to review EM standard operating procedures.

Download cold chain and sample inventory forms

Questions?

EM investigators should contact the EM Research Program Administrator, Erin Ryan (erin.ryan@lifespan.org) with questions regarding good clinical practice.
CONDUCTING INDUSTRY-SPONSORED CLINICAL TRIALS

I’ve been contacted to conduct an industry-sponsored trial; how should I proceed?

EM investigators who would like to conduct an industry-sponsored clinical trial, should contact Erin Ryan (erin.ryan@lifespan.org) and Dr. Francesca Beaudoin (francesca.beaudoin@brownphysicians.org) for approval.

What is the process for establishing an industry-sponsored trial agreement?

**Lifespan approval:**

The following documentation must be reviewed and approved by the Lifespan Clinical Trials Office:

- 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

**IRB approval:**

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?](#)

**Site visit:**

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.

**Start up:**

Enrollment can begin once: (1) Lifespan IRB approval has been received; (2) a Lifespan cost center activation notice has been received; and (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.).

For EM investigators, Erin Ryan (erin.ryan@lifespan.org) will assist you with the agreement, approvals, and start up tasks.
What is the process for invoicing an industry trial sponsor?

The sponsor will be invoiced according to the agreed upon billing schedule. Each department has its own process for clinical trial invoicing. In the Department of Emergency Medicine, clinical trial invoicing is processed by Erin Ryan (erin.ryan@lifespan.org).

What is the ClinicalTrials.Gov reporting requirement?

Click here to determine if your clinical trial is subject to the reporting requirements of the FDA. All clinical trials funded by NIH must register and report the results of their trial in Clinicaltrials.gov (regardless of whether they are subject to the FDA regulation). Click here for more information on this NIH policy.

If applicable, the PI must ensure the study is reported to ClinicalTrials.Gov no later than 21 days after enrollment of the first participant.

Questions?

EM investigators should contact Erin Ryan (erin.ryan@lifespan.org) with questions regarding industry trials and billing.

**Lifespan Clinical Trials Office (CTO)**

Deb Temple  
Lifespan CTO Manager  
dtemple@lifespan.org

**Lifespan CTO Website**

https://www.lifespan.org/office-research-administration/clinical-trial-billing
CONDUCTING DRUG / DEVICE CLINICAL TRIALS

Coming soon!
CONDUCTING ANIMAL RESEARCH

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.

Policies

The Lifespan Institutional Animal Care and Use Committee (IACUC), otherwise known as the Animal Welfare Committee, oversees animal research. Click here to 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.

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 PI, the Dept Chair, and others as needed.

EM investigators must grant access to the following people:
- PI: Full Access
- Suzanne Araujo: Read Only
- Gregory Jay: Read Only
- Any staff member assisting with the IACUC application: Full Access

7. Go to Sign this Package, select PI, then click Sign
8. Ask your Dept Chair to sign the package

EM investigators should send an e-mail to Dr. Gregory Jay (gjay@lifespan.org) requesting he sign the package. Although Lifespan policy states that new IACUC applications must be signed by the Dept Chair, Dr. Gregory Jay (Vice Chair for EM Research) fulfills this role in the Department of Emergency Medicine.

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

Questions?

EM investigators who plan to conduct animal research should first discuss with Dr. Gregory Jay (gjay@lifespan.org).

Lifespan IACUC Coordinator
Kate Brilliant
kbrilliant@lifespan.org

Lifespan IACUC Coordinator
Kate Brilliant
kbrilliant@lifespan.org
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. Download the CITI Training Instructions.

Policies

The Lifespan Institutional Biosafety Committee (IBC) oversees research involving the use of biological hazards, chemical hazards, and recombinant and synthetic nucleic acids. Click here to 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.

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 PI, the Dept Chair, and others as needed.

EM investigators must grant access to the following people:
- PI: Full Access
- Suzanne Araujo: Read Only
- Gregory Jay: Read Only
- Any staff member assisting with the IACUC application: Full Access

7. Go to Sign this Package, select PI, then click Sign
8. Ask your Dept Chair to sign the package

EM investigators should send an e-mail to Dr. Gregory Jay (gjay@lifespan.org) requesting he sign the package. Although Lifespan policy states that new IBC applications must be signed by the Dept Chair, Dr. Gregory Jay (Vice Chair for EM Research) fulfills this role in the Department of Emergency Medicine.

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

Questions?

Lifespan IBC Coordinator
Kate Brilliant
kbrilliant@lifespan.org
DATA COLLECTION & ANALYSIS

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 the Lifespan community. Click here to learn more about REDCap. It is highly recommended that you make an appointment with the REDCap team before building your project.

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

Statistical support

Dr. Janette Baird, an EM faculty member, research scientist and biostatistician, is a wonderful resource for members of the Department of Emergency Medicine. Dr. Baird is available to assist EM investigators with development of statistical and research design, development of research plans for grant applications, and development of manuscripts. EM investigators may contact Dr. Baird to set up an appointment.

Janette Baird, PhD
Associate Professor of Emergency Medicine (Research)  
Research Scientist 
Departmental Biostatistician 
(401) 444-4976 
jbaird@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. Our department provides funding to the Biostatistics Core to ensure these resources are available to our investigators. Click here to schedule a consultation. To learn more, contact:

Jason Machan, PhD 
Lifespan Biostatistics Core Director 
(401) 444-1493 
jmachan@lifespan.org

Questions?

EM investigators may contact Ronke Ilegbusi (aderonke.ilegbusi@lifespan.org) or Dr. Janette Baird (jbaird@lifespan.org) with data capture or data management questions.
GRANTS & FUNDING

Submitting a Grant

The Department of Emergency Medicine’s grant submission process is described below. EM faculty, fellows, residents, and medical students must follow this process when submitting a grant.

What is the grant submission policy?

All applications for external funding originating from the Department of Emergency Medicine (including subawards) must be reviewed and approved by (1) Suzanne Araujo, (2) Dr. Gregory Jay, and (3) the Lifespan Office of Research Administration (ORA) 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. The Department of Emergency Medicine has two departmental research administrators (DRAs), Amy Michaluk (amichaluk@lifespan.org) and Maris Sagamang (maris.sagamang@lifespan.org), who will assist EM investigators in preparing the application, route the application through the chain of approval, and submit the application.

When and how do I start a grant submission?

EM investigators will:

| ≥ 8 weeks prior to the sponsor’s deadline | Give Suzanne Araujo (sarauyo@lifespan.org) a heads up! E-mail her the funding opportunity name, website, and deadline. |
| ≥ 6 weeks prior to the sponsor’s deadline | Submit the Intent to Apply Form. Responses will be sent to Suzanne Araujo and she will assign your application to an EM Departmental Research Administrator (DRA), Amy Michaluk or Maris Sagamang. |
| ≥ 3 weeks prior to the sponsor’s deadline | The 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 the DRA for guidance as needed. |
| ≥ 2 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. The DRA will send you Lifespan business and COI forms that you must sign and return before your application can be routed for approval. |
| ≥ 1 week prior to the sponsor’s deadline | The DRA will route the final application through the chain of approval: (1) Suzanne Araujo, (2) Dr. Gregory Jay, and (3) Lifespan Office of Research Administration (ORA). Your application will be submitted by ORA. |
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 subaward requests in the Department of Emergency Medicine must be reviewed and approved by (1) Suzanne Araujo, (2) Dr. Gregory Jay, and (3) the Lifespan Office of Research Administration (ORA) 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 (i.e. the institution submitting the proposal).** The Department of Emergency Medicine has two departmental research administrators (DRAs), Amy Michaluk (amichaluk@lifespan.org) and Maris Sagamang (maris.sagamang@lifespan.org), who will work with the EM investigator and the administrator at the prime institution to prepare the subaward documentation and route it through the chain of approval.

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

**EM investigators will:**

<table>
<thead>
<tr>
<th>Immediately</th>
<th>As soon as you are aware that you will be participating as a subaward on a proposal, please give Suzanne Araujo (<a href="mailto:saraujo@lifespan.org">saraujo@lifespan.org</a>) a heads up!</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Forward the e-mail requesting subaward documentation to Suzanne Araujo (<a href="mailto:saraujo@lifespan.org">saraujo@lifespan.org</a>). Suzanne will assign your subaward request to an EM Departmental Research Administrator (DRA), Amy Michaluk or Maris Sagamang.</td>
</tr>
<tr>
<td></td>
<td>The 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.</td>
</tr>
<tr>
<td></td>
<td>The DRA will send you Lifespan business and COI forms that you must sign and return before your application can be routed for approval.</td>
</tr>
<tr>
<td>≥ 2 weeks prior to the prime institution’s deadline</td>
<td>The DRA will route the subaward documentation through the chain of approval: (1) Suzanne Araujo, (2) Dr. Gregory Jay, and (3) the Lifespan Office of Research Administration (ORA).</td>
</tr>
<tr>
<td>≥ 1 week prior to the prime institution’s deadline</td>
<td>The DRA will submit the final and approved subaward documentation to the prime institution’s administrator.</td>
</tr>
</tbody>
</table>

**Questions?**

EM investigators should contact the EM Research Program Manager, Suzanne Araujo (saraujo@lifespan.org) with questions concerning grants.
Preparing a Grant Application

What is my applicant organization / primary site?

The applicant organization and primary site for all Emergency Medicine 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 University, however you must make it clear that the applicant organization and primary site of the project is the Department of Emergency Medicine at Rhode Island Hospital and that you work as an emergency physician at Rhode Island Hospital. It’s also important to list your position at Rhode Island Hospital in your biosketch. For pediatric studies, you can refer to the hospital as ‘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 Administration (ORA) and varies by department.

EM investigators should contact Amy Michaluk (amichaluk@lifespan.org) or Maris Sagamang (maris.sagamang@lifespan.org) for this information.

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

This will be someone from the Lifespan Office of Research Administration (ORA) and varies by department.

EM investigators should contact Amy Michaluk (amichaluk@lifespan.org) or Maris Sagamang (maris.sagamang@lifespan.org) for this information.

Where can I find grant forms and templates?

Download EM grant forms and templates

EM investigators should contact Amy Michaluk (amichaluk@lifespan.org) or Maris Sagamang (maris.sagamang@lifespan.org) with questions.

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

EM investigators should contact Suzanne Araujo (saraujo@lifespan.org) for research salary information.

Should I request the maximum amount of the award?

You 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](https://osp.finance.harvard.edu/subrecipient-vs-contractor-guidance)

On EM proposals, a subcontract is generally required in the following circumstances:

<table>
<thead>
<tr>
<th>If the budget includes salary support for:</th>
<th>Subcontract Required?</th>
</tr>
</thead>
<tbody>
<tr>
<td>BEM employees</td>
<td>No</td>
</tr>
<tr>
<td>LPG employees</td>
<td>No</td>
</tr>
<tr>
<td>Rhode Island Hospital / Hasbro employees</td>
<td>No</td>
</tr>
<tr>
<td>The Miriam, Newport, Bradley Hospital employees</td>
<td>Yes</td>
</tr>
<tr>
<td>Brown employees or faculty (non-clinical)</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Employees at any other institution</strong></td>
<td>Yes</td>
</tr>
</tbody>
</table>

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

If a subcontract is required, you will need to develop a separate budget (and budget justification) for each sub-institution. Your departmental research administrator (DRA) 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 his/her employment. Ask yourself: *If this person lost their job, would s/he still be able to provide this service to me?*
- If the service s/he is providing is part of his/her 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.

**EM investigators should contact Amy Michaluk** (amichaluk@lifespan.org) or Maris Sagamang (maris.sagamang@lifespan.org) with questions.
How do I determine if someone is senior/key, non-key, or other?

<table>
<thead>
<tr>
<th>Personnel Category</th>
<th>NIH Definition</th>
<th>Other Definitions</th>
<th>Requirements</th>
</tr>
</thead>
</table>
| **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 s/he meets 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 office for (1) a change in status or (2) a reduction of effort by 25% or more.
I need help developing a budget

EM investigators should contact Amy Michaluk (amichaluk@lifespan.org) or Maris Sagamang (maris.sagamang@lifespan.org) with budget questions.

I need help creating a Biosketch

Download the most current NIH biosketch template. For EM investigators, Amy Michaluk (amichaluk@lifespan.org) or Maris Sagamang (maris.sagamang@lifespan.org) can convert your CV into a biosketch and can review your biosketch to ensure it meets all requirements.

I need help developing the Facilities and Other Resources section

EM investigators should download the Department of Emergency Medicine’s Environment.doc document for a description of our facilities, scientific, academic, and research environment and other resources. Remember to re-download this document for each proposal as it is updated often. This document is maintained by Suzanne Araujo (saraujo@lifespan.org).

I need help drafting a Letter of Support

EM investigators should contact Amy Michaluk (amichaluk@lifespan.org) or Maris Sagamang (maris.sagamang@lifespan.org)

I need help creating or revising a table / figure

EM investigators should contact Amy Michaluk (amichaluk@lifespan.org) or Maris Sagamang (maris.sagamang@lifespan.org) for assistance with formatting and editing grant materials.

I need help with citation management

EM investigators should contact Amy Michaluk (amichaluk@lifespan.org) or Maris Sagamang (maris.sagamang@lifespan.org) for assistance with citations on a grant proposal.

I need a list of my current and pending research support

EM investigators should contact Suzanne Araujo (saraujo@lifespan.org) for this information.

What is a business form?

This form is used by Lifespan to internally review and process funding proposals. It is essentially a face page that accompanies your proposal when it is sent to the Lifespan Office of Research Administration (ORA). It is also used to obtain signatures of the PI, departmental administrator, and department chair attesting that each person has reviewed and approved the proposal. A complete and signed business form must accompany every proposal. Your departmental research administrator (DRA) will assist you with completing the business form and will route it for the appropriate signatures.
What information should be included in a federal proposal to meet the single IRB requirement?

**If Lifespan is the lead site, the PI will need to:**

1. **6 weeks before the proposal deadline:** Review the RFA to determine if the federal sponsor has identified a single IRB that they will require you to use. If there is no required single IRB, you must select a single IRB and obtain their agreement to serve as the single IRB of record for your study.

   **For 2 sites:** The Lifespan IRB will serve as the single IRB for studies involving two sites (inclusive of Lifespan as one of the two sites). Contact the Lifespan RPO Manager, S. Candy Frater (sfrater@lifespan.org) to obtain a letter of commitment and to discuss how you should incorporate single IRB costs into your budget.

   **For 3 or more sites:** The Lifespan IRB will not be able to serve as the single IRB, therefore you will need to look elsewhere. You may contact an IRB of another institution (e.g. the IRB of one of your participating sites). In cases where no other IRB is agreeable, you will need to work with a commercial IRB. Lifespan has an agreement in place with Quorum IRB. As Lifespan will need to approve your choice, you should work with the Lifespan RPO Manager, S. Candy Frater (sfrater@lifespan.org) in conducting your search.

   EM investigators are highly encouraged to have a discussion with Dr. Gregory Jay (gjay@lifespan.org) when searching for an external single IRB. EM investigators have been creative and successful in finding no-cost options.

2. Obtain a project-specific fee schedule (i.e. quote) from the single IRB. Single IRB fees must be included in each year of the budget as a direct cost. Single IRB fees are not included in your institution’s indirect cost rate. Single IRB fees are the responsibility of the lead site and should not be included in subaward budgets. When using a commercial IRB, you must work with the Lifespan RPO Manager, S. Candy Frater (sfrater@lifespan.org) to obtain the commercial IRB’s fee information. When using the IRB of another institution, you will need to work directly with that IRB to obtain fee information.

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

4. Obtain a letter from each site (including Lifespan) affirming that they agree to rely on (i.e. cede authority to) the chosen single IRB for the study. For Lifespan sites, contact S. Candy Frater (sfrater@lifespan.org) to request this letter.

5. For large multi-site studies, the lead site may want to consider budgeting for an additional staff member to manage IRB relations (called an ‘IRB Liaison’). Studies with more than a handful of sites will need significant additional staffing resources to manage the complex communication, documentation, and coordination across sites associated with using a single IRB.

6. Include a Single IRB Plan in your proposal (download the Single IRB Plan template). In this section, you will simply state which institution will serve as the single IRB and affirm that all sites have agreed to cede authority to that IRB. If you believe you qualify for an exemption from the single IRB policy, an exemption request should be included in this section.

**If Lifespan is a participating site (not the lead site), the Lifespan Site-PI will need to:**

1. **3 weeks before the proposal deadline:** Contact S. Candy Frater (sfrater@lifespan.org) to request a letter affirming that the Lifespan Research Protection Office will rely on the chosen single IRB for the study.

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

**If the proposal is funded:**

See Using a Single IRB for next steps.
eRA Commons Account (required for 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 Leslie Simone (lvarone@lifespan.org) to request a new account or to transfer an existing account from another institution.

2. Once your account has been created/transferred, you must log in and delegate access to your departmental research administrator(s).

   EM investigators should delegate access to:
   • Suzanne Araujo - SARAUJO01
   • Amy Michaluk - AAMARAL01
   • Maris Sagamang - MSAGAMANG01

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 Lifespan. If it is not, notify Leslie Simone (lvarone@lifespan.org) immediately to have your account transferred.

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.

Leslie Simone (lvarone@lifespan.org) can reset your password if you are having trouble logging in.
Just in Time Requests

A Just in Time Request is a request for additional information from the NIH prior to making a funding decision. A standard JIT request is e-mailed to all PIs with NIH grant applications receiving an impact score of 30 or less. A response is required 60 days prior to the proposed project start date. A PI may also receive a non-standard JIT request specific to the funding opportunity. These requests usually have a tight turnaround time. A JIT request should not be construed as an indicator of possible award. The PI should notify their grants administrator as soon as they receive a JIT request. JIT information is reviewed and submitted by the Lifespan Office of Research Administration (ORA).

EM investigators should forward a Just in Time request to Suzanne Araujo (saraujo@lifespan.org) right away for processing. Suzanne will gather the requested information, upload it to eRA commons, and notify the Lifespan Office of Research Administration (ORA) when it is ready to submit it.

IRB Approval for Just in Time Requests

Within a JIT request, NIH will ask for the date of final IRB approval. Conditional or pending IRB approval is not sufficient and should not be reported. If final IRB approval is not obtained by the JIT deadline, it may be submitted separately at a later time. If final IRB approval has not been obtained at the time of award, rest assured that funds will not be withheld. However, NIH will restrict you from conducting any human subject activity until the date of final IRB approval is reported and confirmed.

See How early should I submit my IRB application?
Post-award Grants Management

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

The PI should forward all correspondence regarding awards and funding to their grants administrator.

EM investigators should forward correspondence regarding awards and funding to Suzanne Araujo (saraujo@lifespan.org).

How is an award / cost center set up?

The Lifespan Office of Research Administration (ORA) must be notified immediately of all funding award notices. ORA will review the award terms & conditions and formally accept the award. Awards are accepted by the institution (Lifespan), not the PI. If there are any issues or re-budgeting / re-negotiating is necessary, ORA will work this out with the PI before contacting the sponsor.

When the funds are released to Lifespan, ORA will create a cost center (i.e. account) for that award and will send a cost center activation notice to the PI. It is a Lifespan policy that 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?).

PIs must designate who is allowed to use their cost centers by completing ORA’s Grant Signature Authority Form.

When an EM investigator receives a funding award notice, Suzanne Araujo (saraujo@lifespan.org) must be notified right away. Suzanne will work with the Lifespan Office of Research Administration (ORA) to ensure the processes described above are completed.

How can I see my award balance?

The PI should contact their grants administrator to inquire about award balances.

EM investigators may contact Suzanne Araujo (saraujo@lifespan.org) to set up DataWatch access or for a copy of the most recent financial report from ORA.

How do I submit progress and final reports?

The PI should contact their grants administrator to compile progress and final reports. Progress and final reports are reviewed and submitted by the Lifespan Office of Research Administration (ORA).

For EM investigators, Suzanne Araujo (saraujo@lifespan.org) will process and manage your progress and final reports. Suzanne will work with the PI to compile reports and will notify the Lifespan Office of Research Administration (ORA) when ready to submit.
What are the ClinicalTrials.Gov reporting requirements?

Click here to determine if your clinical trial is subject to the reporting requirements of the FDA. All clinical trials funded by NIH must register and report the results of their trial in Clinicaltrials.gov (regardless of whether they are subject to the FDA regulation). Click here for more information on this NIH policy.

If applicable, the PI must ensure the study is reported to ClinicalTrials.Gov no later than 21 days after enrollment of the first participant.

Questions?

EM investigators should contact the EM Research Program Manager, Suzanne Araujo (saraujo@lifespan.org) with questions regarding research grants and funding.
Contract Management

Subcontract agreements

EM investigators should contact Suzanne Araujo (saraujo@lifespan.org) regarding subcontract agreements and invoicing.

Consultant / vendor / professional service agreements

EM investigators should contact Suzanne Araujo (saraujo@lifespan.org) regarding consultant agreements and payments.

Industry-sponsored clinical trial agreements

EM investigators should contact Erin Ryan (erin.ryan@lifespan.org) regarding clinical trial agreements and invoicing.
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).

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

Federal

Use Grants.gov to search all federal agency opportunities. Agencies that EM investigators have submitted to include NIH, CDC, AHRQ, SAMSHA, and DoD.

Foundation

Download SAEM’s list of foundations that fund EM research.

Local

Brown Funding Opportunities

Advance CTR Funding Opportunities

Departmental

Download the Department of Emergency Medicine’s list of departmental funding opportunities.

Questions?

EM investigators should contact the EM Research Program Manager, Suzanne Araujo (saraujo@lifespan.org) with questions regarding funding opportunities.
Research Budget & Accounting

The Department of Emergency Medicine’s research budget is managed by Suzanne Araujo (saraujo@lifespan.org).

Time & Effort Reporting

According to Lifespan policy, all research personnel must report the actual % effort worked on all research projects on a monthly basis.

In the Department of Emergency Medicine, research time & effort (T&E) reporting is processed by Suzanne Araujo (saraujo@lifespan.org). If you are required to report research effort, Suzanne will send you the following two e-mails each month. Please respond promptly as one person’s delay in responding will delay reimbursement of all EM physician salaries to BEM/BPI.

1. The first e-mail will request any changes to your dedicated effort or active projects for the upcoming month, so that Suzanne can generate an accurate report. A response is only required if there are changes.
2. The second e-mail will contain your T&E report, which you will need to complete & return to Suzanne via e-mail.

Research Equipment, Computers, and Devices

All research equipment must have a visible Lifespan equipment tag number. The Lifespan Office of Research Administration (ORA) maintains a database of research equipment. Suzanne Araujo (saraujo@lifespan.org) will process inventory reports when requested from ORA.

To purchase
See Purchasing below to review the process for research purchases and approved vendors.

To dispose
Disposal of research equipment must be reported to the Lifespan Office of Research Administration. Before disposing of a research computer or device, Lifespan Information Services must scrub the device. EM investigators should contact Suzanne Araujo (saraujo@lifespan.org) to coordinate the disposal of research equipment, computers, or devices.
Purchasing

Products should be purchased directly from distributors by submitting a requisition to the Lifespan Purchasing Department. New vendors will require additional time as they must be approved and registered as a Lifespan vendor. Non-approved vendors will require justification and more time for approval. Note that Amazon is not an approved vendor. 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)
- **Clai[[lin** (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)

EM investigators should:

1. Discuss your needs with Suzanne Araujo (saraujo@lifespan.org) *before* making a purchase that will be charged to a research account to ensure that it is allowable and/or reimbursable. Suzanne will warn you if there is a cost limit. If the vendor you are planning to use is not approved by Lifespan, Suzanne can suggest other options.

2. Obtain a quote from the vendor, or generate a shopping list from the vendor’s website, and send it to Suzanne Araujo (saraujo@lifespan.org). Suzanne will review your shopping list and instruct you on the appropriate method to submit a requisition to the Lifespan Purchasing Department. Your shopping list should include the following details:
   - Vendor
   - Item name (website link, if available)
   - Item ID
   - Price per unit
   - # of units
   - Total price
   - Study and cost center
Check Requests & Reimbursements

Check requests for research payments & reimbursements for research expenses in the Department of Emergency Medicine are processed by Suzanne Araujo (saraujo@lifespan.org) in the following manner:

Check Requests

To request a check:
1. Send the invoice (or request for payment) and cost center to Suzanne Araujo (saraujo@lifespan.org).
2. Suzanne will send you a check request form to sign.
3. Return the signed form to Suzanne.

Reimbursements

To request a reimbursement:
1. Contact Suzanne Araujo (saraujo@lifespan.org) to ensure the expense is reimbursable. Suzanne 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 Suzanne. 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
      ii. Gather your travel supporting documentation (see Travel 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 the Lifespan travel policy.

Before planning a trip, EM investigators should:
1. Review the Lifespan travel policy
2. Contact Suzanne Araujo (saraujo@lifespan.org) to determine your reimbursement eligibility and limits.
   - International travel must be approved in advance. Contact Suzanne Araujo (saraujo@lifespan.org) to obtain approval.

*Lifespan Travel Policy Requirements*

- The following **supporting documentation** is required:
  - **Original** 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
Each department has its own process for hiring and onboarding. The Department of Emergency Medicine’s process for hiring and onboarding research staff is described below.

New Research Staff Checklist

The PI is 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 research positions, EM investigators should contact Suzanne Araujo (saraujo@lifespan.org) to initiate the hiring process
  - For unpaid research positions, EM investigators should contact Amy Michaluk (amichaluk@lifespan.org) to initiate the registration process

- **a workspace**
  - EM investigators should note that there is no available workspace in the ED. Workspaces in Claverick must be approved by the Office Manager, Shelly Dow (shelly.dow@brownphysicians.org).

- **completed CITI research training**
  - Download the CITI Training Instructions
  - Employees must be paid for all training hours (i.e. an employee should not be asked to complete any form of training before his/her 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 s/he 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 s/he 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

EM investigators should contact Suzanne Araujo (saraujo@lifespan.org) with questions regarding EM research staffing.
Who do I contact to onboard a new research staff member?

For paid EM research positions, contact Suzanne Araujo (saraujo@lifespan.org) to initiate the hiring process. The hiring process can take up to 1 month.

For unpaid EM research positions, complete this form to initiate the registration process. Form responses are sent to Amy Michaluk (amichaluk@lifespan.org) for processing. The registration process can take up to 1 month.

Who do I contact for an access request?

Requests for EM 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 sent to Amy Michaluk (amichaluk@lifespan.org).

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

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

Does the department offer any research internship opportunities?

Emergency Medicine Research Internship (EMRIntern) Program

Undergraduate upperclassmen from nearby colleges are recruited by the Department of Emergency Medicine to assist with enrollment in our EDs. These interns are available to work about 10 hrs/wk during the academic year (Sep – May) and will receive course credit for their work. This program is intended to give students experience with study recruitment. Participating studies must include patient enrollment. Studies that do not have any patient interaction (e.g. data entry, bench research, etc.) cannot participate.

EM investigators who would like to use an EMRIntern to recruit and enroll for a study must notify Erin Ryan (erin.ryan@lifespan.org) by Mar 1.

The PI will meet with the intern and Erin in Sep to review the study, procedures, and expectations. The PI is expected to meet with the intern monthly to discuss progress.

Coordinator: Erin Ryan (erin.ryan@lifespan.org)
Does the department offer any summer research assistantship (SRA) opportunities?

Summer Research Assistantship in Emergency Medicine (SRA-EM) Program

EM faculty enrolled in this program will select one Brown PLME undergrad or Brown Y1 medical student (for summer before Y2) to work on a summer research project. The student will receive a stipend of $3,500 to work 40 hrs/wk (i.e. full-time) for 10 weeks during the summer (Jun – Aug). The project assigned by the faculty mentor must be a project that can be completed within one summer and must be an independent project (i.e. the student’s responsibilities should not be shared with anyone else). The department budgets for 5 – 8 students per summer. This opportunity is limited to one student per project; one project per faculty mentor.

EM investigators who would like to use an SRA-EM to assist with a summer project must complete the SRA-EM project submission form by Nov 1.

Your project will be posted on the SRA-EM website in Nov. Interested students will contact you directly to set up an interview. You must select one student by Jan 1. The student will prepare and submit the assistantship application forms in Feb. As part of the application, the PI must provide proof of IRB submission and a letter of commitment. We will ensure the student is fully registered and onboarded by Jun 1. The PI will be responsible for supervising the student throughout the summer. The PI is expected to meet with the student weekly to discuss progress. The PI must provide an evaluation letter at the end of the summer describing the student’s performance.

Coordinator: Amy Michaluk (amichaluk@lifespan.org)

The Alpert Medical School’s Summer Assistantship (AMS-SA) Program

Brown faculty enrolled in this program will select one Brown Y1 medical student (for summer before Y2) to work on a summer research project. The student will receive a stipend of $3,500 to work 40 hrs/wk (i.e. full-time) for 10 weeks during the summer (Jun – Aug). The project assigned by the faculty mentor must be a project that can be completed within one summer and must be an independent project (i.e. the student’s responsibilities should not be shared with anyone else).

Investigators who would like to use an AMS-SA to assist with a summer project must complete the AMS-SA project submission form by Nov 1.

Your project will be posted on the SA-AMS website in Nov. Interested students will contact you directly to set up an interview. You must select one student by Jan 1. The student will prepare and submit the assistantship application forms in Feb. As part of the application, the PI must provide proof of IRB submission and a letter of commitment. The PI will be responsible for supervising the student throughout the summer. The PI is expected to meet with the student weekly to discuss progress. The PI must provide an evaluation letter at the end of the summer describing the student’s performance.

EM investigators must follow the New Research Staff Checklist to ensure the student is ready to start by Jun 1.

Coordinator: Chelsea Reyes (chelsea_reyes@brown.edu), AMS Office of Student Development
Authorship Policy

Download the Department of Emergency Medicine’s Authorship Policy

Publication Fees

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

The Department of Emergency Medicine has set aside funds to support open access publication fees for a limited number of manuscripts produced by the department each year.

Download the Department of Emergency Medicine’s Open Access Publication Fee Policy

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 opportunities

Annual emergency medicine conferences:

- **ACEP**: The annual meeting of the national American College of Emergency Physicians
- **SAEM**: The annual meeting of the national Society of Academic Emergency Medicine
- **NERDS**: The New England *regional* meeting of SAEM organized by the New England Research Directors (NERDS)
- **Brown EM Research Day**: The annual research symposium of the Department of Emergency Medicine

Other presenting opportunities:

- **Advance-CTR**: Advance-CTR’s monthly seminar series

Preparing a presentation

When preparing a presentation, always follow the guidelines provided by the conference organizers.

Where can I find presentation templates?

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

How do I order a poster?

The Department of Emergency Medicine will cover the cost of printing a research poster, for presentation at a scientific conference, if printed at the Lifespan Print Shop. Fabric posters are not available.

To order a poster from the Lifespan Print Shop, EM investigators should email the following details to Maris Sagamang (maris.sagamang@lifespan.org) 2 weeks before the date the poster is needed. You will be notified when your poster is ready for pick up in the Claverick Mail Room #232.

- 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 of Emergency Medicine will not reimburse you unless you have a grant or research funds to which the poster can be charged. Before placing an order, EM investigators should contact Suzanne Araujo (sarauco@lifespan.org) to verify that you have funds available.
SOCIAL MEDIA GUIDELINES

It is natural to want to promote the work you are doing, and in today’s world of social networking, it’s easy to do so. Even though social media is a major communication tool, if not used correctly, it could have negative impacts for you and your work. With that in mind, the Lifespan Office of Research Administration has developed the following guidelines to help you promote your work through social media. Be aware that your comments could reflect upon the hospital’s reputation and comment appropriately.

Best practice

A personal blog or your own social networks should never be the first points of publication for any research, reports or announcements. Those announcements should be coordinated with the media relations officer for your partner hospital. If a press release is issued on behalf of the hospital, it will be posted to the Lifespan online newsroom.

It is common and acceptable to mention your work and refer to it in your social communities. It is always best to:

- Refer to the hospital’s online newsroom promoting the research or a news article about the research through a link shared on social network
- Not post any commercially confidential information
- NOT promote research before it is in the public domain
- Wait until a grant is received and the Lifespan Office of Research Administration has received official notification of the grant before discussing it publicly

Promoting recruitment for clinical trials

All communications (paid advertising, press releases, social media posts) MUST be approved in advance by the IRB. Once IRB approval has been obtained, such posting or advertising should be coordinated with the media relations officer at your partner hospital. Your media relations officer will post the approved language to social networks from the hospital account where the research is being conducted. You are also welcome and encouraged to post the approved language.

The name of the hospital at which the research is being conducted should be included in the post (Twitter: @RIHospital, @MiriamHospital, @BradleyHospital) or the hospital should be tagged on Facebook or Google+ posts.

Promoting papers accepted for publication

If a publication/journal has accepted a paper for publication, it is important to honor any embargo dates set by the publication. An embargo date is the date of publication/distribution, or, in many cases, the online-in-advance-of-print date, as many publications now post online on their site prior to actual printing. Please note that any advance promotion posted through social media could jeopardize the actual publication if the embargo is not honored. This is true of both traditional and social media.

Promoting planned studies

For studies that are planned, but have not yet received IRB approval, no public disclosures should be made. This same principle holds true for grant applications that are under review.
Promoting early results

As a general rule, early results should not be promoted by any means as it could jeopardize publication of the final results of the study. If your publication/presentation strategy includes the presentation of interim results at a conference, then all the guidance provided above applies to these disclosures as well.

Promoting funded / sponsored studies

Study sponsors will have their own regulations to which researchers and institutions must adhere. Click here to review NIH’s policy on publicizing NIH-funded research.

Questions?

If you are in any doubt about whether it is appropriate to blog or post a comment about something please speak to your supervisor/manager.

EM investigators should contact Dr. Gregory Jay (gjay@lifespan.org) with public relation concerns related to EM research. EM investigators may also contact Dr. Megan Ranney (megan.ranney@brownphysicians.org) with questions related to social media and EM research.

The above-mentioned social media guidelines were set forth by:

Peggy McGill
Lifespan VP of Research Administration
pmcgill@lifespan.org

Nancy Jean
Lifespan Senior Social Media Strategist
njean@lifespan.org
Lifespan’s IP Policy

Click here to review Lifespan’s Intellectual Property Policy

Invention disclosure

EM investigators should contact Suzanne Araujo (saraujo@lifespan.org) to disclose an invention.

Technology transfers

EM investigators should contact Suzanne Araujo (saraujo@lifespan.org) regarding tech transfers.

Material transfers

EM investigators should contact Suzanne Araujo (saraujo@lifespan.org) regarding biological or other materials that can be protected by patents or written agreements.

Non-disclosure agreements

EM investigators should contact Suzanne Araujo (saraujo@lifespan.org) regarding non-disclosure agreements.

Data use agreements

EM investigators should contact Suzanne Araujo (saraujo@lifespan.org) regarding data use agreements.

Copyright materials

EM investigators should contact Suzanne Araujo (saraujo@lifespan.org) regarding written, visual, or audible works that can be protected by copyright.

Questions?

EM investigators should contact Dr. Gregory Jay (gjay@lifespan.org) with questions concerning IP.

Peggy McGill
Lifespan VP of Research Administration
pmcgill@lifespan.org
Lifespan's COI 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 (i.e. senior/key personnel affiliated with Lifespan).

Anyone who falls under this policy must:

- be familiar with Lifespan’s Research Conflicts of Interest Policy
- complete Lifespan’s mandatory CITI training course on COIs no less than every 4 years
  - Download the CITI Training Instructions
- disclose COIs to Lifespan prior to submitting any application for funding
  - Your departmental research administrator will send you a Lifespan COI disclosure form to complete prior to proposal submission
- disclose COIs to Lifespan within 30 days of discovering or acquiring a new COI
  - 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.

Questions?

EM investigators with a perceived COI should first discuss with Dr. Gregory Jay (gjay@lifespan.org).

Lifespan Research COI’s are managed by:

Peggy McGill
Lifespan VP of Research Administration
pmcgill@lifespan.org
Emergency Medicine Research Lectures & Workshops

Emergency Medicine Research Curriculum: This is a series of 16 didactic lectures covering a range of research skills. These lectures are conducted by EM faculty members and are open to all members of the Department of Emergency Medicine. Topics include study design, clinical prediction modeling, statistics and data analysis, presenting results, manuscript writing, and research ethics. The program is directed by Dr. Siraj Amanullah and Dr. Gregory Jay and coordinated by Maris Sagamang (maris.sagamang@lifespan.org). Click here to learn more.

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.

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 hrs / week from Jul – Jun). To participate in the workshop, investigators must have completed Part I and have a project or proposal.

The Department of Emergency Medicine sponsors two seats per year in this program. EM investigators should contact Dr. Gregory Jay (gjay@lifespan.org) before Aug 1 to enroll or to learn more.

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.
**Emergency Medicine MPH / ScM Research Fellowships**

The SAEM Research Fellowship is available to Brown Emergency Medicine junior faculty members. This is a 2-year non-ACGME research fellowship structured to prepare the recently graduated EM trainee in the rigors of academic medicine; emphasizing scholarship, research and grantsmanship by an acclaimed faculty member with an established funding history in multiple areas. This fellowship offers the pursuit of a Master of Public Health degree or Master of Science in Clinical and Translation Research degree from Brown University. This fellowship program is directed by Dr. Gregory Jay. Applications are due in mid-Sep (for a start date of Jul 1 the following year). If you are interested in applying or would like to learn more, contact Dr. Gregory Jay (gjay@lifespan.org).

The Injury Prevention Research Fellowship is a two-year physician research training program that includes a Master of Public Health degree or Master of Science in Clinical and Translation Research degree from Brown University. Fellows are graduates of emergency medicine or pediatric residency programs and work clinically 2 days per week in the emergency department. They have the remainder of their time protected for research and educational activities. During the two-year program, fellows are expected to pursue mentored research projects in injury or violence prevention and are guided in obtaining skills and training in the established "Core Competencies for Injury and Violence Prevention". Upon completion of the fellowship, graduates will be prepared for an academic career with a dedicated focus on injury and violence research. This fellowship program is directed by Dr. Michael Mello. If you are interested in applying or would like to learn more, contact Dr. Michael Mello (michael_mello_md@brown.edu)

**Other Emergency Medicine Fellowships**

Some of the other fellowships offered by the Department of Emergency Medicine include a research component. Click here to learn more about other Brown Emergency Medicine fellowships.
The Emergency Medicine Research Committee holds open meetings once per month. Meetings begin with staff updates and business items. After all new business has been discussed, the floor opens to investigators for discussion of research projects. All members of the Department of Emergency Medicine are welcome to attend to learn what the committee does and to bring forth new discussion items.

Download the EM Research Committee Meeting Schedule

Agenda Requests

To request time on the agenda, e-mail Maris Sagamang (maris.sagamang@lifespan.org) and Dr. Gregory Jay (gjay@lifespan.org) at least one week prior to the desired meeting date, including the topic of discussion, how much time you will need, and AV requirements.

Project Discussions

To request time on the agenda to discuss a research project, please submit the Project Discussion Form at least one week prior to the desired meeting date. Form responses are sent to Maris Sagamang (maris.sagamang@lifespan.org) and she will confirm the meeting date and your allotted time. Project discussions should begin with a 5-minute presentation of your project and then the floor will open for questions, discussion and feedback. Your presentation can include slides or handouts, although this is not mandatory nor expected.

Committee Members

Gregory Jay, MD, PhD (Committee Chair)
Jeremiah Schuur, MD, MHS (Dept Chair)
Janette Baird, PhD
Francesca Beaudoin, MD, PhD
Bruce Becker, MD, MPH
Linda Brown, MD
Geoff Capraro, MD, MPH
Adam Chodobski, PhD
Thomas Chun, MD, MPH
Susan Duffy, MD, MPH
Aris Garro, MD, MPH
Elizabeth Goldberg, MD, ScM
Traci Green, PhD, MSc
Leo Kobayashi, MD
Adam Levine, MD, MPH
James Linakis, MD, PhD
Tracy Madsen, MD, ScD
Michael Mello, MD, MPH
Lisa Merck, MD, MPH
Megan Ranney, MD, MPH
Selim Suner, MD, MS
Joanna Szmydynger-Chodoba, PhD, MS
Mark Zonfrillo, MD, MSCE

Research Focus

Biomedical Engineering, Biotribology
Health Care Quality and Policy
Injury Prevention and Substance Use
Pain Management
Smoking Cessation
Simulation – Pediatric EM
Sepsis – Pediatric EM
Molecular Mechanisms in TBI
Pediatric EM Trials
Pediatric EM Trials
Respiratory and Infectious Disease – Pediatric EM
Aging and Population Health
Opioid Misuse and Naloxone Treatment
Medical Simulation & Clinical Bedside Informatics
Global Health
Behavioral Health – Pediatric EM
Sex and Gender Research
Injury Control and Prevention
Resuscitation Research Trials
Digital Health and Behavioral Health
Disaster Medicine
Molecular Biomarkers in TBI
Bioinformatics – Pediatric EM
The Emergency Medicine Research Committee serves as a Data and Safety Monitoring Board (DSMB) for studies within the Department of Emergency Medicine.

If you would like the EM DSMB to serve as the DSMB of record on your study, EM investigators should send your DSM plan and study protocol to Maris Sagamang (maris.sagamang@lifespan.org) and Dr. Gregory Jay (gjay@lifespan.org).

The EM DSMB meets as needed during the monthly EM Research Committee meetings. If you need to convene the EM DSMB (e.g. to review 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, Maris Sagamang (maris.sagamang@lifespan.org) will provide a report to the PI summarizing the discussion and recommendations. This report should be submitted to the IRB (and to the sponsor, if requested).

**DSMB Members**
- Gregory Jay, MD, PhD (DSMB Chair)
- Janette Baird, PhD
- Francesca Beaudoin, MD, PhD
- Thomas Chun, MD, MPH
- Adam Levine, MD, MPH
- Michael Mello, MD, MPH
- Megan Ranney, MD, MPH
- Selim Suner, MD, MS
- Joanna Szmydynger-Chodobska, PhD, MS
The Department of Emergency Medicine presents the following research honors to EM investigators:

**Outstanding Investigator Award**
This award recognizes the significant research accomplishments of a faculty member who helped advance the research mission of Brown and of the specialty of Emergency Medicine.

- 2018 – TBA
- 2017 – Megan Ranney
- 2016 – Michael Mello
- 2015 – Thomas Chun

**Translational Impact Award**
This award recognizes the faculty member, fellow, or resident physician who creatively addressed a clinical challenge through translational research.

- 2018 – TBA
- 2017 – Elizabeth Goldberg
- 2016 – Francesca Beaudoin
- 2015 – Lisa Merck

**Michael J. Mello Outstanding Research Mentor Award**
This award recognizes a faculty member and researcher who has served as an exceptional mentor and advisor to research trainees.

- 2018 – TBA
- 2017 – Adam Chodobski & Joanna Szmydynger-Chodob ska
- 2016 – Janette Baird
- 2015 – Michael Mello

**Gregory D. Jay Research Impact Award**
This award recognizes the faculty member who has substantial contributions to scientific literature as measured by the H index, considering research impact over time.

- 2018 – TBA
- 2017 – Michael Mello
- 2016 – Roland C. Merchant
- 2015 – Gregory Jay

**Gregory D. Jay Resident Research Award**
This award recognizes a senior resident that has demonstrated significant accomplishments in the research realm during their residency. This resident has presented at regional and national conferences and has published manuscripts on their work.

- 2018 – Tess Wiskel
- 2017 – Xiao (Tony) Zhang
- 2016 – Naomi George & Elizabeth Samuels
- 2015 – Gregory Hayward
- 2014 – Payal Modi
- 2013 – Stephanie Carreiro & Jared Blum
- 2012 – Tracy Madsen
- 2011 – John Haran
- 2010 – Francesca Beaudoin

**James G. Linakis Outstanding Pediatric Emergency Medicine Research Mentor Award**
This award recognizes a pediatric emergency medicine (PEM) faculty member who has advanced the field of PEM research and has been an exceptional mentor.

- 2018 – TBA
- 2017 – Siraj Amanullah
- 2016 – Dale Steele
- 2015 – James Linakis

**Paul Calabresi Faculty Research Award**
This award recognizes the significant research accomplishments of a faculty member who has helped advance the research mission of Brown, and of the specialty of Emergency Medicine.

- Discontinued -
- 2014 – Megan Ranney
- 2013 – Esther Choo
- 2012 – Laura Chapman
- 2011 – Anthony Napoli
- 2010 – Leo Kobayashi
- 2009 – James Linakis
- 2008 – Selim Suner
- 2007 – Andrew Nathanson
- 2006 – Roland C. Merchant
- 2005 – Selim Suner
- 2004 – Robert Partridge
- 2003 – Robert Woolard
- 2002 – Dale Steele
- 2001 – Bruce Becker
- 2000 – Marc Shapiro
RESEARCH VISION STATEMENT

2017-2022 Department of Emergency Medicine Research Vision Statement:

We will be national leaders in the development and clinical translation of evidence-based treatments and interventions to improve emergency care and related health fields. Our investigators will focus on performing independent and collaborative research in our Department’s areas of research emphasis, capitalizing on our sustainable research infrastructure. We will have a robust and growing portfolio of deferral, private/foundation, and industry-sponsored studies. Our measures of success will be:

1. By 2022, we will have total research funding of over $6 million per year.

2. We will continue to provide up to $150,000 per year in Department-funded research/scholarly grant support (e.g. ADA, RDG, SPG, RES, RRG, Seed Grant).

3. By 2022, EM investigators will be principal investigators on 8 NIH R01 or equivalent grants, 4 R21 or equivalent early-stage or developmental grants, 5 K or equivalent career development grants, 1 training grant & 1 U grant.

4. By 2022, we will have expanded efforts in clinical research trial networks.

5. DEM investigators will submit at least 60 grant applications per year.

6. We will create and support translational research business opportunities, recognizing business creation or collaboration as a vehicle of research funding.

The Department of Emergency Medicine’s areas of research emphasis (est. in 2013) are:

1. Injury Prevention and Control

2. Cardiovascular, Neurologic and Resuscitation Science

3. Pediatric, Age and Gender Specific Care

4. Healthcare Systems Science
QUICK LINKS

Websites

EM Research Website
Lifespan Office of Research Administration Website
Lifespan IRB Website

Schedules

EM Research Committee Schedule
EM Grants and Deadlines
IRB Review Dates and Deadlines

Forms

EM Form to Request a Project Discussion at Research Committee
EM Form to Request RA Support
EM Form to Request IRB Admin Support
EM Intent to Apply for a Grant Form
EM Form to Request a new Research Intern

Guides

CITI Training Instructions
IRB Training Materials

Templates

EM Study Templates and Logs
EM Grant Templates
EM Presentation Templates

Other

EM Research Policies
EM Research Organizational Chart
EM Research Funding Chart