Institutional Review Board (IRB)

For Human Participants in Research

Policies and Procedures Manual



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# Introduction

## Federal Mandate to Protect Human Subjects

The federal government has mandated protection for the rights and welfare of human participants in research since the mid-1970s when the National Research Act (Pub. L. 93-348) was signed into law, thereby creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In 1979, this commission published the “Belmont Report” (see <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html> ), which defines basic ethical principles for the conduct of human subjects research. These ethical principles form the foundation of **Title 45, Code of Federal Regulations, Part 46** (45 CFR 46), the federal policy for the protection of human subjects in research (see http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html).The regulations at **45 CFR Part 46**, established by the United States Department of Health and Human Services (DHHS), apply to all federally supported research involving human subjects and are enforced by the Office for Human Research Protections (OHRP). Although much discretion is left to institutions regarding the policies and procedures of IRBs, federal regulations require the verification of certain protections *before* research begins. Failure to comply with the guidelines for review places an institution at risk for loss of federal funding and the institution and Principal Investigators at risk for lawsuits by subjects whose rights have been violated.

Although the federal guidelines are *required* only for projects that are federally funded, Carroll College’s Federalwide Assurance (FWA) commits Carroll College to assuring that “all of its activities related to human subjects research, regardless of the source of support, will be guided by the [Belmont Report] in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution.” Therefore, the policy of Carroll College shall be to apply those guidelines to **all** human subjects research proposed and conducted by faculty, staff, employees, and students of Carroll College and for research in which Carroll College is otherwise engaged. ***This Institution shall not conduct or provide oversight over human subjects research for which investigational devices or drugs are used.***

## Purpose of the Policy and Procedures Manual

Any institution engaged in federally supported human subjects research must provide *written* documentation ensuring the protection of those subjects and, specifically, of compliance with **45 CFR Part 46**. This “Assurance of Compliance” must be approved by OHRP *before* federal funds can be awarded or human subject research can be initiated. The development of a written document (Policy and Procedures Manual) detailing IRB review, reporting, and operational procedures is a prerequisite for Assurance approval.

In accordance with our Federalwide Assurance (FWA), this manual serves as a reference detailing current policy, procedures, and regulations that govern human subjects research, including specific requirements and procedures for submitting research protocols for review by the Institutional Review Board (IRB) for Human Participants in Research at this institution. The policy and procedures set forth in this manual are applicable to all faculty, staff, employees, and students at Carroll College who propose to use humans as subjects or data about living human subjects in research, development, and related activities. The policy and procedures set forth in this manual are also applicable to all external Principal Investigators (PIs) who wish to conduct human subjects research with Carroll College faculty, staff, employees, or students, whether as co-PIs or as research subjects if Carroll College is engaged in the research. The content of this manual will be updated as necessary to reflect changes in federal regulations and/or institutional policies.

# The Institutional Review Board

## Mission Statement

The mission of the IRB is to determine whether research conducted by faculty, staff, employees, and students affiliated with Carroll College *complies* with applicable law, institutional policies, and standards of professional conduct and practice. Specifically, the IRB is the group given responsibility by Carroll College to review research proposals that involve human subjects. Review assures that the proposed research is evaluated and approved based on the ethical principles described in the “Belmont Report.”

The primary purpose of the IRB is to assure the safety, rights, welfare, and dignity of human subjects. The Carroll College IRB will follow procedures that adhere to federal regulations and guidelines as described at **45 CFR Part 46**. Specifically, the purposes served by the IRB include the following:

* Protection ofhuman participants from being subjected to scrutiny, measurements, procedures, or other interactions or interventions that may violate their basic human rights or put them at unacceptable risk;
* Protection for researchers from repercussions of placing participants at risk;
* Providing to the Carroll community, external PIs, institutions, and human subjects communication concerning policy issues on human participant research; and
* Protection of the existence and viability of such research.

## IRB Administrator

The IRB Administrator will be a staff member at Carroll College. The responsibilities of the Administrator include advising institutional officials, IRB members, and investigators in matters regarding the IRB; managing protocol review; providing or overseeing the education of the Carroll community regarding research with human subjects; recordkeeping; reporting; developing policies and procedures; handling allegations and complaints; conducting quality improvement or assurance reviews; coordinating “off-site” administrative agreements; and serving liaison functions between various parties involved in human subjects research.

In the absence of an IRB Administrator, the IRB Chair and committee members will share these responsibilities.

## Membership

### Chair of the IRB

The IRB Chair will be a member selected among and by the IRB membership and must be a current member of the IRB and a Carroll College employee. The term of an IRB Chair shall be four years, after which time the term may be extended or renewed. The Chair collaborates with institutional officials, the IRB Administrator, IRB members, and investigators toward the common goal of protecting human subjects. Specifically, the Chair ensures the IRB carries out its regulatory responsibilities, conducts or delegates exempt and expedited reviews, provides oversight in review of alleged noncompliance, assists in educating IRB members and researchers, conducts IRB meetings, and keeps the Institutional Officer (IO) informed. The chair fulfills all duties of IRB membership as well. The Chair is responsible for selection of the other members of the IRB.

### Membership

Members of the IRB are appointed by the IRB Administrator, in consultation with the IRB Chair, and serve a term of three years. Members shall be eligible for reappointment to serve additional or extended terms. Responsibilities of IRB members include conducting protocol review, assisting in the proposal and development of IRB policy, attending IRB meetings, disclosing conflicts of interest, completing mandatory education requirements, handling allegations of noncompliance, maintaining confidentiality, and applying disciplinary and regulatory knowledge to these duties

In accordance with federal requirements and institutional policy, the Chair shall employ the following criteria in designating IRB committee members:

1. The committee shall have at least five members from a variety of disciplines and expertise
2. Various backgrounds and professions shall be represented.
3. Membership shall include consideration for diversity of race, culture and gender.
4. At least one member shall be qualified to discuss the research under consideration. A consultant may be called in when deemed necessary, but the consultant would not have voting authority.
5. If the IRB comes to regularly review research that involves a vulnerable category of subjects (such as children, pregnant women, prisoners, or persons with disabilities), consideration will be given to the inclusion of one or more consultants who are knowledgeable and experienced in working with these subjects.
6. At least one member shall be otherwise unaffiliated with the institution ("community member").
7. At least one member will be a scientist (being from a scientific background and/or having a Ph.D.)
8. At least one member will be a “non-scientist.”

## Authority of the IRB

The IRB is responsible for ensuring that the rights and welfare of human subjects in research are protected. To that end, **all** research involving human subjects conducted at Carroll College when Carroll College is engaged, or by Carroll College’s faculty, staff, employees, and students must be prospectively reviewed and either approved or designated officially exempt by the IRB. Specifically, the IRB retains authority to

* **Approve** proposals that comply with federal, state, and institutional requirements,
* **Require modifications**in proposals before granting approval,
* **Disapprove** proposals under full review that fail to meet federal and/or institutional requirements, or
* **Suspend or terminate approval** of research that is not being conducted in accordance with the IRB requirements or that has been associated with unexpected serious harm to subjects.

## Training of IRB Members

IRB members must be able to ascertain the acceptability of proposed research with respect to applicable law, institutional policies, and standards of professional conduct and practice. Before serving on the Board, appointees must complete the [Carroll College Moodle, course Protecting Human Research Participants Training](https://moodle.carroll.edu/course/view.php?id=1151). Course completion certificates will be kept on file with the IRB Administrator. IRB members will have additional training by the IRB Chair. Members will also have the opportunity to continue their training in the roles of IRB membership and IRB processes as resources permit.

## Meetings

Most IRB reviews and other IRB work will be conducted electronically on a continual basis. Additionally, the IRB will meet a minimum of one time per semester (“regularly scheduled meeting”) as determined by the IRB Administrator in consultation with the IRB Chair and members. Additionally, the IRB will meet as needed to conduct full reviews. The IRB Administrator will make arrangements and will notify IRB members of the date, time, and location of the meetings. Additional meetings may be convened at the discretion of the IRB Chair or Administrator.

# The Principal Investigator

As the individual in charge of the implementation of research, the principal investigator assumes the primary responsibility for protecting the rights and welfare of human subjects. Compliance with federal requirements, applicable state law, their institution's Federalwide Assurance, and institutional policies and procedures ensures such protection. Consequently, the principal investigator must accept certain specific responsibilities:

1. **Obtaining IRB approval or designation as exempt *before* beginning research.** Even if the proposed research is believed to be exempt, the investigator must apply for confirmation from the IRB.
2. Receiving appropriate education on the protection of human subjects *and* providing documentation of said education upon submission of an application to the Board. The IRB requires that the principal investigator and all co-investigators complete the [Carroll College Moodle, course Protecting Human Research Participants Training](https://moodle.carroll.edu/course/view.php?id=1151). The site’s completion certificate, printable upon completion of the course, is acceptable as documentation of training. Course completion certificates for all investigators involved in the proposed research should be included with the application and are valid for three years, after which time the investigator must renew their certificate. All co-PIs must also be certified to do research human subjects within three years of submitting a protocol to the IRB.
3. Conducting research according to the IRB-approved protocol and complying with all IRB determinations.
4. Appropriately obtaining and documenting the informed consent of each subject or each subject's legally authorized representative, unless the IRB has waived these requirements.
5. Reporting progress of approved research to the IRB as often as, and in the manner, prescribed by the IRB.
6. Securing continuing review and approval in a timely manner.

The principal investigator is also responsible for promptly reporting to the IRB any of the following:

* **Proposed changes** in previously approved human subject research activities. No changes in approved research may be initiated without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
* **Unanticipated problems or adverse events** involving risks to subjects or others; or
* **Serious or continuing noncompliance** with the HHS regulations or determination of the IRB.

Principle investigators are encouraged to apply to the IRB as early as possible. The IRB cannot guarantee the length of review time for any particular protocol.

# Faculty Advisors for Student Principal Investigators

Faculty advisors for student PIs are ultimately responsible for ensuring that the student research complies with all IRB policies. In order to best advise student PIs on matters regarding the protection of human subjects, faculty advisors must be human subjects certified within three years of the application submittal date. The faculty advisor certification should be included with the application packet.

# Application for Review of Proposed Research

## The Application Packet

The IRB Application form and other IRB documents are available at the [IRB website](https://www.carroll.edu/institutional-review-board/applying-irb-review). These forms are designed to be completed electronically. Electronic copies of the entire application packet should be submitted to the IRB on Moodle as specified in the instructions. Uploading materials to IRB Moodle constitutes an electronic signature. The following completed forms and supporting documentation (as applicable) comprise the Application Packet:

1. **Application for IRB Review of Human Subjects Research**
2. **Research proposal, protocol, or grant application** supporting this application
3. **The Consent Process & Consent Documentation (including waivers)**
4. **Informed Consent Form** (available at the [IRB website](https://www.carroll.edu/institutional-review-board/applying-irb-review))
5. **HIPAA Authorization Form** (available at the [IRB website](https://www.carroll.edu/institutional-review-board/applying-irb-review))
6. **Any questionnaires, surveys, measuring devises, supplemental grant applications, applicable written approvals, or other materials** pertinent to data collection but not fully described in the proposal.
7. **Course Completion Certificates** for the [Moodle course, Protecting Human Research Participants](https://moodle.carroll.edu/course/view.php?id=1151) for all investigators involved, including faculty advisors, in the proposed research.

The principal investigator is responsible for completing all applicable forms in the application packet as well as securing appropriate signatures. If the principal investigator is a student, the signature of a supervising faculty member is required.

## Submitting the Application

1. **Research proposal applications are reviewed throughout the academic year according to established deadlines. Principal investigators are encouraged to submit their applications during the semester prior to the period in which they hope to begin their research. Although applications may be submitted over the summer, PIs should expect a lengthier review process and are encouraged to apply during the academic year.**
2. For each application for review, upload to Upload 1 and Upload 2 on the [IRB Moodle page](https://moodle.carroll.edu/course/view.php?id=1151).
3. Within ten (10) working days of the proposal submission, the IRB Administrator will examine each proposal for the following:

* Completion of theapplication, including necessary signatures;
* Clear and sufficient information in all areas of the application form;
* Attachment of informed consent, HIPAA Authorization and other supporting materials; and
* Attachment of “Protecting Human Research Participants” Course Completion Certificate(s)

Submission of proposals that are incomplete or unclear will delay the review and approval process. Such proposals will be returned to the investigator *without further review*. Properly completed proposals will be forwarded to the IRB Chair for initial review.

## Initial Review

Within at most fifteen (15) working days of receiving the proposal submission from the IRB Administrator, the IRB Chair will review all acceptable proposals. Based upon this initial review, the Chair will determine the level of review appropriate for each proposal, as described below.

# Levels of Review

Proposals will be processed according to one of three levels of review as determined by the IRB Chair: exempt from IRB review, eligible for expedited review, or warranting full Board review. Although investigators may apply for an exemption, the IRB Chair makes the final determination as to the level of review appropriate to each protocol.

## Exempt from IRB Review

The Board may officially exempt from the requirement of review research that poses essentially no risk to subjects. Specific categories of research that are exempt can be found at **45 CFR 46.101(b).** Examples of such research follow:

* Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:  
  (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
* Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph [(b)(2)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101(b)) of this section, if:  
  (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
* Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Investigators proposing such research should submit an application and all supporting material to the IRB Administrator, as is outlined above. The Chair, often in consultation with an IRB member, may:

* Approve the proposal and designate it Exempt from IRB Review
* Withhold approval pending suggested revisions, and/or
* Require either an expedited or a full Board review.

Typically determinations concerning exemption are reached within fifteen (15) working days. Once a determination is made, the investigator will be notified *in writing* of this decision and, when necessary, of requirements for revisions. Projects designated as “Exempt” will be communicated to the full Board at the time of notifying the PI. Records on exempt protocols will be maintained in the same manner as all other submitted protocols.

## Expedited Review

Research that poses minimal risks or involves only minor changes in previously approved research may be eligible for expedited review. A list of categories of research that may be reviewed through an expedited procedure is published as a Notice in the FEDERAL REGISTER and may be viewed at <http://www.hhs.gov/ohrp/policy/expedited98.html> Proposals will be reviewed in accordance with expedited review procedures at **45 CFR 46.110**. Procedures specific to this institution follow:

* The IRB Chair is responsible for determining when/if an expedited review is appropriate.
* Protocols will be reviewed by two members of the IRB.
* A unanimous decision between all reviewers for approval will be final; however either reviewer may withhold approval pending modifications.
* In the event of disagreement between the reviewers, the proposal must be reviewed by the full Board.
* One or more reviewers may send the proposal to the full Board for review.

Once review is completed and a decision is reached, the investigator will be notified *in writing* of the proposal’s status, and if applicable, of requests for modifications. Decisions reached through expedited review will be communicated to the full Board at the time of notifying the PI. Records on expedited protocols will be maintained in the same manner as all other submitted protocols.

## Full Board Review

Most protocols submitted to the Carroll College IRB will qualify either for exemption from review or for expedited review. Research that fits neither exempt nor expedited review criteria must be reviewed by the convened IRB committee, at the next regularly scheduled meeting or at a specially scheduled meeting, as directed at **45 CFR 46.108(b)**. The principal investigator will be invited to attend this meeting to address any concerns or risk implications involved in the proposed research. Changes requested by any Board member must be incorporated prior to approval. After receipt of any requested information or changes, the committee will review the proposal in detail. In order for research to be approved, it must receive the approval of a majority of those members present at the meeting. As soon as possible following the full Board review, investigators will receive written notification of the Board’s decision. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision. Investigators may appeal, in person or in writing, disapprovals or unfavorable decisions by the Board. However, in keeping with **45 CFR 46.112,** no institutional office may approve research that has not been approved by an IRB.

Actions taken by the Board, including detailed accounts of any votes taken on those actions; requirements for changes in or disapproval of research; and summaries of discussions and resolutions shall be included in the official minutes of the meeting.

# Criteria for IRB Approval of Research

Except for research that has been officially exempted, **all** research involving human subjects must be reviewed, approved, and subjected to continuing review. Approvals will be assigned in accordance with **45 CFR 46.111**, as summarized below. *All* of the following requirements must be satisfied:

* The need to use human subjects in lieu of animals is demonstrated.
* Risks to subjects are minimized.
* Risks to subjects are reasonable in relation to anticipated benefits.
* Selection of subjects is equitable.
* Written procedures for appropriately obtaining and documenting informed consent are provided.
* When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
* When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
* When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

IRB Approval means that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional, federal, and state requirements.

# Informed Consent

The IRB must insure that investigators will obtain voluntary informed consent in a manner consistent with the requirements of **45 CFR** **46.116** and **45 CFR** **46.117**. Investigators who will obtain consent written consent must outline the process of obtaining informed consent and provide a copy of the written consent document. Investigators who request a waiver of written consent or a waiver of consent must must complete and submit “The Consent Process and Documentation of Consent (including waivers)” form, available online at http://www.carroll.edu/academics/research/irb/or from the IRB Administrator. This form provides specific instructions for writing a consent form and also provides a section for waiving this requirement, when applicable. When deemed necessary, the IRB may observe or have a third party observe the consent process.

## Basic Elements of Informed Consent

Except where specifically waived or altered by the IRB under Sections 101(i), 116(c) and (d), or 117(c) of the Federal Policy, all human subjects research will require written informed consent, in language understandable to the subject (or the subject's legally authorized representative), including the following basic elements per Section 116(a) and (b) of the Federal Policy:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

## Additional Elements of Informed Consent

Additional elements may be required as per **45 CFR46.116 (b)**.

## HIPAA Authorization

The Health Insurance Portability and Accountability Act (HIPAA) provides privacy regulations governing the use and disclosure of an individuals’ protected health information. HIPAA regulations define *health information* as "any information, whether oral or recorded in any form or medium" that:

* "is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse"; and
* "relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual."

*Protected* health information (PHI) under HIPAA includes any *individually identifiable* health information.

When research requires use and/or disclosure of PHI, authorization, i.e. written permission, must be obtained from individual research participants. HIPAA authorization, though similar to informed consent, is based upon the privacy rules of HIPAA and requires specific details about use and/or disclosure of PHI. (In contrast, an informed consent document is an individual's agreement to participate in the research study and includes a description of the study, anticipated risks and/or benefits, and how the confidentiality of records will be protected, among other things.)

For the purposes of IRB review at Carroll College, HIPAA authorization will be obtained using a stand-alone document available online at the [IRB website, in document 4](https://www.carroll.edu/institutional-review-board/applying-irb-review).

# Continuing Review of Approved Research

## Frequency of Continuing Review

Ongoing research that has been reviewed and approved by the IRB must undergo continuing review at intervals appropriate to the degree of risk, but not less often than once a year. The frequency of continuing review shall be at the discretion of the Board. Research that is likely to require review more often than annually includes but is not limited to the following:

* Research in which some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons; and
* Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects as described at **45 CFR 46.405.**

Review dates for such projects shall be established by the IRB on a per case basis and communicated to the investigator in the approval letter.

## Deadlines

The IRB and investigators must plan ahead to meet required continuing review dates. If an investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the research must stop, unless the IRB finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions. Enrollment of new subjects cannot occur after the expiration of IRB approval.

The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of research must occur on or before the date when IRB approval expires*.* When continuing review occurs annually and the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur.

When continuing review of a research protocol does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. Such expiration of IRB approval does not need to be reported to OHRP as a suspension of IRB approval under HHS regulations.

## Progress Reports

To facilitate the process of continuing review, the investigator must periodically submit to the IRB a status report detailing the progress of ongoing research (“Progress Report”), including:

1. The number of subjects accrued;
2. A summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
3. A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
4. Any relevant multi-center trial reports;
5. Any other relevant information, especially information about risks associated with the research; and
6. A copy of the current informed consent document and any newly proposed consent document.

At a minimum, Progress Reports (available from the IRB Administrator)should be completed annually; however the frequency of continuing review is determined by the IRB. Completed Progress Reports must be submitted to the IRB Chair no later than ten (10) working days prior to the date by which continuing review must occur.

## Expedited Review of Approved Research

Regulations at **45 CFR 46.110(b)(1)** allow the use of expedited review procedures for the review of minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Generally, if research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review. It is also possible that research activities that previously qualified for expedited review have changed or will change, such that expedited IRB review would no longer be permitted for continuing review.

When reviewing research under an expedited review procedure, the IRB Chair or designated IRB member (“reviewer”) will receive and review a protocol summary, a Progress Report, and a copy of the complete protocol including any modifications previously approved by the IRB. Furthermore, upon request, the reviewer shall have access to the complete IRB protocol file and relevant IRB minutes.

The reviewer will also verify that the currently approved or proposed consent document is still accurate and complete and that any significant new findings that may relate to the subject's willingness to continue participation are provided to the subject in accordance with federal regulations.

After reviewing all relevant materials, the reviewer may:

* Re-approve the project for a period up to but not exceeding one year,
* Require modifications before approval, or
* In the event of significant changes, withhold re-approval pending a full Board review.

Once a decision is reached, the investigator will be notified in writing of the proposal’s status, and if applicable, of requests for modifications. Typically, expedited review of approved research is completed within twenty (20) working days of submittal Decisions reached through expedited review will be communicated to the full Board at the time of notifying the PI. Records on renewed protocols will be maintained in the same manner as all other submitted protocols

## Full Board Review of Approved Research

Continuing review by the convened IRB is required unless the research is otherwise appropriate for expedited review under Section 46.110 Criteria for approval of ongoing research include, among other things, determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards for human subjects. The IRB must ensure that all of these criteria are satisfied at the time of continuing review.

All IRB members will receive and review the protocol and a Progress Report for each protocol up for review. IRB members shall have access to the complete IRB protocol file any relevant IRB minutes prior to or during the convened IRB meeting.

The IRB will verify that the currently approved or proposed consent document is still accurate and complete and that any significant new findings that may relate to the subject's willingness to continue participation are provided to the subject in accordance with federal regulations. Review of currently approved or newly proposed consent documents must occur during the scheduled continuing review of research by the IRB, but informed consent documents require review whenever new information becomes available that would require modification of information in the informed consent document.

Investigators will receive written notification promptly following the Board’s decision. If the IRB declines to re-approve a research activity, such notification will include a statement of the reasons for the disapproval. Investigators may appeal, in writing, disapprovals or unfavorable decisions by the Board. However, in keeping with **45 CFR 46.112,** no institutional office may approve research that has not been approved by an IRB.

Actions taken by the Board, including detailed accounts of any votes taken on those actions; requirements for changes in or disapproval of research; and summaries of discussions and resolutions shall be included in the official minutes of the meeting.

# Monitoring and Oversight

## Modifications to Currently Approved Research

Changes in approved research shall not be initiated without IRB review and approval, except when necessary to eliminate apparent, immediate hazards to the subject. To ensure that investigators do not implement protocol changes without prior review and approval by the Board, the IRB shall:

* Require investigator training, upon which approval of research is contingent;
* Inform investigators of this IRB policy by including specific directives in approval letters;
* Conduct random audits of research records.

Prior to implementing any changes in protocol, investigators must complete and submit to the IRB for approval a Request to Modify Approved Researchform(available online at http://www.carroll. edu/academics/research/irb/apply.cc or from the IRB Administrator) outlining the proposed changes. The IRB Chair or a qualified member of the Board will review the Request, with the following possible outcomes:

* If the proposed changes are not significant *and* do not require a change in the informed consent form, the investigator will be approved to continue research. The reviewer’s determination shall be documented in writing and attached to the Request. The Request will be filed with the investigator’s Research Application.
* If the reviewer judges the proposed changes to warrant more than a minor change in either the protocol or the informed consent process, the IRB Chair may require review by the convened Board. Decisions reached by the Board will be documented in the official minutes and will also be filed with the investigator’s Research Application. The investigator may not implement modifications to the protocol prior to Board approval or suspension of research will result. Significant changes in protocol will be reported promptly by the IRB to OHRP and any sponsoring Federal or State Department or Agency head, as applicable. Significant changes in protocol may also be reported to appropriate institutional officials (e.g. Department Chair, faculty advisor).

This type of review typically does not alter the date by which continuing review must occur.

## Unanticipated Problems or Adverse Events

Federal regulations at **45 CFR 46.103(b)(5)** require prompt reporting of unanticipated problems or adverse events involving risks to subjects or others to the IRB. The phrase “unanticipated problem involving risks to subjects or others” is not defined in the federal regulations at **45 CFR 46**; however, OHRP defines unanticipated problems as including those events “that (1) are not expected given the nature of the research procedures and the subject population being studied; and (2) suggest that the research places subjects or others at a greater risk of harm or discomfort related to the research than was previously known or recognized.” Similarly, the term “adverse event” is not defined in the federal regulations, but is defined by OHRP as “any undesirable and unintended, although not necessarily unexpected, effect of the research occurring in human subjects as a result of (a) the interventions and interactions used in the research; or (b) the collection of identifiable private information under the research”. See http://www.hhs.gov/ohrp/policy/advevntguid.html#Q2

The timeframe for reporting unanticipated problems or adverse events will vary according to the specific nature of the problem and of the research associated with the problem. In general, it is recommended by the IRB that the investigator report the nature of the problem to the IRB in writing within five working days of the incident. **Incidents involving any injury or physical or emotional harm to a participant must be reported immediately**. A separate Incident Report (available from the IRB Administrator) must be filed for each incident.

Following review of the Incident Report by the IRB Chair or a qualified member of the Board may:

* Approve the continuation of the research with no changes,
* Require changes to the protocol as suggested by the investigator,
* Require changes other than or in addition to those suggested by the investigator,
* Suspend approval of the research pending further review, or
* Terminate approval of the research.

This determination will be documented in writing, attached to the report, and filed with the investigator’s Research Application. The investigator will be notified in writing of the Board’s decision. Appropriate institutional officials (e.g. Department Chair, faculty advisor) will also be informed. Furthermore, if the research is federally funded, the IRB is required to report to the OHRP and any sponsoring Federal Department or Agency head, all adverse events that caused injury to human subjects or other major effects that involved unanticipated risks or problems.

## Noncompliance

Students, staff, or faculty members involved in the human subjects research are required to report to the IRB any serious or continuing noncompliance with the regulations at **45 CFR Part 46** or any requirements of the IRB. Examples of violations include but are not limited to:

1. Conducting human research without current approval of the Board.
2. Conducting research in a manner that differs from that described in the approved proposal.
3. Failure to follow approved informed consent procedures.
4. Failure to report adverse reactions, injuries, breaches of confidentiality or detrimental effects.

Noncompliance with the regulations or requirements of the IRB will result in immediate **suspension of approval** to conduct research, pending a full Board review. A written notification of the suspension, including the reasons for suspension, will be presented to the investigator. Suspensions will be reported to appropriate institutional officials (e.g. Department Chair, faculty advisor), and if the research is federally funded, OHRP and any sponsoring Federal Department or Agency head will also be notified.

Serious or continuing noncompliance will result in **termination of approval** to conduct research. A written notification of the termination, including the reasons for termination, will be presented to the investigator. Terminations will be reported to appropriate institutional officials (e.g. Department Chair, faculty advisor), and if the research is federally funded, OHRP and any sponsoring Federal Department or Agency head will also be notified.

# IRB Records

The IRB Administrator must document that IRB activities and decisions fully satisfy federal regulatory requirements. Specifically, the IRB Administrator will maintain the following records as required by federal regulations at **45 CFR 46.115**:

* Copies of all research proposals reviewed; scientific evaluations, if any, that accompany the proposals; approved sample consent documents; progress reports submitted by investigators; and reports of injuries to subjects
* Minutes of IRB meetings, including a list of attendees at the meeting; actions taken by the IRB; the vote on these actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; a written summary of the discussion of controverted issues and their resolution.
* Records of continuing review activities.
* Copies of all correspondence between the IRB and the investigators;
* A list of IRB members.
* Written procedures for the IRB.
* Statements of significant new findings provided to subjects.

IRB records shall be retained for a minimum of three years. Records relating to research will be retained for a minimum of three years from the completion of that research.

# Important Related Resources

[“The Belmont Report”](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html)

[The Office for Human Research Protections (OHRP)](http://www.hhs.gov/ohrp/policy/continuingreview2010.html)

[Title 45, Code of Federal Regulations, Part 46](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)