SUBJECT: Use of Research Resources and Study Subjects in Ob/Gyn

PURPOSE

The purpose of this guideline is to establish a process to assess the feasibility of conducting a clinical research study in the CPUP practices in the Department of Obstetrics and Gynecology and the Dickens Center for Women’s Health.

SCOPE

This guideline will apply to all investigators who wish to utilize clinical resources and/or enroll patients receiving care in the practices and clinics supported by the Department of Obstetrics and Gynecology for clinical research trials/studies.

IMPLEMENTATION

This policy will be implemented by the Director of the Women’s Health Clinical Research Center (WHCRC) in the Department of Obstetrics and Gynecology.

PROCESS AND PROCEDURE

I. Statement of Purpose

Our goal is to facilitate the conduct of research in the Department of Obstetrics and Gynecology while maintaining high ethical standards and good clinical practice. Investigators within or external to the department may request research space, access to research subjects and administrative support from the Department. To maximize the efficiency of study conduct, especially subject recruitment, while avoiding interruption of clinical services and to ensure fair allocation of research resources and access to our patient populations the following guidelines have been established.

II. Feasibility Review and Approval Process

Any investigator wishing to use departmental research resources (i.e. space, patients, equipment) is required to submit a request, which will consist of a Research Study Feasibility Assessment form (enclosed), a copy of the protocol summary, and any budgetary documents pertinent to the request.

It is recommended that this process begin at the following time points:

1) For NIH-funded research, at the time a letter of support is requested including resubmissions
2) For Industry or Foundation funded research, at the time a Clinical Trial Agreement is submitted
3) For in-house research, concurrent with IRB submission
When requests are time sensitive, it is the responsibility of the investigator to submit the documents with enough lead time for complete and thorough evaluation.

Requests will be reviewed by the Director of the Women’s Health Clinical Research Center (WHCRC). The Director will ensure that pertinent information from requests are circulated to appropriate practice managers and physicians who may be impacted by the proposed research projects. Feedback from these parties will be considered during the review process. The Director will also solicit advice from a committee of qualified faculty as needed. The committee will be comprised of a minimum of three people. This will include at least one person outside the area of the research, and at least one person from each site where patient recruitment will occur, if applicable.

Submissions will be acknowledged as received. Initial review will occur within 14 days. More time may be required to convene a review committee and render a decision, depending on the complexity of the project.

Criteria to assess and prioritize requests include but are not limited to the following:
- overlap with existing or planned research projects
- impact on the delivery of clinical services
- impact of the study to the career development of the investigator
- impact of the study to our patient population
- feasibility and
- cost implications

General priorities include:
1. NIH investigator initiated (especially junior investigators)
2. Investigator initiated pilot grant
3. Investigator initiated foundation or industry sponsored research
4. Collaborative NIH funded research with other Departments or Centers
5. Industry initiated industry funded research that addresses important clinical needs for our patient population (higher priority given if our faculty will be conducting translational studies in this area at the same time)
6. Industry initiated industry funded research which is scientifically valid, but not necessarily a critical need for our patient population

Once the request has been reviewed, the Director will make a recommendation to the Department Chair. The committee may recommend full approval, or approval of any of the following: the recruitment of Ob/Gyn patients, request for space (i.e. desk space for research staff, exam rooms, and consult rooms), request for use of personnel, or request for other resources as specified in the application (i.e. freezer space, centrifuge).

The Department Chair has the final authority to approve requests for use of departmental resources and to request financial support for their use.
All approvals will be contingent upon the receipt of IRB approval documentation, and relevant staff training and education. All approved research must be in compliance with other applicable requirements, such as research billing compliance, research staff training in human subject research, and Good Clinical Practices.

Investigators are required to notify the Director when a study has been funded with the expected start date, and any changes to the original request for resources.

Investigators must notify the WHCRC when their recruitment efforts are complete and, where applicable, the use of space or other department resources is no longer needed.

### III. Feasibility Amendments

Investigators making minor amendments to their protocol or recruitment plan must notify the WHCRC of such changes. Written acknowledgement will be provided. Major changes will require the resubmission of a Research Study Feasibility Assessment Form. This form will be reviewed in the manner outlined in Section II of this document, with a formal response letter to follow.

### IV. Staff Training and Education

Investigators who are approved to use Departmental resources for research must notify the Practice Manager and Division Chief, and educate the clinical staff in that location about the research project prior to the start of the study. This training must be documented, and the documentation must be submitted to the WHCRC for acknowledgement before the research begins.

### V. Research Conduct

Investigators approved to utilize research resources in the Department of Obstetrics and Gynecology agree to abide by the Department’s standards and guidelines for the conduct of clinical research. Failure to do so will result in a review by the Director of the WHCRC and possible termination of the agreement. Investigators will be asked to provide annual updates on the status of the project and notify the Director of changes to the project that may affect use of resources, including IRB correspondence describing these changes.

### VI. Cost of Research Resources

In some cases, an investigator may be asked to cover the cost of the requested resources. Examples of budgetary items include but are not limited to support of WHCRC research staff, space, equipment.