The Colby Institutional Review Board (IRB) Policy: Questions & Answers

1. What is the IRB?

The Colby IRB is a committee of Colby faculty and Waterville community members charged with protecting the welfare, rights, and privacy of human subjects involved in research. It is responsible for reviewing all research projects conducted by Colby faculty, students, and administrative staff that involves human subjects, including collecting information from human subjects, to ensure that these projects comply with legal and professional standards for ethical research. In addition, and in accordance with applicable regulations, the IRB has the authority to approve, disapprove, monitor, and require modifications in all research activities that fall within its jurisdiction.

2. What research does the Colby IRB review?

The Colby IRB is responsible for reviewing all research involving human subjects, as defined below, to ensure that research is conducted in accordance with applicable federal regulations and Colby policies. Colby College has committed that all human subjects research conducted at the College will be conducted under a set of federal regulations known as the Common Rule. *See* 45 C.F.R. Part 46. Under this rule, research requiring IRB review is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." 45 C.F.R. § 46.102(l). A "human subject" is a living individual about whom the investigator conducting research: "(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens." 45 C.F.R. § 46.102(e)(1). Human subjects research can include projects conducted for scholarly publication or presentation, for independent study courses and honors theses, and for course assignments.

Research also includes any project intended to generate or analyze data about the safety, efficacy, or performance of a medical technology or intervention in humans. It also includes most types of interventional human research conducted to collect data on the safety or effectiveness of drugs, medical devices, in vitro diagnostic products, and other

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[1] The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines the term "drug" as "(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C)." 21 U.S.C. § 321(g)(1).

[2] The FD&C Act defines the term "device" as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is - (A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h)(1).

[3] In vitro diagnostic products "are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body." 21 C.F.R. § 809.3(a). Note, these products are devices as defined in section 201(h) of the FD&C Act (21 U.S.C. § 321(h)(1)), and may also be biological products subject to section 351 of the Public Health Service Act.

medical products may be subject to a separate set of U.S. Food and Drug Administration (FDA) regulations that are similar, but not identical to, the Common Rule. Such human studies may require review and approval by an IRB and by FDA before the study can be initiated.

Please do not attempt to determine for yourself that your project is not research involving human subjects or a clinical investigation. The IRB must make this determination based on your application and will inform you of its determination, and whether it approves of the research (if applicable). You may not proceed with your project until you have received the IRB's decision.

3. What type of research or project is not considered "human subjects research"?

Not all research is subject to IRB review because the applicable regulations at 45 C.F.R. § 46.102(l)(1)-(4) generally exempt the following activities from the definition of human research:

> (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
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> (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
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> (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
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> (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Please do not attempt to determine for yourself that your project does not require IRB review. The IRB must make this determination based on your application and will inform you of its determination, and whether it approves of the research (if applicable). You may not proceed with your project until you have received the IRB's decision.

4. Can I conduct FDA-regulated research?

Generally, it is the policy of Colby College and the Colby College IRB not to authorize the conduct of medical product research subject to FDA regulations by students or faculty, such as clinical investigations. This policy is not intended to restrict students or faculty from conducting or participating in FDA-regulated research that is not under the auspices of Colby College or subject to review by the Colby College IRB. If you have any questions, please contact the IRB Chair.

Medical product research subject to FDA regulations includes research regarding new drugs, biologics, or medical devices not yet approved, cleared, licensed, or authorized for distribution and marketing in the United States, as well as certain human research of "approved products" that are marketed in the United States. As noted above, both FDA and IRB review and approval of the proposed human research, may be required. In particular, clinical investigations involving articles intended to treat, cure, diagnose, or mitigate a disease, such as drugs, biologics, or medical devices, generally require IRB review under applicable FDA regulations for drug research, device research, and related requirements for informed consent and IRB review. *See* Under FDA regulations, "clinical investigation" is generally defined as any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to FDA, or is not subject to requirements for prior submission to FDA, but the results of which are intended to be submitted later to, or held for inspection by, FDA as part of an application for a research or marketing permit. 21 C.F.R. § 50.3(c). In addition, FDA regulations define "human subject" as "an individual who is or becomes a participant in research, either as a recipient of the test article or as a control." 21 C.F.R. § 50.3(g). Such an individual may be a healthy human or a patient. Please note that under FDA regulations, the definition of human subject includes individuals on whose specimens an investigational medical device is used (and subject to the requirement for IRB review).

5. **Should I apply for IRB review and approval of my research project?**

Any Colby student or faculty member planning to conduct research involving human subjects must apply for IRB approval [or who is conducting such research but has not sought IRB approval]. **Please do not attempt to determine for yourself that your project is not research involving human subjects or a clinical investigation. The IRB must make this determination based on your application and will inform you of its determination, and whether it approves of the research (if applicable). You may not proceed with your project until you have received the IRB's decision.**

6. **If I plan to conduct research abroad, should I apply for IRB review and approval?**

Yes. A faculty member or student who plans to conduct research abroad should apply for approval from the Colby IRB, and from any relevant regulatory bodies in the host country.

7. **How can I apply for IRB approval?**

Any Colby student, faculty member, or staff can apply for IRB approval of a research project by emailing a completed IRB application, along with any relevant supporting materials (e.g., consent form, permission-to-record form, debriefing form, copies of questionnaires or interview scripts), to the Chair of the Colby IRB. The IRB application form (faculty or staff and student versions) and sample materials (including consent form, debriefing form, and permission-to-record form) are available at: http://web.colby.edu/psychology/resources-for-research.

8. **As an instructor, if students will be conducting individual or group research projects in my course, can I obtain IRB approval for these projects?**

There are two ways to obtain IRB approval of research projects conducted as course assignments. If the individual students or research groups will all be conducting essentially the same project (i.e., addressing similar research questions using similar procedures), then the instructor can submit a single IRB application for the assignment. However, if the individual students or research groups will be conducting meaningfully different projects (i.e., addressing

different research questions and/or using different procedures), then each student or research group should prepare an IRB application. These applications should be submitted to the instructor, who should then forward them to the IRB chair for review.

9. When can I start my research?

A researcher must not begin collecting data from human subjects or engage in research involving human subjects until after receiving IRB approval for their project or until the IRB has determined that the project is not human subjects research that is subject to IRB review and approval.

10. How long does it take to obtain IRB approval?

New IRB applications are typically reviewed in two to three weeks. However, obtaining final approval may require the researcher to revise and resubmit their application in order to address issues identified by the IRB. Some applications may be reviewed more quickly than two weeks, especially if the IRB Chair determines that the project qualifies for expedited review (e.g., because it involves no risk to participants), or is exempt from review (e.g., because it involves only secondary analysis of existing data). If a researcher believes that a project may qualify for expedited review, or may be exempt from review, they can explain the reasons for this in their IRB application, or in a separate memo.

For information about expedited review, see: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html or https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/categories-research-may-be-reviewed-institutional-review-board-irb-through-expedited-review.

For information about categories of exempt research, see: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/exempt-research-determination/index.html.

11. What are the IRB's standards regarding informed consent?

Obtaining informed consent is a basic ethical obligation and a legal requirement for researchers, defined by the Department of Health and Human Services (HHS) regulations at 45 C.F.R. Part 46, and FDA regulations at 21 C.F.R. Part 50. Potential participants must be provided with information about the research project that is understandable and that permits them to make an informed and voluntary decision about whether or not to participate.

Consistent with Federal Regulations and IRB policy, the basic elements of informed consent that must be provided to the potential participant include the following:

- A statement that the study involves research, an explanation of the purposes of the research purposes (e.g., to test safety or accuracy of a diagnostic test), the expected duration of the subject's participation, a description of the procedures to be followed, an identification of any experimental procedures, and a description of products or interventions under study, including whether such products are approved or cleared for marketing and the approved or cleared use;
- A description of any reasonably foreseeable risks or discomforts to the subject;

- A description of benefits to the subject or others that may be reasonably expected from the research;
- The disclosure of appropriate alternative procedures or course of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent to which confidentiality of records identifying the subject will be maintained and a notation that it is possible the U.S. Food and Drug Administration might inspect the records;
- For clinical research involving more than minimal risk, an explanation as to whether or not any compensation or any medical treatments are available if injury occurs during study participation; if so, what they consist of and where further information may be obtained;
- The identification of an individual who can be contacted by the subject for answers to questions related to the research, research-related injury, or their rights as a research subject;
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which s/he is otherwise entitled.

Each of the above basic elements of consent are required under both FDA regulations and the Common Rule. However, the Common Rule requires additional basic elements of consent regarding any research that involves the collection of identifiable private information or identifiable biospecimens.

Additional elements that should be addressed, as appropriate, include:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;
- The approximate number of subjects involved in the study.
- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

The IRB may require that information, in addition to that specifically mentioned, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

Generally, the IRB requires consent to be documented by a written consent form that includes all the required elements, and all appropriate optional elements, approved by the IRB prior to use. An IRB approved consent document will contain the date of IRB approval.

Researchers are expected to obtain and document informed consent from each participant (e.g., by having them sign a consent form) before collecting data from them. Unless the need for consent is waived by the IRB, the written consent form must be reviewed with the participant (or the participant's representative), and signed and dated by the participant or the participant's representative before any research procedures (including screening) or research data collection can begin. The consent form should also be signed and dated by the individual who obtains the participant's consent. For participants who may not fully appreciate the benefits and risks of research participation (e.g., children), researchers must obtain assent from the participant, as well as consent from an appropriate representative of the participant (e.g., a parent). For some projects, it may be acceptable to modify or waive the informed consent requirement. When requesting a modification or waiver, the researcher should explain the rationale for this request in their IRB application.

For more information about informed consent, including information about requesting a modification or waiver of informed consent, see: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html or https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guide-informed-consent.

12. What are the IRB's standards regarding data confidentiality?

Researchers are expected to maintain the anonymity (by collecting data in such a way that even the researchers cannot match participants' identities with their data records) or confidentiality (by reporting the research findings in such a way that participants cannot be personally identified) of their data. If a researcher plans to personally identify participants in a research report (e.g., by attributing an interview quote using a participant's real name), then the researcher must explain the rationale for this in their IRB application, and must obtain the participant's active consent to be identified (for an example, see the sample permission-to-record form).

13. If I would like to modify a project that has already been approved by the IRB, what should I do?

If a researcher would like to modify an IRB-approved project, then the researcher must describe the proposed changes to the IRB Chair and request approval. If the changes are relatively minor, they can be described in a short memorandum submitted to the IRB Chair. If the changes are more extensive, the researcher can revise and resubmit the originally approved IRB application for the project, along with a memo summarizing the changes. **Human subjects research under the conditions proposed for modification and under IRB review may not proceed until approved by the IRB.**

14. If I have other questions about the IRB process, what should I do?

If you have additional questions about the IRB approval process, please contact the IRB Chair.