

RESEARCH INVOLVING HUMAN PARTICIPANTS

AT MACALESTER COLLEGE

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INTRODUCTION AND CHARGE TO THE COMMITTEE

The purpose of Macalester College's Institutional Review Board (IRB) panels 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, Macalester 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 Macalester community that involves the participation of humans as research subjects must be reviewed by a Macalester College IRB panel. At the present time there are three IRB panels at Macalester. The Psychology Department has an IRB panel that deals primarily with psychological research by students. The Social Science Division has an IRB panel that deals with a wide variety of social science research. In addition, there is a college-wide IRB called the "Macalester College Institutional Review Board." Faculty research proposals should be reviewed by the college-wide IRB.

The Macalester College Institutional Review Board panel reports directly to the Provost, and the other panels report to the Macalester College Institutional Review Board and hence indirectly to the Provost. The Provost has charged the Macalester College IRB with the following responsibilities:

1. Periodic review of guidelines for conducting research involving humans at Macalester College and recommendations for changes;
2. Education of the community regarding legal requirements and ethics for conducting such research;
3. Review of requests from outside agencies for research on campus;
4. Review of research funded by the Federal Government;
5. Review of research proposals by Macalester faculty, students, staff, and college committees;
6. Consultation with those engaged in on-campus research as needed;
7. Monitor the information provided to research participants to ensure their informed consent; and
8. Consultation with members of the community who might have complaints or concerns about on-campus research involving human participants.

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, Macalester 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.

THE IRB AND ITS ROLE

Review of Research Proposals

In general, proposals by Macalester faculty, staff, students or college committees for research involving human participants must be submitted to the Macalester College Institutional Review Board or to a departmental or divisional review board unless the research is exempt from such review as indicated below.

Composition of the Macalester College Institutional Review Board

The Macalester College Institutional Review Board consists of three faculty members and one staff member. At least one member must be a non-scientist, and at least one member must be a scientist in a field that does research involving human participants. The committee should include both men and women. No member should participate in any action of the IRB (except to provide information requested by the IRB) if the member has a material conflict of interest with respect to the matter under consideration.

When research (e.g., federally funded research) requires that assurance be given to the Federal Government, the committee will include, in addition to the four members described above, a community representative who is not currently affiliated with Macalester College nor a member of the immediate family of a person affiliated with Macalester College.

Departmental and Divisional Institutional Review Boards

Departments, divisions and interdisciplinary programs that regularly sponsor research involving human participants may form their own institutional review boards. The procedures adopted by these IRB panels must be approved by the college-wide Macalester College IRB.

Records

All institutional review board panels must keep records for at least three years. In addition, records of particular research projects must be kept for three years after the research has been completed. The records should include at least the following.

1. A list of all IRB members,
2. Proposals submitted to the IRB,
3. Minutes of the meetings of the IRB,
4. Actions taken by the IRB,
5. Copies of all correspondence between the IRB and researchers,
6. Documents regarding consent, and
7. Reports filed by researchers upon completion of their studies.

Department and divisional IRBs must issue year-end reports to the chair of the Macalester College IRB. The chair of the Macalester College IRB will issue a year-end report to the provost. The year-end reports should indicate how many proposals were reviewed, how many were approved and whether there were any problems that arose during the course of research.

TYPES OF RESEARCH

Macalester faculty, staff and students engage in a variety of research involving human participants. Not all of this research meets the technical definition of “research” for purposes of requiring IRB oversight. Macalester College follows federal regulations that define “research” as “a systematic investigation ... designed to develop or contribute to generalizable knowledge.” Research participants are referred to by federal regulations as “human subjects.” [45 CFR Section 46.102]

Exempted Research

The following types of research do not require review by an IRB panel:

1. Research at Macalester involving normal educational practices such as instructional strategies, curricula or classroom management techniques

(Professors who experiment with their class format to improve their teaching or use student evaluations, for instance, do not need the approval of an IRB. In addition, the use of language and other proficiency tests as part of First Year advising do not require IRB approval.)
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures or interview procedures, unless: (a) the information obtained directly or indirectly identifies

individual participants; and (b) disclosures of participants' responses would place the participants at risk of legal liability or would be damaging to their financial standing, employability or reputation

3. Observations of public behavior as long as information is recorded in such a way that individuals cannot be identified

(Basically this includes observation of behavior in public places. Public places are places that are open to the public and in which there is little reasonable expectation of privacy. For example, activity observed in a public restroom is not public behavior. On the other hand, pedestrian traffic flow on the corner of Snelling and Grand is public behavior.)

4. Research of public documents
5. Oral History

Most oral history research is exempt from IRB oversight because it does not meet the technical definition of "research" under federal regulations. Oral history deals with particular individuals who have played a role in particular historical events and does not seek to establish the types of generalizable principles or laws that characterize the technical definition of "research" for purposes of IRB oversight.

Although some universities and colleges nonetheless require IRB review of oral history projects, Macalester College follows the lead of the American Historical Association, the Oral History Association and the U. S. Office for Human Research Protection (OHRP) in treating most oral history projects as exempt from IRB oversight.

Oral history contrasts with ethnography, most of which is subject to IRB review. Macalester College follows the American Anthropological Association in regarding ethnography as meeting the technical definition of "research" requiring IRB oversight.

6. Journalism

Journalists and investigative reporters who are writing stories for news publications such as the *MacWeekly* are typically not engaged in research within the scope of IRB oversight and are exempt from IRB oversight. If, however, research requires IRB approval on other grounds, the fact that the author intends to publish it in a newspaper does not exempt it from IRB approval. For example, a researcher who intends to publish the results of a psychological experiment involving human participants in the *MacWeekly* is not thereby exempt from IRB oversight.

7. Interviews of Experts and Public Figures

Interviews of experts or public figures about the areas of their competence are not considered human subject research and do not require IRB review. This is because the expert or public figure is not the object of the research. For example, asking a Roman Catholic priest about church liturgy is not human subjects research; the priest is functioning as an expert consultant, not a subject. On the other hand, research that involves asking priests about the difficulties they encountered in their commitment to celibacy is human subjects research, since the priests themselves are the objects of the research.

Research Suitable for Expedited Review

Some research that requires IRB approval is suitable for expedited review. This research can be reviewed by one experienced IRB member and typically requires only a few days. To qualify for expedited review the research must present no more than minimal risk to the participants and fall into one of the federally approved categories. The following categories are most relevant for Macalester College:

1. Research of data collected for non-research reasons;
2. Research on individual or group characteristics or behavior conducted by survey or interview;
3. Continuing review of previously approved research;
4. Research involving the collection of blood samples; and
5. Research involving the collection of biological specimens such as hair, saliva, etc. by noninvasive means.

Federally Funded Research

Proposals for research funded in part by the federal government must be submitted to the chair of the Macalester College IRB. If the research is exempt from review under federal regulations, the chair of the IRB will write a memorandum stating that it is exempt. Even in the case of clearly exempt oral history projects the researcher should obtain a statement from the IRB to include with the federal grant application.

Research Subject to Federal Regulation

Research that is made subject to federal regulation by a federal department or agency must be submitted to the chair of the Macalester College IRB. The chair will notify the researcher if the research is exempt from review by the entire board.

Research Involving Minors

Research involving minors as subjects (i.e., children under the age of legal consent, which is 18 years of age for most jurisdictions and purposes) raises special issues and risks. Accordingly, *even if no greater than minimum risk is presented* to minor subjects, the research proposal should be reviewed by an IRB panel. Heightened standards apply to the review of such proposals, and the IRB panel may impose additional and/or different requirements than those described elsewhere in these guidelines pertaining to adult research subjects.

Most of the exceptions to the IRB review listed above will apply to research involving minors. However, research involving (i) survey or interview procedures and (ii) observations of public behavior when the investigator participates in the activities being observed are not exempted from IRB review when minors are involved as research subjects.

Researchers must also obtain the affirmative assent of minors who are old enough to give assent to participate in research, and permission of a parent or legal guardian.

The IRB will review whether adequate provisions for soliciting this assent and permission have been made even if the research involves no risk or no greater than minimum risk.

If the research involves greater than minimal risk, the IRB will also review the extent to which the research holds out the prospect of either (i) direct benefit to the minor subjects or (ii) generalizable knowledge about the minor subjects' disorders or condition that is of vital importance for the understanding or amelioration of that disorder or condition. If the research is potentially justified on the first grounds (i.e., direct benefit to the minor), the IRB will evaluate whether:

1. The risk is justified by the anticipated benefit to the minor subjects;
2. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by alternative approaches; and
3. Adequate provisions have been made for the assent of the children and consent of the parents or guardians. (Typically the consent of one parent or guardian will be sufficient when risks are no more than minimal.)

If the research is justified on the basis of (ii) (i.e., increased generalizable knowledge), the IRB will evaluate whether:

1. The risk represents a minor increase over minimum risk;

2. The intervention or procedure presents experiences to minor subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; and
3. Adequate provisions have been made for the assent of the children and the consent of the parents or guardians. (Where both parents are alive, known, competent and reasonably available the permission of both parents is required.)

Cooperative Research

Federally funded research that is done in cooperation with another institution must be reviewed by the Macalester College IRB unless Macalester has a cooperative agreement with the other institution.

IRB EVALUATION OF RESEARCH PROPOSALS

Criteria

In general, the IRB considers the following factors in reviewing research proposals:

1. Whether the risks to the participant are reasonable when weighed against possible benefits to the participant and the importance of the knowledge expected to be gained by the research;
2. Whether the risks to the participants are minimized;
3. Whether the selection of participants is equitable (e.g., free from racial, gender or other types of bias);
4. Whether arrangements are made to ensure that the informed consent of participants is obtained and, where required by law or these regulations, documented;
5. Whether research data are handled in such a way that the privacy of participants is protected;
6. Whether any of the participants is vulnerable to coercion or undue influence; and
7. Whether there are provisions for monitoring data when necessary to protect human subjects.

IRB Responses to Research Proposals

When the IRB panel reviews a research proposal the IRB panel will provide the researcher with a written report stating whether the proposal is 1) accepted as is, 2) accepted with stipulations that must be incorporated into the research, 3) accepted with suggested changes that are not mandatory, or 4) not accepted. A record of the report will be kept by the chair of the IRB panel. Researchers must reply to IRB stipulations before final approval is granted. Proposals that are not accepted may be reworked and resubmitted. There is, however, no appeal of a decision of the Macalester College IRB.

IRB panels cannot approve research that has already been conducted. It is therefore important to seek IRB approval for non-exempt research before beginning the research.

Reporting Unanticipated Problems

If a researcher encounters unanticipated problems regarding risks to human participants, the researcher should immediately report these problems to the chair of the panel that approved the research as well to the chair of the college-wide Macalester IRB. In addition, researchers are required to report significant deviations from an IRB approved protocol as well as violations of regulations protecting human subjects.

The chair of the panel that originally approved the research will then convene the panel to determine what steps should be taken including possible suspension or termination of the research. Serious harm that occurs to research participants will also be reported to the Provost along with the recommendation of the IRB panel.

Changes in Protocols

Researchers who want to make significant changes in a previously approved protocol must obtain prior permission from the IRB panel that originally approved the protocol.

Subsequent Reviews

The IRB will review all continuing research that it has approved on an annual basis. Depending upon the degree of risk to research participants, review may take place more frequently. In addition, the IRB will meet to consider proposed changes in research programs that it has previously approved.

VOLUNTARY PARTICIPATION

Consent

In general, researchers should insure that their research participants are voluntary participants. In some cases this requires the use of written consent forms signed by the research participants. These forms should be retained by the researcher, and copies should be provided to each participant signing the form. In other cases, it is sufficient to inform the participants of the nature of the research and that their participation is voluntary.

Research Requiring Consent Forms

Research that imposes more than a minimal risk on participants typically requires written consent signed by the participant. The participants should be given an adequate opportunity to read the consent form before signing it. The written consent form should include the following information:

1. A statement of the nature, purposes, procedures, and expected duration of the research that makes it clear to the participants that they are involved in research;
2. A description of any reasonably foreseeable risks, discomforts and benefits to the participants;
3. Disclosure of alternatives to the research (In most cases at Macalester, the alternative will simply be not participating.);
4. A statement regarding the confidentiality of research records;
5. An explanation of whether any type of compensation or medical treatment is available in the event that injury or psychological harm to the participant occurs during the course of research that imposes physical or psychological risks;
6. An explanation of whom to contact regarding concerns about the research and research participants' rights, including the telephone number or e-mail address of the person conducting the research and the name and telephone number or e-mail address of the chair of the IRB; and
7. A statement that participation is voluntary and that the participant may withdraw consent at any time without prejudice.

Assent Forms

Although children are not able to give fully informed and autonomous consent, older children are nonetheless often able to assent to participate in research and should be given the opportunity to assent or refuse participation. Assent forms for children are like consent forms for adults except that they are written in language that can be understood by a child who is eight years old. In addition, assent forms are shorter than consent forms and should typically be only one page long.

Research Not Requiring Written Consent

Research involving no more than minimal risk of harm to human participants still requires the participants' consent, but may not require that participants sign a written consent form. Anonymous surveys, for example, do not require written consent. Subjects who do not consent simply do not fill out the survey. Nonetheless, there are several requirements to insure that the participant is voluntary. Surveys and interviews must be conducted in a setting and manner that is non-coercive. The researcher should provide the participants with the following information.

1. An explanation of the nature of the research so that participants know they will be involved in a research study;
2. The names of those who are conducting the survey and any sponsoring organizations;
3. The uses that will be made of the research information;
4. A description of who is being surveyed or interviewed;
5. Assurance that responding to the survey or interview questions is voluntary and that even if participants decide to participate they may refuse to answer questions or terminate the interview; and
6. An explanation of whether those conducting the survey will know the participant's identity.

Surveys can attach this information as a cover sheet for the survey.

IRB Waiver of Written Consent

The IRB may waive the requirement for written and signed consent in two sorts of cases:

1. When the only record linking the participant to the research would be the written consent form and breach of confidentiality is the principle

risk, provided the participants are asked whether they want to sign a written consent form and allowed to do so if they desire; and

2. When there is no more than minimal risk and consent is usually not required outside the research context.

No Waiver of Liability Language

Whether the participant's consent is written or verbal, it should not include exculpatory language through which the participant is made to waive any of his or her legal rights or release the researchers, research sponsor, or Macalester College from liability.

Deception

Research involving deception will not be approved unless the following conditions are met.

1. Alternative procedures that do not involve deception are not feasible and would invalidate or confound research results.
2. The deception is justified by the study's scientific or educational merit.
3. Subjects are not deceived about matters such as physical or psychological risks that would affect their willingness to participate. In particular, deception must not be used to recruit research participants.
4. Subjects are told of the deception as soon as feasible. This should generally be at the end of their participation, but when necessary may be at the completion of the study.
5. The deception involves no more than minimal risk.
6. When feasible the consent form indicates that deception may be used or that in some research protocols full disclosure is not possible.

HARM TO RESEARCH PARTICIPANTS

It is important to keep in mind that there are a variety of ways in which research involving human participants could harm the participants. What follows is a list of some of the types of harm that may result from research.

Physical Harm

The most obvious sort of harm that could result from research is physical harm. The potential for physical harm is most clearly present in medical

experiments that involve testing new drugs or medical devices. While such studies are not carried on at Macalester, members of the Macalester community who work with medical researchers from major universities may encounter the potential for physical harm. Physical harm may also result from studies conducted on athletes, for example, who are undergoing various sorts of stress tests.

Psychological Harm

Research may also create the potential for serious psychological harm. This can occur in several ways. Surveys and questionnaires, for example, sometimes ask respondents to provide confidential information about private matters such as sexual practices or illegal drug use. If there is a breach of confidentiality, the research participants may find their sudden loss of privacy psychologically traumatic. Psychological harm can also occur when research participants are forced to confront facts about themselves about which they were previously unaware.

Legal Harm

Surveys, interviews and questionnaires that ask participants whether they have engaged in illegal activities such as possession of illegal drugs may expose the respondents to criminal liability if the study does not provide for anonymity. Participants may also be exposed to civil liability if they are asked to answer questions which seek information about harm that they have done to others.

State reporting laws may also pose legal risk. If a research participant reveals that he or she is likely to harm someone, there may be a legal duty to warn the threatened person. There may also be state laws requiring the reporting of certain matters such as child abuse and various diseases. In addition, researchers may at some point be faced with a subpoena for records relating to criminal activity of their research subjects. Research subjects who are being interviewed about illegal activities such as child abuse need to be informed about the limits of confidentiality before the interview begins.

Financial Harm and Harm to Reputation

Disclosure of certain facts may harm a person's financial standing or reputation. Surveys that are not anonymous and that seek information about criminal activity, for example, could serve not only to create legal liability for a person, but also harm the person's reputation and financial standing. Similarly, non-anonymous surveys of employees that seek information regarding job performance, for example, could place an employee in jeopardy.

Violations of Rights:

Participants can also be harmed by having their rights violated. If confidentiality is breached and the participant's privacy is violated, harm to the participant has occurred whether or not the participant also suffers psychological, physical or legal damage. Research participants who are manipulated into participating in experiments or studies without their consent are also harmed whether or not they also suffer physical, legal or psychological damage.

Lack of Respect for Participants

Research procedures that treat participants with a lack of respect should also be considered as harmful. Unnecessary deception constitutes such a lack of respect. In addition, studies that waste the time of participants because the studies repeat previous research or have little scientific or educational merit manifest a lack of respect for participants.

PREVENTING HARMES

Anonymity

Many of the harms listed above can be prevented by maintaining the anonymity of the research participants. Surveys and questionnaires, for example, that seek highly confidential information can be set up so that it is not possible to identify the respondents. In giving questionnaires to a relatively small pool of participants the researcher needs to be careful about what demographic information he or she requests. For this reason, surveys that ask about the respondents age, sex, marital status, ethnicity, race, and living arrangements and then go on to ask about confidential matters such as sexual practices or drug use may pose little risk for participants at a large university, but may pose a serious risk for participants at Macalester College. There may, for example, be only one Asian American male between the ages of 25 and 30 who is a junior living in a culture house at Macalester College.

Confidentiality

It is, of course, not always possible to preserve the anonymity of one's research participants. Researchers using face to face interviews are not in a position to provide anonymity. These researchers can, however, safeguard the participant's confidentiality. Research records can be kept in locked areas, and access to research information can be tightly controlled. It is also important that research data be disposed of in a way that does not pose confidentiality problems. Confidential research data should be shredded, rather than simply thrown into a recycling bin.

Managing Potential Harm

If research is conducted that presents a risk of physical or psychological harm, such harm can be minimized by having on call or present a physician or clinical psychologist who can deal with the effects of the study. For example, research by someone in the Physical Education Department that involves extreme cardiac stress to the participant should be conducted under the supervision of a physician.

Consent

Violations of the participant's rights can often be avoided simply by obtaining the consent of the participant. A researcher does not violate the privacy of a participant who has already waived his or her right to privacy after being fully informed of the nature of the study in which he or she is participating.

The fact that a study involves risks to research participants does not of itself mean that the research should not be conducted. If the study is important, the risks are minimized as far as possible, and the participants consent, the research may be well worth pursuing in spite of the risks. Macalester College does require, however, that any research that presents more than a minimal risk to the research participant be reviewed by an IRB panel.