

UNIVERSITY OF MIAMI MILLER SCHOOL OF MEDICINE
DEPARTMENT OF OBSTETRICS, GYNECOLOGY & REPRODUCTIVE SCIENCES
STANDARD OPERATING PROCEDURE

Document Number ObGynReproSci-200.01
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Effective Date: October 15, 2020
Authors: JoNell Potter, PhD

Title: Research Proposal: Departmental Review

1. PURPOSE

The purpose of this document is to provide guidelines for departmental review of all research proposals developed by faculty, fellows, and residents in the Department.

2. PROCEDURES

2.1 Overview of Review Process

2.1.1 All department research proposals must be reviewed by the Department Protocol Review Committee (DPRC) prior to Institutional Review Board (IRB) submission and department approval.

2.2 Protocol Development

2.2.1 The Principal Investigator and study team members develop specific aims (see 4.3 and 5 for guidance) to identify the research question, conduct a literature review and identify study purpose (aims and objectives), and compile documents utilizing University guidelines.
<https://hsro.uresearch.miami.edu/researchers/forms-andtemplates/templates/index.html>

2.2.2 The Principal Investigator and study team members prepare the following documents and send them to Ob.Gyn.Repro.Sci-Research@med.miami.edu:

2.2.2.1 Full protocol, template accessible from link in 2.2.1 or [click here](#).

2.2.2.2 Consent form, if applicable, template from link in 2.2.1 or [click here](#).

2.3 Review Path Determination

2.3.1 Upon submission, the DPRC Chair will assign a meeting date and primary reviewer from the DPRC Committee.

2.3.2 The protocol, and consent form, if applicable, will be distributed to the Committee members for review prior to the meeting.

2.3.3 At the meeting, the primary reviewer will discuss the purpose of the study and study design.

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- 2.3.4** DPRC Committee members will provide feedback on feasibility for completion, adequacy of study design and methods, and concerns, if applicable.
- 2.3.5** The DPRC Chair or designee may invite the Principal Investigator to provide clarification or additional information, as needed.

2.4 Approval Outcomes

- 2.4.1** Quorum consists of 50% DPRC committee members and outcomes are determined by majority vote.
- 2.4.2** DPRC Committee outcomes:
 - 2.4.2.1** Approved: Protocol is fully approved. Protocol will be approved for submission to Institutional Review Board.
 - 2.4.2.2** Modifications Required to Secure Approved: Protocol requires minor clarifications or response to concerns and does not need to be re-reviewed by the full committee. The Chair or designee may approve the response or may request that the committee reviews the response at the next meeting.
 - 2.4.2.3** Return to the PI with Comments: Protocol requires significant modifications and/or the primary reviewer has significant concerns. The Principal Investigator makes required modifications and submits the revisions and/or response to be reviewed at next committee meeting.
 - 2.4.2.4** Disapproved: Protocol is disapproved. Will not be reconsidered.
- 2.4.3** The Department Protocol Review Committee oversees the prioritization of competing proposals for use of department resources, such as personnel and resources.

2.5 Concept Review

- 2.5.1** Prior to submitting the protocol review application, an investigator may submit the protocol concept ([click here for guidance](#)) to the Departmental Protocol Review Committee, which will be assigned a meeting date. The purpose of this review is to provide the investigator and study team members with feedback and guidance about the study design and

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feasibility early in the protocol development phase. The DPRC Chair may invite the Principal Investigator, as needed.

- 2.5.2** Please complete Concept Project Submission Form (Appendix A) and submit to Ob.Gyn.Repro.Sci-Research@med.miami.edu for review by the Departmental Protocol Review Committee.

3. DOCUMENTS

3.1 DPRC Members and Meeting Dates

- 3.1.1** Members are appointed for two-year terms by DPRC Chair via a nomination process.

3.2 DPRC Determination Form

- 3.2.1** Committee determination form completed by committee designee, sent to Principal Investigator and retained by Department.

3.3 DPRC Specific Aims Guidance

- 3.3.1** Specific aims page is completed by Principal Investigator, as needed, and sent to Ob.Gyn.Repro.Sci-Research@med.miami.edu for support in developing protocol.

4. REFERENCES

S., Michelle (2015). *The Anatomy of a Specific Aims Page*. Retrieved from: <https://www.biosciencewriters.com/NIH-Grant-Applications-The-Anatomy-of-a-Specific-Aims-Page.aspx>

National Institute for Health. *Policy for Scientific Review of Clinical Protocols Utilizing the NIH Intramural Program*. Retrieved from: https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/review_science/policyscientific_review_clinical_protocols.pdf

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5. REVISION HISTORY

Effective Date	Revision Date	Author	Description of Changes

6. SIGNATURES

Prepared JoNell Potter, PhD Date: 10/12/20
by:

Vice Chair, Division of Reproductive Sciences



Signature

Approved Michael Paidas, MD Date: 10/12/2020
by:

Chairman, Department of Obstetrics, Gynecology &
Reproductive Sciences



Signature

APPENDIX A

**Department Protocol Review Committee
CONCEPT PROJECT SUBMISSION FORM**

APPLICANT INFORMATION

Proposal submitter:	
Supervising faculty member:	
Additional authors:	
Project title:	
Date of submission:	
Number of patients:	

PROJECT DESCRIPTION

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RESOURCES REQUIRED

Is statistical support needed?	Yes _____	No _____
If yes who will perform (CTSI, CFAR, BBSR, Dept.)		
Has a request been submitted?	Yes _____	No _____
Is SCCC PRMC submission required?	Yes _____	No _____
Has the project been submitted?	Yes _____	No _____
Will any study-related activities be performed or possibly performed at a Jackson Health Systems (JHS) site?	Yes _____	No _____



**OBSTETRICS, GYNECOLOGY
AND REPRODUCTIVE SCIENCES**

Department Protocol Review Committee CONCEPT PROJECT SUBMISSION FORM	
Database to be used:	
Is research support required from department?	Yes _____ No _____
FUNDING	
Funding Source	
Estimated Budget	
Study Personnel Required (Specify)	Yes _____ No _____
BIOSPECIMEN	
Human Biospecimen Collection	Yes _____ No _____
Type of Biospecimen Collection	Saliva _____ Blood _____ Tissue _____ Other _____
If Tissue What Type	FFPE _____ Snap Frozen _____ Live/Fresh _____
Pathology Collaborator	
DETERMINATION	
Study Approved:	Yes _____ Changes Required _____ Rejected _____
Comments:	
Quorum:	