



Title: Institutional Review Board Standard Operation
Procedure

Code:
EE0109-A

Policy Reference: E0102, Research Projects Conducted for Personal Use or for an
Outside Organization

I. Statement of Policy

Milwaukee Area Technical College ("MATC") recognizes the importance of the protection of the safety and welfare of all human research subjects. All research projects involving MATC students, personnel and/or MATC property, records or other materials are subject to MATC Policy E0102.

MATC is guided by the ethical principles regarding research projects for personal use or for an outside organization involving humans as subjects, as set forth in Federal Policy §46.101-46.505, Code of Federal Regulations, Title 45 Public Welfare, Department of Health and Human Services, Part 46, "Protection of Human Subjects," Revised January 15, 2009, Effective July 14, 2009.

Through District Board policy E0102, the MATC District Board established the MATC Institutional Review Board (IRB). The IRB has responsibility to review all proposed research projects that involve the use of human subjects, even if the proposed research project would be exempt from review under federal regulations. The IRB is authorized to review, approve, conditionally approve or disapprove research activities conducted by or through the College using human subjects. Research that has been reviewed by the IRB is subject to further review and may be disallowed by MATC officials, including the Executive Vice President and Vice President. Those officials may not, however, approve research that has been disapproved by the IRB.

The IRB does not assume the role of evaluating the soundness of the proposed research design or study, the merits of the research design, nor the potential contribution of the research to the scholarly literature. Rather, the purpose of the IRB is to ensure that: 1) human subjects involved in the research are treated ethically; 2) all subjects are provided with substantial information about the study and consent to be a subject in the study; and 3) all private information will be handled confidentially.

II. Basic Principles

The basic principles that govern the IRB in assuring that the rights and welfare of subjects are protected include Respect for Persons, Beneficence and Justice as described in *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* ("The Belmont Report"). The following principles apply to all research, including student projects, involving human subjects at MATC to ensure that adequate safeguards are provided:

1. Subjects' legal rights will be respected; rights to privacy, dignity, and comfort will also be considered in approving proposed research.



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2. Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3. Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject.
4. Adequate provisions should be made for recruiting a subject population that is representative of the population base in terms of gender and minority representation unless scientifically justified.
5. Research involving human subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions.
6. Participation of a human subject in research must be voluntary and the right to withdraw at any time must be provided. Information provided to gain subject consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.
7. All research programs that involve human subjects must be reviewed by and must receive approval of the IRB prior to their initiation or, for continuing research, prior to initiating any changes in protocol. Continuing research programs are subject to periodic review, to be carried out no less often than once per year.
8. All Principal Investigators (PI) and all MATC employees are required to report to the Chair of the IRB as soon as they have knowledge of any of the following:
 - a. Unanticipated problems involving risks to subjects or others; or
 - b. Serious or continuing noncompliance with the federal regulations or the requirements, conditions or determinations of the IRB.

In the event that a research project is suspended or terminated by the IRB, the IRB Chair will make a written report to the IRB and President of MATC, the head of any department or agency sponsoring the research, and any applicable regulatory body, including the OHRP.

III. Authority of the IRB



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Authority of the IRB is as set forth in District Board policy E0102. The IRB has authority to approve, require modifications to secure approval, or disapprove all research activities covered by the HHS regulations, including proposed changes in ongoing, previously approved, human subjects research. The IRB further has the authority to suspend or terminate the approval of ongoing, previously approved research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected, serious harm to subjects.

- A. MATC is authorized to participate in research in one or more of the following categories, subject to IRB approval:
- (1) Research conducted in established or commonly accepted educational settings, involving recognized educational practices, including, but not limited to:
 - (i) Research of regular and/or special education instructional strategies,
 - (ii) Research of the effectiveness of or the comparison among instructional technologies, curricula, or classroom management methods.
 - (2) Research involving the collection or study of existing data, documents, and records 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.
 - (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. If any of the following conditions apply, the investigator must obtain the legally effective informed consent of the human subject or the human subject's legally authorized representative.
 - (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects.
 - (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 subject's financial standing, employability, or reputation.
- B. The IRB is authorized to review all projects and programs involving human subjects in accordance with policy E0102 and these Standard Operating



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Procedures, applicable federal regulations and any applicable sponsor policies and guidelines.

- C. The IRB has approval authority of human subject protocols and can disapprove, conditionally approve or approve studies based upon consideration of any issue it deems relevant to human subject protection. Research that has been approved by the IRB may be subject to further appropriate review and approval by the Vice President, or designee. However, the VP for Learn or designee may not approve the research if it has not been approved by the IRB.
- D. The IRB has authority to require progress reports from the investigators and oversee the conduct of the study.
- E. The IRB has authority to suspend or terminate approval of a study, or to place restrictions on a study, when this is deemed to be in the best interests of the subjects in that study.
- F. The IRB has authority to, at its discretion, observe the informed consent process as practiced by any investigator or authorized person in any approved protocol, especially in cases where the consentee is from a vulnerable population.
- G. The IRB has authority to access, and to make copies of, records related to any research approved by the IRB, regardless of the location of those records, for any reason. Appropriate notice will be given, where feasible.

IV. IRB Membership

The IRB is composed of at least five voting members, including up to two members who are not affiliated with MATC and whose immediate family members are not affiliated with MATC. All appointments are made in accordance with the requirements of policy E0102 by the Vice President supervising the Office of Institutional Research.

The IRB is composed of members with varying backgrounds and expertise in special areas to provide a complete and adequate review of research. Committee members should possess not only broad specific competence sufficient to comprehend the nature of the research, but also other competencies necessary for judgments as to the acceptability of the research in terms of MATC's mission, policies, relevant legal requirements, ethical standards and standards of professional practice. The IRB may consult with members of the MATC community with specific subject matter expertise as needed.

The IRB must include both men and women, at least one member whose primary concerns are in the sciences areas, one member whose primary concerns are



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nonscientific areas, and at least one member who is not otherwise affiliated with MATC (directly or indirectly). At least two (2) IRB members should maintain a Ph.D.

All IRB members are required to complete a formal training at the time of their initial appointment. Training that satisfies the requirement is the online tutorial offered by OHRP: <http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>

IRB members should submit verification of training forms to the IRB Chairperson, at least every three (3) years.

Liability coverage for the IRB is provided through MATC's professional liability insurance coverage.

V. Conflict of Interest Policy

investigators shall not be involved in the selection of IRB members.

Investigators, including those employed by MATC, will be asked whether they have a vested interest in any commercial enterprise associated with any aspect of the protocol, and, if yes, to fully explain and identify the safeguards taken to prevent investigator bias in subject recruitment and/or the consent process.

Investigators and IRB members who are MATC employees and who apply for federal grants and contracts are subject to the MATC District Employee Code of Ethics, policy C0700 including the conflict of interest provisions stated therein.

IRB members are expected to recuse themselves from deliberations and actions on matters for which they have, or may be perceived to have, a potential conflict of interest. An IRB member is said to have a conflict of interest whenever that IRB member, or spouse, or household member of the IRB member:

1. Is an investigator or sub-investigator on the protocol;
2. Has a significant financial interest (more than five percent ownership) in the sponsor or agent of the sponsor of a study being reviewed by the IRB, whereby the outcome of the study could influence the value of the financial interest;
3. Acts as an officer or a director of the sponsor or an agent of the sponsor of a study being reviewed by the IRB; or
4. Has identified himself or herself for any other reason as having a conflict of interest.

It is the responsibility of each IRB member to identify and avoid any situations in which he or she, either personally or by virtue of their position, might have a conflict of interest, or may be perceived by others as having a conflict of interest, arising in connection with a matter before the IRB. If an IRB member feels that he or she may have a conflict of interest, the IRB member must notify the IRB Chairperson immediately. The IRB



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Chairperson may request a substitution for the member who is recused. In order not to delay the review process, it is important that reviewers consider the matters upcoming for IRB review immediately upon receipt of the agenda to determine whether they may have a conflict.

Minutes of IRB meetings will reflect the absence of a member (by name) when he or she leaves the meeting during deliberations and actions regarding matters for which they have, or may be perceived to have, a conflict of interest.

VI. Initial Review Procedures

MATC recognizes that federal regulations permit exemption from full IRB review of research involving no risk or minimal risk to participants. However, the MATC IRB, consistent with District Board policy E-0102 does not utilize the exempt category. Full IRB review is required for all research involving human subjects involving the MATC community.

A. Expedited Review

MATC recognizes that under federal regulations certain types of research qualify for an “expedited” review. MATC does not typically utilize expedited review. However, the IRB Chairperson may request expedited review of research activities that (1) present no more than minimal risk to human subjects; and 2) minor changes in approved research. The Prospective Principal Investigators (PI’s) seeking expedited review must clearly indicate the request for expedited review to the IRB Chairperson. Expedited review may be completed electronically outside of a regularly scheduled IRB meeting. The IRB members participating in expedited review may approve, conditionally approve, or table for review by the full IRB. If it is determined that the protocol requires full IRB review, it will be returned to the PI, with comments, for revision and submission to the full IRB.

B. Full IRB Review

Protocols for full board IRB review must be submitted at least five (5) business days prior to the regularly scheduled IRB meeting. The PI is to submit to the IRB Chairperson original signed and completed “Request for Institutional Review Board Action” and the completed “Human Subjects Review Protocol” copies of informed consent documents to be used and any other documents requested by the IRB Chairperson. In addition, the PI should present any information that will aid in evaluating the protocol for compliance with MATC policy and this procedure.



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The PI must be available to discuss the protocol and/or consent forms at the discretion of the IRB.

1. Actions of the IRB

The IRB may take one of the following actions in regard to the proposed protocol and consent form: 1) Approved, 2) Conditionally Approved, 3) Tabled or 4) Disapproved.

i. Approved

When a protocol has been approved, the Chair prepares notice of approval documents, signs it and distributes one copy to the PI, a copy for the IRB files and, if appropriate, the performance site. Approval of the protocol will be based on the following:

- a. The extent to which the protocol makes explicit in design and procedures the protection of subjects' rights.
- b. Should a degree of deception and/or withholding of information be necessary for adequate testing of the hypotheses and in the absence of any practical alternative, sufficient justification that the potential benefits to the subject or the importance of the knowledge to be gained outweighs any potential risks that may be present as a result of any such deception.
- c. Assurances of acceptable debriefing, if appropriate.¹
- d. The adequacy of facilities and other resources necessary for completion of the study and protection of subjects' rights.
- e. Anticipated benefits, if any.
- f. The personal risk to the subject in relation to expected benefits.
- g. The adequacy of procedures for securing informed consent from the subject.
- h. The adequacy of measures for minimizing of risk and the protection of the health, safety, comfort and legal rights of the subject.

¹ It is the responsibility of the PI to give each subject an explanation to questions ensuing from participation in the research project following its conclusion. It is strongly recommended that this occur immediately following participation for each subject. But, if in the judgment of the IRB, such information could adversely affect subsequent data collection in the same study, the full explanation may be delayed for a reasonable period of time, provided that in cases where it is unavoidable to mislead the subjects and/or in which it is possible that the experimental treatment may result in emotional stress for the subjects, it is required that they receive a full debriefing following participation.



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i. The adequacy of measures for protecting the privacy of subjects and maintaining confidentiality of data.

ii. Conditionally Approved

Conditional approval is approval subject to defined conditions or restrictions identified by the IRB. If the protocol is conditionally approved, the IRB documents notice to the PI stating the conditions of approval, signs and dates the document, and sends this document to the PI notice outlining the restrictions or conditions upon which the research is approved. The IRB Chairperson may also specify a time period for satisfaction of the conditions or restrictions. The PI must then respond in writing to the IRB Chairperson addressing the restrictions or conditions as indicated within the designated time frame, if any. The IRB Chairperson will circulate the PI's responses to the IRB members electronically. Upon receipt and approval by a majority of the IRB members, the restrictions are removed and the protocol is then processed as an approval and notice of approval distributed as described above.

iii. Tabled

Tabled action means that the protocol was not sufficiently complete for the IRB to reach a final decision and that additional information or clarification of information is needed by the IRB. In this case, the PI is notified by the IRB Chairperson and the additional information or clarification is requested. In the case of a tabled protocol, the PI may be invited to attend the next regularly scheduled IRB meeting to present/clarify the protocol for the Board.

iv. Disapproved

If the protocol is disapproved, the PI will be informed in writing of the reasons for the disapproval. The PI may revise and resubmit his/her protocol for another review.

VII. Continuing Review

The IRB may conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. Principal Investigators will be informed of the annual review by the Continuing Review Questionnaire distributed by the IRB Chairperson, or designee. Principal Investigators are asked to complete and return the Continuing Review Questionnaire to the Chair of the IRB along with the informed consent document currently in use with the project being reviewed. The PI will be notified of the action taken following Continuing Review.



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When a request for Continuing Review is submitted, the IRB shall consider the following: changes to the research, protocol deviations and violations, since the last scheduled review; adverse event reports; reports of unanticipated problems involving risks to subjects and, if available, data safety monitoring reports; and investigator compliance.

If the protocol and/or other documents used in the project will be amended, the PI will be required to submit a new protocol incorporating these amendments. Pursuant to OHRP guidelines, the IRB approval period may be held constant from year to year throughout the life of each project. When continuing review occurs annually and the IRB performs continuing review within 45 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur.

However, if an investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the research must stop, unless the IRB Chair finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions, and this finding is ratified at the next convened IRB meeting. However, after the expiration of IRB approval, the protocol will be considered closed and enrollment of new subjects cannot occur nor can any data collected be used for research purposes.

VIII. Operations of the IRB

- A. The IRB schedules regular meetings on a monthly basis, or as required based upon the number of research requests received.
- B. The place and time of the meeting, agenda and submissions to be reviewed are distributed to IRB members at least five (5) business days prior to the scheduled IRB meeting.
- C. At the discretion of the IRB Chair, based upon the nature of the research request and volume of requests, the IRB Chair may assign one primary reviewer and at least one secondary reviewer for each new protocol, who receive the complete study documentation for review. The primary reviewer is assigned consistent with protocol content and reviewer expertise. Secondary reviewer(s) may be assigned using additional factors such as their ability to provide a valuable perspective on salient, non-scientific aspects of the research. The reviewers, who are assigned, based on their expertise, lead the discussion of that protocol. Other IRB members may review summary information, or may review the complete study documentation, upon request.



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D. Voting Requirements

1. A quorum of the IRB, duly convened through written notice, shall be a majority of the voting members with varying backgrounds to promote complete and adequate review of research activities, including at least one member whose primary concerns are in non-scientific areas, at least one administrator and one faculty member.
2. In order for the research to be approved, it shall receive the approval of the majority of those voting members present at the meeting. IRB members may participate and vote by telephone as permitted pursuant to OHRP guidelines.
3. Principal Investigators, including those who are also IRB members, may be called upon to offer information and answer questions about their protocol at a convened meeting at the request of the IRB Chair, but may not be present during voting.
4. Although convened meetings of the IRB are open to the public, materials submitted for review, discussions of protocols, and individual votes are considered confidential and should not be discussed outside the meeting context. If during an IRB meeting the Chair moves the meeting to executive session then any visitors will be asked to leave the room until the executive session has ended.

E. Appeals

The PI may request review of a decision of the IRB when a protocol has been disapproved or conditionally approved and mutual agreement cannot be reached as to acceptable conditions. Upon written notification of appeal from the PI, the IRB shall name an *ad hoc* committee of three or more members of the faculty and administration to review the protocol a second time. The *ad hoc* committee members must be acceptable to both the PI and the IRB. The protocol will be reviewed in accordance with the guidelines established herein and the decision of the *ad hoc* committee will be referred to the IRB for final consideration and decision by the IRB. The PI will be promptly notified of the decision by the IRB. Final disapproval of the IRB cannot be overridden by any institutional official.

F. Amendments in Protocol

Amendments are categorized as minor changes or significant changes. Minor changes include those proposed changes in research related activities that do not significantly affect an assessment of the risks and benefits of the study and



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do not substantially change the specific aims or design of the study. Minor changes may be reviewed and approved using an expedited review process. Minor changes include the following:

- Addition or deletion of study team members;
- Addition of procedures that do not significantly increase the risk to subjects, considering the original purpose and design of the approved study;
- Removal of research procedures that would thereby reduce the risks to subjects;
- Addition of non-sensitive questions to unvalidated survey or interview procedures;
- Addition of or revisions to recruitment materials or strategies;
- Correction of spelling, typographical or grammatical errors or other editing of study materials for purposes of clarity.

Significant changes are those that affect an assessment of the risks and benefits of the study or substantially change the specific aims or designs of the study. Significant changes will generally be reviewed at the same level of review at which the study was first reviewed by the full IRB. Examples of significant changes include:

- Addition of a new and/or separate subject population;
 - Addition of research procedures that involve greater than minimal risk to subjects;
- Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for subjects or damage their financial standing, employability, insurability or reputation;
- Removal of follow-up visits that appear necessary for monitoring subject safety and welfare.

Modifications can be made only to IRB approved studies.

G. Grievances

The IRB shall be informed of all grievances (including those of a research subject against a PI) and, if requested, the IRB will act in an advisory capacity.

IX. **Recordkeeping Requirements**

The IRB prepares and maintains adequate documentation of IRB activities including:

1. Copies of all research proposals reviewed, approved sample consent documents, and continuing reports submitted by PI's;



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2. Minutes of IRB meetings showing: members present; results of discussions on debated issues and record of IRB decisions; and records of voting;
3. Records of continuing review activities, updated consent documents and summaries of on-going project activities. Consent documents should be stamped to show IRB approval and date of approval expiration;
4. Copies of correspondence between IRB and investigators;
5. Any statements of significant new findings provided to subjects;
6. Adverse reaction reports and documentation that the IRB reviews such reports;
7. Emergency use reports; and
8. General project information provided to subjects.

IRB records shall be retained for at least three (3) years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services, the Food and Drug Administration, the Department of Veterans Affairs, and other federal regulatory agencies, at reasonable times and in a reasonable manner.

In addition, the IRB maintains a permanent record of the list of current IRB members, and written procedures for the IRB.

IRB records are maintained by and in custody of the IRB Chair.

X. Information the Investigator Provides to the IRB

- A. Professional qualifications to do the research (including a description of any necessary support services and facilities).
- B. Appropriate MATC review form including protocol summary.
- C. Complete study protocol and description including:
 1. Title of the study and summary of research;
 2. Purpose of the study (including expected benefits);
 3. Sponsor of the study and source of financial support for the research;
 4. Status of the PI;
 5. Supervising faculty (advisor) approval; MATC supervising administrator approval when applicable;
 6. Subject inclusion/exclusion criteria (including reasoning for excluding subjects who might otherwise benefit from the research);
 7. Justification for use of any special/vulnerable subject populations (such as children under age 18, prisoners, disabled, pregnant or mentally disabled);
 8. Study design and research methods description;
 9. Provisions for managing adverse reactions;



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10. Procedures for documentation of informed consent, including procedures for consent of minors, if any, use of legally authorized representatives, translators and document storage;
11. Remuneration to subjects for their participation;
12. Any compensation for injured research subjects;
13. Extra costs to subjects for their participation in the study;
14. Inclusion/exclusion of women, minorities, and/or children.

D. Investigator's brochure or advertising material, if any.

E. Survey instrument, questionnaire or interview protocol, if any.

F. The proposed consent document, including translated consent documents, as necessary, considering the likely subject population(s); or request for waiver of requirement to obtain informed consent.

G. Requests for changes in study after initiation including changes to consent forms.

H. Reports of unexpected adverse events and unanticipated problems involving risks to subjects, including, if available, data safety monitoring reports.

I. Reports/interim reports that include reports of protocol violations and/or deviations and any other instances of investigator non-compliance.

XI. Principles of Informed Consent

A. Study participants are entitled to certain information, including a full and frank disclosure of all the facts, probabilities, options and opinions which a reasonable person might be expected to consider before giving his/her consent to participating in the study. A copy of the signed consent form must be given to the person signing the form and a copy must be kept on file with the investigator or MATC as indicated below.

B. "Informed consent" means insuring that all potential subjects and/or their legally authorized representatives are fully informed of all aspects of their participation in a research project so as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent are found at:

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46>

C. The informed consent of subjects will be obtained by methods that are adequate and appropriate. Consent must be obtained from the subjects themselves except when the subjects are not legally capable of giving informed consent because of



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age, mental incapacity, or inability to communicate. In the case of a minor, the IRB may accept the permission of the minor's parents (or parent) or legal guardian, along with the assent of the minor, in accordance with applicable federal regulations. In the case of other subjects not legally capable of giving informed consent, the IRB may accept the consent from a legally authorized representative (LAR). The LAR must be authorized either by a power of attorney or a court order.

- D. The IRB shall determine whether consent is adequate in light of the risks to the subject and the circumstances of the research. The IRB shall also determine whether the information to be given to the subject or to qualified third parties, verbally or in writing, is a fair explanation of the procedure, any possible benefits, and attendant hazards. Where debriefing procedures are considered as a necessary part of the research plan, the IRB will ascertain that any such debriefings will be complete and prompt. In addition, the language used should be clear and unambiguous with every attempt to eliminate technical terms and jargon.
- E. For research involving more than minimal risk to subjects or if determined by the IRB during the ordinary review process to involve more than minimal risk, a compensation for injury statement will be required in the consent form. This statement should clarify who is responsible for any costs associated with any medical treatments required or any personal compensation for injuries received as a result of participation in the research.
- F. Some research may not impose on the rights and welfare of human subjects so as to make informed consent a requirement. Therefore, the IRB may choose to waive the requirement to obtain a signed consent form for some or all subjects in some cases when it finds either:
 - 1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
 - 2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. Examples of such research where use of a cover letter is generally appropriate are collecting data by survey or interview.



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Any waiver of documentation by the IRB must be based upon clearly defensible grounds. A request for waiver of documentation by the PI must include justifiable reasons in the protocol.

The IRB may also choose to approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

G. Informed consent need not be based on full pre-study information. However, it is the responsibility of the IRB to set limits on the incompleteness of such information. Further, in those studies in which it is proposed to mislead the studies during data collection, the IRB has the responsibility of assessing the degree to which this violates the rights of subjects, and then setting the limits for such procedures.

Office of Responsibility: Office of Institutional Research
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