Table of Contents

How to Submit a Research Study	Page 2-6
Online Resources	Page 7-9
Research Registration Form	Page 10-19
Research Project Checklist for Statistical Analysis	Page 20-21
Research Submission Process Overview	Page 22-23
Regulatory Binder Tabs	Page 24-25
Grant Opportunities for Residents and Fellows	Page 25-24

How to Submit a Research Study

Sinai Central \rightarrow	Financial Conflict of Interest (FCOI) \rightarrow	Gives IF #
Info Ed \rightarrow	Grants and Contracts Office (GCO) \rightarrow	Gives GCO #
Ideate or Email \rightarrow	Institutional Review Board (IRB) \rightarrow	Gives HS #

NEW SUBMISSION

• Research Registration Form

Ensure you are using the most updated version

Fill out all appropriate areas

Have the department chair sign

Submit the form to Joyce Preisinger at joyce.preisinger@mssm.edu

• Sinai Central

Log into Sinai Central: https://sinaicentral.mssm.edu/

Go to 'COI' on left hand side

Click Annual Report of outside Relationships (tab must be completed yearly)

Click 'Investigator Form'

Complete New Investigator Form

Add all personnel as well as their role and ensure they complete their FCOI in a timely fashion, hit the save button, once this is done, all personnel listed will receive an email with a link to complete the form on Sinai Central.

Make sure educational requirements are up to date CITI and FCOIR

Once everyone has signed their conflict of interest, it will be submitted to the GCO department.

Contact person in GCO is Claribel Santos and Arlene Reisman. They could be reached at <u>Claribel.santos@mssm.edu</u> and <u>Arlene.Reisman@mssm.edu</u>

The new investigator form will be give you a new IF or investigator form # (make sure to use this on all submissions)

• InfoEd

This is how you communicate with grants and contracts

Log onto InfoEd: https://eresearch.mssm.edu/ (use chrome)

On left hand side click 'Create New'

Complete all steps for a NEW submission, hit finalize button, build pdf

The PI needs to sign off on this not anybody else!, PI hits submit for internal review, the PI will enter username and password and click thumbs up, (it will take a few minutes to route, be patient! the PI will

• Ideate

This is how you communicate to the Institutional Review Board

Log onto Ideate via https://www.ideate.mssm.edu (use fire fox)

Fill out all appropriate fields

The PI needs to sign off on this, not anybody else!

All communication with the IRB will be submitted through Ideate and only the PI will get email notifications informing him/her that revisions are required

RENEWALS

Research Registration Form

Ensure you are using the most updated version

Fill out all appropriate areas

Have the department chair sign

Scan and save a copy on the J drive

Submit the form to Joyce Presinger at joyce.preisinger@mssm.edu

• Sinai Central

Log into Sinai Central: https://sinaicentral.mssm.edu/

Go to 'COI' on left hand side

Click 'Investigator Form'

Complete New Investigator Form

Add all personnel as well as their role and ensure they complete their FCOI in a timely fashion

Make sure educational requirements are up to date CITI and FCOIR

Once everyone has signed their conflict of interest, it will be submitted to the GCO department.

Contact person in GCO is Claribel Santos and Arlene Reisman. They could be reached at Claribel.santos@mssm.edu and Arlene.Reisman@mssm.edu

The new investigator form will be give you a new IF or investigator form # (make sure to use this on all submissions)

• InfoEd

This is how you communicate with grants and contracts

Log onto InfoEd: <u>https://eresearch.mssm.edu/</u>

On left hand side click 'Create New'

Complete all steps for a CONTINUATION study

Progress report with updates will need to be included

Ensure research personnel are updated

The PI needs to sign off on this, not anybody else!

• Ideate (if study was submitted using this system)

This is how you communicate to the Institutional Review Board

Log onto Ideate via https://www.ideate.mssm.edu

Fill out all appropriate fields

The PI needs to sign off on this, not anybody else!

All communication with the IRB will be submitted through Ideate and only the PI will get email notifications informing him/her that revisions are required

• Email IRB (if study was submitted in email format - pre-IDEATE)

For renewals, you could find blank documents of all IRB forms at:

(http://icahn.mssm.edu/research/pphs/researcher/forms)

HRP 211 application for human research, update as necessary

HRP-212 continuation/final report, update as necessary

HRP 503 protocol, update as necessary (clean and tracked copy if applicable)

If any modifications have occurred in the last year, include an HRP 213 form

Add CV's of any new research personnel

Updated consent form (clean and tracked if applicable) or waiver of consent signed by PI

CLOSING OUT A STUDY

• InfoEd

This is how you communicate with grants and contracts Log onto InfoEd: <u>https://eresearch.mssm.edu/</u> On left hand side click 'Create New' Complete all steps for a FINAL REVIEW study Progress report with updates will need to be included The PI needs to sign off on this, not anybody else!

• Ideate if study was submitted using this system

This is how you communicate to the Institutional Review Board

Log onto Ideate via https://www.ideate.mssm.edu

Fill out all appropriate fields final closing out the study

The PI needs to sign off on this, not anybody else!

All communication with the IRB will be submitted through Ideate and only the PI will get email notifications informing him/her that revisions are required

• Email the IRB if study was submitted in email format

HRP- 212 final report form

GENERAL HELPFUL TIPS

InfoEd HELP – click top left hand icon SUPPORT located on the main page – this will take you to a helpful page with links to user guides, classes and how to open a research ticket.

IRB analyst assigned to your project will send you comments/suggestions during pre-review of project items – You must respond to the email addressing the comments within 1 week (normally 1 week turnaround)

Save approval forms and all approved items (i.e. consent forms) in the shared drive.

Online Resources

Important/Key Websites

Add to "Bookmarks" list in Firefox the following web addresses for quick and easy access to the Grants and Contracts website, the Program for the Protection of Human Subjects website, the Institutional Animal Care and Use Committee, etc.:

Grants & Contracts (GCO) website:

http://icahn.mssm.edu/research/resources/grants-and-contract-office

Sinai Central website:

http://sinaicental.mssm.edu/

InfoEd website:

Log-in http://eresearch.mssm.edu/

Program for the Protection of Human Subjects (PPHS) website:

http://icahn.mssm.edu/research/resources/program-for-the-protection-of-human-subjects

IDEATE website:

http://ideate.mssm.edu/home/

Institutional Animal Care and Use Committee (IACUC) website:

http://icahn.mssm.edu/education/postdoctoral-training/postdoc-resources/institutional-services/iacuc

Office of Research Services (ORS) website:

http://icahn.mssm.edu/research/resources/office-of-clinical-research

Research Web Portal website:

http://icahn.mssm.edu/research-portal

Supplemental Resource Information

Grants and Contracts (GCO)

https://icahn.mssm.edu/research/portal/resources/gco/application

Getting Started:

GCO Application Submission Process

GCO application Submission Process for Unfunded Human Subject Studies

Grants and Contracts Office Application Submission Checklist

ISMMS Grants and Contracts Office Application Submission Checklist Instructions

Submission, Review, and approval Process Pictorial

InfoEd:

Instructions → Instructions for Creating an InfoEd Application

Ideate:

InfoEd \rightarrow Policy: Training Request \rightarrow Support Center Home \rightarrow Ideate Human Subjects for Researchers \rightarrow Ideate Human Subjects User Guide

Program for the Protection of Human Subjects (PPHS)

http://icahn.mssm.edu/research/pphs

Guidance and Policies:

Investigator Manual

9

For Researchers:

Forms and Documents-->E-Submission Checklist Information for Sponsored Research--> ISMMS IRB Review Fees ISMMS IRB Review Deadlines & Board Meeting Dates

Office of Research Services

http:ljicahn.mssm.edu/research/portal/resources/office-research-services

Research Orientation for New Faculty and Staff --> Principal Investigator--> Principal

Investigator/Co-Investigator- Research Startup Tool

Clinical Trials

http://icahn.mssm.edu/about/finance/clinical-trials Financial Administration of Clinical Trials Services (FACTS) <u>http://www.mountsinai.org/hea_lth-professionals/pharmacy-services/investigational-drug-service</u> Investigational Drug Service (IDS) --> IDS Review Form Investigational Drug Service (IDS)--> IDS Review Form Guidance Investigational Drug Service (IDS) --> IDS Usage Fees

Compliance/Quality Improvement

http://icahn.mssm.edu/research/pphs

For Researchers:

Forms and Documents --> E-Submission Checklist --> HRP-430 Checklist: Investigator

Quality Improvement Assessment

Icahn School of Medicine at Mount Sinai Department of Obstetrics, Gynecology, and Reproductive Science

Research Registration Form

Project Approved by Division Director:

NAME: _____

SIGNATURE: _____

DATE: _____

Principal Investigator/Department:

Co-Investigator(s)/Department(s): <u>All co-investigators and their departmental affiliations</u> <u>should be listed</u>

Is this a Fellow's Project?

Yes

No No

Is this a Resident's Project?

Yes

No No

Sponsor: <u>This section must be completed</u>. *If the research project has received extramural funding or there is a request for extramural funding, please list the funding source. Otherwise, list the Sponsor as the Icahn School of Medicine at Mount Sinai (ISMMS).*

Brief Title:

GCO #: If known, please include.

I. New submission or resubmission

New submission

Continuation, changes made to original submission. Check all that apply

Change in investigators

Change in protocol

Change in funding source

Other

Continuation, no changes made

All projects, including continuation projects, must have a complete PPHS/IRB packet submitted

II. Brief Description of Project [Maximum 300 words;. For all prospective human subject research - please include in the study description all proposed study sites (FPA, D&TC practice, labor floor, other inpatient units, off-campus practices, etc) as well as targeted enrollments (if known) for each site. Also, please include number of proposed study visits over what period of time. For research involving human tissue/specimens, please include type of tissue/specimens, number of tissue/specimens to be evaluated and which laboratory will be responsible for proposed analyses. If archived specimens will be studied, please list where material is currently archived.] Submit IRB paperwork in addition to the brief description.

12

III. Type of Research: (check all that apply)

Human Subject Research

Research on Human Data/Specimens Collected During Previous Research/Clinical Care

Uertebrate Animal Research

Basic Science Research

Resident/Fellow Research Project

Pilot Data for Grant Submission

Other - please explain

IV. Location of Study (Check all that apply and provide address(s) where enrollment will take place)

MSH (Mount Sinai Hospital)

MSW (Mount Sinai West)	

BI (Beth Israel)	

Other

V. Is this a retrospective chart review?

Yes

🗌 No

VI. Is this a Global Health study?

Yes

🗌 No

If yes, respond to the following:

Is this an existing Sinai site overseas?

	No
Do you have plans for a foreign IRB approval?	Yes No
you have a partnership with a University at the	site? 🗌 Yes 🗌 No
Are there any potential conflicts of interest?	Yes No

No

VII. Is this a prospective research study?

Yes

No No

If yes, respond to the following:

Include a description of study methods including selection criteria,

Interventions, procedures to be performed, and timeline.

VIII. Enrollment information:				
Will subjects be enrolled in E-Level Clinic? Yes				
□ No				
Will subjects be enrolled on Labor & Delivery? 🛛 🗌 Yes				
□ No				
Other enrollment locations:				
Total number to be enrolled				
Who will recruit subjects?				
Are Residents involved with recruiting?				
Total number enrolled to date				
IX. Will this study include the collection of maternal/fetal specimens (swabs, blood, urine, amniotic fluid, umbilical cord blood placenta, etc.) on Labor and Delivery?				
Yes				
If cord blood is to be collected, how many samples are planned?				
If cord blood is to be collected, are Residents doing the collection?				

If tissue samples are to be collected, how many are planned?

If tissue samples are to be collected, are Residents doing the collection?

If you are collecting blood samples, tissue samples, or any other specimens who is

paying for the tests?	
paying for the tootor	

X. Will this study include the collection of newborn specimens (urine, cheek swabs, merconium, etc.) after delivery?

|--|

No No

If specimens are to be collected, what type? _____

How many samples are planned? _____

If you are collecting blood samples, tissue samples, or any other specimens who is

paying for the tests? _____

- XI. Is this an industry sponsored trial?
- Yes
- 🗌 No

If yes, answer the following:

Number of enrollment sites _____

Number to be enrolled across all sites
Estimated date enrollment to be completed across all sites
Total number enrolled to date across all sites
Duration of Study
Number plan to enroll at Mount Sinai Hospital
Number plan to enroll at Mount Sinai West
Number plan to enroll at Mount Sinai Beth Israel
Number enrolled at Mount Sinai to date

XII. Status of Current Proposal

GCO/IRB submission in progress, no extramural grant being prepared

GCO/IRB submission in progress, extramural grant also being prepared for submission

If an NIH application (or other extramural grant) is being prepared, the extramural budget must be submitted for review at least 4 weeks before project is due at lcahn School of Medicine at Mount Sinai GCO

XIII. Is there/will there be a FDA IND or IDE associated with this project?

Yes

No No

XVI. Do you or a related party have any financial interests related to the conduct of this research?

Yes

No No

XV. Are there any individual-investigator and/or institutional financial interests related to the conduct of this research?

If this is a project being conducted by a PI in another department and you are asked as an obs-gyn co-investigator to recruit obs-gyn subjects, don't answer "no" without confirming in writing with the PI

Yes

🗌 No

XIVI. Is this project/will this project be registered in clinicaltrials.gov? All intervention studies must be registered at clinicaltrials.gov .

Yes

🗌 No

XVII. Do you need help with any of the following?

- ☐ Yes ☐ No Preparation of an extramural grant application
- ☐ Yes ☐ No Budget preparation for an extramural grant application
- □ Yes □ No Other, please specify

XVIII. Will bio-statistical support be required to assist with either study design or data analyses?

Yes

If yes, who will you utilize for this service? ______

No

XIX. Other Financial Support

Other than statistical support, will financial support be requested from the department for this project?

Yes [If yes, please provide itemized budget. Examples of items in this category include but are not limited to items such as (, (1) \$ for lab reagents, (2) \$ for shipping/handling specimens, and (3) \$ for travel expenses.]

🗌 No

XX. For Fellow Projects

Proposed budget and budget justification are attached

No financial support requested

XXI. For Resident Projects

Proposed budget and budget justification are attached

□ No financial support requested

XXII. Please list all abstracts, presentations, and publications related to this research project

Failure to provide this information could jeopardize ongoing departmental approval. Scholarly activity related to research will be used as a metric to judge project merit as well as ongoing departmental approval and financial support.

Approved:			
	Elizabeth Howell, M.D.	Denise Berdebes	Michael Brodman, M.D.
	Date:	Date:	Date:

For projects with external or departmental funding:

Approved:	

Andres Licari

Date: _____

DEPT OB-GYN RESEARCH PROJECT CHECKLIST FOR STATISTICAL ANALYSIS

(Key overall thinking: What is your hypothesis or research question and how are you going to prove it?)

1) Date:

2) Researcher Name:

3) Mentor Name (if applicable):

4) Topic:

5) Description (including number of groups and what you are measuring):

Examples: (1) Retrospective chart review from November 2014 to 2015 of patients induced with cytotec vs cervedil to look at various outcomes such as... (2) Prospective study...... (3) Randomized controlled trial involving......

6) Hypothesis (stating a succinct quantitative hypothesis):

Primary:

Secondary:

7) Number of patients planned:

8) Statistics planned (if known):

9) IRB proposal type planned:

10) IRB status submitted?

- 11) When do you expect to have all your data?
- 12) What's your rationale for that timeframe?
- 13) Number of patients' data collected to date:
- 14) Your deadline? Presentation date, abstract deadline, manuscript submission date, grant deadline etc.

Department of OB/GYN Research Submission Process Overview

Departmental Requirement:

- Departmental Research Registration Form
 - A completed Research Registration Form (RRF) is required for every New and Continuation submission.
 - The completed RRF should be submitted to the Research Office and reviewed before the InfoEd submission is Finalized.

Institutional Requirements:

- A Grants and Contracts section for each submission that is prepared in InfoEd
 - An InfoEd submission is required for every New and Continuation submission.
 - A FCOI section is required for every New and Continuation submission and it is set-up on Sinai Central.

• A regulatory section for each Human Subjects study that will be reviewed by the Internal Review Board (IRB)

- New studies and Continuations that were previously set-up in Ideate are submitted in Ideate
- Continuation studies not previously set-up in Ideate are sent by email to <u>IRB@mssm.edu</u>

» PPHS (Program for the Protection of Human Subjects) works from a Friday submission deadline. This means that all submissions received Monday thru Friday of a given week will have met the Friday deadline of that particular week.

» Pre-review is a 5-day process beginning the Monday after the Friday deadline.

» If questions arise regarding this process, call the PPHS Office at 212-824-8200.

• A regulator section for each animal study that will be reviewed by Institutional Animal Care and Use Committee (IACUC)

- New and Continuation animal study submissions are prepared in Ideate.

Annual Renewals and Closure

• Every research study must be renewed on an annual basis. The same basic submission process is required for study renewals. This includes: a completed Research Registration Form; setting- up the FCOI requirement on Sinai Central; preparing a Continuation submission in InfoEd; and preparing the IRB Continuation submission in IDEATE or on forms posted to the PPHS website and sent by email to IRB@mssm.edu as appropriate.

• For studies that are completed, close-out is required. A Final Report has to be prepared in InfoEd for the GCO and IRB close-out requirements must also be satisfied.

Regulatory Binder Tabs for Clinical Research Studies

The original version of this document was prepared by the

Department of Emergency Medicine at the

Icahn School of Medicine at Mount Sinai

*Denotes documentation that is required only for certain types of studies (for e.g. FDA-governed studies)

Table or Regulatory Binder Tabs

Tab 1: Study Protocol and Supporting Documents

Tab 2: Case Report Forms/Research Data Capture Forms

Tab 3: Informed Consent and Supporting Documents

Tab 4: Correspondence

Tab 5: IRB Information/Protocol Review Correspondence

Tab 6: Study Participants

Tab 7: Adverse Events & Unanticipated Problems

Tab 8: Study Personnel

Tab 9: Laboratory*

Tab 10: Drug Device Accountability*

Tab 11: Pharmaceutical Submissions: FDA 1571 and 1572 Forms*

Potential Grant Opportunities for Residents & Fellows in OBGYN

General OBGYN Grants

March of Dimes

General Research Grants

The general March of Dimes research portfolio funds many different areas of research on topics related to our mission to prevent birth defects, premature birth and infant mortality. These investigations include — but are not limited to — basic biological processes of development, genetics, clinical studies, studies of reproductive health, environmental toxicology, and studies in social and behavioral sciences that focus on factors contributing to adverse pregnancy outcomes, and on consequences of birth defects and prematurity.

Basil O'Connor Started Scholar Research Awards

The Basil O'Connor Starter Scholar Research Awards (BOC) are funded in a program specifically designed to support scientists just embarking on their independent research careers. Created in 1973 and named for the first March of Dimes chairman and president, this program provides funding to young investigators to start their own research projects on topics related to the March of Dimes mission.

ACOG

Warren H. Pearse Women's Health Policy Award

Purpose: To explore an aspect of health care policy.

Description/Criteria: This research award will provide \$10,000 to support research which explores an aspect of health care policy that assists, defines, or restricts the ability of a physician to deliver health care to women in the general population, or in a specific area. Application deadline: December 15.

The American Association of Obstetricians and Gynecologists Foundation

The total annual funding for each scholar is \$120,000. Sufficient funds to support travel to the annual fellows' retreat must be set aside. The balance of funds may be used for salary, technical support, and

supplies. The award is made under the direction of the AAOGF Scholar Committee. The award cosponsored by the SMFM is also under the direction of the Foundation for SMFM Board.

The award is intended to fund three consecutive years of research training. The initial award is for one year and is renewable annually for two additional consecutive years of research training, based on satisfactory progress of the scholar in meeting programmatic requirements and on the availability of funds. Only one year of the three funded years may be part of a subspecialty fellowship-training program. Indirect costs are not provided.

Recipients must agree to provide career development reports and follow-up after the conclusion of the scholarship on an annual basis and as requested. It is expected that the scholarship training will be conducted at the same institution for the entire period of funding. Transfer of institutions or change of mentors during the period of funding must receive the prior approval of AAOGF and, in the case of a jointly sponsored award, the Foundation for SMFM. Unexpended funds must be returned to the sponsoring organization unless approval is granted for an extension of the training period.

Candidates must have been awarded an M.D. degree and must be eligible for the certification process of ABOG at the time of the award. This award is not intended to fund clinical training leading to specialty or subspecialty certification. However, applicants who are in their second year of an ABOG-approved fellowship can apply for funding through this mechanism to start in the 3rd year of fellowship, as long as that year is devoted to research for at least 75% of the year

Bridge Funding Award

Investigators who are at the rank of assistant professor of Obstetrics and Gynecology or above, who have successfully completed a mentored research award or have previously had an R01 grant and who have applied for funding but who have not been successful in either obtaining or maintaining independent research funding may submit an application for this award. Investigators who currently have an R award for the period of funding are not eligible. Submission of critiques of recent funding applications for the project must be provided with the application. Assurance of adequate protected research time for the research project and a delineation of financial support provided by the applicant's Department or institution will be important factors in considering applications.

Maternal Fetal Medicine Grants

SMFM Available Grants

Foundation for SMFM and the American Association of Obstetricians and Gynecologists Foundation (AAOGF).

The Foundation for SMFM's premier scholarship training grant, funded jointly with <u>AAOGF</u>, is designed for future academic physician leaders who seek additional science training that will pave the way to a productive career as a physician-scientist in the area of pregnancy. The research training may be either laboratory-based or clinical, and focused on basic or translational research, disease pathobiology, diagnostics, therapeutics or prevention. The total annual funding for each scholar is \$120,000 and the deadline for receiving applications is July 1.

Foundation for SMFM's Thomas Garite Mini-Sabbatical Grant

The Foundation for SMFM is pleased to award up to two mini-sabbatical grants each year, one for regular members of the SMFM and one for Maternal-Fetal Medicine (MFM) Fellows who are in an ABOG-approved or DO-approved MFM program. The Garite Mini-Sabbatical Grants allow recipients to gain or expand skills in clinical practice or research under the guidance of experts in the field of maternal-fetal medicine. Up to \$10,000 in funding is available for individuals who apply for the grants and the deadline for receiving applications is is July 1.

Foundation for SMFM's Quilligan Scholars Program

The Foundation for SMFM recognizes the importance of identifying promising residents who will be leaders in maternal-fetal medicine. The Quilligan Scholars Program identifies future leaders early in their careers to offer mentoring and educational opportunities for two years. Candidates must be PGY 3 residents (or PGY4 in Canada) starting July 1 of the application year in an accredited residency program in obstetrics and gynecology in the United States or Canada. Only one candidate may be proposed from each residency program in the United States and Canada. The application deadline is October 1.

Foundation for SMFM's Queenan Fellowships for Global Health

The Foundation for SMFM launched the Queenan Fellowships for Global Health in 2015. Dr. Queenan has had an illustrious career in the field of obstetrics with his pioneering work in Rhesus disease management and prevention, academic research in ultrasound and fetal physiology, and mentorship of obstetrician gynecologists, as well as maternal fetal medicine subspecialists. The fellowships named in his honor and fostered with his assistance seek to provide vital care and key improvements in reproductive health within developing nations. The application deadline is Juy 1.

Gynecology-Oncology Grants

Mary Kay Foundation

The Mary Kay Foundation is a non-profit public foundation, which focuses on funding research for innovative grants for translational research in ovarian, uterine, breast or cervical cancer. Translational research is broadly defined as research that will provide a scientific link between laboratory research and the clinic. Ultimately, such research would lead to improvement in diagnosis, prognosis, prevention,

or treatment of the cancer. One application may be submitted from the Icahn School of Medicine at Mount Sinai.

"Grants are awarded each year to researchers at medical schools recommended by The Mary Kay Foundation Research Review Committee, which is composed of prominent doctors who volunteer their time to help the Foundation select the best recipients across the United States. After reviewing these recommendations, the Board of Directors at the Foundation selects the grant recipients."

This year's application is due on February 2, 2018, 5 PM (CST). <u>http://www.mkacf.org/Pages/CancerGrantProgram.aspx</u> Found for Women's Cancer Ovarian Cancer

For Fellows-in-Training:

Ovarinnovate: Ovarcome Research Excellence Award Two \$10.000 one-year awards

Please Note: Candidates are required to be a Fellow-in-Training member of the SGO to be eligible for this award. Applicants are encouraged to develop research proposals related to ovarian cancer that incorporate cooperation with colleagues from other institutions.

The Foundation gratefully acknowledges Ovarcome for the support of this grant. This is the second year the research grant is being supported by Ovarcome.

ENDOMETRIAL CANCER

For Fellows-in-Training:

Ovarian and Gynecologic Cancer Coalition/Rhonda's Club Uterine Research Excellence Award \$12,500 one-year award

Please Note: Candidates are required to be a Fellow-in-Training member of the SGO to be eligible for this award. *The Foundation gratefully acknowledges Rhonda's Club for support of this grant. This is the first year this research grant being offered.*

CERVICAL CANCER

ME STRONG Young Investigator's Award \$25,000 one-year award

Related to cervical cancer biology aimed at novel therapies with an emphasis on immune component. *The Foundation gratefully acknowledges MESTRONG for support of this grant. This is the third research grant being offered.*

OTHER GRANTS

Pacira Pharmaceuticals Inc. Clinical Research Grant \$25,000 one-year award

Related to clinical research on the study of opioid minimization pain management techniques to better understand impact on post-surgical recovery and quality of life among gynecologic oncology patients.

The Foundation gratefully acknowledges Pacira Pharmaceuticals for the support of this grant. This is the first year the research grant is being supported by Pacira.

Bruce Patsner Research Grant for Innovative Research and Technology

\$10,000 one-year award

Related to clinical research and technology concepts that seek to better understand and/or illuminate disease-related biology.

The Foundation gratefully acknowledges Bruce Patsner, MD, for the support of this grant. This is the third year the research grant is being offered.

2017-2018 FOUNDATION FOR WOMEN'S CANCER RESEARCH PRIZES

Foundation for Women's Cancer Prize For Outstanding Gynecologic Cancer Researcher \$10,000 one-year award

This is the first time this prize is being supported by the Foundation for Women's Cancer. The prize will be announced at the 2018 SGO Annual Meeting on Women's Cancer in New Orleans, LA.

Foundation for Women's Cancer/Norma Livingston Ovarian Cancer Foundation Excellence in Ovarian Cancer Research Prize in Honor of Ronald D. Alvarez, MD

\$5,000 one-year award

The Foundation gratefully acknowledges the Norma Livingston Ovarian Cancer Foundation for their generous support of the prize. This is the seventh prize supported by the Norma Livingston Ovarian Cancer Foundation.

Perlman Family CCARE Lynch Syndrome Research Prize \$1,500 one-year award

The Foundation gratefully acknowledges the Perlman Family for its generous support of this prize. This is the sixth prize being supported by the Perlman Family.

Nina Donnelley and The Dickens Fund of the Donnelley Foundation Young Investigator Award in honor of Laurel W. Rice, MD

\$1,000 one-year award

The Foundation gratefully acknowledges The Dickens Fund of the Donnelley Foundation for its generous support of this prize. This is the third prize being supported by the Dickens Fund of the Donnelley Foundation.

Reproductive Endocrinology & Infertility Grants

NIH Funding

ASRM & SREI Research Grants:

The primary purpose of the ASRM and SREI Research Grant Programs is to provide funds for new investigators to establish independent research programs. New investigators are those who have completed their training within the past three years and have independent faculty appointments at the commencement of the research. In special cases applications for bridge funding (i.e., between grant funding periods) for projects that are of benefit to other members of the Society, or for funding of new, highly innovative research projects by established investigators will be considered. Both the ASRM Research Grants, which are funded by the ASRM, and the SREI Research Grant, which is funded by SREI, are reviewed by the ASRM Research Committee and awarded by the Board of Directors. Grants in amounts of \$10,000 to \$50,000 will be considered for funding by the ASRM Board of Directors on an annual basis. A total of \$200,000 is available for 2017. The SREI Board of Directors will fund one grant of up to \$40,000. Funds are available for project expenses, technical assistance, patient expenses, research supplies and durable laboratory equipment. Up to ten percent (10%) of funds may be used for indirect costs or institutional overhead in circumstances deemed to be rare and extraordinary that are explained to the Research Committee. Research grant funds may be expended over a 2-year time interval. If residual funds remain after 2 years, the principal investigator can apply for a no-cost extension. An individual is eligible to receive only one grant. Grants may be renewed under extraordinary circumstances, such as may be necessary to sustain an ongoing activity of importance to the Society. An individual should indicate which grant(s) he/she is applying for though he/she is eligible to receive only one grant.

Recipients of an ASRM or SREI Research Grant may also have other grants contributing to the funding of their project; however, the additional funding amounts must be noted on the grant application. A progress report and a financial report on the work sponsored by the grant are required annually and within 60 days of the completion date of funding for the project. The final report should include a summary of the project and an accounting of funds spent, be signed by the recipient of the award and the institutional grants officer, and submitted to the ASRM office. All unused funds will be returned to the ASRM at the completion of the project unless additional time has been

approved by no-cost as described above, or if the project has not been initiated at the end of the first year. An abstract should be submitted for consideration at an ASRM Scientific Congress either prior to or after completion of the project.

To be eligible for an ASRM Research Grant, the Candidate/Principal Investigator must:

- Have earned an M.D. and/or Ph.D. and/or D.O. and/or D.V.M. degree or their equivalents.
- Be an independent investigator who has a full-time faculty/research staff appointment; note that clinical and research students, residents, fellows and postdoctoral trainees are not eligible.
- Have completed clinical, scientific and professional training within 3 years prior to the start of the grant.
- Have been an active or associate member of ASRM for a year.

To be eligible for the SREI Research Grant, the Candidate/Principal Investigator must:

- Have earned an M.D., D.O. degree or equivalent.
- Be an independent investigator who has completed his/her training and has a full-time faculty/research staff appointment
- Have been an active or associate member of SREI for a year.

Applications should be written in 11-point font with 0.5 inch margins. Pages should be numbered starting with the first page of the proposal. The application consists of the following items in this order:

- 1. Cover sheet including title of research proposal, applicant's name and degree(s), address, telephone, fax, and email; indicate which one of the three priorities is being addressed by the application (new investigators, bridge funding, initiation of innovative research project)
- Research Proposal the description of the research project should be presented using 6 (6) pages or less, including bibliography. The research proposal must include: Specific Aims, Background and Significance, Experimental Design and Methods, Expected Results, Schedule of Performance, and Bibliography
- 3. A one-page budget should be prepared and signed by the applicant and by the Department Chair and the appropriate institutional official. Recipients may have other grants that contribute to funding of their project, and notation of this funding must be included in the application budget.
- 4. Applicable institutional certifications of regulatory compliance, e.g., human subjects, animals, biohazards, radioactive materials, recombinant DNA, etc.
- 5. Statement of Career Goals briefly list and/or describe career goals if the applicant is a new investigator.
- 6. Curriculum Vitae this should include basic personal data, educational background, past and present positions, honors, achievements, and publications; limited to three pages; an NIH biosketch is acceptable.
- 7. Letter of Recommendation from Division Director or Department Chair signed letter on company/organizational letterhead.
- 8. Letter of Intent from Chair of the Department this letter should state that the award money will only be allocated for the items noted in the budget and should affirm that the appropriate time will be allotted for completion of the research by the faculty member and that appropriate facilities will be available for the grant recipient to carry out the project.

Selection is based primarily on the scientific merit of the proposed study, the qualifications of the applicant, and the significance of the research. The Research Committee may utilize the review services of non-Committee experts if necessary to ensure a competent and balanced review. Members of this Committee will recuse themselves from the selection process for a given year if any proposals for that year involve members of their institutions. Projects proposed by new investigators, studies of high scientific merit requiring bridge funding, and highly innovative studies will have priority. Evaluation of the proposals by the ASRM/SREI Research Committee will include the availability of resources to conduct the proposed study and the identification of a principal investigator who can offer an appropriate environment for the pursuit of the proposals for that year involve their institutions. In addition the ASRM Scientific Congress. Members of the Executive Committee are not eligible to submit applications and they will recuse themselves from this review if any of the proposals for that year involve their institutions. In addition the ASRM research Committee will review the progress reports and financial reports on the work sponsored by the ASRM research grants annually and upon completion of funding for the project. Members of the Research Committee will recuse themselves from the review of reports for any project that involves their institutions of employment.

Viviere sponsored grants

(http://www.viverehealth.com/physicians/scientific-advisory-board/sab-researchgrants/)

The Scientific Advisory Board of Vivere, is pleased to announce the availability of 3 grants of \$10,000 each for reproductive endocrinology and infertility fellows whose research goals reflect the mission and goals of the board.

As an organization of clinical advisors dedicated to shaping the future of women's health and reproductive medicine, we know how important continuing education is to our medical professionals. Our five-member board of fertility and reproductive health experts is able to provide these types of educational opportunities through support from our sponsor, Vivere a fertility management and equity partner.

The Scientific Advisory Board provides financial support, oversees medical research and sponsors scientific education to advance fertility care and meet the long-term reproductive health needs of physicians and patients nationwide.

The mission of the board is to bring young people to thought leaders by support of residents/fellows in scientific research and knowledge.

The goals of the board include:

- support residents/fellow attendance at national meetings/programs;
- support education programs;
- support scientific research;
- promote business aspects of SREI

New England Fertility Society – Ferring sponsored grant

(http://www.nefs.org/reigrant.htm):

Two Research Awards of \$10,000 each for basic science or clinical research are available.

ELIGIBILITY:

- a. Applicant must be a REI fellow in first or second year of fellowship of an accredited program
- b. The applicant must be an NEFS member (you may apply prior to submission at \$160 standard rate)
- c. Only one proposal can be submitted per applicant in any given application year
- d. Previous winners may not apply

e. Winners must be able to complete research in 2017 calendar year and present at the 2018 annual meeting held in Spring 2018

APPLICATION PROCESS:

Applicants will submit the following:

- Curriculum Vitae
- · Scientific abstract (500 words maximum)

• Research Plan including specific aims, background and significance and project design with projected timeline for completion of specific phases of the project (3 page maximum). A budget clearly stating what aspects of the project will be supported by the award must be submitted. Indirect costs are allowed, but not for institutional overhead. (3 page maximum)

• Letter of support from a Mentor (who will be present and introduce applicant - if selected - at 2018 meeting)

SUBMISSION DEADLINE:

Award applications should be submitted by the September **30, 2016.** Winners of the awards will be announced in December via email and online at our website. Award distribution is planned for January 15 of the following year. **(January 15, 2017)**

OBLIGATIONS OF AWARD RECIPIENT:

Upon acceptance of the research award, recipient will be asked to sign a research agreement which will clearly state the recipient's obligation to provide NEFS and Ferring with an end of the award year progress report. If a selected award recipient fails to sign a research agreement, the award will be granted to the next highest scoring proposal.

• A progress report will be sent to the NEFS research committee and Ferring at the end of the first award year. The progress report will include a summary of research completed including:

a) results;

b) description of relevance of results with appropriate statistical analysis;

c) placement of these results in the context of the project's objectives and hypothesis, and

d) clearly stated conclusions.

Results will be presented at 2018 NEFS annual meeting following the end of the funding year –
 2017(may be presented elsewhere first and presented at NEFS in the previously-submitted category)

 \cdot The annual NEFS meeting registration fee will be waived for the award recipient presenting research results.