

**Emory Specialized Center of Research Excellence  
on Sex Differences (Emory SCORE)  
Career Enhancement Core  
announces  
Pilot Grants Available**



The Emory Specialized Center of Research Excellence on Sex Differences (Emory SCORE) will fund a **variable number of one-year, non-renewable awards ranging from \$10K - \$30K for projects that account for sex as a biological variable when examining key sex influences on health processes and outcomes.** Additional awards that are in line with the overlapping missions of Emory SCORE -- to strengthen science through accounting for sex -- and its partner organizations may be funded in partnership with the Emory Center for AIDS Research (CFAR), the Emory Diabetes Center (EDC), and the Emory Women's Interagency HIV Study (WIHS). Applications outside these fields are also strongly encouraged.

**Key Dates**

	<b>Date</b>	<b>Notes</b>
Lunch and Learn Information Session	September 17, 2019 12:00—1:00 pm	School of Nursing Room 114 Zoom: <a href="https://zoom.us/j/795685838">https://zoom.us/j/795685838</a> Phone one-tap: US: +19292056099,,795685838# or +16699006833,,795685838# RSVP: <a href="https://form.jotform.com/EmorySCORE/InformationSession">https://form.jotform.com/EmorySCORE/InformationSession</a>
Letter of Intent due	September 30, 2019	Submit online to: <a href="https://form.jotform.com/EmorySCORE/LOI">https://form.jotform.com/EmorySCORE/LOI</a>
Application due	November 1, 2019	Submit online to: <a href="https://form.jotform.com/EmorySCORE/Application">https://form.jotform.com/EmorySCORE/Application</a>
Notification of award status	January 6, 2020	All applications that are scored will receive a Summary Statement.
Project Period begins	February 1, 2020	Regulatory clearances must be in place prior to release of funding.

**Lunch and Learn Information Session:  
September 17, 2019**

12:00 – 1:00 pm

School of Nursing Room 114

Meeting URL: <https://zoom.us/j/795685838>

Phone one-tap: US: +19292056099,,795685838# or +16699006833,,795685838#

RSVP attendance to: <https://form.jotform.com/EmorySCORE/InformationSession>

**Eligibility**

- Emory faculty members at any level who are eligible to receive NIH R01-equivalent funding through the University AND
  - Have no history of NIH funding at the R01-equivalent level (early stage investigator) **or**
  - Have a history of only one R01-equivalent NIH award (early established investigator) **or**

- Are independent and funded scientists who have not been funded at the R01 level in sex differences research.

### **Examples of studies eligible for funding:**

1. Pilot or feasibility studies
2. Secondary analysis of existing data
3. Sub-study or addition of a new research aim or question (to a currently funded project) in which the sub-study or new aim/question focuses on sex as a biological variable
4. Development of research methods, technology, or interventions that promote the study of sex as a biological research variable.

### **Emory SCORE Research Priorities**

Examples of priority areas for Emory SCORE funding include, but are not limited to:

- Basic, clinical, social/behavioral, and translational science questions that explore the key influences underlying sex-based differences in the:
  - Presentation and natural history of disease
  - Tolerance of, response to, and/or outcomes attributable from therapeutics including vaccines and medications.
- Basic, clinical, social/behavioral and translational science questions that explore the intersection of research on sex differences and diabetes (EDC), HIV (CFAR), or women's health (WIHS).

### **Funding Exclusions**

Emory SCORE funding may be used to investigate sex-based differences alone, or sex and gender-based differences in conjunction with each other, but it may not be used to investigate gender-based differences alone. (See definitions of 'sex' and 'gender' terms below).

**Applicants are encouraged to consult CEC Director Dr. Marcia Holstad (see contact information below) before submitting an LOI to determine if a proposed project is in line with the funding mechanism's purpose and goals.**

### **Rationale**

The Emory (U54AG062334) SCORE is funded by the NIH to promote the NIH Policy on Sex as a Biological Variable (<https://orwh.od.nih.gov/sex-gender/nih-policy-sex-biological-variable>). That policy states:

“[Historically]... biomedical research has focused on male animals and cells. An over-reliance on male animals and cells may obscure understanding of key sex influences on health processes and outcomes.

“Accounting for sex as a biological variable begins with the development of research questions and study design. It also includes data collection and analysis of results, as well as reporting of findings. Consideration of sex may be critical to the interpretation, validation, and generalizability of research findings. Adequate consideration of both sexes in experiments and disaggregation of data by sex allows for sex-based comparisons and may inform clinical interventions. Appropriate analysis and transparent reporting of data by sex may therefore enhance the rigor and applicability of preclinical biomedical research.

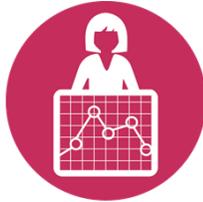
“NIH expects that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex.”

## The 4 Cs of Studying Sex to Strengthen Science



### Consider

Design studies that take sex into account, or explain why it isn't incorporated



### Collect

Tabulate sex-based data



### Characterize

Analyze sex-based data



### Communicate

Report and publish sex-based data

**NIH definition of sex vs gender:** "Sex' refers to biological differences between females and males, including chromosomes, sex organs, and endogenous hormonal profiles. 'Gender' refers to socially constructed and enacted roles and behaviors which occur in a historical and cultural context and vary across societies and over time. All individuals act in many ways that fulfill the gender expectations of their society. With continuous interaction between sex and gender, health is determined by both biology and the expression of gender." (<https://orwh.od.nih.gov/sex-gender>)

## APPLICATION INSTRUCTIONS

- Read NIH NOT-OD-15-102: <https://grants.nih.gov/grants/guide/notice-files/not-od-15-102.html> (*Consideration of Sex as a Biological Variable in NIH-funded Research*)
- Watch the videos at <https://orwh.od.nih.gov/research/sex-gender/methods-and-techniques> (*Methods and Techniques for Integrating Sex into Research*)
- Identify a Research Mentor
  - Applicants without a history of R01-equivalent funding must have a research mentor on the study team. The Emory SCORE Career Enhancement Core (CEC) faculty can assist with mentor matching as needed.
- Meet with Emory SCORE Bioinformatics Resource Core (BRC) faculty to obtain a required letter of verification.
  - Please schedule the meeting well in advance of the grant deadline; **one month in advance is optimal**.
    - We cannot guarantee onward referral for additional support (see below) if the BRC is contracted after October 4, 2019 (4 weeks before the grant deadline).
    - We cannot guarantee provision of the required letter of verification if the BRC is contacted after October 18, 2019 (2 weeks before the grant deadline).
  - Please send a draft of the application's Specific Aims and an outline of the proposed Methods section to BRC director Dr. Christina Mehta ([christina.mehta@emory.edu](mailto:christina.mehta@emory.edu)) prior to the meeting.
  - BRC staff will assess your Specific Aims and proposed study design, data collection, and analysis plans to determine if they meet the goals of the new NIH policy on sex as a biological variable. They will also provide biostatistical review of your proposal plus onward referral for additional statistical support, power analyses, etc. as needed in order to enhance the rigor and competitiveness of your application.
- Prepare the application:
  - **Preparation:** Use Emory's Cayuse 424 system to prepare the application packet
  - **FOA number:** PA-19-052. **No clinical trials allowed.**
  - **Forms:** Use an updated NIH **FORMS-E** form set and following all relevant NIH rules for submitting an NIH R03-type application, including limits on narrative length (**6 pages**). See below for required R03 grant sections and checklist.
  - **Project Timeline:** Include a project activities timeline in the narrative's Approach section
  - **Budget:** Use the R&R, NOT modular, budget

- It is not required that the PI(s) request salary, however, PI may request salary support and provide appropriate justification.
- It is strongly recommended to include budgeted effort for statistical support.
- Funds may be requested for travel and activities associated with writing an NIH research grant proposal based on project findings and/or attending meetings to establish collaborations or to present project-related data. Supported travel must be completed within the award's project period.
- Do not request:
  - Salary or travel for senior faculty
  - Equipment purchases of > \$5,000
  - Indirect Costs (although these may be awarded later, depending on the source(s) of funding used to support the award)
- **Letters:** Include, in addition to any other letters of support you collect, the following required letters:
  - **Cover Letter:** The cover letter should be signed by the **PI and the PI's department chair** and include:
    - PI name
    - Application title
    - Direct Costs requested
    - Post Award administrator name and contact information
    - A statement, if applicable, confirming that the PI's Research Mentor provided pre-review comments on a final draft of the application
  - **Emory SCORE Bioinformatics Resource Core Letter:** Letter of verification that the proposed study design and data collection and analysis plans meet the goals of the NIH policy on sex as a biological variable
  - **Research Mentor Letter** (if applicable): Applicants without prior R01-equivalent funding must include a letter from a research mentor that describes the PI's professional development goals for the project period, success indicators for each professional development goal, a communication plan describing the method and frequency with which the mentor and PI will be in formal and informal contact, and a proposed list of mentoring, education, and / or training activities.
- **Required Attachment:**
  - **"Future Plans for NIH Applications:"** Describe how findings from the proposed research will help ground a future NIH application that will advance knowledge about sex differences, either in general or – if applicable – within the context of women's health, HIV, or Diabetes. Include an outline of the remaining experiments or data collection, if any, that will need to take place before an R01 application may be submitted. **The content of this Attachment will carry considerable weight on review.**
- **Additional Requirements:**
  - See Checklist in Appendix A.
- **Submit the Application:**
  - Upload the completed application packet as a single pdf document to: <https://form.jotform.com/EmorySCORE/Application>;
  - Do **NOT** route through or deliver the application to Emory's OSP office.

## RELEASE OF FUNDS

A response to the summary statement and proof of all necessary institutional approvals (e.g. CITI, IRB/HIC, IACUC, biohazard, radiation safety) must be provided to the SCORE prior to release of funds. Additional stipulations may also be included in the Notice of Award.

## RESPONSIBILITIES OF SCORE AWARDEES:

- Complete the project within the one year funding period.

- Participate in developmental and training activities sponsored by the Career Enhancement Core (e.g., sex and gender training, research in progress seminars, mentoring activities) as required by the Office of Research in Women's Health (our funding agency).
- Present research projects at research seminars, national meetings.
- Serve as peer reviewers for future Emory SCORE applications.
- Participate in regular progress meetings with the SCORE CEC director and submit progress reports as required in the NOA.
- Acknowledge SCORE funding in all presentations and publications.

**CONTACTS:**

Scientific Questions:

Dr. Marcia Holstad  
Career Enhancement Core Director  
404-727-1307  
[nurmmcd@emory.edu](mailto:nurmmcd@emory.edu)

Application or Administrative Questions:

Shannon Walker  
Emory SCORE Program Director  
404-251-8937  
[shannon.walker@emory.edu](mailto:shannon.walker@emory.edu)

## SCORE Pilot Proposal Sections Checklist

- Cover Letter signed by PI and Department Chair
- Mentor Letter
- SCORE Bioinformatics Resource Core Letter
- Project Summary/Abstract
- Project Narrative
- Facilities and Other Resources
- Equipment (if indicated)
- R&R Budget
- Budget Justification
- Biosketches (PI, co-I, mentor)
- Specific Aims
- Research Strategy
- References
- Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals (if animal research)
- Select Agent Research (if select agents used)
- Multiple PD/PI Leadership Plan (if there are multiple PI)
- Consortium/Contractual Arrangements ( if there is additional contractual arrangements, subcontracts, etc)
- Letters of Support (as needed)
- Authentication of Key Biological and/or Chemical Resources (if using biological, chemical resources)
- Appendix—Future Plans for NIH applications