

Site-Based Research Charter

Duke University School of Medicine



DUKE UNIVERSITY SCHOOL OF MEDICINE

Name of SBR: **OB/GYN**

Date: **3/12/2010**

SBR Director Signature: _____

Department Chair Signature: _____

1. Scope of Research within the SBR:

The scope of the Ob/Gyn Site-Based Research includes all clinical research studies conducted by Duke University School of Medicine, Department of Ob/Gyn faculty members in the Divisions of Clinical and Epidemiological Research, General Obstetrics and Gynecology, Maternal-Fetal Medicine, Reproductive Endocrinology and Fertility, Urogynecology, and members of the Durham Women's Health Associates and Harris and Smith Ob/Gyn. Our philosophy is that clinical, translational and basic research within obstetrics, gynecology, and women's reproductive health is a continuum and thus our SBR is integrated within the Office of Research of the Department of Obstetrics and Gynecology. In addition, because of the unique characteristics of clinical research in reproduction and gender-based biology, our SBR will provide oversight for all research in these areas. While the primary SBR might appropriately be different from the Ob/Gyn SBR, we will provide secondary oversight. Therefore we will require that all protocols conducted on women and children enrolled in our department clinics be subjected to our SBR review process and the study coordinators from other SBRs who conduct studies in the department of obstetrics and gynecology clinics must complete a short course on protection of human subjects in the childbearing years.

2. Key Personnel:

Director Amy Murtha, MD
SBR Manager – Research Practices Bonnie Thiele
SBR Manager – Financial Practices Lisa Hall
Other Rhonda Reaves, William Hackney

3. Define Clusters & Leadership within Clusters;

This SBR group functions as a whole, without clusters.



4. Faculty Advisory Board

Composition:

The SBR Advisory Board consists of members of the Department's Research Committee and meets quarterly to review business. Review of protocols is done by three members of the Advisory Board on a rotating basis as the protocols are submitted to the SBR. The review is in the IRB format and is done within one week of submission by an on-line process. All decisions are made by majority vote.

Members of the Advisory Board are appointed by the Vice-Chair for Research following consultation with and approval of the Chair.

Current members are:

Amy Murtha, MD, Chair
Phyllis C. Leppert, MD, PhD
Haywood Brown, MD
Cynthia Amundsen, MD
Andrew Berchuck, MD
Monique Chireau, MD, MPH
Susannah Copland, MD
Phil Heine, MD
Andra James, MD, MPH
Elizabeth Livingston, MD
Evan Myers, MD, MPH
Susan Murphy, PhD
Thomas Price, MD
Craig Sobolewski, MD
David Walmer, MD
Alison Weidner, MD
Anthony Visco, MD
Chad Grotegut, MD
David Schomberg, PhD
And one fellow and one resident representative

Function: The SBR Advisory Board makes recommendations to the principal investigators and SBR Medical Director on the feasibility and quality of clinical research within the SBR. The SBR Medical Director manages the SBR Advisory Board and will issue the final motion (approve/disapprove) for OBGYN SBR.

5. SBR Governance and Financial Plan:

The Ob/GYN SBR reports to the Chair of the Department of Ob/Gyn. It is the expressed purpose that the indirect cost funds that are returned to the department by the Dean's office will be the source of the funds to provide salary support for the key personnel of the SBR. The current percentage effort is as follows: Faculty Leader (20%); Lead Study Coordinator (50%); Financial



Manager (50%); Financial Analyst (50%); and Administrative Assistant (20%). Funding support will eventually include an additional SBR oversight charge of externally funded projects (other than those funded by Federal Government or nationally funded projects) and a percentage of residual funds remaining at study close out from pharmaceutical trials. The OB/GYN Department's Committee on Research unanimously decided to increase the administrative fee within the budget for all research proposals supported by industry-sponsors and for-profit entities which are managed by the Obstetrics and Gynecology Site-Based Research Group (SBR). There will continue to be no fee for federal or foundation grants. Effective July 1, 2009, the study initiation fee is \$2,500.00 for each new grant and \$1,000.00 annually until study closeout has occurred. Allocation of fixed SBR fees for internally funded projects is in development.

Residual unexpended revenue remaining after study has closed will be disbursed as follows: 30% to the Division; 30% to the SBR; 40% to PI's discretionary code.

6. SBR Stakeholders:

The Department of Obstetrics and Gynecology is currently the only stakeholder in the OBGYN SBR.

7. Communication Plan:

SBR Administration and staff will communicate SBR related information during biweekly Office of Research Meetings. Information and action plans are then communicated to the Department of OBGYN during the following regularly scheduled meetings and events:

- OBGYN Grand Rounds
- Monthly OBGYN Clinical Coordinator Meetings
- Weekly Division Meetings
- Monthly Fellow Meetings
- Monthly Morning Resident Board Rounds
- Research Retreats

Other mechanisms of communication include email, newsletters and the department's website. Meetings are also scheduled on an individual basis with principal investigators, clinical research coordinators and other research support staff when needed.



4. OBGYN SBR Organization Chart:

