

REQUEST FOR RESEARCH PROPOSALS

The Connors Center IGNITE Award Program

Investigating female-specific and sex-differentiating effects in novel diagnostics and therapeutics

<https://connorscenter.bwh.harvard.edu/ignite/>

Letters of Intent Due: November 10, 2023	Full Proposals Due: January 8, 2024	Award Announced: March 11, 2024
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Sponsored by the Mary Horrigan Connors Center for Women's Health and Gender Biology at Brigham and Women's Hospital (BWH)

The Connors Center for Women's Health and Gender Biology is pleased to announce a request for research proposals (RFP) from the Brigham and Women's Hospital research community for our 2024 IGNITE Awards. These awards build on the existing IGNITE Awards program that began in 2019. To view previous IGNITE Awardees, visit: <https://connorscenter.bwh.harvard.edu/ignite/>.

Award Opportunities:

The goal of the IGNITE Award Program is to promote and support early-phase, proof-of-concept studies, in the specific area of expertise of the candidate, aimed at advancing our understanding of the role of female-specific and sex-differentiating factors implicated in the development and utilization of novel diagnostics and therapeutics - drugs, devices, and digital strategies.

BWH Connors Center IGNITE Awards

These \$50,000 awards (inclusive of 20% indirect costs) will support up to three awards for Brigham and Women's Hospital investigators to conduct new and innovative projects for one year in the following areas. Applications that have high translational impact are particularly encouraged. This includes projects that focus on biomarker discovery and drug delivery systems in all disease areas affecting women exclusively, predominately and differentially.

1. One award will be given to support an investigator conducting research that seeks to investigate sex- and gender-differentials with any disease focus.
2. One award - the Cardiac and Vascular IGNITE Award - will be given to support one Brigham and Women's Hospital investigator to conduct research in the field of cardio-metabolic and vascular diseases in women and/or sex- and gender-differences in cardio-metabolic and vascular diseases, including studies on disease mechanisms, biomarkers, diagnostics and therapeutics.
3. One award - the Breast Cancer Research Award - aims to promote and support pilot and proof-of-concept studies in the specific area of breast cancer aimed at advancing our understanding of disease mechanisms,

treatment, and related health impacts, with the ultimate goal of generating pilot data to support further funding for larger translational projects. Projects can include development and utilization of novel diagnostics and therapeutics - drugs, devices, and digital strategies targeting breast cancer, as well as health services research, and clinical research projects focused on the course of breast cancer and its treatments. Studies that also involve other cancers in women together with breast cancer will be considered.

Connors Center BWH-MGB Collaborative IGNITE Awards

One Connors BWH-MGB Collaborative IGNITE will support a BWH principal investigator who is collaborating with an investigator from another MGB institution on a joint project in the specific area of expertise of the candidates, aimed at advancing our understanding of female-specific and sex-differentiating factors in the development and utilization of novel diagnostics and therapeutics – drugs, devices, and digital strategies – for diseases affecting women exclusively, predominately, or differentially. A joint project from a BWH investigator and a Mass General Brigham investigator will be funded for \$100,000 (inclusive of 20% indirect costs) to support one year of work.

Background:

The broad goal of the IGNITE Awards program is to ensure that medical advances are optimized for the health of women through scientific investigation. These awards aim to advance our understanding of the role of **female-specific and sex-differentiating factors across different stages of the drug and device development process, from target identification to post-approval monitoring and uptake in the community, as well as in the development and optimization of novel diagnostics and digital strategies**. Specifically, the IGNITE Awards program aims to promote and support research projects that focus on:

- 1) uncovering sex-specific and sex-differentiating factors that may affect the efficacy, tolerability, safety, acceptability, and uptake of novel therapeutics;
- 2) identifying female-specific and sex-differentiating factors that may represent novel therapeutic targets or disease biomarkers;
- 3) developing and/or optimizing diagnostics in a sex- and gender-informed fashion;
- 4) examining innovative and effective approaches to include and retain women in early-phase development of drugs, devices, and digital diagnostics and therapeutics.

IGNITE investigations are important components of the Connors Center's **First.In.Women Precision Medicine Platform**. First.In.Women is a translational research platform that is advancing the inclusion and specific investigation of women in studies of the development and utilization of new drugs, devices, digital diagnostics and therapeutics to produce sex-specific knowledge about treatments for both women and men. First.In.Women is a go-to hub for national efforts to advance our investigation of sex as a biological variable in relation to novel diagnostics and therapeutics.

IGNITE Awardees and First.In.Women Partnership:

Both IGNITE Awardees will benefit from the Connors Center First.In.Women program supports and activities, including having the opportunity to engage with scientific leaders and staff both individually and as a group

through Work-in-Progress meetings (see below), mentoring meetings, and scientific meetings, such as the Connors Center Annual Research Symposium. The overall purpose of these meetings is to stimulate scientific exchanges, provide mentorship and sponsorship, integrate the First.In.Women translational framework, and facilitate networking and collaboration across the First.In.Women research community. These meetings will provide the opportunity to: 1) review project goals, milestones and deliverables to ensure progress on study aims; 2) evaluate alignment between the First.In.Women mission and the clinical translation of the proposed research project; 3) connect with Connors Center and First.In.Women resources; and 4) receive feedback from both internal and external content experts in the field. These meetings will support and maintain the momentum of the studies in order to maximize each project's future growth and potential for impact.

Work-in-Progress Meetings:

IGNITE Awardees will be expected to attend and present their work at least at one Work-in-Progress (WiP) meetings hosted by the Connors Center during the year of funding. The purpose of WiP meetings is to support the growth of all IGNITE Awardees and maximize the impact of First.In.Women translational science by providing IGNITE investigators an opportunity to obtain feedback on their ongoing work by experts in sex- and gender-informed research, subject-matters experts, and First.In.Women Faculty.

Award Administration:

Principal Investigators of these IGNITE Awards must have a primary affiliation at Brigham and Women's Hospital and will be responsible for reporting and communicating with the Connors Center Administrators who will be overseeing this award. For BWH Connors Center IGNITE grants, awardees will be granted up to \$50,000 each, inclusive of 20% indirect costs. For Connors Center BWH-MGB Collaborative IGNITE grants, awardees will receive a total of \$100,000, \$50,000 to each PI, inclusive of 20% indirect costs.

The initial funding period will run for 12 months. Competing renewals are allowable if first year progress shows promise for an expanded investigation. No-cost extensions are discouraged. Projects must be ready to commence upon receipt of award.

Timeline:

Request for proposals announced:	September 25, 2023
Letter of Intent due:	November 10, 2023
Invitations to submit full proposals distributed:	November 20, 2023
Full proposals due:	January 8, 2024
Award recipients announced:	March 11, 2024
Earliest start date:	April 1, 2024

Eligibility:

We welcome applications that meet the following criteria. Both US and non-US citizens are welcome to apply. Projects with a special focus on disparities associated with minoritized groups are also encouraged.

- The Principal Investigator's primary appointment is at Brigham and Women's Hospital.
- ***For Connors Center BWH-MGB Collaborative IGNITE Awards Only-*** The co-Principal Investigator's primary appointment is at a non-BWH Mass General Brigham Institution (i.e. MGH, McLean, Spalding, MEEI, etc.)

- The Principal Investigator must have a doctoral degree (MD and/or PhD or equivalent).
- The Principal Investigator must have an HMS appointment at the Instructor level or above.
 - *HMS Research Fellows whose promotion to Instructor at HMS is pending and expected to be completed during the period of the Award will be considered if a written letter from the Division Chief or Department Chair confirms the status of the faculty appointment consistent with these criteria.*
- Prior IGNITE award recipients may apply for funding, either to extend a previously funded IGNITE project or to support a new research study.
- Applicants may apply as a Principal Investigator to both the BWH Connors Center IGNITE Awards and the Connors Center BWH-MGB Collaborative IGNITE Awards, provided they complete separate applications and meet the eligibility criteria for each award type.
- Applicants to the BWH Connors Center IGNITE Awards will need to indicate on the application form if their project has a cardio-metabolic or vascular focus to be considered for the specialized Cardiac and Vascular BWH Connors Center IGNITE Awards.
- Applicants can submit only one application for each grant type (BWH Connors Center IGNITE Awards, Connors Center BWH-MGB Collaborative IGNITE Awards)
- Principal Investigators may only be granted one IGNITE award each cycle.

Application Process and Materials:

Part 1: Cover Sheet and Letter of Intent – Due November 10, 2023, at 12:00pm:

1. Research Proposal Cover Sheet (Download here: <https://connorscenter.bwh.harvard.edu/funding-opportunities/>)
 - a) Please indicate which award you are applying for using the check box provided.
 - b) **Please note that the coversheet for the BWH Connors Center IGNITE Awards and the Connors Center BWH-MGB Collaborative IGNITE Awards are different.**
2. 1-page Letter of Intent, which addresses all the following:
 - a) What is the major problem in medicine that you plan to study, and how does your proposal address either a female-specific or sex-differentiating question?
 - b) How do you plan on using this IGNITE Award to support your work to advance our understanding of novel diagnostics or therapeutics in women?
 - c) How do your previous experiences and accomplishments inform the current project?

Letters of Intent will be reviewed by a panel of established researchers. *Based on Letters of Intent, select applicants will be invited to submit full proposals for review.* Decisions from the review panel will be communicated by November 24, 2023 and will be final. No written feedback will be provided.

Part 2: Full Proposals - Due January 8, 2024, at 12:00pm (By Invitation Only):

1. Research proposal cover sheet

2. A 2-page research statement describing your scientific proposal that includes a timeline with planned milestones and deliverables. Figures, tables, and images may be included within the two pages. A maximum of 10 references may be included on an additional page.
3. Brief description of plans for future grant applications and investigations using these pilot data (150-word max).
4. Brief description of involvement/collaboration (current or prospective) in the proposed project of biopharma or biotech companies (100-word max).
5. A 1-year budget for up to \$50,000, including indirect costs at 20%, using the provided template with a corresponding budget justification (200-word max).
 - a. **For the Connors Center BWH-MGB Collaborative IGNITE Award please submit separate budget forms for each PI**
6. NIH biosketch for PI(s)
7. A brief letter of support (up to 1 page) on letterhead for the PI(s) from their Division Chief, Department Chair, Laboratory PI, or Mentor.
 - a. **For the Connors Center BWH-MGB Collaborative IGNITE Award please submit a letter of support for both the BWH PI and the MGB PI**

Proposal Review Criteria:

- Application text must be in Arial, 11-point font. Single-spacing is allowed. All margins must be at least 0.5 inches. All items above must be compiled into a single PDF in the stated order. You may make reasonable edits to your Project Summary when re-submitting the application cover sheet with your full proposal. Incomplete applications, applications submitted in multiple files, and multiple applications submitted to one award opportunity will not be considered.
- Applications will be judged based on scientific merit, feasibility, fit with the goals and objectives of the Connors Center First.In.Women Precision Medicine Platform, and potential for obtaining independent funding to continue the study once the funding period has ceased.
- Special considerations that will be weighed advantageously during review:
 - Projects led conducted by early-stage investigators
 - Projects with high translational impact
 - For Connors Center BWH-MGB Collaborative IGNITE: Project teams that represent different departments/specialties and leverage different approaches

Terms of the IGNITE Program:

- Awardees may only be funded one IGNITE Award per application cycle. Applicants who applied for multiple IGNITE Awards may only receive funding for one of these awards.
- Recipients will be expected to meet with Connors Center leadership individually and to attend WiP research meetings as described above.
- In addition to WiP meetings, recipients will be required to present their project at two or more Connors Center events (e.g. annual research symposium, donor events).
- Recipients will submit brief 6-month and final written reports (1 page each) of research activity.

- Recipients must maintain their primary appointment at BWH for the duration of the funding period. If an awardee leaves their home institution, the unspent funds will be returned to the Connors Center.
- Recipients are expected to remain in touch with the Connors Center for at least 3 years post-award to report on publications, grants, and other outcomes from the award.
- Recipients must cite the funding source on all publications and presentations related to this project.

Please submit all materials electronically to ConnorsCenter@bwh.harvard.edu.

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