The Ottawa Hospital | L'Hôpital d'Ottawa

Department of Obstetrics, Gynecology and Newborn Care

Policy and Procedure

Approval for Conduct of Prospective Clinical Research

NO.:		**DATE ISSUED:**	**June 20, 2013**
SOURCE:	**Clinical Research Committee Department of Obstetrics, Gynecology and Newborn Care**	**DATE REVISED:**	**August 8, 2018**
SECTION:	**Research**		
APPROVED BY:	**Clinical Research Committee Department of Obstetrics, Gynecology and Newborn Care; Department of Obstetrics, Gynecology and Newborn Care Executive Committee**		

1. POLICY STATEMENT

To ensure that the safety and well-being of our patients is respected and that the research conducted in the department is in accordance with the vision of the hospital, department and all applicable regulatory requirements, any research conducted within the Department of Obstetrics, Gynecology and Newborn Care (Department) that involves prospective recruitment of a patient (including the newborn) shall be reviewed and approved by the Clinical Research Committee (CRC) for the Department prior to implementation.

2. DEFINITION

- Department - Department of Obstetrics, Gynecology and Newborn Care
- Chief – Chief of the Department of Obstetrics, Gynecology and Newborn Care
- CRC – Clinical Research Committee, Department of Obstetrics, Gynecology and Newborn Care

3. PROCEDURE

A. The Principal Investigator of a clinical study which requires recruitment of a patient within the Department will submit the study protocol/proposal, informed consent form and a completed Impact Assessment Form (Appendix A) for review and approval by the CRC. Approval must be obtained from the CRC as part of the submission to the Ottawa Health Sciences – Research Ethics Board (OHSN-REB), or funding agency for potential funding (whichever occurs first).

B. A member of the Department shall be identified as a Principal or Co-investigator on the OHSN-REB of any research project being conducted in the Department. In circumstances where a Department member is not the Principal Investigator or a Co-Investigator, the CRC for the Department may assist to identify an appropriate Co-Investigator from the Department to collaborate and assist with the project.

C. Upon review and approval of the project by the CRC, the Chief listed on the OHSN-REB application form, will be the Chief of the Department, as applicable by OHREB guidelines, and signature will be obtained through the CRC.

D. When prospectively recruiting research only impacts the NICU or Rich Little Unit, the Chief of Neonatology may sign in place of the Chief of the Department. Projects where both Obstetrics and Neonatology are impacted will undergo review and approval by both the Chief of the Department and the Chief of Neonatology.

4. RELATED POLICIES AND/OR LEGISLATIONS

1. http://ichgcp.net/clarification-of-certain-investigator-responsibilities
2. http://www.ohri.ca/ohsn-reb/default.asp

Department of Obstetrics, Gynecology and Newborn Care
Impact Assessment

Date:

Study Title:

Principal Investigator:

Co-Investigator(s):

Funded by:

Research Coordinator:

1. Total Sample Size at TOH Overall Sample Size

   ☐ Multicentre ☐ Single Site

2. Duration of the study (moths/years)

   Anticipated Start date End date

3. Identify all units where recruitment, data collection, study visits will occur:

   a) ☐ Civic Total number of participants anticipated

   ☐ Birthing Unit ☐ OBS Clinic ☐ High Risk Clinic ☐ SPU Clinic
   ☐ Ultrasound ☐ Mother Baby Unit ☐ SCN ☐ Gynecology

   b) ☐ General Total number of participants anticipated

   ☐ Birthing Unit ☐ OBS Clinic ☐ High Risk Clinic ☐ SPU Clinic
   ☐ Ultrasound ☐ Mother Baby Unit ☐ NICU ☐ Gynecology

   c) ☐ Riverside Total number of participants anticipated

   ☐ SGWHC ☐ Operating Room

4. ☐ Identify resource requirements

a) ☐ Space – List

b) ☐ Equipment – List

c) ☐ Staff – if yes,

		Yes	No	
i.	Nursing	☐	☐	
ii.	Clerical	☐	☐	
iii.	Other Health Care Provider	☐	☐	List all:

d) List the study procedures on the unit that will be conducted by the research team (i.e. consenting, draw of study specimens, surveys/questionnaires)

e) List the study procedures on the unit that will be conducted by the clinical staff or health care providers on the unit.

f) What training or education to the clinical staff or health care providers will be done to implement the protocol?

g) How will the proposed teaching be provided to the clinical staff or health care providers?

h) Estimate the number of Departmental resources (nursing/clerk/educator/etc.) hours/minutes per patient/sample size required for study procedures.

i) Describe the study population e.g. preterm infants

5. ☐ A copy of the Protocol submitted to OHSN-REB for review is attached
6. ☐ A copy of the ICF submitted to OHSN-REB for review is attached
7. ☐ A copy of the nursing impact form signed by all clinical managers of units where study activities occur, include consenting and all study procedures is attached

Please submit all final documents pending approval from REB upon receipt. These documents are required for committee approval.

Additional comments:

Reviewed by:

_____ _____
Ruth Rennicks White Date
Clinical Research Program Manager
Department of Obstetrics, Gynecology and Newborn Care
The Ottawa Hospital
Ottawa Hospital Research Institute

Approved by:

_____ _____
Paula Archambault Date
Director, Maternal Newborn Services
The Ottawa Hospital