

**Grinnell College Institutional Review Board Policies and Procedures**  
[IRB Registration #00008002; Federalwide Assurance #00023277]  
2016-2017 Academic Year

The purpose of Grinnell College's Institutional Review Board (IRB) is to protect the rights and safety of persons participating in research while facilitating research and safeguarding the academic freedom of researchers. Federal law requires an institution engaged in human subjects research supported by a federal agency to establish an IRB. Accordingly, Grinnell College has submitted a written assurance to the Office for Human Research Protections (OHRP) stating that it will comply with federal regulations regarding human subjects research. This is a condition for receipt of federal support for human subjects research. In general, non-exempt research conducted by members of the Grinnell College community that involves the participation of humans as research subjects must be reviewed by the Grinnell College IRB.

The Grinnell College IRB reports directly to the Vice President for Academic Affairs and Dean of the College (hereafter referred to as the Dean) who serves as the Institutional Official for research involving humans. As the Institutional Official, the Dean has the authority to act and speak for the institution, ensure adequate resources for IRB operations, and ensures that Grinnell College effectively fulfills its research oversight function. This authority has been delegated to the Dean by the President, through written appointment.

The Dean has charged the Grinnell College IRB with the following responsibilities:

1. Periodic review of guidelines for conducting research involving humans at Grinnell College and recommendations for changes;
2. Education of the community regarding legal requirements and ethics for conducting such research;
3. Follow written procedures as described in this document and in the same detail as in Title 45 of the Code of Federal Regulations (CFR) Part 46.103(b)(4) and to the extent required by 46.103(b)(5)
4. Review of requests from outside agencies for research on campus;
5. Review of research funded by the Federal Government;
6. Review of research proposals by Grinnell College faculty, students, staff, and college committees;
7. Review and approval of requests from outside agencies regarding IRB authorization agreements
8. Consultation with those engaged in on-campus research as needed;
9. Monitor the information provided to research participants to ensure their informed consent; and
10. Consultation with members of the community who might have complaints or concerns about human subjects research conducted by Grinnell College faculty, staff, or students.

Grinnell College has “unchecked the boxes” on its federal-wide assurance, which limits federal oversight of the Grinnell human research protections program to federally funded activities. The Grinnell College IRB will apply ethical principles and protections and the following policies and procedures to *all* human subjects research activities; to do otherwise would create what OHRP would consider “an unacceptable double standard.” In most cases,

protections from the Common Rule (45 CFR 46) will be applied. Grinnell College may also apply other protections that are equivalent to Common Rule protections, if adopted and approved by the IRB.

These policies are written to satisfy federal regulations that require written policies and procedures. They serve two other functions. One, they can be consulted and revised by the IRB to ensure its best work. Two, these or a subset of these, will be posted on the College website in order to allow researchers with human participants to consult, be informed, and/or understand the Grinnell College IRB policies and procedures.

The regulations in this document are not intended to be definitive. Depending upon the nature, sponsorship, or funding source of the research and the participants involved, Grinnell College, its IRB, and/or various governmental agencies may impose different or additional requirements not contained in these regulations as permitted or required by law. Moreover, the laws governing human subject research are subject to change, which may require changes to these regulations without prior notice.

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## Policies

### **Board membership and function**

The Grinnell College IRB must meet the minimal federal regulations for staffing (see [45 CFR 46.107](#)). It must consist of a minimum of five members. Of these, the IRB must include one member of the Grinnell community who is not employed by the College and is not part of the immediate family of a person who is affiliated with the College. The remainder of the IRB consists of members of the Grinnell College faculty, including one nonscientist, one scientist, and members of differing gender identities. A member of the Grinnell College faculty serves as Chair of the IRB, and the Grinnell College Research Compliance Manager serves as the IRB's Vice Chair. If the IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or decisionally-impaired persons, the IRB shall consider inclusion of one or more individuals who are knowledgeable about and experienced in working with those subjects. The Faculty Organization Committee (FOC) recruits the faculty board members, and the President of the College appoints the chair, based on FOC recommendation. The College Compliance Officer recruits the community member(s). The service year begins June 1 and ends May 31 of the next year. The board works 52 weeks a year.

The IRB reviews research proposals for projects involving human subjects. "Research" is defined by the Code of Federal Regulations (CFR; see [45 CFR 46.102](#)) as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." In addition, 45 CFR 46 defines a "human subject" as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information."

In accordance with the College's compliance agreement with the Office of Human Research Protection (OHRP) within the Department of Health and Human Services (DHHS), the IRB operates in accordance with the [45 CFR 46](#). Grinnell College is guided by the ethical principles set forth in the Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the [Belmont Report](#)): respect for persons, beneficence, and justice. The College ensures that persons involved in conducting research document their respect for the dignity and integrity of the persons being studied, including their right not to be the subject of potentially harmful research.

### **IRB authority**

The [Federal-Wide Assurance](#) details the relationship of Grinnell College and OHRP within DHHS. This agreement and other DHHS policies empower the IRB with the authority to review, approve, require modification in, or disapprove research activities conducted by Grinnell College investigators, including jurisdiction over proposed changes in previously approved human participants research. For approved research, the Grinnell College IRB also determines which activities require continuing review more frequently than the maximum interval of one year.

Grinnell College IRB decisions and requirements for revisions, if any, are conveyed to investigators in writing, with the provision of an opportunity for appeal to the Grinnell College IRB by the investigator in the case of disapproval. Although a research project may receive Grinnell College IRB approval, the Dean may conclude that the research project does not meet the policies and goals of the College and may disapprove, suspend, or terminate a project. However, Grinnell College IRB decisions to require modifications in, disapprove as submitted, suspend or terminate a project are final. Further, no committee or official can approve an investigator to conduct any human participants research that the Grinnell College IRB has not approved (see [45 CFR 46.112](#)).

The Grinnell College IRB must insure that voluntary informed consent will be obtained by research investigators and their staff in a manner that meets the requirements of [45 CFR 46.116-117](#). If research will involve minors, the IRB must ensure that parental consent and assent is obtained, as required in [45 CFR 46.401\(d\)](#). State law is used to define a minor. The Grinnell College IRB holds the authority to observe or have a third party observe the consent process when deemed necessary. Grinnell College IRB approval means that the research has been reviewed and may be conducted within the constraints set forth by the Grinnell College IRB and by other institutional and federal requirements.

### **Meetings**

All full-board votes require a quorum (i.e., a majority of the voting members are present) of IRB members that includes at least one nonscientist. The IRB conducts full-board business in person only. Exempt or expedited review may occur electronically by email and does not require a full-board meeting. The chair presides over meetings and sets the agenda. The IRB meets biweekly or more often, as needed, to review human subjects research proposals. Investigators who submit proposals that require full-board review will be invited to attend the meeting. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting (see [45 CFR 46.108](#)).

A controverted issue is an issue discussed at an IRB meeting for which there is a disagreement between some IRB members or there are opposing viewpoints among IRB members that are voiced during the IRB's deliberations. In the absence of such disagreement or opposing viewpoints, it is unlikely that the discussion of an issue would be a discussion of a controverted issue. Federal regulations require a summary of controverted issues and their resolution to be included in IRB meeting minutes ([45 CFR 46.115\(a\)\(2\)](#)).

### **Pre-meeting distribution of materials to the IRB**

The Chair or IRB staff will forward the following information to all IRB members at least three days prior to the meeting.

- Agenda
- Protocol documentation for the protocols scheduled for review including the application and attachments, informed consent, advertisement, survey instruments, etc.
- Minutes from the previous meeting

- A report of research deemed exempt and those reviewed through expedited procedures, including continuing review.
- Any other materials for voting and/or discussion.

### **Meeting Minutes**

All full-board meetings require the taking of minutes. These minutes are created to enable a reader who was not present at the meeting to determine how and with what justification the IRB arrived at its decision(s). They are also intended to provide the IRB with sufficient detail to help it reconstruct its discussions at a later date, if necessary.

The meeting minutes include the following information:

- Which members attended the meeting and if quorum was met.
- Which IRB members were absent.
- Which members were recused from a vote for conflict of interest.
- Actions taken by the IRB.
- The vote on these actions, including the number of members for, against, and abstaining.
- The basis for requiring changes in or disproving research.
- A written summary of the discussion of controverted issues and their resolution.
- Frequency of required continuing review for research protocols.
- Documentation that the research meets each of the required criteria and the protocol-specific information justifying a waiver of some or all of the required elements of consent, or when waiving the requirement to obtain informed consent as specified in [45 CFR 46.116\(d\)](#)
- Documentation that the research meets each of the required criteria and the protocol specific information when approving or granting a waiver of written documentation of consent (i.e., a signed form) as specified in [46.117\(c\)](#).
- When approving research that involves populations covered by 45 CFR 46 Subparts B ([Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research](#)), C ([Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects](#)), or D ([Additional Protections for Children Involved as Subjects in Research](#)), the minutes will reflect the IRB's protocol-specific justifications and findings regarding the determinations stated in the Subparts or the IRB's agreement with the findings and justifications as presented by the Investigator in IRB forms.
- The minutes will reflect approvals of protocols by the full board that are determined to be minimal risk and that may use expedited review and approval for follow-up activity.
- The report of the chair of all expedited review activities.

The minutes are written impersonally, without attributing opinions and votes to specific members by a non-voting member of the IRB support staff. These minutes will be prepared and distributed within one month after a meeting, except for unusual and extraordinary circumstances. Meeting minutes will be considered accepted at the end of the first IRB meeting after the prepared minutes have been distributed, unless objections are raised by an IRB member.

Minutes will be retained for at least three years, and records relating to research that is conducted shall be retained for at least three years after the completion of the research. The IRB fulfills the federal regulatory requirement to notify the institution of its actions by providing on a



regular basis the minutes to the Dean, as Institutional Official. The Institutional Official also has access to the secure server on which the archival minutes are stored (see 45 CFR 46.115).

### **Records and documentation**

All IRB policies, records, and documentation are stored on an internal, password-protected server, located at [//storage/sciences/IRB](https://storage/sciences/IRB). Only members of the IRB, IRB support staff, and the Dean, as Institutional Official, have access to this server. All proposals, records, documentation, and copies of correspondence between members of the IRB and researchers are saved on that server as either Microsoft Word documents (e.g., .docx) or in Portable Document Format (.pdf). All records shall be accessible for inspection and copying by authorized representatives of the OHRP at reasonable times and in a reasonable manner.

The IRB maintains [an internal-facing webpage on GrinnellShare \(https://grinco.sharepoint.com/sites/academics/IRB/SitePages/Home.aspx\)](https://grinco.sharepoint.com/sites/academics/IRB/SitePages/Home.aspx). That webpage contains links federal guidelines, policies and procedures, a description of the review process, training in the protection of human research participants, and documents used to submit research for IRB initial and continuation review, as well as protocol modification. All documents on that webpage are provided in .pdf.

### **IRB Member Training**

The IRB Chair and its members are required to complete ongoing training in research ethics, the review of human subjects research, and the operation of a federally compliant IRB. Minimally, IRB members must complete the CITI IRB Members course and pass the accompanying tests with a score of at least 80% prior to serving on the IRB. In addition to the CITI IRB Members course, IRB Chairs are required to complete the CITI IRB Chair course and pass the accompanying tests with a score of at least 80% prior to serving as chair. These courses have an expiration date set four years after the successful completion of the test. Prior to that expiration date, IRB members and chairs must complete a refresher course in order to continue service on the IRB. Refresher courses are also available from CITI. Additional trainings may occur at convened IRB meetings, through webinars, or by attending professional conferences.

### **Chair duties**

- Is educated on current legal, ethical, and policy issues (e.g., reads and understands federal guidelines, views webinars or attends workshops) related to the ethical and federally compliant conduct of research and the operation of a federally compliant IRB.
- Ensures policies and procedures for IRB functioning are up to date.
- Ensures that proposal forms are available to investigators (via the internal-facing Web page).
- Ensures that proposals to [irb@grinnell.edu](mailto:irb@grinnell.edu) are received by the proper party (e.g., staff support) and filed on the storage server.
- Ensures that the participants have completed training in the protection of human research participants (verifies noncollege training is acceptable, assists staff support in verifying Grinnell training).

- Reports to the Dean by providing full-board meeting minutes and by writing and submitting an end of year report.
- Follows procedures for handling complaints from participants, research investigators, or fellow board members.
- Schedules IRB meetings and sets the meeting agenda.
- Keeps current with federal guidelines.
- Provides feedback to members on their work.
- Ensures that reviews are properly processed (e.g., that staff support sends proposals to board members, collects reviews, relays the reviews and decisions to investigators, and documents all to the server space).
- Provides updates to board members on the results of expedited and exempt reviews.
- Ensures that staff support appropriately update records of reviewed proposals (date submitted and approved, name of investigators, title of project, class of participants, level of risk, and any special notes).
- Solicits and reviews reports from research investigators of approved studies.
- Initiates and completes routine and for-cause audits.
- Coordinates and implements training for IRB members.
- Coordinates and implements outreach and training to the College community.
- Assigns duties, as needed.

#### **Vice Chair duties**

- Serves as Chair when the Chair is unable to perform assigned duties.
- Serves as Chair when the Chair is unable to review or vote due to conflict of interest.
- Conducts all exempt reviews and not human subjects research determinations.
- Coordinates with researchers to ensure their protocol proposals are complete.
- Assists the Chair with training of IRB members and support staff.
- Assists the Chair with outreach and training to the College community.
- Notifies Chair if unable to serve a period of time (e.g., vacation, conferences, illness).
- Participates in discussions of proposals, policy, and any issues confronting the board.
- Is educated on current legal, ethical, and policy issues (e.g., reads and understands federal guidelines, views webinars or attends workshops) related to the ethical and federally compliant conduct of research and the operation of a federally compliant IRB.
- Suggests ways to improve the efficiency of the IRB, its policies, and quality of proposals.
- Helps to answer questions from colleagues about IRB policies or research ethics.
- Assists the chair in for-cause audits.

#### **Members duties**

- Review all proposals within seven days or before scheduled IRB meetings, whichever is earlier.
- Notifies Chair if unable to serve a period of time (e.g., vacation, conferences, illness).
- Participates in discussions of proposals, policy, and any issues confronting the board
- Is educated on current legal, ethical, and policy issues (e.g., reads and understands federal guidelines, views webinars or attends workshops).
- Suggests ways to improve the efficiency of the IRB, its policies, and quality of proposals.

- Helps to answer questions from colleagues about IRB policies or research ethics.
- Assists the chair in for-cause audits.

### **Staff support duties**

- Checks [IRB@grinnell.edu](mailto:IRB@grinnell.edu) account twice daily during the work week. Notifies the chair when unable to do so.
- Processes all reviews: enters proposal and tracking information into Excel spreadsheet, creates folders on server space, sends receipt to PI, sends materials to board member (on rotating basis) for all but full board reviews (in which case all members receive proposal), and coordinates all correspondence that occur until the final decision, in which case staff support sends out the appropriate decision letter.
- Attends board meetings and takes minutes, saves minutes to storage server.
- Offers any support needed by the chair or members to maintain functioning of the board (e.g., reserve meeting rooms, arrange meetings, type or scan documents)
- Saves all email to [IRB@grinnell.edu](mailto:IRB@grinnell.edu) and logs information in proper way so outside auditor has access to all records.

### **Conflicts of interest (board members and Chair)**

Board members identify any conflict of interest (e.g., relationship with principle investigator) when they receive a proposal and do not vote on it. The Chair appoints Vice Chair to handle reviews on any proposal the Chair has a conflict. In such cases, the Chair can process expedited or full board reviews (e.g., save to storage server) but will not vote or exert influence on board members.

### **Expert advice**

The board has the right to ask others to review and provide consultation on proposals due to their expertise. The expert does not have voting power on proposal.

### **Requests from outside-of-the-college investigators for review**

Occasionally the Grinnell College IRB is asked to review a research project even though the investigator is not a student, staff, or faculty of Grinnell College. We do not offer review services for these projects.

Occasionally someone who is not a member of the Grinnell College community wants to use Grinnell College students, faculty, or staff as research participants, and they contact the Grinnell College IRB with the request for review or permission. The Grinnell College IRB does not review this research. Our college community is free to consent to participate in any research study conducted by investigators who are not Grinnell College community investigators without our review. If the outside investigator is looking for the contact information of Grinnell College faculty, students, or staff, that investigator will be referred to the Dean or Vice President of Student Affairs to accommodate that request.

The one exception to this prohibition is for recently graduated students who will be conducting research as part of a Fulbright, Watson, or some other similar award and where that

former student is not affiliated during the completion of that project with another institution that has a federally compliant IRB. In such cases, the Grinnell College IRB will offer to provide assistance for such research projects.

### **Multi-site studies or reviews**

Collaborative studies often involve two or more investigators at two or more colleges. The Grinnell College IRB is willing to accept the approval of other college's IRBs in lieu of an additional Grinnell College review. This acceptance will be contingent upon the completion of either an Individual Investigator Agreement (see [Guidance on Extension of an FWA to Cover Collaborating Individual Investigators](#)) or IRB Authorization Agreement. If the other college requires the Grinnell College IRB to conduct a review, that review will be provided. Documentation of training in the protection of human research participants would be required of all team members. The Grinnell College IRB forms should be used for Grinnell College IRB review.

### **IRB Authorization Agreements**

IRB Authorization Agreements are sometimes referred to as a Reliance Agreements, Cooperative Agreements, or Memoranda of Understanding. These agreements allow for the delegation of institutional review of research conducted by researchers at multiple institutions to a single IRB at only one of the institutions. The Dean, as Institutional Officer has delegated authority of review of these agreements with other institutions to the IRB. Upon review, the IRB will and make a recommendation to the Dean regarding the merits of entering such an agreement.

The Dean is responsible, as Institutional Officer for authorizing such agreements. In the absence of the Dean (e.g., on leave), the Dean will delegate authority to an Associate Dean for entering or refusing such agreements.

### **Transfer of previously approved protocols**

When the investigator is a new employee who has an IRB-approved and unexpired protocol from their previous employment (e.g., graduate school), they do not need additional approval from the Grinnell College IRB in order to continue their research. Approval from the IRB of the previous employer will be accepted, and the new employment status does not require Grinnell College IRB also review the project. If either the investigator or the previous employer's IRB requests the Grinnell College IRB to review the project, then that review will be provided, but the investigator must submit the proposal on Grinnell College forms and not that of the other institution. If the new employee designs a new study not reviewed by another IRB after their employment begins here, then the Grinnell College IRB requires a review of the new study.

### **Auditing investigators**

[Federal regulations](#) for compliance require IRBs to audit investigators and document that projects are being conducted as proposed. There are two types of audit, routine and for-cause.

Both types of audits use systematic methods to evaluate compliance with federal regulations, state and local laws, and College policies and procedures. They also seek to verify that research is conducted in accordance with the IRB approved protocols. The procedures for conducting audits are described below in the procedures section of this document.

Procedures for initiating a routine audit. The IRB Chair or designee selects an investigator or study for a routine audit based on criteria which includes, but is not limited to, studies involving procedures that are greater than minimal risk to participants, studies involving vulnerable populations, drug or device studies, and investigators conducting a large number of studies.

Procedures for initiating a for-cause audit. The IRB or IRB subcommittee may direct the IRB Chair or designee to conduct an audit in response to a particular concern. Concerns which may prompt a for-cause audit include, but are not limited to the following: complaints or concerns made by a research participant, family member of the research participant, research team member, or an employee of the College; reports of audits or monitoring conducted by other committees affiliated federal agencies, data and safety monitoring committees, or other agencies involved in the conduct of a study.

### **Reporting unanticipated problems**

If an investigator encounters unanticipated problems regarding risks to participants, the investigator should immediately report these problems to the IRB Chair. OHRP defines unanticipated problems as: “unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized” (see Guidance [here](#)). In addition, investigators are required to report violations of regulations protecting human participants. The IRB Chair will convene a panel to determine what steps should be taken, including possible suspension or termination of the research. Serious harm that occurs to participants will also be reported to the Dean, along with the recommendation of the IRB. Unanticipated problems that result from a research conducted or supported by HHS also will be reported promptly to OHRP.

### **Changes in protocols**

Researchers who want to make significant changes in a previously approved protocol must obtain prior permission from the IRB. Those proposed changes must be submitted to the IRB using the Protocol Modification Form.

**Subsequent reviews**

The IRB will review all continuing research that it approved on an annual basis. Depending upon the degree of risk to research participants, review may take place more frequently. At a minimum, researchers will be required to update the IRB on the implementation of their proposed research plan once per year but no later than the study's expiration date. In addition, Grinnell College IRB approves research for up to one year at a time. If a project is expected to last beyond that one-year window, researchers are required to complete a Continuation Proposal Form that enables investigators who ask for extensions to document that no harm has come to participants, report any new information that may impact the willingness of a volunteer to participate in the research, and to note any changes that may warrant additional review. This continuation proposal must be reviewed prior to the study's expiration date.

## **Policies Governing the Conduct of Research**

### **Investigators' responsibilities**

Investigators acknowledge and accept their own responsibilities for protecting the rights, privacy, and welfare of the human participants. The application submitted to the Grinnell College IRB for review must demonstrate full compliance with federal, state, and College regulations and with all components of the Grinnell College Federal-Wide Assurance for the protection of human participants in research.

### **Maintaining records**

Once Grinnell College IRB approval has been obtained, investigators must maintain updated records to include the initial application, approval letter(s) from the IRB, modifications requested and approved, continuation or re-approval progress reports, instruments completed, consent forms administered and signed, correspondence related to the study, adverse event reports, if any, etc. These records must be maintained for review or audit by the Grinnell College IRB for a minimum period of three years after official closure of the study. In the case of student investigators, the sponsor or sponsoring department must maintain the records.

### **Protocol submission, continuation, and revision**

Using the Grinnell College IRB Proposal Form for Research with Human Subjects, investigators must present the study's purposes, rationale, design and methods are clearly stated and are scientifically sound;

- the protocol conforms to the norms, ethical standards and methods of procedure of the scholarly discipline;
- the proposed study involves no known risks to human participants other than those specified;
- the principal investigator and other researchers are qualified to conduct the proposed study and have completed training in the protection of human research participants;
- the study facilities and resources are adequate for the safe conduct of the research;
- and the participant population, sampling procedures, and data to be collected are justified and adequate to meet study objectives.

All amendments and modifications, including changes in personnel, to a study need Grinnell College IRB approval before they are implemented. If the investigator wants to change *anything* in the research that would impact the participants, such as recruitment procedures, key personnel, inclusion/exclusion criteria, research procedures, the informed consent document / process, or data elements collected, the investigator must obtain Grinnell College IRB review and approval prior to implementation of the changes. The only exception are changes necessary to immediately protect participants' safety. If an investigator is unsure about reporting changes to the IRB, they should contact the Grinnell College IRB chair and ask for guidance. The Grinnell College IRB can also provide investigators with instructions for submitting a request to modify an IRB-approved research.

### **Progress Reports**

Progress reports for non-exempt research that have previously received an approved extension must be submitted in writing to the IRB using the Progress Report Form by the end of their approval period. If all research-related interventions or interactions with human subjects have been completed, and all data collection and analysis of identifiable private information described in the IRB-approved research plan have been finished, then the human subjects research study has been completed. When a human subjects research study has been completed, the investigators no longer are required to obtain continuing review and approval of that study by the IRB. At that time, the investigators should file a Progress Report Form to notify the IRB of the study's completion.

### **Changes in research personnel**

Changes in research personnel must be submitted to the IRB using the Modification Form. These changes will be reviewed using the procedures outlined for subsequent reviews.

### **Unanticipated problems, adverse events, and complaints**

Federal regulations require investigators to report unanticipated problems, adverse events, and complaints to the Grinnell College IRB in a timely fashion.

The Department of Health and Human Services (HHS) defines these terms as follows (also see guidance [here](#)):

- Unanticipated problem: “unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; related or possibly related to participation in the research; and suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.”
- Adverse event: “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. 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.”

Under these federal requirements, investigators must report to the Grinnell College IRB in writing the nature of the problem within five working days of the occurrence by submitting an Unanticipated Problems and Adverse Events form. In addition, any injury or physical or emotional harm to a participant must be reported immediately to the IRB. Other examples include, but are not limited to, a breach in confidentiality or privacy, problems with recruitment and/or the consent form process, noncompliance with federal regulations or Grinnell College IRB policies, complications or complaints occurring during the research, or any other problem that presents changes in the risk-benefit ratio and affects the rights, welfare, and safety of



participants. A separate report must be filed for each incident summarizing the problem or event encountered along with a statement by the investigator indicating whether a change in the protocol and/or consent form is warranted and whether, in the investigator's opinion, the adverse event was related to the research activity. The IRB has authority, under [45 CFR 46.109\(a\)](#), to require, as a condition of continued approval by the IRB, submission of more detailed information by the investigator(s) about any adverse event or unanticipated problem occurring in a research protocol.

HHS advises IRBs to review this information. In doing so, IRBs are charged with considering whether the affected research protocol still satisfies the requirements of the IRB under [45 CFR 46.111](#). In particular, the IRB will consider whether risks to participants are still minimized and reasonable in relation to the anticipated benefits, if any, to the participants and the importance of the knowledge that may reasonably be expected to result. Any proposed changes to a research study in response to an unanticipated problem also must be reviewed and approved by the IRB before being implemented, except when necessary to eliminate apparent immediate hazards to subjects.

Unanticipated problems or adverse events occurring in research covered by our OHRP FWA also must be reported by the institution to the supporting HHS agency head (or designee) and OHRP ([45 CFR 46.103\(a\)](#)). To satisfy this requirement the Chair will notify the Dean of the Unanticipated problem or adverse event and of the intention to file an official report to HHS and OHRP by contacting the Director of the Division of Compliance Oversight (see [here](#) for additional guidance). Reports also will be filed with sponsoring agencies requiring such reports. In accordance with OHRP guidance, these reports will be filed within days of a more serious incident and within a few weeks for less serious incidence. The problem also will be noted in the IRB's end-of-year report.

### **Informed Consent**

If the research is approved by the IRB, investigators must obtain documented and legal informed consent from all research participants involved in each protocol, unless the Grinnell College IRB has granted a waiver, exception, or alteration as provided for in the federal regulations. The IRB cannot grant a waiver of informed consent if either the Family Educational Rights and Privacy Act (FERPA; 20 U.S.C. § 1232g; 34 CFR Part 99) or the Health Insurance Portability and Accountability Act of 1996 (HIPAA; Pub.L. 104–191, 110 Stat. 1936) is applicable.

### **Training in the Protection of Human Research Participants**

The policy of the Grinnell College IRB is that all faculty, staff, and students involved in research with human participants complete training in the protection of human research participants (PHRP). Grinnell College offers such training through a series of educational modules hosted by the Collaborative Institutional Training Initiative (CITI; [www.citiprogram.org](http://www.citiprogram.org)), but the College IRB accepts other approved training (e.g., National Science Foundation) where documentation can be provided to that effect. Instructions on how to

access and complete the appropriate CITI required modules are found on the Grinnell College IRB's GrinnellShare website.

The Grinnell College modules locally hosted on PioneerWeb will no longer be available starting August 1, 2016, and that training will no longer be accepted starting August 1, 2017.

The IRB requires those who oversee the IRB in the administration (e.g., Dean, Compliance Officer) should have PHRP training as well, in order to assist the board in forming and upholding the institution's policies.

#### *Types of Training for Faculty and Staff*

All faculty and staff who wish to conduct research with human participants will be required to complete PHRP training that includes the following topics: the Belmont Report, ethical principles, definition of human subjects, the federal regulations related to human subjects research (e.g., 45 CFR 46), assessment of risk, required provisions of informed consent, the distinctions between privacy and confidentiality, how to handle unanticipated problems and the reporting requirements for social and behavioral research, cultural competence in research, and conflicts of interest in research involving human subjects. Each of these topics is covered by the CITI program called Basic Social-Behavioral-Educational (SBE) Modules.

Additional training may be required by the IRB depending upon the research populations studied or methods employed. The CITI program is set up to provide these additional required training and include the following topics: HIPAA privacy protections, research with prisoners, research with children, research in public elementary and secondary schools, international research, research about gender and sexual diversity, research regarding illegal activities or undocumented status, research involving participants at the end of life, research with critically ill subjects, research with decisionally impaired subjects, research with persons who are socially or economically disadvantaged, research with persons with physical disability and impairments, research involving workers or employees, students in research, internet-based research, community engaged research, community-based participatory research, remuneration, and external IRB review.

The CITI program requires the completion of participants to complete a test at the end of all modules. Grinnell College requires that researchers correctly respond to a minimum of 80% of these questions prior to PHRP training acceptance.

#### *Types of Training for Students*

Student researchers who wish to conduct research with human participants will be required to complete PHRP training that includes the following topics: Belmont Report, ethical principles, required provisions of informed consent, the distinctions between privacy and confidentiality, and cultural competence in research. Additional modules may be required by the IRB depending upon the research population studied and methods employed.

The CITI program requires the completion of participants to complete a test at the end of all modules. Grinnell College requires that researchers correctly respond to a minimum of 80% of these questions prior to PHRP training acceptance.

### *Expiration and Refresher Courses*

All PHRP trainings expire four years after successful completion. This expiration applies to all trainings regardless of source (e.g., CITI, NSF). Prior to expiration, researchers are required to complete a refresher course. Grinnell College has a subscription to such refresher courses through the CITI program. These courses include a subset of the topics listed above and are only available to those who have previously completed the full CITI SBE course. CITI will prompt those users at least one month prior to the expiration of their PHRP training. Successful completion of the refresher training will remain valid for four years.

### *Grace Period for former training through Grinnell College*

Prior to August 1, 2016, Grinnell College hosted their own PHRP training modules on PioneerWeb. Those modules will no longer be accepted by the Grinnell College IRB starting August 1, 2017. Before that time, Grinnell College faculty, staff, and students are strongly encouraged to complete the CITI SBE training.

## **Conflicts of interest (investigators and College)**

To help the IRB determine investigator conflicts of interest (e.g., if an investigator has a grant to study smoking from a tobacco company), the protocol proposal form asks the investigator to identify their source of funding and any known conflicts of interest (e.g., Financial, Conflict of Conscience). If the Grinnell College IRB has concerns about the conflict of interests of investigators, it may require the conflict to be noted on consent forms, require modified procedures (e.g., require another investigator to handle the data analysis or data collection), or under extreme conditions reject the proposal. The Grinnell College IRB has the right to reject a proposal that the College wants approved (e.g., institutional conflict of interest). The College cannot exert power over the Grinnell College IRB because of conflict of interest. The College may restrict a project further than the Grinnell College IRB stated in its approval.

If the researcher learns of a new conflict of interest after initiating an approved protocol, that researcher is required to notify the IRB in writing using a Modification Form within 14 days of that discovery.

Researchers are directed to the CITI modules on conflicts of interest for more information on reporting requirement. Additional information about different federal agency's (e.g., NIH, NSF, FDA) requirements related to conflicts of interest are linked at the bottom of the CITI modules

## **Research by Students**

### *Classroom projects*

Classroom activities may or may not be considered "research" as defined by federal regulations, depending upon the nature of the work. In general, it is the policy of the Grinnell College IRB that projects undertaken solely as part of a classroom assignment are usually not classified as research, and thus will typically not require IRB review. Title 45 CFR 46, also known as the "Common Rule," defines research as a systematic investigation designed to

develop or contribute to generalizable knowledge. The purpose of most classroom projects is to help students learn the process of doing research, rather than to actually contribute to generalizable knowledge, and thus such projects fall outside the scope of IRB review. Still, faculty advisors and students are strongly encouraged to follow Grinnell College IRB policies when designing and conducting class projects and assignments involving human volunteers or respondents, and to exercise appropriate care to protect human subjects. Training in the protection of human research participants through the assignment of CITI modules is also encouraged. Although class projects may not meet the formal definition of research under federal guidelines, investigators should be aware that they represent Grinnell College when carrying out their studies and should thus exercise the highest ethical standards. If faculty members have questions about a particular project or assignment, they are encouraged to contact a member of the IRB for guidance.

#### *Student Researchers and Faculty Responsibility*

Although most work by students does not require IRB review, two types of student work will often require IRB involvement.

1. Work conducted as part of the Mentored Advanced Project (MAP) program and through independent research (Catalog number 299 or 399) is often intended to be shared in off-campus forums, and so may be more likely to contribute to generalizable knowledge. Thus, perhaps most MAP projects and many independent research projects involving human subjects should be submitted for IRB approval. If investigators are uncertain about whether to submit a particular project, they should contact the IRB chair for guidance.
2. Class projects that involve vulnerable populations or greater than minimal risk require IRB approval. Vulnerable populations may include but are not limited to elderly persons, persons with physical or mental disabilities, pregnant women, prisoners, and children. In particular, most exemptions in the federal regulations do not apply to studies with these populations. The Grinnell College IRB will work with investigators to ensure that studies involving vulnerable populations or greater than minimal risk meet the appropriate guidelines.

#### *Students and Principal Investigators*

Students may be a principal investigator (PI), but they must have a staff or faculty supervisor. In addition to the student's own training in research ethics (see section on Training in the Protection of Human Research Participants), the supervisor must be trained in research ethics and be willing to take responsibility for the competent and ethical conduct of the research project by the student PI. Oversight of student projects may require the faculty or staff supervisor to provide training and assess the student's competence in specific research methodologies with specific human subject populations prior to the initiation of the project. CITI training modules are available to assist in the ethical conduct of research with many human subjects populations and are strongly encouraged prior to the initiation of all student research projects.

#### **Incentives, Compensation, and Reimbursement of Expenses Associated with Participation**

The IRB is responsible for the review and approval of participant payment arrangements offered to a participant or family, as part of a research protocol. The IRB will permit

reimbursement to participants for expenses related to travel, time or inconvenience and will permit compensation for study participation when the compensation is considered fair, honest and appropriate. For studies that involve greater than minimal risk, the IRB will apply a “Wage” model for determining fair and appropriate compensation (see below).

### *Definitions*

**Incentives:** Incentives are low value payment instruments and/or goods given to participants to entice them to engage in a research study. Incentives include gift cards, gift certificates, intrinsic personal property, and other items of value less than \$20.00.

**Compensation:** Compensation is a payment to research participants provided during or after engaging in the covered research activity. The researcher is compensating the participant for time and services related to a given study. Compensation may include gift cards, gift certificates, personal property, and other items of value.

**Reimbursement of Expenses:** Reimbursement is a payment to research participants for expenses incurred as a result of research participation, such as lodging, travel expenses, parking, childcare fees, or meals. Payments of these types should be designed to offset actual anticipated expenses so as not to create an undue inducement.

### *Researchers' Responsibility*

Researchers are encouraged to provide compensation and reimbursement for research-related visits. Actual compensation and reimbursement may require participants to provide copies of receipts (see *Tax Implications* below). These costs can and often should be added to the incentive amount paid to participants.

Researchers are responsible for ensuring that the risks to human participants are reasonable in relation to benefits [45 CFR 46.111(a)(3), 45 CFR 46.116] and that the consent process and the consent document provide an adequate description of the study procedures as well as the risks and benefits.

Payments to research participants for participation are not considered a benefit of participation. The amount and schedule of all payments should be presented to the IRB at the time of initial review. The IRB will review both the amount of the payment and the proposed method and timing of reimbursement to assure that neither are coercive or present undue influence.

Any credit for payment should accrue as the study progresses and not be contingent upon the participant completing the entire study.

- Investigators are encouraged to implement a prorated system of payment for studies involving several tasks or visits. In this way, participants who do not finish the study are paid in proportion to the part completed. While a small bonus for completion might be acceptable, large bonuses or withholding of payment until the end of the study are not.
- Prorated payment may not be appropriate for all research activities. As 45 CFR 46.116(a) requires that participants' voluntary refusal to participate or discontinue participation involve

no penalty, the IRB will require full payment for participants' partial completion of surveys or questionnaires or for "inadequate" participation in group discussions.

While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion of the study is acceptable, provided that such incentive is not coercive. The IRB will determine that the amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn. All information concerning payment, including the amount and schedule of payment(s), should be set forth in the informed consent document.

For research involving minors, researchers must specify whether the payment is provided directly to the minor participant or to the legal guardian.

#### *Wage-Payment Model*

For studies involving greater than minimal risk, the IRB will determine the amount of payment to participants by using a standardized hourly wage and an estimated time for completing the research task. The amount of payment may depend on the level of anticipated risk. Payments for adults should be based on a wage-model, calibrated to the least well off amongst anticipated study participants. Payments to children nine years and older should be based on a wage-model, with the wage scaled to those that children can actually earn for common jobs such as baby-sitting or snow shoveling. Payments for children younger than nine years should be either non-monetary or based on tokens of appreciation.

#### *IRB Determinations*

The IRB will make the following determinations related to incentives, compensation, and reimbursement during a research protocol proposal.

1. Payment offered for participation does not constitute undue influence
2. Payment offered is reasonable, given the complexity and the inconvenience of the study.
3. Payment is made on a schedule appropriate to the length or intensity of the study.
4. Credit for payment accrues as the study progresses and is not contingent upon completion of the entire study.
5. Any amount paid as a bonus for completion is reasonable and not so large as to unduly influence participants to stay in the study when they would otherwise have withdrawn.
6. The payment described in the protocol, the recruitment documents and the consent form are consistent and complete.

#### *Tax implications*

Monetary incentives and compensation of any value and tangible incentives (e.g., water bottles, sweatshirts) with a value of \$50 or greater constitute taxable income for U.S. residents and non-residents. The participant's residency status and relationship to the College will determine the method of payment and documentation needed to process payments.

#### US Citizens or Residents

Participants must file the Federal W-9 and the Iowa Centralized Employee Registry forms with the Accounting Office.

For participants actively employed by the College, incentive payments are taxed through payroll and reported as income on Form W-2.

For participants not actively employed by the College, incentive payments are reported on Form 1099-MISC at the end of the calendar year if total income is over \$600 (wages from campus employment is reported separately on Form W-2).

#### Non-Residents

Participants must file the Federal W8-BEN form with the Accounting Office (note: the Accounting Office may already have this form on file for most international students).

All income is taxable and is reported on Form 1042-S at the end of the calendar year. If taxes cannot be withheld from the incentive payment, the College budget paying for the incentives will be charged for the federal tax.

#### Required Documentation from Researchers

A disbursement log should be maintained and submitted to the Accounting Office within seven (7) days of distributing the incentives.

The disbursement log should include the following information:

- Participant Name (printed legibly)
- College ID # (if applicable)
- Date incentive is paid
- Amount (or value) of incentive
- Description of incentive: cash, gift card or other (if other – please describe)
- Participant Signature (verifying receipt of incentive payment)

Researchers may be required to absorb costs for incentives where documentation is incomplete or not provided. The College, researcher and research participants have a responsibility to document and report payments received from sponsored programs to the Internal Revenue Service.

#### Personally Identifiable Information

Research participants should be informed that any personal data collected for tax purposes is needed for the College to meet government reporting obligations. This disclosure should occur during the informed consent process. The researcher and the College take the necessary precautions to keep any personal information secure. Participants may be given the opportunity to participate without receiving payment if they do not wish to provide personally identifiable information.

The collection of personally identifiable information for tax purposes, such as Social Security Numbers, should be collected only when necessary. If collected, that data should be stored separately from other research records, unless that information is essential to the approved research questions and data analytic strategy to answer those questions. Destroy all personally identifiable information as soon as feasible.

## Data security

### *Definitions*

Anonymous data: data that by virtue of the method of collection can *never* reasonably be connected with the person providing them. Anonymous data can be obtained by using questionnaires that are returned by mail (in envelopes with no return address or other identifying markers), questionnaires that are collected by one of a group of participants and returned to the researcher, or Internet surveys (with software that renders it virtually impossible to connect answers with respondents). Questionnaires that collect data anonymously do not require separate written consent; consent to use the data is implied when the respondent completes the questionnaire (a statement that explains this principle should be printed at the beginning of any such survey). *See also non-anonymous data.*

Non-anonymous data: data that, by virtue of how it is collected or the nature of the information, can be connected at some point, no matter how brief, to the person providing them. This category includes questionnaires that the researcher collects personally from a group of subjects (unless a ballot box or envelopes are used). It also may include cases in which the researcher can recognize the handwriting of one or more of the subjects and could therefore potentially match the data with a specific respondent. *See also anonymous data.*

Confidential data: non-anonymous data that a human participant gives an investigator with the understanding or assumption that the participant's privacy will be honored. Divulging the source of non-anonymous data to an outside party, or failing to ensure that no outside parties will be able to connect data with their source, normally constitutes a violation of confidentiality. This IRB presumes that all data collected from human subjects is properly considered confidential, unless subjects have explicitly waived their presumption of confidentiality in writing.

Privacy: control over the extent, timing, and circumstances of sharing personal information about oneself with others.

### *Investigator Responsibilities*

Investigators must respect the privacy of their participants. Investigators must protect confidential information given to them and must advise participants in advance of any limits on their ability to ensure that the information will remain confidential.

### *Stewardship*

Each Data Set will have identified data stewards. In most cases, the principal investigator will serve as the data steward. In the event that someone other than the principal investigator will serve as the data steward, that information should be provided on the protocol proposal form.

Data stewards are responsible for the managing, classifying, and assigning the correct level of access to the data. Data stewards must ensure that the policy is enforced for their data set, and that the appropriate confidentiality, integrity, and availability of the data are maintained. As data are developed, data stewards assure that storage of and access to the data is appropriately managed.



Individuals with access to data have been granted a level of trust by the data stewards and as such are responsible for upholding the security and integrity of the data to which they have access, and should be aware of best practices in secure data management.

If the data gathered by a student researcher is non-anonymous, the IRB recommends that the data be turned over to the faculty sponsor, who then becomes the data steward and responsible for either ensuring that it is destroyed or archiving it with their existing data. In cases in which a student is planning to go on to graduate school and may want to continue the research or use the data in future projects, the student may request permission from the IRB to retain the data. Permission is contingent on the student's agreement to protect the confidentiality of the data.

#### *Data Security Levels*

At the time of review, the IRB will assign one of three data security levels based on the sensitivity of the data. Each data security level outlines specific measures the principal investigator should take in order to protect participant data.

*Level 3 – Extremely Sensitive Data.* Extremely Sensitive Data is defined as all data that is regulated by law (e.g., the Health Insurance Portability and Privacy Act, Federal Educational Rights and Privacy Act). Extremely sensitive data also includes data that, if disclosed in a breach, could result in serious social, psychological, reputational, financial, or legal harm to research participants, reputational loss to the College, or punitive action toward the researcher or the College. This data classification includes Social Security numbers, financial account numbers, account and ID numbers (driver's license numbers, personal ID numbers). In addition, Extremely Sensitive Data may include information which, when used in various combinations, can be associated with an individual:

- Name
- Date of Birth
- Home address
- Email or phone number
- Mother's maiden name
- Vehicle license number
- Health information
- Employment history
- Class Schedules
- Academic Actions
- Grade Point Averages and Transcripts
- Passport Numbers
- Payment Card Data

Safeguards for Extremely Sensitive Data should include an approved enterprise storage location and regular monitoring and auditing of access to Extremely Sensitive Data. Additionally, access should be limited to only those who have a legitimate need to use Extremely Sensitive Data. Transmission of Extremely Sensitive Data outside of a Grinnell-approved enterprise storage location requires both encryption and verification of the identities of the

recipient. Any Extremely Sensitive Data transmitted from the enterprise storage location should be done in such a way that it cannot be modified. Extremely Sensitive Data should not be stored unencrypted in cloud solutions (e.g., iCloud, Dropbox), particularly those not contracted by the institution. Extremely Sensitive Data should have a retention timeline and should be destroyed when no longer in use and when legally permissible.

Data Stewards should conduct regular audits of access to extremely sensitive data to ensure appropriate access.

Data stewards will work with ITS to ensure that appropriate technologies are available to provide adequate safeguards for Extremely Sensitive Data while ensuring the availability for appropriate use. Data stewards will also work with ITS to ensure that ITS staff access to that data is restricted during routine technology maintenance.

*Level 2 – Sensitive Data.* Sensitive Data is data that, while not protected by state or federal law or regulatory standards, might impact Grinnell's reputation or result in a civil action against the institution, should it be breached. A breach of this type of data may also result in moderate social, psychological, reputational, or financial harm to research participants. Examples of this type of information include, but are not limited to personnel records, financial information, personally held attitudes and beliefs, and some performance metrics.

Access to Sensitive Data should be limited to data stewards and only those members of the institution to whom data stewards have granted access. The data stewards should conduct regular audits of Sensitive Data to ensure appropriate access. Access to Sensitive Data should be needs based, with the needs assessed by the data stewards.

Safeguards for Sensitive Data should include password-protected electronic devices (e.g., computers, audio or video recorders) or locked data storage facilities where the data steward restricts access.

#### *Level 1 – Public Data*

Public Data is considered to be any data that does not fall into the Extremely Sensitive Data or Sensitive Data classes. The disclosure of Public Data does not pose a risk to the participant or the institution. Public Data may be publicly accessible but does not require public access. There are no restrictions on the storage or distribution of Public Data. Examples of public data include, but are not limited to benign research information, research data that has been de-identified in accordance with applicable rules/laws, and published research.

#### *Other applicable laws*

This policy does not supersede any other local, state, or federal law regarding data security, specifically the Health Insurance Portability and Privacy Act (HIPAA; <http://www.hhs.gov/hipaa/>) and the Federal Educational Rights and Privacy Act (FERPA; <http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html>), or any other data use agreements that require greater data security than those listed above.

## **International research**

Research conducted outside the United States by Grinnell College investigators remains under the College IRB's purview and guidelines. Though the IRB will not impose Code of Federal Regulations standards for written documentation on other cultures, the IRB will not relax standards for ethical conduct of research or for a meaningful consent and/or assent process.

Special attention should be given to local customs and to local cultural and religious norms in drafting recruitment materials, written consent documents, and data collection instruments. When it is appropriate the IRB will consider alternative consent formats, if culturally appropriate. In some instances it may be appropriate for the IRB to waive some or all requirements for written consent in favor of a verbal consent for cultural or religious reasons. Research proposals for which this may be reasonable should include explanations of cultural norms or conditions requiring such as waiver (e.g., societies where no written language is used, societies where signatures represent the surrender of spirit or soul to the researcher).

Where appropriate, research projects must have been approved by the local equivalent of an IRB before they are presented to the College IRB. Where there is no equivalent board or group, investigators are expected to consult with local experts or community leaders about the project and to secure their support for the conduct of the research. The IRB does require that there be good faith effort applied to secure local cooperation for the research and to document those efforts as part of the application.

Local customs with regard to minors are often in conflict with standards used in the United States. With all due sensitivity for local customs, minors who are treated as adults in their own country will be treated as minors for the purpose of protection in research. However, the definition of who may provide 'parental permission' to participate may appropriately be adjusted based on cultural norms. It is possible, that grandparents or even tribal leaders may be the cultural head of household and may ethically serve as the designated guardian for a minor participating in research. The cultural norms in question must be identified in the proposal and the exception to policy anticipated.

OHRP publishes the [International Compilation of Human Research Standards](#), a listing of over 1,000 laws, regulations, and guidelines on human subjects protections in over 100 countries and from several international organizations. This document should be consulted to determine country level guidelines on human subject research.

## **Research involving victims of sexual assault and abuse**

Grinnell College employees, faculty members, and certain student leaders are required to report disclosures of sexual misconduct to the Title IX Coordinator. Sexual misconduct includes, but is not limited to: sexual harassment, sexual assault, partner violence, dating violence, relationship abuse, stalking, gender-based harassment, unwanted touching, and quid pro quo. A narrowly defined exception to these reporting responsibilities exists for specific types of research regarding sexual misconduct. That exception is described in the Grinnell College policy titled, *Research Exemption to Reporting Responsibility of Employee* and located online at

<http://www.grinnell.edu/sites/default/files/documents/GUIDE%20Sexual%20Misconduct%20Prevention%20Response%20Guide%2002.2016.pdf> or [here](#).

In addition to its normal research oversight functions, that policy requires the Grinnell College IRB to review and approve researchers' trauma-informed training to support survivors and victims of sexual misconduct. To facilitate that review, researchers who intend to conduct human subjects research on topics related to sexual misconduct are required to complete the Application for Waiver of Mandatory Reporting Requirement form. This application must be submitted along with the standard protocol proposal form.

## **Procedures**

### **Nature of reviews**

There are three federally-defined levels of review: exempt, expedited, and full. All three levels require an IRB proposal to be submitted and documented. Approvals are valid for a maximum one year minus one day period, according to federal regulations.

Federal regulations require the IRB to conduct "continuing review" of ongoing (non-exempt) research, including multi-year studies, no less than annually. The IRB sets the next review date at the time of initial approval based primarily on the degree of risk of the study: the higher the risk, the earlier the IRB may set the expiration date of the initial approval. Other factors include the nature of the study and the vulnerability of the participant population. The IRB notifies the investigator of the expiration date for "re-approval," and a reminder notice is sent to the investigator at least one month in advance of the actual date.

The IRB makes every effort to conduct reviews within 14 days from initial submission.

### **Exempt reviews**

The IRB Vice Chair is responsible for all preliminary reviews (e.g., determination of not human subjects research) and exempt determinations. Research activities that involve human participants in one or more of the following ways are exempt from IRB review.

- Category 1 (45 CFR §46.101(b)(1)) includes 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.
- Category 2 (45 CFR §46.101(b)(2)) includes 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.

- The exemption at §46.101(b)(2) for research involving survey or interview procedures or observations of public behavior with children does not apply, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.
- Category 3 (45 CFR §46.101(b)(3)) includes 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 Category 2 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.
- Category 4 (45 CFR §46.101(b)(4)) includes 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.
- Category 5 (45 CFR §46.101(b)(5)) involves research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- Category 6 (45 CFR §46.101(b)(6)) involves taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Generally, exemptions do not apply to:

- research involving prisoners, fetuses, pregnant women, human in vitro fertilization, the mentally disabled, or for certain research involving surveys or interviews of children except where the research involves only educational tests and observations where the investigator does not participate in or manipulate the activities being observed.
- surveys, interviews, or observations involving sensitive topics (such as drug abuse, sexual behaviors, etc.) where there is a link or code between the information and the participant;
- studies in which a participant can be identified (directly or indirectly) and disclosure of the participant's responses outside of the research could result in risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation.

Only the Grinnell College IRB may determine whether a study or research protocol qualifies for exemption, so the investigator must file a Grinnell College IRB Review application. As part of the narrative, the investigator must identify and explain which federal exemption [from 45 CFR 46.101 (b)(1-6)] applies to the proposed research. In addition, the investigator should attach any interview guides, survey questions or other instruments to be used in the gathering of information. The Grinnell College IRB will evaluate the application and notify the investigator in writing as to the determination (using the exemption letter template).

A determination that research is exempt does not imply that investigators have no ethical responsibilities to participants in such research; it means only that the regulatory requirements related to IRB review, informed consent, and assurance of compliance do not apply to the research. Further, a claim of exemption in the application does not necessarily exempt investigators from the requirement of gaining consent or permission from participants.

Research activities in which the only involvement of human participants fits one or more of the categories listed above may qualify for exemption from review. These exempt categories do not apply to research involving deception of participants where the investigator does not disclose the true purpose of the research and/or the results of the participant's participation in the study.

### **Expedited reviews**

One board member, designated as the primary reviewer, expeditiously reviews proposals with minimal risk and nonvulnerable participants. A complete list of categories of activities eligible for expedited review may be found at: <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html>. In addition, the reviewer will consider the following questions when deciding whether or not to approve the research protocol and ensure the requirements for approval at [45 CFR 46.111](#) have been met.

- Have the risks (psychological, physical, social, and economic) to participants been accurately identified, described, and minimized?
- Are the risks reasonable in relation to benefits (participants, societal, educational)?
- Is the selection of participants equitable, avoiding exploitation, exclusion, overprotection?
- Are adequate procedures in place to respect privacy and ensure confidentiality?
- Has appropriate informed consent been sought and documented? Is the consent process documented (including debriefing, appropriate language, voluntary nature of project, risks and benefits, and contact information)?
- If there are any special factors (i.e., vulnerability), has the investigator explained details in the proposal (i.e., precautions, debriefing, and permissions)? Have additional safeguards been included in the study to protect the rights and welfare of vulnerable subjects?
- Has the investigator (and student's supervisor) completed training in the protection of human research participants?

In reviewing the research, the reviewers may exercise all of the authorities of the IRB except disapproval of research (45 CFR 46.111). Revisions may be requested based on the review. If a determination is made to approve the study, that determination with the corresponding rationale is conveyed to the IRB Chair or designee as a secondary check on the rationale for approval. If the Chair or designee determines approval is warranted, that approval is sent to the investigator using an expedited review letter. In the event that the Chair does not agree with the rationale for approval, the proposal will be moved to a full board review.

**Full board reviews**

The Chair (or designated substitute) forwards to the board any proposal that does not receive exempt status or an approval through expedited review for full board review. Criteria for approval involve consideration of risk, informed consent, vulnerabilities of participants, and protection of privacy and storage of the data.

Final vote of full board reviews is determined by majority vote when a quorum has been obtained. In order for approval, the majority must include at least one nonscientist. Should there be a tie with votes, the Chair will be the deciding vote. Investigators are informed of the no-vote member's concerns and, if possible, offered an opportunity to revise their proposal in light of those concerns. Revisions that address the modifications requested by the board are reviewed by the Chair who decides whether the revision meets the board's concerns. If there is doubt that it has, the chair sends it back to either the full board or to the member who made the requested revision for their review. Approval is sent with the full-board review letter.

The IRB makes every effort to conduct full board reviews within 14 days from initial submission. Deadlines will be posted a full semester in advance of all Grinnell College IRB meetings so that students and supervisors can plan to have the full board review completed prior to the start of the research project.

**Subsequent reviews**

The IRB will review all continuing research that it approved through expedited or full board procedures prior to the protocol's expiration date. Depending upon the degree of risk to research participants, review may take place more frequently. If a project is expected to last beyond that one-year window, researchers are required to complete a Continuation Proposal Form that enables investigators who ask for extensions to document that no harm has come to participants, report any new information that may impact the willingness of a volunteer to participate in the research, and to note any changes that may warrant additional review.

To apply for continuation of the research, the investigator submits a Grinnell College IRB Continuation Form, which is a progress report requesting re-approval. By completing this report the investigator also informs the Grinnell College IRB of the status of the research project, including:

- progress toward completion, including status of participant enrollments;
- difficulties encountered, if any;
- adverse events summary, if applicable;
- unanticipated problems involving risks to participants or the withdrawal of participants;
- a copy of the informed consent document currently in use for the study; and
- updated conflict of interest forms for investigators.

The IRB Chair or one or more experienced reviewers designated by the IRB Chair will conduct initial review of continuing research under an expedited review procedure. During this initial and expedited review, the Chair or designated member will determine if the protocol continues to qualify for expedited review. If a determination is made that the protocol no longer qualifies for expedited review, the Chair or designated member will forward the Continuation

Proposal Form and any additional documentation to the rest of the IRB for review at a convened meeting. The procedures used to review this continuation request will be the same as those specified above for full board review. If the protocol qualifies for continued expedited review, The Chair or designated member will follow the expedited review procedures outlined above. The IRB Chair or designated member can only approve or require modification in (to secure approval of) research, but may not disapprove research using the expedited procedures. Disapproval of a research project at the time of continuing review can only occur after review by the IRB at a convened meeting, not by the expedited review process. All IRB members will be advised of research that has been approved under an expedited review procedure at a convened meeting.

### **Determining primary reviewers**

The IRB Vice Chair will complete an initial review of all protocols for a determination of exempt status or recommend the protocol for an expedited or full board review. Expedited reviews and full board review determinations will rotate amongst the IRB members, except for the Chair and the community member. After a new protocol is determined to be human subjects research but not qualifying for exempt status, that proposal is assigned to the IRB member with the fewest number of completed reviews, unless the new protocol presents a conflict of interest. The Chair or Vice Chair will serve as the secondary reviewer on all expedited reviews and grant final approval. The community member is only required to participate in full-board reviews.

### **Notification of approval expiration dates**

The IRB Chair or designee will notify principle investigator(s) by email of impending approval expiration dates no less than one month prior to that date. In that email, the investigator(s) will be advised of the impending expiration date and the investigator's responsibility to file either a Protocol Closure or Continuation Form by the end of their approval. Submission of a Protocol Closure Form by the investigator(s) will end IRB approval of the research protocol, and any subsequent research activities related to that project will require the submission of a new proposal by that investigator. Submission of a Continuation Form will result in a continuation review, as outlined above.

### **Procedure for determining expiration dates and frequency of review**

The IRB sets the next review date at the time of initial or continuation approval based primarily on the degree of risk of the study: the higher the risk, the earlier the IRB may set the expiration date of the initial approval. The following factors will be considered when determining review and approval expiration dates: the nature of any risks posed by the research project; the degree of uncertainty regarding the risks involved; the vulnerability of the subject population; the experience of the investigators in conducting research; the IRB's previous experience with the investigators (e.g., compliance history, previous problems with the investigator obtaining informed consent, or prior complaints from subjects about the investigator); the projected rate of enrollment; and whether the research project involve novel interventions.



The effective dates of approval are determined as follows. If the research protocol is approved through expedited review, the approval period starts on the date that the Chair signifies approval and directs the IRB support staff to inform the investigator of approval through the use of an approval letter. The effective expiration date will be no more than one year from that approval start date. If the research protocol is approved through full board review without conditions, the approval period starts on the date of that full board meeting and extends no more than one year from the approval start date. If the research protocol is conditionally approved through full board review, the approval period starts on the date the IRB Chair approves all resubmitted materials from the investigator(s) and directs IRB support staff to inform the investigator of approval through the use of an approval letter. The approval period extends no more than one year from the approval start date. Approval of modifications does not affect the expiration date. The IRB notifies the investigator of the expiration date for initial or continued approval, and a reminder notice is sent to the investigator at least one month in advance of the actual date.

### **Confirming completion of training in the protection of human research participants**

The Chair (or support staff) must confirm that all members of the research team have documented completion of responsible and ethical conduct of research training before sending approval. In order to check that investigators have completed the CITI modules required by the IRB, the chair (or support staff) logs in to the CITI program site and downloads completion reports on a weekly basis and saves those reports to the Grinnell College IRB storage server to maintain a current documented record of completed training.

The Grinnell College IRB accepts training in the protection of human research participants completed elsewhere (e.g., NSF, previous college attended by investigator) in lieu of the College's CITI modules. Grinnell College investigators are required to complete the training in the protection of human research participants course or a similar refresher course every four years.

### **Handling correspondence (receipt of proposal, letter of outcome)**

After email is sent to IRB@grinnell.edu, the Chair (or support staff) processes the proposal and sends a receipt to the principal investigator (PI) that states the proposal was received. If the reviews request a revision, the PI receives an email that lists the required revisions. After the review is done, the PI receives by email a Portable Document Format (.pdf) letter on Grinnell letterhead with the official notification if the project is approved.

Most email correspondence from PI to the Grinnell College IRB and among board members is considered part of the official record and is saved to the storage server space, most often in the specific proposal folder or in other folders if it is of broad nature. All emails currently are saved as Microsoft Outlook files (.msg).

Phone calls may be considered correspondence that needs documentation. Most phone calls are inquiries of whether a project needs review, questions about the proposal form, or

questions about a requested revision. Depending on the specificity, the chair will type a note about the nature of the phone call and save it to the server space. It is not the policy of the Grinnell College IRB to record phone calls. If the Chair is concerned that content of the phone call is important and requires documentation, he or she will request the caller to put the information in writing and email it to the Grinnell College IRB for a written record of the conversation.

All meetings of the Grinnell College IRB are documented in written minutes to include an agenda of topics, attendance, protocols reviewed, actions taken, voting results, reasons for requiring changes in a project, or reasons for disapproving, suspending, or terminating a project. These minutes are available for review and action by Grinnell College IRB members at subsequent meetings; when approved in final form, the minutes are available for review by the Dean, the signatory official for human participants research at Grinnell, the compliance officer, and Grinnell College legal counsel.

### **Handling reviews during the summer and breaks**

When members are not available to serve due to breaks in the academic calendar, travel to conferences, leaves, or vacation, they should contact the chair with the dates they will be unavailable. Federal guidelines require IRBs to not approve a project requiring full board review, unless there is a quorum of members present and at least one of the members present is a nonscientist. Therefore, in the rare event that a quorum is not possible, the vote on the proposal will be postponed until more members return to service.

### **Handling problems**

#### **(1) Problems reported by investigators**

Federal regulations require investigators to report unanticipated problems, adverse events, and complaints to the Grinnell College IRB in a timely fashion.

The Department of Health and Human Services (HHS) defines these terms as follows (also see guidance [here](#)):

- Unanticipated problem: “unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; related or possibly related to participation in the research; and suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.”
- Adverse event: “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. 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.”

Under these federal requirements, investigators must report to the Grinnell College IRB in writing the nature of the problem within five working days of the occurrence by submitting an Unanticipated Problems and Adverse Events form. In addition, any injury or physical or emotional harm to a participant must be reported immediately to the IRB. Other examples include, but are not limited to, a breach in confidentiality or privacy, problems with recruitment and/or the consent form process, noncompliance with federal regulations or Grinnell College IRB policies, complications or complaints occurring during the research, or any other problem that presents changes in the risk-benefit ratio and affects the rights, welfare, and safety of participants. A separate report must be filed for each incident summarizing the problem or event encountered along with a statement by the investigator indicating whether a change in the protocol and/or consent form is warranted and whether, in the investigator's opinion, the adverse event was related to the research activity. The IRB has authority, under [45 CFR 46.109\(a\)](#), to require, as a condition of continued approval by the IRB, submission of more detailed information by the investigator(s) about any adverse event or unanticipated problem occurring in a research protocol.

HHS advises IRBs to review this information. In doing so, IRBs are charged with considering whether the affected research protocol still satisfies the requirements of the IRB under [45 CFR 46.111](#). In particular, the IRB will consider whether risks to participants are still minimized and reasonable in relation to the anticipated benefits, if any, to the participants and the importance of the knowledge that may reasonably be expected to result. Any proposed changes to a research study in response to an unanticipated problem also must be reviewed and approved by the IRB before being implemented, except when necessary to eliminate apparent immediate hazards to subjects.

Unanticipated problems or adverse events occurring in research covered by our OHRP FWA also must be reported by the institution to the supporting HHS agency head (or designee) and OHRP ([45 CFR 46.103\(a\)](#)). To satisfy this requirement the Chair will notify the Dean of the Unanticipated problem or adverse event and of the intention to file an official report to HHS and OHRP by contacting the Director of the Division of Compliance Oversight (see [here](#) for additional guidance). Reports also will be filed with sponsoring agencies requiring such reports. In accordance with OHRP guidance, These reports will be filed within days of a more serious incident and within a few weeks for less serious incidence. The problem also will be noted in the IRB's end-of-year report.

## (2) Problems reported by research participants

When the Chair or other member of the IRB receives a complaint from a participant, the Grinnell College IRB will review the information to determine whether any further actions, beyond any changes or amendments to the protocol that are proposed by the investigator, are warranted. The Grinnell College IRB reserves the right to review and approve all the proposed changes and determine whether the study should be continued as originally approved, modified, or discontinued. Further, the Grinnell College IRB is required to report to the Dean, OHRP, and

any sponsoring agency, all adverse events that caused injury to human participants or other major effects that involved unanticipated risks or problems; investigators must also comply with any reporting requirements in the protocol itself or as stipulated by the sponsoring agency in grant documents or agency regulations.

### (3) Problems with the quality of the research proposal

The board helps investigators to raise the quality of their proposals. If the problems are unclear writing, poor writing, or confusing/conflicting statements, the board (and Chair) can reject the proposal, but more often, requests for a revision where the writing must be improved will be made. If the problem is procedural in nature, the board will provide suggestions to resolve the problem, to the point of specifically making suggestions of how to modify the proposal (e.g., what wording to use in the consent form, what box to check on the proposal form, or to explicitly state a phrase in a section of the project description).

### (4) Problems with board members

If a board member is found to not be fulfilling their role on the board, to where he or she is not doing reviews or displaying minimal consideration of relevant legal and ethical issues in their reviews, the Chair will address these concerns with the board member (by email or in person) to clarify expectations for both parties. If resolution through these discussions is not achieved, the Chair will send a request to the Dean and the Faculty Organization Committee (FOC) for a replacement. The problem should be noted in the end of the year report.

If board members have problems with the Chair, and the Chair has not addressed the problems to any member's satisfaction, the board members should discuss the problem with the Dean to identify strategies to resolve such issues.

### (5) Problems with the administration

Federal regulations require the institution to be responsible for supporting the IRB. Working with the compliance officer, the Grinnell College IRB chair is responsible to communicate with the Dean any problems the board is having with institutional support.

## **Audits of approved projects**

[Federal regulations](#) for compliance require IRBs to audit investigators and document that projects are being conducted as proposed. There are two types of audit, routine and for-cause. Both types of audits use systematic methods to evaluate compliance with federal regulations, state and local laws, and College policies and procedures. They also seek to verify that research is conducted in accordance with the IRB approved protocols.

Procedures for initiating a routine audit. The IRB Chair or designee selects an investigator or study for a routine audit based on criteria which includes, but is not limited to, studies involving procedures that are greater than minimal risk to participants, studies involving vulnerable populations, drug or device studies, and investigators conducting a large number of

studies. The IRB Chair or designee contacts the investigator and establishes a time and place for the audit to take place. The IRB Chair informs the investigator which documents are necessary for the audit. The investigator must make such documents available at the time of the audit. Any other materials the IRB administrator deems necessary to accurately understand the research process under investigation shall be made available by the investigator upon request.

Procedures for initiating a for-cause audit. The IRB or IRB subcommittee may direct the IRB Chair or designee to conduct an audit in response to a particular concern. Concerns which may prompt a for-cause audit include, but are not limited to the following: complaints or concerns made by a research participant, family member of the research participant, research team member, or an employee of the College; reports of audits or monitoring conducted by other committees affiliated federal agencies, data and safety monitoring committees, or other agencies involved in the conduct of a study. The IRB Chair or designee contacts the investigator and establishes a time and place for the audit to take place. The IRB Chair informs the investigator which documents are necessary for the audit. The investigator must make such documents available at the time of the audit. Any other materials the IRB administrator deems necessary to accurately understand the research process under investigation shall be made available by the investigator upon request.

After an audit, the investigator is informed of the results of the review in a written report from the IRB Chair or designee. The written report is also sent to the Dean and other college officials as appropriate. If the audit does not identify any problems, no action is taken. If the audit identifies problems or deficiencies, the IRB Chair includes appropriate corrective actions in the written report. The investigator is expected to respond or comply with the corrective actions in a time frame determined by the IRB Chair. The Chair follows up with the investigator to ensure these corrective actions are completed. If the corrective actions are not completed, the IRB Chair may recommend to the convened IRB that a suspension be considered for the study that was audited or for the studies that an investigator is conducting.

### **Non-compliance inquiries and reporting of findings**

The Grinnell College IRB may become aware of possible non-compliance by any of several venues. These may include:

- complaints or concerns from research participants, research staff or employees of the unit;
- audit findings;
- continuing reviews for re-approval;
- unanticipated problem or adverse event reports submitted by investigators; or
- quality improvement reviews conducted by the IRB.

Reports of possible non-compliance may be forwarded to the Grinnell College IRB by phone, in writing, or by emailing the Chair. Anyone, regardless of affiliation, who suspects noncompliance may submit a complaint or concern. The person submitting the report may be asked to describe the problem or the concern in writing, unless the person chooses to remain anonymous.

Upon receipt of a report, the Grinnell College IRB Chair will evaluate the concern and determine next steps. Minor violations may be disposed of administratively following an initial inquiry by the Chair or an IRB subcommittee. All serious or continuing noncompliance with regulations or the determinations of the Grinnell College IRB will be reported promptly to the Grinnell College IRB members at a full review meeting and to other College officials, the OHRP, and the federal Department or Agency Directors, as applicable.

Examples of non-compliance include:

- serious violations discovered after completion of a protocol audit;
- instances where non-exempt research was conducted without IRB review and approval or without appropriate informed consent procedures;
- implementation of significant modifications without IRB prior approval;
- instances of repeated or multiple problems with noncompliance by protocol investigators even after IRB warnings.

Allegations or any evidence of serious non-compliance will constitute sufficient cause for the Grinnell College IRB to initiate a protocol audit or investigation upon written notification to the principal investigator. Audits or investigations may be conducted by the Grinnell College IRB Chair or a subcommittee of the full Grinnell College IRB in a manner that will protect human participants as well as the investigator's rights to due process to include the right of appeal. The seriousness of the allegations and any preliminary evidence will determine whether or not a temporary suspension of the research should be imposed by the Grinnell College IRB pending a full inquiry and a final determination at a convened meeting.

Suspensions and final reports detailing the implementation of corrective actions must be reported to the Dean and other College and Federal Officials depending on the seriousness of the violations after the Grinnell College IRB has determined that noncompliance has occurred. Notification to the Dean or officials as appropriate will include the following pertinent information:

- name of principal investigator
- the project title,
- protocol and grant numbers
- detailed description of the non-compliance
- the actions, including any institutional corrective actions that may be required, taken or planned in order to address or correct the violations.

Possible outcomes or corrective actions by the Grinnell College IRB may include:

- education requirements for the investigator and research staff engaged in the research;
- temporary or permanent suspension of the research and/or the investigator;
- random audits of the research or investigator;
- disallowance of research use of data collected; or
- other actions deemed appropriate by the IRB and communicated in writing to the investigator in a final notification.

The inquiry process of the IRB will include the following stages:

1. *The Complaint or Concern*: Review by the IRB Chair to determine seriousness and validity.

2. *Initial Inquiry*: Administrative review by the IRB Chair or a Subcommittee with notification to investigator of complaint or concerns. The result of this step might result in minor corrective actions for resolution or referral to full IRB at a convened meeting.
3. *IRB Investigation*: Audit of protocol by IRB Chair or IRB Subcommittee with a report of findings at a convened meeting with notification to investigator. The result of this step might result in major correction actions, suspension, or termination of study.
4. *Appeal Hearing*: Investigator responds in writing and/or in person at a Grinnell College IRB convened meeting.
5. *Final IRB Determination*: Report of full IRB meeting with any corrective actions, resolutions or stipulations regarding the future of the research study or its termination if warranted.

### **Managing web pages**

The board reviews information on the website annually or as needed to keep the site in excellent condition. The site contains directions for enrolling in training in the protection of human research participants, proposal forms, a information about the IRB's policies and procedures, FAQs, and links to various research ethics-relevant webpages (including the federal regulations). The Chair (or board members) should check that links are active and fix dead links or problems found on the website.

### **Chair turnover**

The current chair of the Grinnell College IRB helps the next chair assume the responsibilities of chair. Help includes a) providing the login and password to the training in the protection of human research participants module and database, b) providing access to the [irb@grinnell.edu](mailto:irb@grinnell.edu) account; c) facilitating introductions with the staff support, d) providing an understanding of the storage server space, e) and being available for questions that the new chair may have.

If circumstances prevent the current chair from helping the incoming chair, board members who are continuing are responsible to help the new chair review policy and procedures of the IRB. When there is a change in Dean or compliance officer, the Chair should help fill in the new administrator with necessary information to help them help the IRB function and meet compliance regulations.

### **Updating and Renewal of IRB Registration**

Federal guidelines require that the IRB's registration be renewed every three years. The Chair is responsible for submitting the renewal of this registration no later than one month prior to the registration expiration. The Grinnell College IRB number is IRB00008002, and the current registration is set to expire on January 3, 2017.

Federal guidelines also require that IRBs must update their registration within 90 days after changes occur to IRB membership or to the designated contact person on the registration.

The Chair or Vice Chair is responsible for updating this registration each year or as necessary to reflect the current membership.

### **Updating and Renewal of Federal-Wide Assurance (FWA)**

Federal guidelines require that an institution's FWA be renewed every five years, even if no changes have occurred, in order to maintain an active FWA. The Chair is responsible for renewing the College's FWA the July before expiration.

Federal guidelines also require that institutions update their FWA within 90 days of any changes regarding the legal name of the institution, the Human Protections Administrator, or the Signatory Official. The Chair is responsible for updating the FWA each July or as necessary.

### **Updating the Grinnell College IRB policies and procedures**

The written policies stated in this document should be reviewed minimally every 2 years and be revised to best serve the College in its research practices and in complying with federal regulations. Changes to the policy at the word level can be made at any time by an individual board member in consultation with the Chair, but changes at the conceptual level should occur with full board consent and consent of our compliance officer. The full version will be maintained on the IRB server storage space. An external version will be posted to our website (controlled by the Grinnell College Webmaster who oversees posting of all College compliance policies).

These policies were approved by the Grinnell College IRB on January 17, 2017 and by the Institutional Officer on January, 30, 2017.