

**PERINATAL AND GYNECOLOGIC RESEARCH COMMITTEE APPLICATION  
UNIVERSITY OF ROCHESTER MEDICAL CENTER**

***Title of Proposal:***

***Principal:***

***Investigator:***

***PI's Phone(s):***

***Address:***

***Co-Investigator(s):***

***Date:***

Directions: Please complete this form and include the original and nine copies of your proposal submitted to the Perinatal and Gynecologic Research Committee or email the proposal and completed application to: [Jackie White@urmc.rochester.edu](mailto:Jackie.White@urmc.rochester.edu). If you send the proposal via email, please mail one hard copy to Jackie White, Dept. Ob/Gyn, Box 668. Check (✓) below the materials that have been included with your application. See the corresponding number(s) under "Application Process" for further information. The following materials are included in this application:

- 1. Application: Letter and/or proposal describing the research.
- 2. Faculty members are responsible for research proposals submitted to the Committee. (Graduate students working on faculty research projects need to have the research presented to this Committee by their faculty advisor.)
- 3. Population sought: Information in detail about subjects, specimens or data which investigator(s) requests to access; availability of population in Strong Memorial Hospital.
- 4. Time: Length of time anticipated for data collection.
- 5. Staff: Will there be any involvement of staff? Has this been arranged? Provide necessary information.
- 6. HSRB: Plans for, date of or approval granted by The University of Rochester Medical Center Human Subjects Review Board.
- 7. Consent: Include copies of letters and/or consent forms for patients/parents.
- 8. Written proof that Strong Memorial Hospital's physicians were asked for consent to contact their private patients (If applicable)
- 9. Neonatology approval for access to Strong Memorial Hospital's newborns. (If applicable)
- 10. Supporting letters, if pertinent.

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For Committee Use Only:

Application received on: \_\_\_\_\_ Application complete? Yes No 1 2 3 4 5 6 7 8 9 10 Other

Application reviewed on: \_\_\_\_\_ Action taken: \_\_\_\_\_

Date Investigator was notified: \_\_\_\_\_

Data Collection began on \_\_\_\_\_ ended on \_\_\_\_\_

Comments: \_\_\_\_\_

# ***PERINATAL AND GYNECOLOGIC RESEARCH COMMITTEE APPLICATION***

## ***Application Process***

Application to the Perinatal and Gynecologic Research Committee for access to Strong Memorial Hospital perinatal/neonatal patients, specimens or data should be made as cited below.

Send the original and nine copies of the application to Dr. Richard K. Miller, Chair of the Perinatal and Gynecologic Research Committee, Department of Obstetrics and Gynecology, Box 668, x52520. For electronic submissions, please use email address: [richardk\\_miller@urmc.rochester.edu](mailto:richardk_miller@urmc.rochester.edu)

Applications should be submitted no later than 4 PM on the second Wednesday of each Month. Meetings are schedule for the third Wednesday of every month.

The Perinatal and Gynecologic Research Committee members are all University faculty members experienced in research. They are available to consult or speak with you about your research and access to subjects at Strong Memorial Hospital. Please contact any Committee Member if you think they could be helpful to you prior to submission.

***APPLICATIONS*** (should include the following information):

### ***Description of Proposed Research***

The application should succinctly describe the research , a cover letter accompanied with the proposal as submitted to the Human Subjects Review Board (HSRB), funding agencies and/or your school/department may be submitted.

The research aims or purpose, importance or significance in the field and the rational should be clearly stated. The hypothesis tested, research methods, procedures for data collection and data analyses should be concisely described. Key references should be cited. Relevant appendices should be included if helpful and appropriate to review to the review of the study.

### ***Faculty Research***

The responsibility for the research proposal submitted to the Committee resides with the faculty member. Graduate students research may on be conducted within the research program of a faculty member. Only faculty should make all communications with the Perinatal and Gynecologic Research Committee.

### ***Subjects/Patients***

Woman being provided care in Obs/Gyn who are non-pregnant, pregnant to post-partum, women having aborted, neonates, their families, specimens or existing data sought should be clearly described. Availability of the population should be noted whenever possible. Specifically, the following information about subjects will be helpful in the review process:

- The number of subjects
- Ages of subjects
- The gravity and parity of desired pregnant subjects. Are only primiparas sought? Multiparas? Both?
- Any characteristics, which define or limit the subjects sought.
- Amounts or numbers of specimens or other data, as appropriate to specific study.
- Please include plans for obtaining, contacting, approaching subjects/patients.

### ***Length of Time***

Anticipated for the data collection should be estimated as closely as possible.

The Committee grants permission for up to one year for access to specific populations; longer investigations require annual review of the status of data collection for continued approval.

Upon approval researchers will be asked to notify the Committee as soon as their data collection has been completed. This courtesy facilitates the conduct of other investigations.

Specific starting and ending dates may be requested when essential to the design or conduct of the study. These are honored whenever possible.

### ***Involvement of Staff***

Investigators should also describe any involvement required by Strong Memorial Hospital staff members (house officers, nurses, faculty, support staff, students etc). If required, arrangements for this involvement should be made and this information provided to the committee.

### ***Human Subjects Review Boards (HSRB)***

HSRB approval or date of submission should be provided to the Perinatal and Gynecologic Research Committee if done. Investigators may apply to the Perinatal and Gynecologic Research Committee before, concurrently or after submission to HSRB. (Prior or concurrent may be advantageous to investigators.)

### ***Consent Forms***

Patient and/or parent information letters and consent forms should be submitted with the application when appropriate to the research.

### ***Physician Approval(s)***

Written approval is necessary from Strong Memorial Hospital physicians (obstetricians, pediatricians and/or neonatologists) whose private patients will be approached for perinatal research.

***The following additional documentation should accompany the proposal whenever pertinent:***

### ***Newborn-Neonatology Review***

Research involving healthy or at-risk newborns at Strong Memorial Hospital must be reviewed with and have the approval of the neonatologists for access to these patients. This review should precede submission of the application to the Perinatal and Gynecologic Research Committee. Investigators may contact any member of the Neonatology faculty to submit their proposal for review. Presentation to the neonatologists and discussion are often requested.

### ***Supporting Letters***

Supporting letter(s) from colleague(s), expert(s) or administrator(s) may be included if pertinent to the research and/or if they add clarity, especially regarding the value of the research. Colleagues within one's own discipline or a related discipline may be helpful.