



Institutional Review Board

Standard Operating Procedures

1. Nature and Purpose of the IRB

Regis University maintains a Research Protections Program under the oversight of its Institutional Official, the Associate Provost. The Institutional Official convenes a Research Protections Committee (RPC) that consists of the appropriate officers responsible for the safe and ethical conduct of research at Regis University. This list includes, but may not be limited to the Institutional Animal Care and Use Committee (IACUC) chair, the Institutional Biosafety Committee (IBC) chair, and the Institutional Review Board (IRB) chair, University Legal Counsel, and University officials who have official oversight of Environmental Health and Safety, risk management, and insurance.

The Institutional Official, in consultation with the RPC, is responsible for maintaining the Institution's assurances, reviewing the compliance committees, and responding to adverse events. The IRB is recognized as a faculty governed committee operating in accordance with this larger program, who shares specific responsibility for the ethical and safe conduct of research on human subjects within the broader program of protections overseen by the Institutional Official.

Regis University certifies through a Federalwide Assurance that it complies with the rules and regulations set forth by the Office for Human Research Protections (OHRP) in the US Department of Health and Human Services regarding the conduct of research. As a part of this assurance Regis affirms to maintain an Institutional Review Board (IRB), charged with the review of human subject research conducted by the University and/or its members. In accordance with our University mission the University has elected to ensure projects not funded by the US HHS are also subject to review by the IRB, except for where it is deemed to fall outside of the scope of the committee per its bylaws. Supported by institutional policies and written procedures, the IRB ensures that the rights and welfare of human research subjects are overseen and protected uniformly, regardless of personnel changes.

The IRB is guided primarily by the Code of Federal Regulations Title 45 part 46 (45 CFR 46), a uniform set of regulations informally known as the "Common Rule". 45 CFR 46 contains the majority of regulations useful to guiding the IRB in making the most appropriate decisions regarding the protection of human subjects. In addition to the Common Rule it is also expected that the IRB will be familiar with and sensitive to the regulations outlined in *The Health Insurance Portability and Accountability Act of 1996* (HIPAA) and the *Family Educational Rights and Privacy Act* (FERPA), along with other laws and regulations applicable to specific projects.

2. Membership and Appointment

2.1. Composition of the Board

The IRB at Regis University is composed of 13 members representing the following constituencies:

- One Chair drawn from the Regis University IRB Board of the University
- Two faculty members representing each of Regis' five colleges; a Chair person and Vice-Chairperson will be selected from among these members One member of the Dayton Memorial Library
- One nonaffiliated community member
- Total representation on the Regis University will be 13 persons.

- All Regis University IRB members will take responsibility for advising faculty, faculty advisors on how to navigate the IRB with respect to research activities that will provide new knowledge and result in a broad dissemination opportunity
- The Regis University IRB must ensure that **at least one** member on the Board can be defined as a scientist and **at least one other** member on the Board can be defined as a non-scientist according the OHRP definition:

“Scientist/Nonscientist - Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist” (Attachment B: Recommendation on IRB Membership and Definition of Non-scientist under 45 CFR 46 and 21 CFR 56).

2.2. Appointment of Members

2.2.1 IRB Board Members

IRB members are appointed by the Institutional Official in consultation with the Provost following the rules set out in these Standard Operating Procedures (especially section 3.1) and in reference to federal code. Ranked faculty appointments are made based on dean recommendations in accordance with established processes specific to each College and the Library. These units are best suited to vet the qualifications of potential IRB members and confirm their ability to serve effectively on the committee. The community member will be recommended to the Institutional Official by the IRB Chair and the University Compliance Coordinator. Members must be qualified through their experience and expertise to comment knowledgeably on and make recommendations regarding research on human subjects. As a body, the IRB must include diverse membership and members with a broad a base of backgrounds to ensure that diverse viewpoints are considered with respect to the rights and welfare of human subjects. Outside expertise may be consulted if IRB members do not have the requisite expertise.

2.2.2 IRB Vice-Chair

At the election of a new IRB Chair all sitting board members are invited to nominate (of self-nominate) a sitting faculty member from the Regis University community to be Vice-Chair. Nominations or self-nominations for the role of vice chair must made in writing to the Institutional Official by October 15th. Only current IRB members will be eligible for the role of vice chair.

2.2.3 IRB Chair

The IRB Chair will be appointed by the Institutional Official after having served at least one year’s term as Vice Chair satisfactorily.

2.3. Term of Service

2.3.1 IRB Board Member Term Length

All IRB members will serve two-year terms. Terms begin on September 1 of the first year and end on August 31 of the second year. These terms are renewable so long as doing so complies with established University policies and processes within individual colleges and the Dayton Memorial Library. The two members from each college have terms expiring in

alternating years. In the event of member turnover, replacement members will serve out the term of the member whom they replace. Members' terms expire as scheduled regardless of sabbatical or other University-approved leaves.

Units may opt to provide temporary replacements for IRB members on University-approved sabbaticals or long-term leave. Temporary replacement members must also meet the University's established CITI requirements for IRB members.

2.3.2 IRB Chair Term Length

The IRB Chair serves a 2 year term and is appointed after serving for at least one year as Vice-Chair.

2.3.3 IRB Vice-Chair Term Length

The IRB Vice-Chair serves a 2 year term, at the end of which time they are invited to become IRB Chair.

2.3.4 Recusal and Removal from Service

Members may resign from the Board at any time. A replacement member will be appointed following the appropriate processes designated above. Members may also be removed from IRB by the Institutional Official based on recommendation from the IRB Chair for failure to perform, failure to complete required training, conflict of interest or breach of ethics.

3. Expectations of IRB Members

3.1. Training and Certification

It will be generally expected that IRB members remain current on all aspects related to the safe and ethical conduct of human subject research.

3.1.1 CITI Certification

All IRB members are required to complete the Collaborative Institutional Training Initiative (CITI) modules for social-behavioral and biomedical research before they may vote on or participate in protocol review. CITI certification entails approximately 15 to 20 hours of online education and tests. CITI certification is considered valid for three years at which point CITI refresher courses must be satisfactorily completed.

Members will not be issued official appointment letters until satisfactory completion of required CITI modules is verified.

3.2. General Duties

The scope of the IRB is limited to that described in 45 CFR 46, namely reviewing protocols entailing formal human subjects research with the explicit purpose of ensuring that no harm or unnecessary risk is born by its participants.

The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of the IRB members. IRB members must maintain the IRB's reputation for being fair and impartial, immune from pressure either by the institution's administration, the Investigators whose protocols are brought before it, or other professional and nonprofessional sources. Members are accessible to the University community for consultation, and are proactive regarding training and communication efforts.

3.2.1. Expertise and Commentary

All members of the IRB are expected to provide guidance, expertise, and advice regarding the potential risks and impacts of proposed research projects. It is expected that members will do their best to limit their advice to areas of proposals within their own general expertise. Thus, a scientific member will refrain from providing extensive commentary on non-science merits of proposals, while non-scientific members ought to refrain from commenting extensively on the scientific merits of proposals. The Community Member is expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective. The community member is expected to participate in full-board reviews and may be assigned a limited number of other reviews. If any member feels additional specific expertise is required to ensure a thoughtful review or decision, they are expected to formally declare such needs to the Chair, prior to a full board review, so that additional experts can be brought in without disrupting the timeline of the review process.

3.3. Specific Duties of IRB Members

3.3.1. Full Board Review and Monthly Meeting

The IRB is scheduled to meet once a month as a full board during the academic year (fall and spring semesters). Members are expected to actively participate in these meetings in person or via phone unless they are on sabbatical. Meetings will be scheduled as needed during the summer semester to address protocols requiring full board review.

Members are expected to have read and analyzed necessary documents prior to meetings. During meetings members are expected to participate in discussion in a respectful and knowledgeable manner.

All IRB members are expected to actively participate in IRB meetings, IRB reviews as assigned, and periodic IRB training as needed. Ad hoc meetings may be called at the discretion of the chair or vice-chair.

3.3.2. College Representation

IRB members are expected to serve as points of contact for faculty and students engaged in human subject research within their respective units. Members provide advice for researchers or review services for research projects involving human subjects (45CFR46.101(b) exempt categories). Through proactive training and communication, members are also responsible for ensuring a general level of conversancy regarding the purpose of the IRB and the definition of human subject research within their respective units.

3.3.3. Reviews

In addition to participating in full board reviews, IRB members will periodically be tasked with conducting *exempt* and *expedited* reviews as defined in section 4.

3.4. Reporting Adverse Events

Members are expected to report adverse events to the IRB Chair within 24 hours of learning about them. The Chair will then inform the Administrative Institutional Officer in the Provost's Office of Regis University.

The HHS regulations at 45 CFR part 46 do not define or use the term adverse event, nor is there a common definition of this term across government and non-government entities. In this guidance document, the term adverse event in general is used very broadly and includes any event meeting the following definition:

Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice). Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research. In the context of multicenter clinical trials, adverse events can be characterized as either internal adverse events or external adverse events. From the perspective of one particular institution engaged in a multicenter clinical trial, internal adverse events are those adverse events experienced by subjects enrolled by the investigator(s) at that institution, whereas external adverse events are those adverse events experienced by subjects enrolled by investigators at other institutions engaged in the clinical trial. In the context of a single-center clinical trial, all adverse events would be considered internal adverse events. In the case of an internal adverse event at a particular institution, an investigator at that institution typically becomes aware of the event directly from the subject, another collaborating investigator at the same institution, or the subject's healthcare provider. In the case of external adverse events, the investigators at all participating institutions learn of such events via reports that are distributed by the sponsor or coordinating center of the multicenter clinical trials. At many institutions, reports of external adverse events represent the majority of adverse event reports currently being submitted by investigators to IRBs.

3.5. Duties of IRB Chair and Vice-Chair

3.5.1. Chair full board reviews

The IRB chair is expected to facilitate and conduct the business of the full board. It is also the duty of the IRB chair to review any minutes taken during the meeting and to solicit feedback from the members. The IRB Chair and IRB Vice-Chair will require members who may have a conflict of interest to leave the room during deliberation and voting.

The IRB Chair acts as a tie-breaking vote if necessary.

The Chair establishes meeting agendas in consultation with the Vice Chair and University Compliance Coordinator.

The IRB Vice-Chair performs Chair duties in the absence of the Chair.

3.5.2. Adverse Events

IRB Chair is responsible for notifying the I/O immediately when a serious adverse event occurs.

Serious adverse events are defined by OHRP as any event that:

- Results in death;
- is life-threatening (places the subject at immediate risk of death from the event as it occurred);
- Results in inpatient hospitalization or prolongation of existing hospitalization;
- Results in a persistent or significant disability/incapacity;
- Results in a congenital anomaly/birth defect; or
- based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition." (OHRP Guidance on UPs and AEs, Jan. 15, 2007)

The IRB Chair and Vice-Chair may review adverse events which are not serious in nature and recommend appropriate sanctions to the Institutional Official, who will convene the Research Protection Committee for review, discussion, modification, and/or approval of recommended sanctions.

3.5.3. Representation on Research Protections Committee

The IRB Chair represents the IRB on the Research Protection Committee, which oversees all research activities at Regis University.

Committee for review, discussion, modification, and/or approval of recommended sanctions.

3.5.4. Performance Review and Evaluation of Members

The IRB Chair, in consultation with the IRB Vice-Chair, reviews and evaluates the attendance, preparation, performance and contributions of IRB members at least annually, and as concerns merit. The chair and vice chair meet with the Institutional Official in May of each year (or as situations merit) to share these findings.

3.6. Confidentiality

All IRB members are expected to maintain confidentiality with respect to IRB discussions and reviews.

4. IRB Practices and Procedures

4.1. Full Board Review

One time per month the full board will be scheduled to meet in order to discuss proposed protocols requiring full board review. The following categories of research require Committee review:

1. Studies for which the level of risk is determined by the IRB Chair to be greater than minimal.
2. All sponsored and non-sponsored-driven Clinical Trials (investigational drug or device) subject to FDA regulations.
3. Studies that involve the intentional deception of subjects, such that misleading or untruthful information will be provided to participants.
4. Studies that involve sensitive, vulnerable, or protected populations (such as children, elderly, prisoners, or cognitively disabled individuals).
5. Studies that plan to use procedures that are personally intrusive, stressful, or potentially traumatic (stress can be physical, psychological, social, financial or legal).

Any proposed research not qualifying for Exempt status or Expedited review requires a Full Review, in which a majority of IRB members review and vote on the proposal. These typically involve projects that place human subjects at more than minimal risk, or that involve sensitive topics or vulnerable populations such as prisoners, terminally ill patients, children, veterans, cognitively impaired persons, or economically disadvantaged persons.

The meeting is run by the IRB chair, who establishes an agenda, and ensures relevant materials are circulated to the board in advance.

Full-board reviews will be assigned a lead reviewer by the IRB Chair and/or Vice-Chair and discussed during the scheduled monthly meeting. In many cases, the Chair or Vice-Chair will

assume the role as the lead reviewer for full-board studies. All IRB members are expected to review full-board protocols and provide appropriate feedback before and during the IRB meeting.

Votes taken during a full board meeting are considered binding, if quorum is present, and will be recorded in the minutes

4.1.1 Quorum

A quorum is attained when six members are present, of which at least one member has scientific expertise and another has non-scientific expertise. This definition of a quorum meets the federal definition of a quorum, and exceeds it by one member.

The IRB may review protocols if a quorum is not present. The IRB may not vote without a quorum present. Presence may be defined as physical presence in a meeting or full participation via phone or virtual attendance. E-mail does not constitute presence. The University Compliance Coordinator is responsible for monitoring quorum, and notifying the chair if quorum is lost due to member recusal for any reason. The chair must then suspend voting activity until quorum is re-established (45 CFR Part 46 Sec. 108 (b)).

4.2. Exempt and Expedited Reviews

4.2.1 Exempt From Review

Research may be exempt from review when human participants conform to one of the categories from section [46.101\(b\) of 45 CFR 46](#) that suggest the activities will involve minimal or no risk. Projects will not be given Exempt status if they include any degree of deception, involve more than very minimal risk to participants, involve sensitive information, or include protected classes or vulnerable populations. Please note that researchers must always engage in practices that ensure privacy and that minimize the risks to participants, regardless of the level of review. All of the rights and protections afforded to human subjects in research are required in Exempt status cases.

Exempt Reviews involve a member of the IRB board certifying that the protocol is indeed exempt from further discussion by the board.

Protocols suitable for an exemption will be assigned to a board member in good standing for review by the IRB chair outside of the monthly IRB meeting.

4.2.2 Expedited Review

A proposal that does not fulfill the criteria for Exempt status may undergo an Expedited review if it involves no more than minimal risk to the participants and meets other standards, such as not including protected classes or vulnerable populations, and not using intentional deception. Expedited review may also be used when minor changes are proposed to an approved research project during the period for which approval is authorized.

Protocols suitable for an exemption will be assigned to a board member in good standing for review by the IRB chair outside of the monthly IRB meeting.

4.3. Continuations and Extension Requests

Unless there are concerns with the study, protocol continuation/extension requests will be reviewed by the University Compliance Coordinator who is authorized to extend the date. Items concern will be referred to the IRB Chair.

Protocol modifications will also be initially screened by the University Compliance Coordinator. If there are no significant changes to the study (e.g., addition of new personnel), the modification can be reviewed and approved by the University Compliance Coordinator. Studies which have significant alterations may receive additional IRB review which can potentially include a full-board review even if full-board review was not initially conducted.

Study closures will also be reviewed for adverse or unexpected results by the University Compliance Coordinator. In cases with unexpected or adverse results, the University Compliance Coordinator will refer those studies to the IRB Chair and Vice-Chair, and will immediately notify the Institutional Official.

OHRP defines *unexpected adverse event* as follows:

Any adverse event occurring in one or more subjects participating in a research protocol, the nature, severity, or frequency of which is **not** consistent with either:

1. the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
2. the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event. (Modified from the definition of *unexpected adverse drug experience* in FDA regulations at 21 CFR 312.32(a).)

4.4. Annual Report

The IRB shall submit an annual report to the Institutional Official regarding its activities for the year and anticipated areas of concern. The Institutional Official shall make the final report available to the Research Protection Committee and other parties as appropriate

4.5. Changes to IRB Operating Procedures

Members will be instructed in the general operating procedures of the IRB following their formal appointment. These procedures can also be found in instructional documents maintained by the Center for Scholarship and Research Engagement.

If members desire a change be made to any of the standard operating procedures, forms, and systems employed by the IRB, they may recommend them to the Chair and Vice Chair. The Chair and Vice Chair will then assess the utility and benefit of such request and may bring recommendations to the IRB for a vote on implementation into practice.

5. Administrative Support

The Center for Scholarship and Research Engagement (CSRE) provides administrative support for the Human Research Protection Program and the IRB. The primary point of contact for all administrative support is the University Compliance Coordinator.

5.1. Screening protocols for applicability to IRB review

The University Compliance Coordinator is authorized to conduct a limited pre-screening of all protocols to check for appropriate CITI certification, any required faculty advisor approval, incomplete forms, and whether the project adheres to the federal definition of human subject research.

Persons requesting a decision regarding whether research or scholarly activity is subject to the University's Human Research Protection Program, and thus requires IRB approval, must consult with the University Compliance Coordinator. Decisions will be made in consultation with the IRB Chair based on the following factors: (1) whether or not the activity involves human subjects, (2) whether the activity meets OHRP's definition of research and (3) the degree to which Regis University personnel, designees or students will be engaged in the research activity.

The University Compliance Coordinator or the IRB will respond to written requests with a written determination. All correspondence and a copy of the determination notification will be kept on file.

CSRE, acting for the IRB, shall maintain minutes of all meetings and shall record their findings and recommendations as part of these minutes.

The University Compliance Coordinator must maintain valid CITI certification and is expected to complete the same CITI courses as other IRB members.

6. Procedures for Review, Revision and Approval of these Standard Operating Procedures (SOP)

These SOP and all policies, processes, and procedures described herein (hereafter "SOP") will be reviewed no less than three years from the date of approval as described in this policy. Reviews may also occur as needed in order to maintain compliance with federal regulations and Regis University policies and procedures, or as requested by the IRB Chair or Institutional Official. The review date is determined as three years from the last date of approval by the Regis University Research Protection Committee, which shall not occur without prior review and approval by the Institutional Official and Provost

The IRB Chair must ensure that current IRB members have opportunity to review and comment any time IRB bylaws are reviewed.

The review and approval of these bylaws is documented by the University's Compliance Coordinator, who records the policy and procedure, the date approved (e.g. mm/dd/yyyy and the member(s) responsible for approval). In all cases, the effective date of bylaw revisions is the same as the date of RPC approval. Any changes to the bylaws will be filed by the University Compliance Coordinator and circulated to all current members.

7. Health Insurance Portability and Accountability Act (HIPAA) 1996

All IRB Members and Staff must comply with the HIPAA regulations of confidentiality. The HIPAA privacy rule protects individually identifiable health information from disclosure without authorization unless there are special circumstances, according to HHS. Patients also have the right to access their medical records for a small fee pursuant to the privacy rule.

The HIPAA security rule sets nationwide standards for covered entities to protect individually identifiable health information from disclosure and was enacted in light of medical field's shift to storing medical records electronically, explains HHS.

HIPAA requires covered entities to notify affected individuals when their health information has been disclosed without authorization, notes HHS. Covered entities must also notify the secretary of HHS of any breaches of patient health information. If the privacy breach affects more than 500 individuals, the covered entity must notify the media.

The Office of Civil Rights for HHS enforces HIPAA and is responsible for investigating complaints. Fines for HIPAA violations range from \$100 to \$50,000 per violation, up to \$1.5 million for violations of a single provision, according to TrueVault. The U.S. Department of Justice may seek criminal penalties for egregious violations.

HIPPA Website: <https://www.hhs.gov/hipaa/index.html>

8. Family Educational Rights and Privacy Act (FERPA)

All IRB Members and Staff must comply with the FERPA regulations of confidentiality. The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) is a Federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.

FERPA gives parents certain rights with respect to their children's education records. These rights transfer to the student when he or she reaches the age of 18 or attends a school beyond the high school level. Students to whom the rights have transferred are "eligible students."

- Parents or eligible students have the right to inspect and review the student's education records maintained by the school. Schools are not required to provide copies of records unless, for reasons such as great distance, it is impossible for parents or eligible students to review the records. Schools may charge a fee for copies.
- Parents or eligible students have the right to request that a school correct records which they believe to be inaccurate or misleading. If the school decides not to amend the record, the parent or eligible student then has the right to a formal hearing. After the hearing, if the school still decides not to amend the record, the parent or eligible student has the right to place a statement with the record setting forth his or her view about the contested information.
- Generally, schools must have written permission from the parent or eligible student in order to release any information from a student's education record. However, FERPA allows schools to disclose those records, without consent, to the following parties or under the following conditions (34 CFR § 99.31):
 - School officials with legitimate educational interest;
 - Other schools to which a student is transferring;
 - Specified officials for audit or evaluation purposes;
 - Appropriate parties in connection with financial aid to a student;
 - Organizations conducting certain studies for or on behalf of the school;
 - Accrediting organizations;
 - To comply with a judicial order or lawfully issued subpoena;
 - Appropriate officials in cases of health and safety emergencies; and
 - State and local authorities, within a juvenile justice system, pursuant to specific State law.

Schools may disclose, without consent, "directory" information such as a student's name, address, telephone number, date and place of birth, honors and awards, and dates of

attendance. However, schools must tell parents and eligible students about directory information and allow parents and eligible students a reasonable amount of time to request that the school not disclose directory information about them. Schools must notify parents and eligible students annually of their rights under FERPA. The actual means of notification (special letter, inclusion in a PTA bulletin, student handbook, or newspaper article) is left to the discretion of each school.

FERPA Website: <https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html>

Ratified by the Regis University Institutional Review Board (IRB) on March 12, 2018.

A handwritten signature in cursive script, reading "Vincent C. Wincelowicz". The signature is written in dark ink and is positioned above a horizontal line.

Vincent C. Wincelowicz, IRB Chair