

# FSU College of Medicine

## Policies for Human Subjects Research Projects

### INTRODUCTION

It is the policy of the FSU College of Medicine (CoM) to advance medical discoveries and knowledge through systematic, scientific research that adheres to federal regulations and internationally accepted standards for ethical conduct in the treatment of human subjects. This includes, but is not limited to, all research in biomedical sciences, behavioral sciences/social medicine, clinical sciences, geriatrics, residency or fellowship programs, rural health and family medicine.

The CoM recognizes that the use of human subjects in research has many societal benefits. These can include the discovery of new medical treatment procedures, breakthroughs in the development of life-saving drugs, and enhanced understanding of human behavior and its associated health impacts. The risks involved, however, must never outweigh the benefits, which is why human subjects research is carefully regulated at the federal, state and local levels, including at FSU and the CoM. These laws, regulations and policies are grounded in international ethical principles and guidelines for human subjects research developed after World War II. They were further refined following the issuance of The Belmont Report in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

As is the case for FSU as a whole, all CoM faculty – full-time, part-time and clerkship/community – as well as residents, fellows, staff and students must follow the ethical principles established by The Belmont Report for any type of human subjects research, regardless of the funding source, sponsorship or regulatory jurisdiction involved. Three main ethical principles embodied in The Belmont Report are a required practice for all CoM-related research:

- **Respect for Persons** – This is a recognition of the personal dignity and autonomy of all individuals, with special protection of individuals having diminished autonomy. A voluntary informed consent/assent process is a requirement of this principle.
- **Beneficence** – This is an obligation to protect individuals from harm that includes conducting a risk/benefit analysis to minimize potential risks and maximize expected benefits.
- **Justice** – This requires the research subjects to be fairly selected and that particular care is taken when working with vulnerable populations such as children and individuals with cognitive or physical impairments.

In assuring that these ethical principles are applied consistently, the federal government requires submissions of formal assurances by institutions conducting human subjects research that they will abide by federal scientific guidelines, regulations and administrative procedures. This includes the establishment of Institutional Review Boards (IRBs) and associated committees to review all human research protocols.

FSU holds a Federal-wide Assurance (FWA) and has established an IRB process through the Human Subjects Committee of the FSU Office of Research. The CoM Division of Research works closely with the IRB to ensure appropriate CoM administrative oversight of all CoM-related research involving human subjects.

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**SUBJECT: Definition of Human Subjects Research**

It is the policy of the FSU College of Medicine (CoM) that research proposals by an FSU CoM faculty member, FSU CoM clerkship/community faculty member, resident, fellow, staff member or student must undergo a determination as to whether the project is *research involving human subjects* as defined under the Code of Federal Regulations (45 CFR 46). This determination must be made before any project proposal is submitted to the FSU Institutional Review Board or other IRB providing study oversight and shall be made by the Chair of the CoM Research Advisory Committee.

Generally, three critical questions provide the federal regulatory framework for determination as to whether a project or activity constitutes human subjects research:

1. Does the activity meet the definition of research by being a systematic investigation that is designed to contribute to generalizable knowledge?
2. Will the activity involve gathering information or data about living individuals that is private and individually identifiable?
3. Will the investigator (faculty, professional staff or student) obtain the information or data through intervention or interaction with living individuals?

**1. Is the activity a systematic investigation that is designed to contribute to generalizable knowledge?**

An activity must meet the definition of “research.” To be research, the project must be both a systematic investigation and have a goal or intent to develop or contribute to generalizable knowledge. If the project has only one of these properties then the activity is not “research” and need not continue through the CoM Research Review process.

A “systematic investigation” uses a scientific approach that typically is described in a formal protocol containing an objective and a set of procedures designed to reach that objective. The approach can cover studies that are experimental or observational, surveys, tests and recordings. Activities that are research also can include testing a hypothesis using appropriate method(s) leading to results from which conclusions are drawn. This generalizable knowledge is often conveyed as theories, principles or statements of relationships.

In determining whether a project meets the definition of “research,” it also is helpful to ascertain whether the investigator intends to publish or present the results of the project in a medical journal or at an academic meeting. However, there is a difference between publishing information that is simply intended to be educational and specifically reporting on knowledge gained from a systematic investigation – the latter would indicate research activity.

**2. Will the activity involve gathering information or data about living individuals that is private and individually identifiable?**

Upon defining that the activity is research, there must be a determination as to whether the project will involve living individuals, or human subjects, and if the data or information collected are private and individually identifiable.

Private information involves a reasonable expectation by the individual to which it pertains that the information will not be made public; for example, a medical record. Private information is identifiable if it contains at least one data element that can be combined with other information to identify an individual.

### **3. Will the investigator (professional faculty or student) obtain the information or data through intervention or interaction with living individuals?**

Finally, human subjects research must also involve the collection of information through either an intervention or interaction with living individuals. For example, “intervention” includes physical procedures by which data can be gathered – such as venipuncture – as well as manipulation of the human subject or his/her environment as part of the research activities.

Interaction with the human subject includes communication or interpersonal contact between the investigator and the subject. For example, interviewing cancer survivors about their coping techniques is considered human subjects research.

### **Activities that are Not Defined as Human Subjects Research**

In defining a research activity, it is important to note that “research” does not include the following activities:

- Surveys or other data collection whose purpose is to evaluate the performance of faculty, staff, students or other personnel.
- Studies, surveys or other data collection activities that are for internal institutional use, such as improving educational curricula or a CoM course or clerkship.
- Analysis of data that is in the public domain, such as US Census data.
- Clinical activities that are not a component of any research project.
- Retrospective reviews of existing medical charts/records that are intended:
  - for quality assurance purposes or to review a physician’s performance,
  - for compliance, such as reviewing third-party billing issues or Principal Investigator (PI) non-compliance,
  - to obtain clinical information for teaching purposes.

### **Case Reports**

A medical case report typically is not considered human subjects research, since the information it provides is not considered generalizable knowledge, thus failing to meet the federal definition of human subjects research. FSU COM policy is that case reports need not be submitted through the Research Advisory Committee process and IRB, if the report meets all of the standard exemption criteria of a case report.

A medical case report is not human subjects research if it fulfills all of the following:

1. A description of medical observations or interesting medical condition, innovative treatment, disease presentation, disease progression or outcome, and
2. Reports on three or fewer patients, and
3. Reports on patients treated by the clinician preparing the case report, and
4. Is a description of observations which is not a systematic investigation designed to advance generalizable knowledge, and
5. Is a retrospective report with no data analysis or testing of a hypothesis

### **Important Additional Considerations**

1. The review of medical records for publication of case reports is subject to HIPAA rules and may require authorization from the patient to use the protected health information if the patient cannot be

completely de-identified. The keeper of the Medical Record or the Medical Record Department where the case is housed should be contacted for the appropriate chart/patient record review permissions.

2. It is always best to check with your affiliated IRB(s) in advance to ensure that your specific approach to your report doesn't fall under their rules regarding human subjects research. The FSU College of Medicine's Office of Research Administration, which provides administrative support for the College's internal review process, can facilitate that contact with the FSU IRB if needed. Other IRBs can be contacted through their specific administrator.
3. Some Journals will not accept case reports in any form without indication that the report was approved or exempted by an IRB. In these situations, the case report must be submitted to the FSU COM Research Advisory Committee process, so it may be sent on to the governing IRB.

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**SUBJECT: College of Medicine Research Review Process**

The FSU College of Medicine (CoM) is committed to academic freedom in the conduct of research that adheres to federal, state, local, FSU and CoM requirements and follows the ethical principles of The Belmont Report. To ensure a consistent and systematic approach to scientific research, it is the policy of the CoM that all research proposals involving human subjects and affiliated with a CoM faculty member, CoM clerkship/community faculty member, resident, fellow, staff member or student must be reviewed by the CoM Research Advisory Committee Chair and/or the full Research Advisory Committee prior to submission to the FSU/Institutional Review Board (FSU/IRB) or other IRB providing study oversight.

**Review Timeline**

The CoM Division of Research provides administrative support to the Research Advisory Committee (RAC) through the Office of Research Administration. The RAC Chair will make every effort to ensure that proposals are expeditiously reviewed and that the CoM-affiliated investigator is timely notified of the disposition of the review. Except for unforeseen circumstances, the general turnaround time for review by the RAC Chair is three business days for initial determination as to whether the protocol is complete, meets the definition of human subjects research as described in CoM Policy **RSCH-01-2012**, and requires full review by the entire Research Advisory Committee.

**Submission & Review Process**

The review process begins when the CoM-affiliated investigator submits a research proposal. If the investigator is a clerkship/community faculty member affiliated with a regional campus or rural site, the proposal must be reviewed and approved by the investigator's applicable regional campus dean and the CoM Associate Dean for Clinical Research prior to submission to the Office of Research Administration in the Division of Research. If the investigator is a CoM-affiliated resident or fellow, the applicable residency/fellowship program director must review and approve. If the investigator is a student, a faculty mentor must be identified and shall submit the proposal on behalf of the student. If the investigator is a full-time CoM faculty member, the proposal must be reviewed and approved by the investigator's applicable Department Chair prior to submission to the Office of Research Administration.

For any study proposal, the investigator shall notify all Department Chairs and Campus Deans whose areas of responsibility or assigned campus fall within the proposal's topic area or geographic region of study.

Upon submission to the Office of Research Administration, the proposal is date-stamped and a review file created.

*Proposals Seeking Sponsored Funding*

Any human subjects research proposal seeking sponsored funding goes through the Office of Research Administration's normal process for preparing and submitting grant-funded proposals to the FSU Office of Sponsored Research. Because the proposal also must be reviewed by the Research Advisory Committee Chair or the full RAC before being submitted to the FSU/IRB, it is strongly encouraged that any grant-funded proposal be submitted for RAC review as soon as possible. The RAC Chair determines if the proposal is complete, meets the

definition of human subjects research and requires full review by the entire RAC. Proposals that have successfully completed the RAC review process will be forwarded to the investigator for submission to the FSU/IRB or other governing IRB.

If sponsored funding is not being sought, the Office of Research Administration routes the proposal to the RAC Chair for processing similar to proposals seeking sponsored funding. Proposals that do not meet the established definition of human subjects research per CoM policy shall not proceed to the FSU/IRB.

#### Proposal Review

Research proposals that qualify as human subjects research shall be reviewed by the Research Advisory Committee Chair and/or the full RAC and may consider the following:

- How well the research fits with and/or helps fulfill the CoM mission
- The demonstration of scientific value
- The research design is sound and follows a scientific process for hypothesis development, data collection, evaluation and conclusion
- Investigator qualifications include prior FSU CoM-affiliated training in research through the Collaborative Institutional Training Initiative (CITI)
- The type of funding resources used
- The proper accounting of dollars through the CoM Research Division for all CoM-related proposals using FSU or the CoM as the investigator's affiliated institution/college

The RAC Chair will review protocols that meet federal criteria for exempt, expedited or full committee review as applied by the FSU/IRB under IRB Policies 004, 005 and 006. At the RAC Chair's discretion, additional members of the RAC may be requested to review a protocol. Once the proposal has successfully completed the RAC review process, the investigator is notified for submission of the proposal to the FSU/IRB or other governing IRB.

The investigator may be required to attend a CoM-RAC meeting to answer questions or provide clarifications on the research proposal. Whenever possible, the investigator shall attend in person; however, investigators who are not able to physically attend a meeting may participate through telephone, video or online conference. Proposals that successfully complete RAC review shall be returned to the investigator by the CoM Office of Research Administration with written notification (using U.S. mail, fax or electronic means) that the proposal is ready for submission to the FSU/IRB or other governing IRB.

The disposition of proposals that are not complete, do not meet the definition of human subjects research and/or do not successfully complete RAC review shall be timely conveyed to the investigator in writing (using U.S. mail, fax or electronic means) by the CoM Office of Research Administration. The investigator may revise the proposal and resubmit to the Research Advisory Committee Chair for additional review by the Chair and/or full RAC.

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**SUBJECT: College of Medicine Research Advisory Committee (CoM-RAC)**

The Research Advisory Committee falls under the oversight of the Senior Associate Dean for Research and has responsibility for review of CoM faculty, clerkship/community faculty, resident, fellow, staff and student protocols that meet the federal regulatory definition for human subjects research. This includes protocols in which the CoM-affiliated investigator is in any way a researcher for a study, regardless of its funding source or origination within or external to the CoM.

**Membership**

The voting membership of the CoM-RAC consists of four standing members and at least seven rotating members. The standing members are the:

- Senior Associate Dean for Research or designee (CoM-RAC Chair)
- Associate Dean for Clinical Research or designee
- Clinical Research Network Director
- CoM Translational Science Laboratory Director

The rotating members consist of faculty appointed by the Senior Associate Dean for Research from a pool of nominees submitted by the Senior Associate Dean for Medical Education and Academic Affairs, the Senior Associate Dean for Regional Campuses and the five CoM Department Chairs. The rotating members will be selected to ensure a diverse representation of clinical faculty, basic scientists and medical education faculty.

At the RAC Chair's discretion, a biostatistics advisor may be appointed to the RAC who shall participate in RAC meetings and/or consult with the Chair as needed.

**Terms**

Standing members or their designees serve at the pleasure of the Senior Associate Dean for Research. Seven of the initial rotating members to be appointed will serve the following staggered terms:

- Three initial members will serve one-year terms
- Two initial members will serve two-year terms
- Two initial members will serve three-year terms

As the terms of the initial rotating members expire, all new rotating members will serve three-year terms, which may be renewed by the Senior Associate Dean for Research. This process will provide continuity in committee membership by avoiding a complete turnover of rotating members at the same time.

**Committee Member Responsibilities**

1. Meet the attendance requirements of the committee
2. Maintain current FSU CoM-affiliated CITI training certification
3. Review assigned research proposals
4. Request additional reviewer(s) based upon needs for reviewer expertise related to the assigned proposal
5. Prepare documentation of assigned reviews in a timely fashion

6. Help identify real and potential conflicts of interest
7. Abide by FSU CoM policies concerning research conduct

### **Meetings**

The CoM-RAC's meeting schedule, frequency and location shall be determined by the RAC Chair. If necessary to ensure prompt review of protocols, the Committee may also meet upon the call of the CoM-RAC Chair. Whenever possible, the CoM-RAC members shall meet in person; however, members who are not able to physically attend a meeting may participate through telephone, video or online conference.

An agenda and associated meeting materials will be distributed on behalf of the Chair prior to each meeting on a schedule that allows each member sufficient time for advance review. Minutes shall be recorded for each meeting. CoM-RAC members are expected to attend the majority of meetings and notify the Chair of any absence. More than one unexcused absence or failure to attend a majority of CoM-RAC meetings can result in the member's removal from the Committee. A simple majority of voting members, including the Chair and two of the standing CoM-RAC members, represents a quorum for purposes of conducting CoM-RAC meetings.

Voting by proxy is not allowed. In addition, any CoM-RAC member who has a conflict of interest, either actual or perceived, in association with a project being reviewed shall abstain from voting and participation in review of the protocol. The member's declared conflict and abstention shall be recorded in the meeting minutes.

### **Records Retention**

Copies of meeting minutes and associated documentation of protocols shall be kept on file in the CoM Office of Research Administration in the Division of Research for at least three years after the completion of the study, including protocols that were not approved.

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**SUBJECT: Responsible Conduct for Research**

It is the policy of the College of Medicine to ensure the highest standards of integrity in research and to protect the rights and safety of all human subjects in studies. All CoM-affiliated researchers must comply with FSU and CoM policies and procedures in addition to all applicable federal and state laws governing the protection of human subjects in research.

This policy outlines a list of key requirements that researchers must adhere to but is not intended to represent the totality of responsible conduct expected by FSU, the CoM, the FSU Institutional Review Board (FSU/IRB) or other governing IRB.

**Use of COM Research Proposal Review Process**

Every human subjects protocol in which a CoM-affiliated researcher is involved must be reviewed and approved by the CoM Research Advisory Committee Chair and/or full RAC *before* it can be submitted to the FSU/IRB or other governing IRB. This is required regardless of whether the protocol originates within or external to the CoM and regardless of funding source(s).

The FSU/IRB will not consider a study from any CoM-affiliated researcher that has not first completed the protocol review process of the CoM Research Advisory Committee.

**Training in Human Subjects**

To foster and promote ethical decision-making, professionalism and best practices, the CoM requires that everyone engaged in research understand and abide by fundamental ethical principles for the responsible conduct of research. Therefore, it is the policy of the CoM that every CoM-affiliated researcher involved in human subjects research be certified in the protection of human subjects during research.

This certification requirement will be fulfilled by taking the FSU-affiliated training modules provided by the Collaborative Institutional Training Initiative (CITI) Course in The Protection of Human Research Subjects. This web-based training program in human research subjects protection is hosted at the University of Miami and accessed through this web link: <https://www.citiprogram.org/>.

**Informed Consent**

The Principal Investigator holds the primary responsibility to protect a research subject's rights and safety. Each Principal Investigator must be certain that every subject is adequately informed and freely consents to participate in the research. This requires obtaining legal informed consent of the subject or his/her legally authorized representative as provided in federal regulations.

**Confidentiality and Records/Data Maintenance**

The Principal Investigator must maintain research records in a secure depository for three years after the completion of the Human Subjects study, under FSU/IRB policies. Provisions must be made to safeguard sensitive and confidential information; however, records must be accessible for authorized representatives of the CoM or FSU/IRB or other regulatory body specific to the study to inspect as necessary.

It is the Principal Investigator's responsibility to clearly understand the records retention requirements of the sponsoring organization (funder) or other oversight entities, which could extend beyond three years.

### **Research Management and Oversight**

Each Principal Investigator is responsible for ensuring that the research is performed in accordance with the protocol and that all procedures are conducted with the appropriate oversight and by qualified individuals according to federal regulations, state laws and FSU/CoM policies. The Principal Investigator shall report all changes of key personnel at any stage of the study, including during the application and review process, to the FSU/IRB. Changes to key personnel prior to the completion of the CoM-RAC review also should be promptly reported to the RAC Chair by the CoM-affiliated investigator.

### **Conflicts of Interest**

Every CoM-affiliated researcher is expected to adhere to the fundamental values of trust, honesty, transparency, accuracy and objectivity. Undisclosed situations that create perceived or actual conflicts of interest related to personal financial gain of any CoM-affiliated researcher are inappropriate and are a violation of this policy. This includes situations involving the employment of a spouse, child or other close relative on research projects that are conducted in affiliation with FSU or the CoM. Investigators shall take care to avoid conflicts and shall promptly notify the CoM Research Advisory Committee Chair when a perceived or actual conflict arises.

### **Financial Management of Research**

All funds associated with research that is conducted in affiliation with FSU or the CoM – or that uses FSU or CoM facilities, personnel, services or other resources -- shall be monitored and accounted for through the CoM Division of Research. This applies to all CoM-affiliated investigators when applying for any sponsored research or grant funding, regardless of the source, or when using non-sponsored research dollars such as those appropriated to the investigator by the CoM or FSU.

### **Clerkship/Community Faculty Engaging in Research**

Clerkship/Community Faculty are considered independent contractors in the FSU system and may have interest in conducting research utilizing FSU resources, systems and students. All clerkship/community faculty engaging in research with FSU must abide by FSU CoM research implementation policies and research conduct policies, and must have CoM-approved training in human subjects research (CITI). Clerkship/community faculty must submit all research proposals involving any aspect of FSU to the Associate Dean for Clinical Research for pre-approval. If approved, then the proposal will be submitted through the standard FSU CoM research review process. Furthermore, clerkship/community faculty may not use their FSU CoM credentials, the FSU CoM name, FSU or FSU CoM staff/personnel, or FSU or FSU CoM students in any fashion in the application for or conduct of research, whether internal or external to FSU or FSU CoM, without the express written consent and approval of the Associate Dean for Clinical Research and the College of Medicine Research Advisory Committee (CoM-RAC). Unauthorized research conduct and application in the name of FSU or FSU CoM can result in termination of faculty appointment or affect the faculty's standing within FSU CoM.

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**SUBJECT: Use of CoM Student Data in Human Subjects Research**

It is the policy of the FSU College of Medicine that the confidentiality and integrity of student data be safeguarded in accordance with all applicable state and federal laws. Use of any student data for research purposes must first be reviewed and approved by the Senior Associate Dean for Research, regardless of whether FSU/IRB approval is required. "Data" include but are not limited to: graded exams, term papers, portfolio content, course assignment documents, student/team projects, student evaluations for grading, course grades, transcripts, class rosters, name, date of birth and social security number.

**Educational Research**

Human Subjects research proposals involving student data, including educational research that is exempted from IRB review under federal regulations and/or the FSU/IRB, shall go through the CoM Research Review Process. Educational research on human subjects must meet the definition of research as provided in CoM Policy **RSCH-01-2012**. An example of educational research would be a protocol that intends to test a hypothesis such as *"Are student grades and test scores for specified medical courses a reliable predictor of whether the student will seek a career in family medicine or specialize?"* The Principal Investigator would intend to publicize the results of the research through a scholarly journal, a conference or poster presentation, or other means of public dissemination.

Human subjects research does not include data such as:

- Quality enhancement reviews, surveys or other data collection whose purpose is to evaluate the performance of faculty, staff, students or other personnel.
- Studies, surveys or other data collection activities that are for internal institutional use, such as improving educational curricula or a CoM course or clerkship.
- Aggregated student testing data that are not individually identifiable and that are being shared to educate or inform rather than to demonstrate, and draw conclusions from, the results of a systematic testing of a research hypothesis.
- Analysis of data that are in the public domain, such as US Census data.

**Informed Consent Requirements for CoM Student Data**

Florida statutes governing consent requirements for student data follow the federal Family Educational Rights and Privacy Act, 20 U.S.C. s. 1232g (FERPA). The federal Act provides certain conditions under which student records can be released without student or parental consent. These include:

- Requests from school officials, including teachers within the educational institution or local educational agency, who have been determined by such agency or institution to have legitimate educational interests.
- Organizations conducting studies for, or on behalf of, educational agencies or institutions for the purpose of developing, validating or administering predictive tests, administering student aid programs, and improving instruction, if such studies are conducted in such a manner as will not permit the personal identification of students and their parents by persons other than representatives of such organizations and such information will be destroyed when no longer needed for the purpose for which it is conducted.