Duke Obstetrics and Gynecology
Science Culture and Accountability Plan (SCAP)

Duke University is committed to maintaining the highest quality and integrity of all its scientific enterprises. Research integrity is a critical and mandatory component of research quality, and underlies the validity of and confidence in the research findings achieved. As part of an overall commitment to research quality, departments within the School of Medicine will implement policies and procedures to ensure scientific accountability and integrity, and seek to provide all members of the research community with the resources necessary to accomplish this.

Introduction

The Department of Obstetrics and Gynecology (Ob/Gyn) has developed this Scientific Culture and Accountability Plan (SCAP) that applies to all personnel engaged in research and serves to foster scientific integrity through innovation, discovery, open communication, and supportive mentorship and training. Alongside the Ob/Gyn research mission that encompasses excellence in basic, clinical and population health research across the lifespan, the SCAP outlines the department's guiding principles used by all research members for daily research practices.

The department is committed to ensuring that policies and procedures are in place and followed to reflect the highest professional conduct and rigor. This will further promote a culture in which scientific results are critically reviewed and accountability for data integrity is clearly delineated. The Department will review the SCAP at least annually to ensure continued relevance and compliance in a highly dynamic and fast paced research environment. It is required that all Ob/Gyn faculty, trainees, and staff engaged in research read and attest to adhering to the SCAP within 90 days of employment, following significant changes, and at least every 3 years.

I. Principles

Fundamental principles that guide research practices in the department include:

- adherence to the highest ethical standards
- respect for co-workers, collaborators, research subjects, animals used in research, and the scientific method
- equal participation and responsibility for ensuring research quality and integrity
- open discussion of any concerns regarding research conduct and integrity

These principles encourage an environment of honesty, transparency, and constructive scrutiny of research methods. Each and every member of the Ob/Gyn Department is expected to reflect and embrace these values. While principal Investigators are responsible to review all primary data, including negative data, all members of the research team are empowered to raise concerns about quality and integrity in a safe environment, without fear of reprisal.

Questions or comments:

Contact Megan Huchko, Research Quality Officer (RQO) for the Ob/Gyn Department: megan.huchko@duke.edu or the Duke Office of Scientific Integrity: https://dosi.duke.edu

II. Structural Organization of the Entity

Ob/Gyn is led by the interim department chair, Dr. Brenna Hughes. The organization is structured into multiple divisions, each led by a named chief. Research active divisions include those listed below:

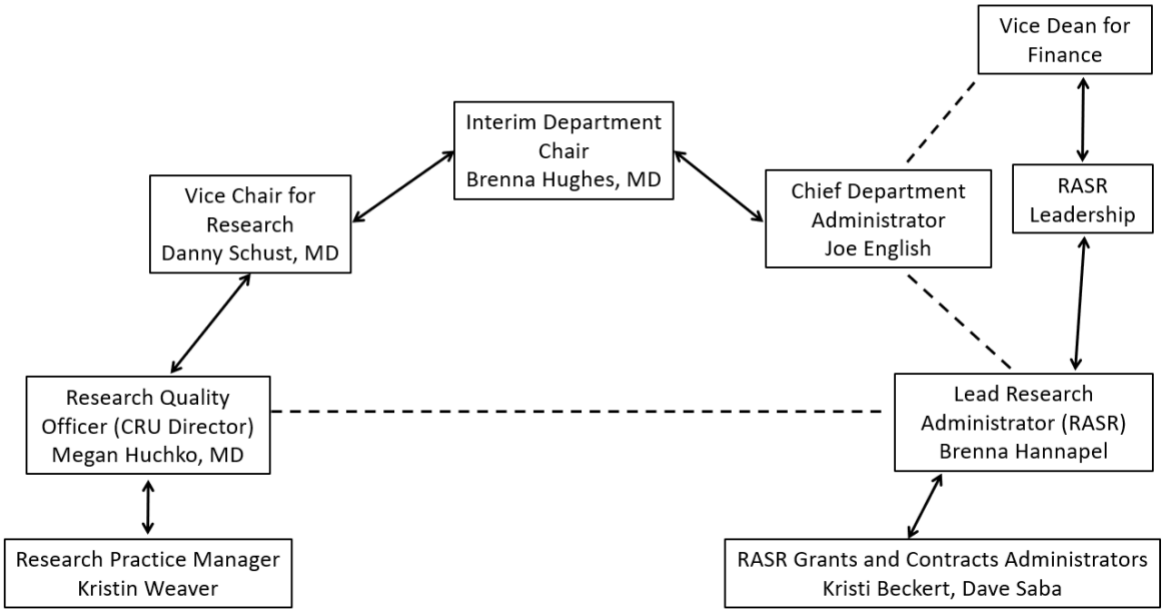
- Gynecologic Oncology
- Maternal Fetal Medicine
- Urogynecology
- Minimally Invasive Gynecologic Surgery
- Reproductive Endocrinology & Infertility
- Women's Community and Population Health
- Reproductive Sciences

Within the department, the Vice-Chair of Research leads the Office of Research, which includes the Clinical Research Unit and Research Administration.

The organizational chart below describes members of the Research Quality Management Team (RQMT) including, Lead Research Administrator (LRA) and Research Quality Officer (RQO).

Date: 03NOV2025

Organizational Chart for Research Quality Management Program



Within each research division, principal investigators, with support from their Division Chief and Vice Chair for Research, take primary responsible for ensuring that the environment supports the guiding principles of research and data integrity.

The SCAP will be reviewed and, if needed, revised at least annually by the Research Quality Management Team. Within the RQMT the RQO takes primary responsibility and is the key contact should department members wish to discuss or propose changes.

III. Promoting a Culture of Accountability

A) Education of faculty, staff, and trainees

There are multiple resources/programs that department faculty, staff, and trainees are encouraged or required to participate in to ensure that these guiding principles are communicated, discussed, and implemented.

Faculty, staff and trainees are **encouraged** to take advantage of the wide range of services offered by the Duke Office of Clinical Research (DOCR) that cover the entire range of the study life cycle from study planning and start up to study close out for research involving human subjects. New faculty and trainees are encouraged to consult with DOCR and the Ob/Gyn CRU RPM when beginning a new study or planning to conduct clinical research at Duke.

All Duke Ob/Gyn faculty, staff members, undergraduate/graduate students, and postdoctoral associates/trainees engaged in research are **required** to complete one self-directed, asynchronous 100-level Responsible Conduct of Research (RCR) course and one collaborative 200-level RCR course every three years. If someone is newly identified as engaging in research, they must complete **either** a 100-level or a 200-level course within 90 days of joining the Duke research community. Completion of this initial course starts the three-year renewal clock for both 100-level and 200-level requirements. Faculty with external research funding are required to complete the training series on Stewardship and Compliance for Research Investigators (SCRI). Ob/Gyn CRU Research Staff are required to complete assigned Duke LMS course offerings, OESO training modules and protocol specific training prior to the completion of the 90-Day Orientation Probationary Period or when a new task is assigned. Training is role-based and determined by the Ob/Gyn RPM and Division Lead Research Program Leader and/or Coordinator, as appropriate. Continuing education and professional development is assessed annually and upon assignment of a new task. Documentation of course completion is monitored by the Ob/Gyn RPM.

Ob/Gyn CRU and institutional resources, upcoming scientific meeting dates, professional development workshops for improving listening and communication skills, and informal learning exchanges such as seminars or meetings are announced at departmental grand rounds and via the following e-Newletters sent regularly to the department research community: Department of Ob/Gyn Department Updates, Ob/Gyn Newsworthy and Noteworthy, and the Chair's Weekly Message.

In addition, the office of research updates faculty at bimonthly faculty meetings, and the RPM communicates to Division-level clinical research staff at monthly research meetings. The RQO or Vice Chair for Research will join the biweekly Division of Reproductive Sciences division meetings on at least a quarterly basis to ensure awareness and compliance in the department's laboratory-based research efforts.

The Office of Research publishes their contact information, obgynresearch@duke.edu, on the department website and department newsletters. Face to face meetings are encouraged.

B) Scientific Rigor and Reproducibility

1) Communication

All research teams should collect and store data in a way that facilitates external review of the entire, de-identified database or spreadsheet, with the expectation that this dataset will be available for critical review at the time results are disseminated. Research teams are encouraged to use quality control measures to establish and maintain high standards of data quality. A quality control plan should be developed before research project start and adhered to through completion.

2) Research methods, study design

High-quality research begins with careful planning and study or experiment design. We encourage investigators to engage appropriate collaborators, statisticians and other relevant team members for constructive input into study or experiment design.

Members of the Ob/Gyn research team are encouraged to use scientific methods that encourage research reproducibility, including rigorous study design and analytic methods. To ensure that non-interventional studies and studies in which the scope and funding may not permit randomized controlled trials employ rigorous methodology, all studies submitted to the IRB must undergo peer review, either internal or external, prior to approval by the Clinical Research Unit for ethical review.

Data integrity is of the utmost importance in ensuring accurate and unbiased results. The majority of data integrity breaches occur due to lack of systems to prevent purposeful or inadvertent manipulation of data. Research teams should implement specific practices and policies to ensure responsible management of data. Key to this is cross-training of personnel to ensure that one person can independently verify the data of another, and no single team member is alone in providing data or analysis.

Principal investigators, or their designees, should ensure the ability to re-analyze all critical studies, such as those included in grant or manuscript submissions, starting with the archived raw data. If the PIs or other primary members of the research team are unable to carry out the analysis themselves, some teams may consider including a person with the appropriate expertise from outside the lab, or an independent analysis by a statistician separate from the investigative team. Statistical support via the Biostatistics, Epidemiology, and Research Design (BERD) Methods Core is available to Ob/Gyn junior faculty as well as residents, fellows, students and other trainees working with Ob/Gyn faculty. The link to request this support is posted on the Duke Department of Ob/Gyn Website at https://obgyn.duke.edu on the Research and Data Science tab.

3) Data management, storage, provenance

a. Clinical Research

The Ob/Gyn CRU promotes best practices in data management, including management, provenance, security and storage of data as it relates to human subject research. All Ob/Gyn CRU research faculty, trainees and staff are required to read the SOP titled “OBGYN CRU Research Folder Management Procedures” and complete the DOCR course titled “Research Data Integrity and Security” prior to orientation completion.

All Duke IRB approved **prospective** studies requiring Ob/Gyn CRU oversight that store electronic PHI (ePHI) within the Department of Ob/Gyn share drive are expected to save data within a study specific secure file that will restrict user access. In order to maintain compliance with minimal use standards and reduce other concerns about data access, data integrity and data tracking, secure study efolders are created by Duke Medicine DHTS Academic Support upon CRU Leadership request. Only individuals listed on the DHTS Secure Folder Request Form may access files in this location. Ideally study efolders are requested prior to DUHS IRB submission of a new protocol. ePHI and research data within the Ob/Gyn private drive is located at \duhsnas-pri\dusom_obgyn\Private\CRU\Studies. Parent research division folders and subfolders within each division include the name of the principal investigator (PI), study title and protocol number. The study team is required to indicate in the protocol's Duke Research Data Lifecycle (DRDL) (formerly Research Date Security Plan (RDSP)), that electronic research data, even if the storage is temporary, contains protected health information. Amendments to the protocol's DRDL is required if the location of the ePHI is modified. Additional details located in the Ob/Gyn CRU SOP titled "OBGYN CRU Research Folder Management Procedures'.

When a PI is non-Ob/Gyn faculty and wishes to store ePHI from prospective studies in a secure folder outside of the Ob/Gyn private drive, the PI must receive permission from Ob/Gyn CRU Leadership prior to entering ePHI in this workspace. This location must be documented in the protocol's DRDL and also include language that the study specific secure file will restrict user access.

All Duke IRB approved **retrospective** studies (e.g. unconsented patient data) requiring Ob/Gyn CRU oversight that store ePHI are expected to store data in the Protected Research Compute Cluster (PRCC) (formerly known as PACE) to ensure that data sets are securely and properly managed. During onboarding of new Ob/Gyn faculty and staff, completion of the "PACE Training for Duke Employees and Affiliates -Citrix Users" (ID: DOCR-PACE-101) is encouraged. The CRU will assist with utilization of the PRCC when available to researchers.

Duke Ob/Gyn research teams are encouraged to utilize REDCap @ Duke for building and managing online databases and surveys. DOCR's instance of REDCap has been systematically tested and validated and REDCap's Data Resolution Workflow documents the process of resolving data issues. DOCR programmer effort is available to Ob/Gyn junior faculty as well as residents, fellows, students and other trainees working with Ob/Gyn faculty to build a REDCap database to the study team's specifications. The link to request this support is posted on the Duke Department of Ob/Gyn Website at https://obgyn.duke.edu on the Research and Data Science tab.

Prior to investigators leaving Duke, a REDCap tool, "OBGYN Investigator Leaving Duke" is sent by the Ob/Gyn RPM to help the plan for the transfer of data or stewardship. Before departing, research team members are expected to organize and index the data and research records for which they have been responsible, and discuss with the Ob/Gyn CRU and or PI whether it is permissible to retain any copies. The Ob/Gyn CRU RPM or designee will review the survey responses entered into REDCap and the files with the soon-to-be-departing person, to ensure there is a good understanding of the organization and location of the remaining data and research records.

b. Laboratory Research

Research in the Division of Reproductive Sciences and other laboratory research within the department requires use of an electronic lab notebook (LabArchives) for recording and managing experimental procedures and results, enabling activity tracking in support of data provenance. LabArchives integrates with many other programs used for data collection and analysis, and allows importing of those files for storage and access. Each faculty member in the division is the “Notebook Owner” for their laboratory group, and the lab members and staff working for that faculty member create LabArchives notebooks under the Notebook Owner. Upon departure from the lab, the faculty member continues to have access to the data generated by that lab member. Lab members automatically share their notebook with the Notebook Owner and with other members of the lab group as appropriate, for example, for experimental protocols. For purposes of reproducibility and quality control, all researchers are asked to record relevant information about the kits and reagents used in experimental procedures in their LabArchives notebook, including the name of the reagent or kit, date received, expiration date, the lot number, catalog number and manufacturer of the product.

For experiments in which data is produced by equipment in the laboratory and output in electronic or non-digital format, that data must be scanned, photographed or otherwise transferred into the LabArchives lab notebook with clear labeling as to the date and experiment with all information included such that anyone would be able to understand what the data represents.

Gel images (agarose, Western blots, etc.) should be annotated with the lanes and markers clearly labeled. An unlabeled image should also be included for purposes of presentation and/or publication.

Server Storage. One limitation of LabArchives is that it will not allow for upload and storage of larger datasets (>15 Gb). These types of data are stored on the OBGYN server, in folders specific to the faculty member in whose lab the data were generated. Upon notification of completion of data generation by the coreresource or other provider, the raw data must be transferred to an assigned folder on the OBGYN server, which is to also include a manifest of the samples that were used, relevant experimental details, relevant protocols and any regulatory approvals that are associated with the dataset. This folder is then protected from future modification and labeled as the original raw data. The server location and path are recorded in the LabArchives notebook, along with the description of the analysis performed, links to those files and conclusions. Any subsequent manipulations of the raw data must be made using copies of the original data, in a manner such that versioning is clearly indicated as well as the name of the person performing the analysis. Each version is to be maintained in a separate folder on the server that is clearly named as containing working data for the original data files.

Biological Specimens. Quality control and assurance measures will be outlined in laboratory-specific standard operating procedures (SOPs).

c) Voicing Concerns

Raising concerns about data integrity is not the same as accusing someone of scientific misconduct. The Department of Ob/Gyn strives to uphold a culture in which all aspects of

scientific findings are critically reviewed. This includes steps in the scientific process, from study design to data acquisition to methods of analysis to formulation of conclusions. Raising these questions should be seen as a routine part of the critical review process, and should not be reserved solely for cases of suspected scientific misconduct.

The Ob/Gyn Department encourages all faculty, staff and trainees engaged in research to voice concerns openly and without fear of reprisal. In order to do this, we provide information on the chain of command, as well as resources for questions or anonymous complaints about data integrity, analytic methods or scientific misconduct. It is the goal of the Ob/Gyn Department to support a culture in which critical review of all scientific findings is the norm.

The Department will have a no-tolerance policy related to falsifying data, deceptive reporting or enrollment of subjects not qualified to be in studies.

IV. Resources:

In addition to the RQO, LRA and RPM, the below are essential resources for questions, concerns and further information about research quality and integrity.

Duke Office of Scientific Integrity: https://dosi.duke.edu

Anonymous Duke Integrity Hot Line: 1-800-826-8109. You do not need to leave a name and calls will not be traced. Or call Duke's Research Integrity Officer: 919-668-5115

Human Subjects

- DUHS Institutional Review Board
- Campus Institutional Review Board

Animal Subjects

- Duke Animal Care and Use Program

Workplace Environment

- Occupational and Environmental Safety Office
- Office for Institutional Equity

Office of the Ombuds

- Contact information: Ombuds website, 919-864-0722 or ombuds@duke.edu
- Jessica Kuchta-Miller, 919-864-1032 or jessica.kuchta-miller@duke.edu

Faculty or staff members engaged in research are required to attest to the Ob/Gyn Science Culture and Accountability Plan within 90 days of the start of research engagement and then annually thereafter.