C LGA E- I R I

Institutional Review Board

Research with H uman Participants: A Manual for nvestigators

Statement of Policy[1]

Colgate University is committed to academic freedom. Research will not be forbidden because it is innovative, unorthodox, sensitive or otherwise extraordinary. The University protects the right of faculty to conduct research when that research has been reviewed and approved by the nstitutional Review Board (RB).

Colgate University 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. All persons involved in conducting research have an obligation to respect the dignity and integrity of the persons being studied, including their right not to be the subject of potentially harmful research. Where possible, potential participants should be provided the opportunity and means to decide freely whether to participate. Researchers who promise confidentiality are responsible for maintaining it and for informing participants of the limits of their capacity to meet that responsibility. Research procedures should minimize the risk of harm and maximize the possible benefits to the participant and to society. Participants should be selected for reasons directly related to the problem being studied, not because of their easy availability, their compromised position, or their manipulability. Researchers must exercise special care when the participants of research are especially vulnerable to harm because they cannot understand the risks or because they are not in a position to refuse their participation in the research.

The nstitutional Review Board

The nstitutional Review Board (RB) is responsible for approving all research with human participants conducted by faculty, staff, and students of Colgate University, when conducted as part of their work or study for or at Colgate.

There are 12 seats on the board. The Associate Dean of the Faculty holds one, ex-officio, and one is held by a community member with no other Colgate affiliations (see below). Membership on the RB is appointed through the Dean of the Faculty Office.

Members serve for three-year terms, which should be staggered. These terms are renewable. n making appointments to the committee, the following guidelines must be observed: There must be both scientists and non-scientists on the board, and there must be at least one member who has no affiliation with Colgate University (e.g., is not an employee or student and is not a member of the immediate household of an employee or student). Efforts should be made to have a balance of gender, ethnicity, and disciplinary specialties on the Board.

While administrators of the University might be able to restrict a research project that has received RB approval, they may not overturn an RB decision to disapprove a research project. H owever, it is the intent of the RB to work with investigators to mutually agree on a protocol that will receive RB and University approval.

Research Subject to Review

Definition of Research with H uman Participants

"Research" means a systematic investigation calculated to develop or contribute to generalizable knowledge. t does include educational activities whose results are not intended for publication and would not constitute original research in the field. t also does not include institutional research intended for use only at and by Colgate employees or students.

H owever, it is the policy of Colgate University that ll educational activities and institutional research involving human participants be conducted in accordance with

RB Review Criteria

The RB will consider the following questions in reviewing proposals:

- Have the risks to participants been minimized?
- Are the risks reasonable in relation to anticipated benefits?
- Is the selection of participants equitable?
- Are adequate procedures in place to ensure privacy and confidentiality?
- Has informed consent been sought and documented?

The RB will consider the merits of the research only insofar as it affects the balance of risks and benefits. For example, research should be both valid and of value to

Participants may also feel distress when debriefed about deception in a study. Most psychological risks are minimal and transitory, but the investigator and the RB must be aware of the potential for serious psychological harm.

n many cases risk can be eliminated or reduced by careful procedures for ensuring confidentiality. Psychological support and referrals can be built into studies when emotional distress may be an outcome. Consent forms describing the kinds of questions the researcher will ask allow participants to choose whether they wish to divulge certain types of information or explore certain issues.

Benefit:

Many kinds of research provide no direct benefits to participants, and it may be many years before the results of the research are promulgated and made useful to society or to groups of people. They may never be. ague promises of benefit to science or society are not adequate descriptions of benefit. Where there is no direct bene.7(t)-l7(r)-5.f people. Tpsh

Prisoners. f the research involves prisoners, a prisoner or a prisoner representative will be asked to participate in review of the research. The RB will employ a heightened level of review for such proposals, as set out in 45 CFR sec. 46.305. n general, only research seeking knowledge about criminals or prisoners as a class or penal practices will be approved.

Pregnant Women and Neonates. f the research involves pregnant women, the investigator must consider risks to both the woman and the fetus, and inform the participant of risks to the fetus. The RB will employ a heightened level of review for research on pregnant women and neonates, as set out in 45 CFR secs. 46.201 through 46.207.

Children. The protections for children are set out in the sections on informed consent. The RB will review research proposals according to the criteria set out in 45 CFR secs. 46.403 through 46.409.

Privacy and Confidentiality

An individual's right to privacy is generally protected by the right to refuse to participate in research. Privacy issues arise when investigators wish to use personally identifiable records without obtaining consent or conduct covert observation or participant observation.

Records. f a data set with information about individuals is publicly available and the information it contains cannot be linked to the individual participants, there are no privacy concerns. n such cases, the research probably does not qualify as "research with human participants," and thus, no RB review would be required.

Observations of public behavior. The RB must review observations of public behavior which are recorded in a way that would allow the participants to be identified and (if made public) could reasonably place the participant at risk of criminal or civil liability or damage the participant's financial standing, employability, or reputation. The RB must determine that the knowledge to be gained is important enough to involve unconsenting participants.

Confidentiality. irtually all studies in which information about participants is collected must provide that the information remain confidential. f confidentiality is promised, identifying information should not be stored with the research data. Every effort should be made to protect identifying information through the use of passwords, locked computers, locked cabinets, etc. dentifying information or coding keys should be destroyed as soon as possible. (Consent forms must be kept for three years after a research project ends.)

nformed Consent

nformed consent must be sought from each participant and appropriately documented, except where deception or incomplete disclosure is necessary. nformed consent must:

- Describe what the research is about;
- Tell the participants what they will be asked to do and for how long;
- Explain any risks and benefits. f there is no direct benefit to the participant, the investigator should explain what the study hopes to discover and why;
- Describe how confidentiality will be maintained;
- Describe any compensation the participant will receive and conditions under which no, or partial, payment will be made;
- Make it clear that participation is voluntary;
- Tell participants that they may skip questions or withdrawhey wn15.1(d)b8 w1ipa5.84 -11.7hey v

nvestigators may plan to withhold information about the real purpose of the research or give false information about some aspects of the research. This means that the participants' consent will not be fully informed. n deciding whether to approve such studies, the RB will consider whether:

- The research involves no more than minimal risk;
- The nature of the study is such that it could not be carried out without deception;
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- Tell why the study is being conducted;
- Describe what will happen and for how long or how often;
- Say it's up to the child to participate and that it's OK to say no;
- Tell them they can stop at any time;
- Explain if it will hurt and for how long or how often;
- Say what the child's other choices are;
- Describe any good things that might happen;
- Ask for questions.

Some children under 8 may be capable of granting or withholding consent, and the RB expects the investigator to be sensitive to the needs of these children on an individual basis.

The Mechanics of Securing Approval for Research

Procedures

The investigator is responsible for (1) determining whether the project involves research with human participants and (2) submitting a complete application for approval with all supporting documents. After reviewing the application and its supporting materials, the RB may ask the investigator to explain some elements of the protocol and may require revisions in the protocol. When the investigator revises a project, the RB reviews the project again to see whether its concerns have been adequately addressed.

To fully protect participants, the RB must approve a project before investigators start to work on it—even before they begin to recruit participants, since recruitment strategies are part of the review.

Research projects are reviewed at one of three levels, depending on the RB's interpretation of the project's risk to the participants and on the federal guidelines that define the categories of review, which are:

- screening for exemption from full RB review
- expedited RB review
- full RB review

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Exempt Research

[illegible] (45 CFR 46.101( ) ( ). Hence, while research that involves only minimal risk to participants is sometimes exempt from full

RB review, that does not mean that it is exempt from peer review. Researchers must file an application requesting that a project be classified as exempt.

n general, the federal guidelines for research on human participants allow a project to be exempt from full review only if the research involves no risk to the participant. Criteria of exempt research include:

1. Routine nstructional Research:

> Research on instructional strategies conducted in educational settings, involving normal educational practices (such as research on regular and special educational strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods).

2. Anonymous Survey and Public Behavior Research (on adults):

> Research involving the use of educational tests (cognitive, diagnostic aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) the information obtained is recorded in such a manner that participants can be identified; and (b) any disclosure of the participants' responses outside the research could place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation. This exemption does not apply to research involving children, except for research involving observation of public behavior in which the investigator does not interact with the child.

3. Survey and Public Behavior Research on Public Officials:

or other specific identifiers, such as social security numbers or student id numbers, is sufficient to qualify a study as anonymous.

NOTE: Observational research involving sensitive aspects of participants' behavior, or in settings where participants have a reasonable expectation of privacy, is not exempt. Similarly, sensitive survey research is seldom exempt from review. A sensitive survey includes questions about illegal activities or highly personal aspects of the participants' behavior, life expe

2) Collection of biological specimens (like hair or nail clippings) through noninvasive means;
3) Research on existing data or specimens (note: some research in this category is exempt);
4) Collection of data from voice, video, digital or image recordings;
5) Research on individual or group characteristics or behavior or involving surveys, interviews, oral history or focus groups (note: some research in this category is exempt);
6) Continuing review of non-exempt research previously approved by the RB, where no new participants will be enrolled or where the research involves no greater than minimal risk.

Note: There are a few other categories eligible for expedited review, but they involve clinical studies seldom performed at Colgate. These additional categories are listed in 45 CFR 46.

The researcher must show on the application how the proposed project activities fall into one or more of these categories.

The RB chair assures that all of the elements essential for review, including consent forms and supporting information, have been submitted. The application is then forwarded to a designated committee member for review and decision. Either the committee member approves the research or it is forwarded for full review.

Full review

A project that involves greater than minimal risk requires approval by the RB committee.

Survey research that involves sensitive questions or information about A DS is subject to full review, in keeping with federal guidelines that identify A DS sufferers as a vulnerable population and that identify information about A DS as likely to cause stress to survey participants. Any survey or interview that is likely to be stressful for the participant requires full review.

Full review means that a convened meeting of a majority of the RB members occurs, during which discussion of the proposal occurs. Among the members present there must be at least one scientist and one non-scientist, and the member who is otherwise unaffiliated with Colgate University. Because of scheduling issues, investigators should expect that full review of a proposal can take up to several weeks.

Continuing Oversight:

All non-exempt research is subject to at least annual review and renewal. f research involves extreme risk to participants, the

re-applying for approval after the initial RB approval expires. The RB will conduct an expedited review of these applications, unless the research protocol has been modified or new participants are to be added and full review is otherwise appropriate.

Procedure for Addressing Complaints from Research Participants

f possible, participants must be told that they can direct complaints about the conduct of the research to the Chair of the RB. f the research is on-going, the RB will document complaints and review research procedures. f the research is completed, the RB will investigate the complaint, including discussing it with the investigator, and prepare a report. The report will be forwarded to the investigator and to the appropriate University administrator.