

104 CMR 31.00: HUMAN SUBJECT RESEARCH AUTHORIZATION AND MONITORING

Section

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31.01: Authority and Scope

(1) Authority. 104 CMR 31.00 is promulgated pursuant to M.G.L. c. 19, §§ 1 and 18; and M.G.L. c. 123, §2, ~~and 45 CFR 46.~~

(2) Scope. 104 CMR 31.00 ~~establishes the approval process and the standards for human subject research when applies to research, regardless of funding source, if:~~

(a) ~~a Department employee, as an employee, participates as a research investigator or subject; a Department employee, in his or her role as an employee, participates as a research investigator or subject;~~

(b) the recruitment of any subjects for the research is conducted at a facility or program operated or contracted by the Department, or individuals are recruited as subjects for the research because they receive services from the Department;

(c) the research is conducted at a facility or program operated or contracted for by the Department;

~~(b) a client of the Department is a subject of the research, unless the research in no way is related to the Department, or a facility or program operated or contracted for by the Department;~~

(d) the research involves disclosure by the Department of private information or protected health information~~data as defined in 104 CMR 31.02;~~ or

(e) the terms of another regulation or an agreement or contract with the Department~~other regulation specifically make 104 CMR 31.00 apply.~~

~~104 CMR 31.00 does not apply to the disclosure by the Department of information or documents that are public records pursuant to M.G.L. c. 66, § 10 and c. 4 §7(26).~~

No research within the scope of 104 CMR 31.00 may be conducted without the prior approval of the Department's Institutional Review Board.

(3) Mandatory Review. ~~No research within the scope of 104 CMR 31.00 may be conducted without the prior review and approval of the Department Research Review Committee that has jurisdiction.~~

(4) Power to Terminate, Suspend and Modify. ~~The Commissioner, an Area Director, or a Department Facility Director, in consultation with the Area Director, may with good cause:~~

(a) ~~terminate the research;~~

(b) ~~impose additional conditions;~~

(c) ~~require additional review by the applicable Department Research Review Committee;~~

(d) ~~delay the initiation of the research until the completion of the additional review; or~~

(e) ~~temporarily suspend the research, pending other action.~~

~~The Commissioner's authority extends to all research. The authority of an Area Director and a Facility Director extends only to research in his or her Area or facility. A Facility Director may act independently if immediate action is necessary to protect the health or safety of a research subject. The decision to take an action pursuant to 104 CMR 31.01(4) is final and not subject to further review, judicial or otherwise. Written notice of the action taken and the reason for it will be given promptly to the principal investigator. These powers are in addition to the power of a Department Research Review Committee to terminate research pursuant to 104 CMR 31.03(5).~~

(5) Research Implementation. ~~Area Directors, Department Facility Directors, and Directors of Programs operated or contracted for by the Department must accept the approval or disapproval of research by a Department Research Review Committee. However, an Area Director, and a~~

~~Facility or Program Director, in consultation with the Area Director, must address implementation issues, including the appropriateness of the research for a particular site. Any restrictions placed on implementing the research must be reasonable and minimized to the extent possible.~~

31.02: Definitions

As used in 104 CMR 31.00:

Client of the Department means any person receiving care or treatment through a facility or program operated or contracted for by the Department.~~who is a patient, resident or client of a facility or program operated or contracted for by the Department, for the purpose of receiving care or treatment.~~

Human Subject means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information. Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Interactions include communication or interpersonal contact between an investigator and subject.

Human Subject Research means research involving human subjects or the use of protected health information or identifiable private information.

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~~Data means any individually identifiable information relating to the past, present or future physical or mental health or condition of an individual, provision of health care to an individual, or the past, present or future payment for health care provided to an individual and any other information concerning an individual which, because of name, identifying number, mark or description, can be readily associated with a particular individual.~~

~~Informed Consent means a voluntary agreement to participate in research given by a subject, or if the subject is legally incapacitated (e.g., a minor), by the subject's legally authorized representative, following a process that includes a description of the research and the associated risks and benefits. knowing consent given by a subject, or if the subject is legally incompetent (e.g., a minor), by the subject's legally authorized representative or by a court of competent jurisdiction. The subject, or legally authorized representative, must be able to exercise free power of choice to participate in research without undue inducement or any element of force, deceit, duress, or other forms or constraint or coercion. The subject or legally authorized representative must have the capacity to understand and weigh the risks and benefits of the proposed research for the research subject.~~

~~Institutional Review Board (IRB) means the Department's Institutional Review Board registered with the U.S. Department of Health & Human Services Office for Human Research Protections.~~

~~Private Information means individually identifiable information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and/or information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects.~~

~~Protected Health Information means individually identifiable information relating to the past, present or future physical or mental health or condition of an individual, provision of health care to an individual, or the past, present or future payment for health care provided to an individual.~~

~~Minimal Risk means the risk of physical or psychological harm or discomfort is not greater, in terms of probability and magnitude, than those ordinarily encountered in daily life or in routine medical or psychological examinations.~~

~~Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Research includes an experiment that involves a) a drug other than the use of a U.S. Food and Drug Administration (FDA) approved drug in the course of medical practice; b) a medical device being evaluated for safety or effectiveness; or c) an article subject to regulation by the Federal Food, Drug, and Cosmetic Act where the results of the research are intended to be submitted to or held for inspection by the FDA.~~

~~any investigation designed to lead to generalizable knowledge and involving access to any subject or data but shall not include:~~

~~(a) any ad hoc evaluation or treatment of an individual when such evaluation or treatment is for the purpose of improving the individual's social, emotional or physical well-being and is not for research purposes; or~~

~~(b) collection of information for the Department's management purposes when conducted under the direction of Departmental employees.~~

~~Research Subject or "subject" means any person who participates in research as a subject of such activity, regardless of whether the person is a client of the Department.~~

31.03: Research Review, Approval, Implementation, Termination, Suspension or Modification Department Research Review Committees

(1) Promote the Mission of the Department. Research within the scope of 104 CMR 31.00 may only be conducted if the Commissioner, or designee, determines that the research will promote the mission of the Department as defined in M.G.L. c.19, §1.

(2) Mandatory Review by the IRB. All research involving human subjects must be reviewed and approved by the IRB prior to implementation. As determined by the IRB, for research to be approved it must meet the requirements and standards set forth in 104 CMR 31.05.

(3) Research Implementation. Department Area Directors, Facility Directors, or Directors of Programs operated by or contracted for by the Department must accept the approval or disapproval of research by the IRB. However, the applicable Area Director(s), Facility Director(s), and Directors of Programs may place restrictions on implementing research at a particular site. The restrictions that are placed must be reasonable and minimized as determined by the IRB.

(4) Power to Terminate, Suspend or Modify. The Commissioner or the IRB may as to any research, including research formerly approved by the IRB, take the following actions for good cause:

- (a) terminate the research;
- (b) restrict the implementation of the research at a particular Department site;
- (c) impose additional conditions;
- (d) require additional IRB review;
- (e) delay the implementation of the research until the completion of the additional review; or
- (f) temporarily suspend the research, pending other action.

(5) Final Decision. Any action pursuant to 104 CMR 31.03 is final and not subject to further review, judicial or otherwise. Written notice of the action taken and the reason for it will be given promptly to the principal investigator.

~~(1) Central Office Research Review Committee (CORRC).~~ The Commissioner shall appoint members to a Central Office Research Review Committee (CORRC).—

~~(2) Local Research Review Committee.~~

~~(a) Appointment.~~ An Area Director, or Department Facility Director, in consultation with the Area Director, may appoint a Local Research Review Committee. A Local Research Review Committee can be either a permanent or *ad hoc* committee. An *ad hoc* committee is for reviewing and monitoring a specific project. The same rules apply to both types of committees, except the terms of office for *ad hoc* committee members are limited to the duration of the committee's project.

~~(b) CORRC Certification.~~ Upon the creation of a Local Research Review Committee, the CORRC must certify that the credentials of its members satisfy 104 CMR 31.03(4). The CORRC shall review the credentials annually and upon change of members. The CORRC shall also periodically audit the Local Research Review Committees to ensure, that they have developed and are adhering to written procedures pursuant to 104 CMR 31.03(5). The CORRC may require a Local Research Review Committee to take corrective actions, or may terminate a Committee, if it determines that the Committee has not promulgated or is not adhering to written procedures that comply with 104 CMR 31.00.

~~(3) Jurisdiction of the Department Research Review Committees.~~ The CORRC and Local Research Review Committees shall only review and monitor research within their jurisdiction.

~~(a) CORRC Jurisdiction.~~ The CORRC is responsible for research involving:

- ~~1. access to data or subjects within Department facilities or Department operated or contracted for programs located in two or more Department Areas;~~
- ~~2. federal funding;~~
- ~~3. the Department and another government agency;~~
- ~~4. subjects or data under the immediate jurisdiction of the Department's Central Office;~~
- ~~or~~
- ~~5. a facility or Area that does not have a Local Research Review Committee.~~

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~~(b) Local Research Review Committee Jurisdiction. A Local Research Review Committee is responsible for research involving Department employees, subjects, or data under the primary control of the applicable Area or facility. If a Local Research Review Committee determines that it cannot conduct an objective review because of a real or perceived conflict of interest, or for other good reasons, the Committee, at its discretion, may refer the research for review and monitoring to the CORRC. A conflict of interest may exist if the Area or facility that created the Local Research Committee could directly benefit, financially or otherwise, from the research project (e.g., the research project involves purchasing equipment that Area personnel will be allowed to use). Additionally, a conflict of interest will exist if a quorum cannot be obtained because of 104 CMR 31.03(4)(g).~~

~~(c) Concurrent Jurisdiction.~~

~~1. If the CORRC has jurisdiction over a research project, a Local Research Review Committee must accept the approval or disapproval of the project by the CORRC.~~

~~2. If the CORRC does not have jurisdiction over a research project but multiple Local Research Review Committees in one Area do, the Area Director will designate one Committee to be responsible for the review and monitoring of the research. The other Local Research Review Committees must accept approval or disapproval of the research by the designated Committee.~~

~~(d) Cooperative Research Projects. If a research project involves another state agency or entity that has an Institutional Review Board (IRB) approved by the Office for Protection of Research Risks of the U.S. Department of Health and Human Services, the Department Research Review Committee that has jurisdiction may enter into a joint review arrangement with the other IRB, or make similar arrangements to avoid duplication of effort. The CORRC must approve all joint review arrangements and if the Department Committee that has jurisdiction is a Local Research Review Committee, the Area Director must also approve the joint arrangement.~~

~~(4) Members.~~

~~(a) Number. Each Department Research Review Committee must have at least five members. At least one member must not be affiliated with the Department, or the applicable Area or facility, or with any entity sponsoring or conducting research subject to the Committee's approval, or be part of the immediate family of a person who is so affiliated.~~

~~(b) Qualifications. A Committee must be sufficiently qualified through the experience and expertise of its members to promote complete and adequate review of research activities commonly conducted by or for the Department and the applicable Area or facility. When appointing members, consideration must be given to factors that enhance diversity, including, but not limited to, race, cultural backgrounds, and sensitivity to such issues as community attitudes. Appointments should be made to promote respect for the Committee's advice and counsel in safeguarding the rights and welfare of human subjects. A Committee must consist of members of different genders and professions. A Committee must include members knowledgeable in the applicable laws, regulations and standards of professional conduct and practice. A Committee must include at least one member whose primary concerns are in the scientific areas and one whose primary concerns are in the nonscientific areas.~~

~~(c) Consultants. If a Committee decides that it does not have the expertise required for the review of a particular research proposal, it may use consultants. Consultants cannot be voting members of the Committee.~~

~~(d) Research Involving Minors. If a Committee reviews research involving minors, the authority creating the Committee must appoint one or more members knowledgeable about and experienced in working with children.~~

~~(e) Terms of Office. Subject to 104 CMR 31.03(2)(a), a member will be appointed to a term of three or five years, as determined by the appointing authority. If a vacancy occurs prior to the expiration of the applicable term, the appointing authority may appoint a person to serve the remainder of the unexpired term. A member may be reappointed for additional terms. Additional members may be appointed from time to time for full terms or specific research projects.~~

~~(f) Status. Members shall serve without compensation and shall be special state employees for the purposes of the conflict of interest law, M.G.L. c. 268A.~~

~~(g) Conflict of Interest. A member cannot participate in the review or monitoring of any research in which the member has a financial or personal interest in the research project or the company sponsoring it, except to provide information requested by the Committee.~~

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~~(h) Removal. A member may be removed at the discretion of the appointing authority.~~

~~(5) Duties and Powers.~~

~~(a) General Duties. Each Department Research Review Committee must:~~

- ~~1. hold regularly scheduled meetings and other meetings as needed;~~
- ~~2. develop, maintain, and comply with written procedures for carrying out its responsibilities under 104 CMR 31.00;~~
- ~~3. provide information as needed to maintain the registry required by 104 CMR 31.03(5)(b);~~
- ~~4. review and approve, approve subject to conditions, or disapprove, research proposals;~~
- ~~5. appoint witnesses as part of the informed consent process pursuant to 104 CMR 31.05(5)(d);~~
- ~~6. monitor approved research. The monitoring must be done at least once a year, or once during the duration of the project, whichever is shorter. The monitoring must be appropriate to the type of research and the degree of risk to subjects. A Committee may have a third party participate in the monitoring;~~
- ~~7. suspend or terminate research that is not being conducted in accordance with the Committee's requirements, or that is associated with unexpected harm to subjects;~~
- ~~8. provide updated information concerning state and federal regulations covering research and human rights; and~~
- ~~9. investigate complaints pursuant to 104 CMR 31.06.~~

~~(b) Additional Duties. The CORRC has the following additional powers and duties:~~

- ~~1. to serve, with the approval of the Office for Protection of Research Risks of the U.S. Department of Health and Human Services, as the Institutional Review Board (IRB) of the Department of Mental Health;~~
- ~~2. to certify Local Research Review Committees pursuant to 104 CMR 31.03(2);~~
- ~~3. to maintain a registry of all research approved by the Department Research Review Committees;~~
- ~~4. to provide technical assistance to Local Research Review Committees;~~
- ~~5. to monitor Local Research Review Committees activities. Monitoring may include site visits to the Committees and locations of research projects. Local Research Review Committees and research personnel must respond to requests for interviews and documents; and~~
- ~~6. to review actions taken by Local Research Review Committees.~~

~~(6) Quorum. A Department Research Review Committee, except when it uses expedited review pursuant to 104 CMR 31.03(7), must review proposed research at meetings where a majority of the members of the Committee are present, including at least one member whose primary concerns are in a nonscientific area. The approval or disapproval of a research proposal requires the majority vote of those members present at a properly convened meeting.~~

~~(7) Expedited Review. Expedited review is the review of a research proposal by a member or a subgroup of a Research Review Committee as designated by the Committee. Expedited review can be used only if the research:~~

- ~~(a) represents a minor change(s), or an expansion to another site, of previously approved research during the period (of one year or less) for which approval is authorized; or~~
- ~~(b) consists of a review of records for the sole purpose of extracting information for a demographic or statistical study in which no person can be identified; or~~
- ~~(c) has been previously approved by an Institutional Review Board approved by the Office for Protection of Research Risks pursuant to 45 CFR 46.110. The Department Research Review Committee's review must occur during the period (of one year or less) for which approval is authorized.~~

~~The reviewer(s) may exercise all rights and duties of the Committee except disapproval of a research proposal and waiver of the informed consent requirements. Disapproval of a proposal and waiver of the informed consent requirements require full Committee review. A Committee must be authorized by its appointing authority to use expedited review. The appointing authority may retract, suspend, terminate or choose not to authorize its use. If authorized to use expedited review, a Committee must adopt procedures to ensure all members will be timely notified when a proposal is approved by its use.~~

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~~(8) Minutes and Records. Each Department Research Review Committee must keep written minutes of its proceedings which record the names of members present, those absent, and non-members who are present; the numerical vote of the members approving or disapproving a research proposal; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution. In addition, each Committee must maintain records of all monitoring and investigation activities. Minutes and records must be kept at a place designated by the Committee.~~

31.04: Institutional Review Board (IRB) Review Process and Proposal Requirements

(1) IRB. The IRB shall be guided by the ethical principles regarding human subject research set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (The "Belmont Report").

(2) IRB Operations and Review Process. The IRB shall operate in compliance with and review research in accordance with the requirements and standards set forth in:

(a) 45 CFR Part 46 and 21 CFR Parts 50 and 56;

(b) M.G.L. c. 94C;

(c) applicable state laws relating to the use and disclosure of personal data;

(d) 104 CMR 31.054;

(e) Health Insurance Portability and Accountability Act of 1996 (HIPAA, Pub.L. 104-191, 110 Stat. 1936, enacted August 21, 1996); and 104 CMR 27.17 and 28.09;

(f) if the research is supported by a federal department or agency, the additional human subject regulations and policies, if any, imposed by the supporting department or agency; and

(g) applicable procedures and guidelines developed by the IRB.

(3) Membership. The Commissioner shall appoint the members of the IRB as required by the standards set forth in 104 CMR 31.04(2), ~~and (3)~~. If the IRB reviews research involving minors, it must have one or more members knowledgeable about and experienced in working with children. A member may be removed at any time at the discretion of the Commissioner.

~~(1) Proposal Contents. To commence review by a Department Research Review Committee, a written proposal must be submitted by the principal investigator. The proposal must include, at a minimum, the following information:~~

~~(a) identification of the investigators conducting the research and their credentials;~~

~~(b) purposes and objectives of the research;~~

~~(c) location(s) where the project will be conducted (street address(es), program name(s) and the name(s), telephone number(s) and address(es) of the person(s) in charge of the program at the stated location(s));~~

~~(d) description of the data and subjects to which access is sought;~~

~~(e) the expected benefits of the research to the subjects, direct and indirect;~~

~~(f) the foreseeable financial cost(s) to subjects and what, if anything, subjects will receive to offset such cost(s);~~

~~(g) why the research requires the participation of persons with mental illness;~~

~~(h) description of the research methods and procedures to be used;~~

~~(i) duration of the research;~~

~~(j) identification of all foreseeable risks (physical, psychological, social, economic, legal or other), their likelihood and potential severity;~~

~~(k) procedures to be followed if there is any adverse effect to a subject during or upon suspension or termination of the research;~~

~~(l) how the care and treatment of subjects may be affected during and after the research;~~

~~(m) the intended informed consent procedures and form that will be used;~~

~~(n) safeguards for maintaining confidentiality, including the manner of data disposal at the termination of the research;~~

~~(o) the expected final product, its intended use and manner of dissemination or publication;~~

~~(p) where applicable, disclosure of the intent to establish copyright, patents, or similar rights and the identification of all interested parties in such rights;~~

~~(q) a financial summary showing the projected categories of expenditures and sources and~~

~~amounts of funding for the research;~~

~~(r) description of any insurance (type, amount, and purpose) the principal investigator intends to purchase for the project; and~~

~~(s) where applicable, the manner in which Department resources will be used in conducting the research and the expected compensation to the Department. The Department is not financially responsible for any research conducted under these regulations unless otherwise specifically agreed to by the Department.—~~

~~(2) Appearance Before the Committee.— A Department Research Review Committee may require research personnel to appear before the Committee to address the proposal. It may also require the submission of additional documentation and materials. The principal investigator may request to be heard by the Committee.~~

~~(3) Appointment of a Research Subject Advocate.— A Department Research Review Committee may appoint a research subject advocate for one or more research subjects or for an entire research project. The advocate shall provide counseling, assistance, and advocacy to subjects with respect to their participation in the research. An advocate may not be a member of the Committee or the research project staff. An advocate may be an employee of the Department, facility or program, including a member of a subject's own treatment team. If an advocate is appointed, the Committee shall inform the subject(s) of the advocate's name and address.~~

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- ~~(4) Subject to Audit. No person involved in conducting research may receive compensation, either money or in kind, for the research unless:~~
- ~~(a) the compensation is from or passes through an organization that has agreed that all its fiscal records pertaining to the research will be subject to audit by the Department at any time; or~~
 - ~~(b) the compensation is from the Commonwealth of Massachusetts; or~~
 - ~~(c) the compensation consists solely of funds from a federal government agency or authority.~~

31.05: Research Review Standards, Monitoring and Audit

Research at all times must meet the standards and requirements set forth in 104 CMR 31.04(2)(a) through (g). In addition, for research to be approved by the IRB it must meet the following standards:

- (1) Informed Consent Process. The participation of each subject in a research project requires the written informed consent of the subject or the subject's legally authorized representative unless specifically waived by the IRB in accordance with the standards set forth in 104 CMR 31.04.
- (a) The informed consent process must begin with a description of the research and include an evaluation of the subject's comprehension. The process must also include an on-going assessment of each subject's continued consent to participate in the research.
 - (b) If research will involve clients of the Department as subjects, the informed consent process must provide the following information:
 - 1. a statement to the effect that the provision of Department services to the client is not dependent on his or her participation in the research; and
 - 2. where applicable, a description of any controlled substance as defined in the Massachusetts Department of Public Health regulations implementing M.G.L. c. 94, and any other substances to be used, and their anticipated effects, side effects and interactions.
- (2) Objection by the Subject. An individual's participation in a research project must cease if the individual objects, by verbal or nonverbal means, to participation. This applies even if the individual's legally authorized representative consents to the research.
- (3) Monitoring. The IRB shall monitor all approved research at least once a year, or once during the duration of the study, whichever is shorter. The monitoring must be appropriate to the type of research and the degree of risk to subjects. At a minimum the research shall be monitored at least once a year, or once during the duration of the study, whichever is shorter.
- (4) Subject to Audit. A person involved in conducting research who receives compensation, either money or in-kind, for the research must provide fiscal records pertaining to the compensation upon request of the IRB.

~~(1) Research That Will Not Be Approved.~~

- ~~(a) Research Involving an Unapproved Drug. Research involving a drug that has not been approved for trial in human beings by the Federal Food and Drug Administration cannot be approved by a Department Research Review Committee.~~
- ~~(b) Research that Does Not Meet the Review Standards. Research that does not meet the standards of 104 CMR 31.05(2) through (6) cannot be approved by a Department Research Review Committee.~~

~~(2) Evaluation of Risks and Benefits.~~

- ~~(a) Rights of Subjects. A Department Research Review Committee must review each research proposal for the primary purpose of protecting the rights and welfare of subjects. At a minimum, it must consider the impact the proposed research may have on subjects in terms of health and physical safety; confidentiality and privacy; human dignity; self-determination; freedom of choice; right to adequate care and treatment; freedom from undue discomfort, distress and deprivation; right to fair and equal treatment without discrimination; and such other interests that may be implicated by the particular research project.~~

~~(b) Weighing the Risks. Foreseeable risks to the rights of subjects must be reasonable in relation to anticipated benefits. To make this determination, the Committee must consider: available clinical experience and expertise; existing knowledge of relevant research findings; canons of professional conduct and professional ethics; applicable laws, policies, and procedural guidelines; standards of scientific methodology in the conduct of such research, the scientific merit of the research; the potential value of the research in the advancement of knowledge; and the necessity or importance of clients of the Department participating as subjects.~~

~~(3) Basic Requirement. If the research involves subjects, it must satisfy the following conditions:~~

- ~~(a) the selection of subjects is equitable to the extent practicable by the objectives of the research;~~
- ~~(b) the risks to subjects are minimized by using procedures consistent with sound research design and which do not present unnecessary risks to the subjects;~~
- ~~(c) the risks to subjects are reasonable in relation to anticipated direct benefits to subjects and importance of the knowledge gained; and~~
- ~~(d) Informed consent and authorization will be sought and documented in accordance with 104 CMR 31.05(5).~~

~~(4) Research Involving Clients of the Department.~~

- ~~(a) Purpose. If research will involve clients of the Department as subjects, the principal investigator must satisfy the Department Research Review Committee that:
 - ~~1. there will be direct, therapeutic benefit to each research subject who is a client of the Department; or~~
 - ~~2. the research will be conducted for the purpose of alleviating or preventing mental illness or obtaining knowledge relevant to it; or~~
 - ~~3. the research will be conducted for the purpose of obtaining information regarding services, opportunities or needs of clients of the Department.~~~~
- ~~(b) Risk. Additionally, the principal investigator must satisfy the Department Research Review Committee that:~~

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- ~~1. on the basis of available and present knowledge, the anticipated benefit from the research for each research subject who is a client of the Department will be equal to or greater than the probability and magnitude of any anticipated risk of physical or psychological harm or illness; or~~
- ~~2. the risk will be no more than minimal; or~~
- ~~3. the project's proposed informed consent form and procedures are specially designed to warn the client that there are substantial risks involved and specifically what those risks are and that the informed consent process will be carefully monitored to ensure compliance with approved procedures.~~

~~(5) Informed Consent and Authorization Procedures.~~

~~(a) Required of all Subjects. The participation of each subject in a research project and access to data requires the written informed consent of the subject as defined in 104 CMR 31.02 and the authorization for the use and disclosure of data required by 45 CFR 164.508, unless the applicable Department Research Review Committee grants waivers pursuant to 104 CMR 31.05(5)(f) and (g) or agrees to redact all personal data pursuant to 104 CMR 31.05(5)(h). A consent form meeting the requirements of 104 CMR 31.05(5)(b) and an authorization form meeting the requirements of 45 CFR 164.508 shall be used for these purposes. An authorization may be combined with the informed consent documentation and/or any other type of written permission for the research study. Each subject and legally authorized representative, if applicable, must receive a copy of signed consent and authorization form(s).~~

~~(b) Contents of the Consent Form. The consent form must be written in a language and in terms understandable to the research subject and legally authorized representative, if any. The form may not include any waiver of a subject's rights or any exculpatory language absolving the investigator, the sponsor, the Department, the facility or program, or their agents from liability for research related injury. A Department Research Review Committee must review and approve the contents of the written consent form and the procedures for obtaining it. The form must provide the following information:~~

- ~~1. a statement that the study involves research and a full explanation of its purposes and objectives;~~
- ~~2. the basis for selection of the subject and the expected duration of the subject's participation;~~
- ~~3. a description of the procedures to be followed and the identification of any procedures which are experimental;~~
- ~~4. a description of any reasonably foreseeable risks or discomforts to the subject and their expected severity and duration;~~
- ~~5. a description of any expected benefits to the subject or others;~~
- ~~6. a description of any appropriate alternative procedures or courses of treatment that could be used instead of the experimental procedure;~~
- ~~7. a statement of how to contact a named staff member of the research project for the purpose of answering questions about the procedures and the rights of subjects and to obtain more information;~~
- ~~8. a statement that participation is voluntary and the individual will be informed, both orally and in writing, that he or she is free to withhold consent or to withdraw consent and to discontinue participation in the research at any time without prejudice;~~
- ~~9. if the prospective subject is a client of the Department, a statement to the effect that the provision of Department services to the client is not dependent on participation in the research; and~~
- ~~10. where applicable, a description of any controlled substance as defined in the Massachusetts Department of Public Health regulations implementing M.G.L. c. 94, and any other substances to be used, and their anticipated effects, side effects and interactions.~~

~~(c) Clinical Determination. When a subject signs an informed consent form, a member of the research staff shall document that he or she made a clinical determination that the subject had the capacity to give informed consent.~~

~~31.05: continued~~

~~(d) Witness. A Department Research Committee shall appoint a witness for the signing of informed consent forms of research projects that, in terms of probability and magnitude, pose a substantial risk of physical or psychological harm or discomfort to any subject. A Committee, may in its discretion, appoint a witness for the signing of informed consent forms in other circumstances. The witness shall attest that the subject read the form, or that it was read to the subject; the subject had an opportunity to ask questions; and the subject signed it. Additionally, the witness shall attest that the documentation required by 104 CMR 31.05 (5)(c) was completed. A Committee may appoint more than one witness for a research project. A witness may be employed by or associated with the Department, Area, facility or program where the research is being conducted. However, a witness cannot be employed by or associated with the research project.~~

~~(e) Objection by the Subject. Notwithstanding the consent of a legally authorized representative, an individual's participation in a research project must cease if the individual objects, by verbal or nonverbal means, to participation.~~

~~(f) Waiver of Informed Consent. A Department Research Review Committee may waive the requirement of informed consent if the research is limited to access of data (as defined in 104 CMR 31.02) and involves:~~

- ~~1. only the study of historical records and the principal investigator presents, to the satisfaction of the Committee, plans to protect the confidentiality of the information and preclude the identification of particular individuals; or~~
- ~~2. the study of records for the sole purpose of extracting information for a demographic or statistical study in which no person can be identified.~~

~~If the requirement is waived, the Committee may impose such special conditions to safeguard the rights of subjects it considers appropriate. If the principal investigator wants a waiver, the investigator must submit a request in writing explaining the reasons for seeking such waiver.~~

~~(g) Waiver of Authorization. A Department Research Review Committee may waive the authorization requirement if one of the circumstances set forth below applies. If a Department Research Review Committee waives the authorization requirement, it must document the date the waiver was approved, the grounds for the approval, a brief description of the data for which use or access has been determined necessary, and a statement whether the review was done under regular or expedited review procedures. The authorization may be waived if:~~

- ~~1. The use or disclosure of the data involves no more than a minimal risk to the privacy of the individual based on, at least, the presence of the following elements:

 - ~~a. an adequate plan to protect the identifiers from improper use and disclosure;~~
 - ~~b. an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and~~
 - ~~c. adequate written assurances that data will not be re-used or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or other research for which the use or disclosure of data is permitted without an authorization.~~~~

~~In addition, the Department Research Review Committee must find that the research could not be practicably conducted without the waiver or access to and use of the data.~~

- ~~2. The use or disclosure of the data is wanted for preparation of research and the Department Research Review Committee obtains from the principal investigator representations that:

 - ~~a. the use or disclosure of the data is sought solely to prepare a research protocol or for similar purposes preparatory to research;~~
 - ~~b. no data will be removed from the Department in the course of review; and~~
 - ~~c. The data to which use and access is sought is necessary for research purposes.~~~~

~~(h) De-identification of Data. Informed consent and authorization is not required if the research will be limited to a study of records and:~~

- ~~1. the Department, in its discretion, agrees to de-identify all data (as defined in 104 CMR 31.02) from such records consistent with 45 CFR 164.514 or agrees to use and disclose a limited data set that meets the requirements of 45 CFR 164.514(e);~~
- ~~2. the principal investigator agrees to compensate the Department for all costs attributable to copying and redacting the information; and~~
- ~~3. the study will be written in such a way so that no person can be identified.~~

~~31.05: continued~~

~~(6) Commissioner Approval. Prior to approving a proposal, a Department Research Review Committee must obtain a decision from the Commissioner, or designee, that the research will promote the mission of the Department.~~

~~(7) Notification and Finality of Committee Review. Notice of the approval of a research proposal must be given promptly by a Department Research Review Committee to the principal investigator, Area Directors, and directors of facilities and programs where research activity will occur. If the review was done by a Local Research Review Committee, a copy of the proposal and the Committee's minutes shall be sent to the CORRC. If any other action is taken by a Department Research Review Committee regarding a research proposal, a statement of the reason(s) for the action shall be furnished promptly to the principal investigator. If a proposal is disapproved, the applicable Committee must provide the principal investigator with an opportunity to respond to the statement either in person or in writing. Except as provided in 104 CMR 31.06(3), the decision by a Department Research Review Committee to disapprove or terminate a research project is final and not subject to further review, judicial or otherwise.~~

31.06: Complaints and Sanctions. , Sanctions and CORRC Review

~~(1) (4) Complaints Regarding Human Subject Research. Any person may file a complaint about a human subject research project with the chairperson of the IRB. Such complaints shall be resolved in accordance with the standards set forth in 104 CMR 31.06. Department Research Review Committee that approved the research.~~

~~(a) Chairperson Review. The chairperson shall notify promptly the principal investigator of~~

~~(2) Initial Review. The chairperson, or designee, shall conduct a preliminary investigation. If the chairperson determines the complaint has merit it shall be referred to the IRB for further review. The chairperson has the right to immediately suspend a study that poses an immediate risk to participants. The complaint shall be investigated by the chairperson or referred to the Department's Office of Investigations. If the chairperson determines that the complaint falls within the scope of 104 CMR 32.05(2)(d), it shall be referred to the Office of Investigations and resolved in accordance with 104 CMR 32.00. However, in making the referral, the IRB retains its authority under 104 CMR 31.03(4) to make decisions with respect to research that may relate to the complaint.~~

~~(3) IRB Investigation. The IRB, as part of its investigation of a complaint, shall provide the complainant and the principal investigator the opportunity to present relevant information to the IRB. Within 30 days of receiving the complaint, or as soon thereafter as practical, the IRB shall take such action as it determines appropriate, including, but not limited to:~~

- ~~1. termination of the research;~~
- ~~2. imposition of additional conditions on the research;~~
- ~~3. temporary suspension of the research pending further investigation or other action; or~~
- ~~4. dismissal of the complaint.~~

~~(4) Notification. The IRB shall give prompt notification to the complainant and the investigator(s) of its action. The IRB shall keep written records of all complaints, investigations, action taken, and reasons for such action.~~

~~(5) No Appeal. Any action taken by the IRB with respect to research is final and not subject to further review, judicial or otherwise.~~

~~the receipt of a complaint. The chairperson shall conduct a preliminary investigation. If the chairperson determines the complaint has merit, it shall be referred to the full Committee for further review. Upon referral to the full Committee, the chairperson shall notify the Commissioner and applicable Area Directors and Department facility directors of the complaint. The Commissioner, Area Directors, and Facility Directors, in consultation with the Area Directors, may temporarily suspend a research project pending further investigation.~~

~~(b) Committee Investigation. The Committee, as part of its investigation of a complaint, shall provide the complainant and the principal investigator the opportunity to present relevant information to the Committee. Within 30 days of receiving the complaint, the Committee shall take such action as it determines appropriate, including, but not limited to:~~

- ~~1. termination of the research;~~
 - ~~2. imposition of additional conditions on the research;~~
 - ~~3. temporary suspension of the research pending further investigation or other action; or~~
 - ~~4. dismissal of the complaint.~~
- ~~(e) Notification. The Committee shall give prompt notification to the complainant and the investigator(s) of its action. The Committee shall keep written records of all complaints, investigations, action taken, and reasons for such action.~~
- ~~(d) No Appeal. Except as provided in 104 CMR 31.06(3). Any action taken by the Committee on a complaint is final and not subject to further review, judicial or otherwise.~~
- ~~(2) Sanctions. Sanctions may be imposed if there is a violation of the human rights of subjects, or if the research is not conducted in accordance with applicable statutes, regulations or Department Research Review Committee requirements. The sanctions may be imposed by the Commissioner as to all research, an Area Director as to research conducted in his or her Area, and the Facility Director, in consultation with the Area Director, as to research conducted in his or her facility. Sanctions may include the immediate suspension or termination of the research project and disciplinary action against project personnel.~~
- ~~(3) CORRC Review. Any member of a Local Research Review Committee may at any time request (and such a request shall be granted) a review by the CORRC of any procedures, action or inaction by the Local Research Review Committee. Additionally, concerning any complaint filed with a Local Research Review Committee, the person who filed the complaint, or the principal investigator, if aggrieved by the decision of the Local Research Review Committee following its investigation, may request a review of the decision by the CORRC. The request must be made in writing and filed within 14 days of the date of the Local Research Review Committee's decision. The decision of the CORRC shall be rendered in writing setting forth the basis of its decision within 30 days of receiving the request for review. The decision of the CORRC shall be final and not subject to further review, judicial or otherwise.~~

31.06: continued

(64) DepartmentMH Complaint Process. Nothing in 104 CMR 31.06 shall preclude the chairperson from referring a complaint for investigation ~~any person from filing a complaint~~ under 104 CMR 32.00.

REGULATORY AUTHORITY

104 CMR 31.00: M.G.L. c. 19, §§ 1 and 18; c. 123, § 2; ~~45 CFR 46~~.