

DEPARTMENT: Yale University
POLICY NUMBER:
SECTION: IRB Policies for Research Affiliate Institutions
REVIEW RESPONSIBILITY: IRB Leadership and Research Collaborators
ORIGINAL CREATION DATE: April 14, 2005
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Human Subject Protection Policies

All Institutions that rely on a Yale Institutional Review Board (IRB) as the IRB of record must have and adhere to appropriate policies for the protection of human research subjects. These policies must be submitted with an application for IRB reliance, which will be reviewed and acknowledged by Yale before the Institution's FederalWide Assurance (FWA) listing Yale's IRB(s) is finalized. Federal regulations and Yale policy will not permit an Institution to rely on a Yale IRB as the IRB of record unless appropriate policies are in place at the Institution and an inter-Institutional agreement is signed between the two parties

In recognition of the fact that Yale's partners in research are diverse and widely varied in terms of size and available resources, the following policy template may be adopted in full or modified as appropriate. This template serves as an example of a policy statement that addresses the standards required by federal regulation and Yale policy to support a human subject protection program. Individual Institutions should adopt a policy statement that meets these standards and may adopt additional policies or procedures tailored to that Institution. The template includes policies regarding the following required elements:

1. Scope and Authority of the Human Subject Protection Program
2. Investigator/Staff Training and Education
3. Compliance with Yale IRB Policies
4. Reporting of Adverse Events
5. Reporting Noncompliance
6. Investigator Access to Policies
7. Document Retention
8. Investigator Conflict of Interest
9. Research Oversight and Auditing

Template

Policies and Standard Practices for the Protection of Human Subjects in Research

[Enter name of Institution (note abbreviated name if it is referred to throughout the document)], supports the advancement of scientific knowledge through research. [Enter name of Institution] is grateful to individuals who choose to participate in such research and is committed to the protection of human subjects who participate in research conducted by its staff or at its facility.

The following human research subject protection policies are hereby adopted and will immediately become effective. This document will be updated and revised as necessary and will be periodically reviewed in its entirety. This Institution will establish all procedures necessary to implement these policies.

I. Policies

A. Ethical Framework for Conducting Human Subjects Research

1. All research involving human volunteers conducted by this Institution will be conducted ethically and in accordance with pertinent federal regulations and state laws regardless of source of funding.
2. This Institution will enact all policies and procedures necessary to carry out its responsibilities and ensure ethical conduct of research.
3. All research conducted by this Institution will be guided by the ethical principles for human subject research articulated in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (The Belmont Report)*.
4. All human subject research conducted by this Institution will receive IRB approval before being initiated. This Institution will adhere to and comply with federal human research subject regulations at Code of Federal Regulations Title 45, Part 46 (45 CFR 46).
5. Where appropriate, this Institution will require adequate additional protections for fetuses, pregnant women, prisoners and children, per Subparts B, C and D of 45 CFR 46.

[If the research being submitted to a Yale IRB for review involves any of the above-mentioned classes of subjects, you must include a specific policy statement that identifies the additional protections the Institution will apply to research involving such subjects. This policy statement must be inserted into Section III.

“Special Topic Policy Statement”. You may choose to adopt one of the individual policy templates provided to you or you can create your own.]

6. Where appropriate, this Institution will require adequate additional protections for other classes of special populations, including but not limited to, decisionally impaired individuals, HIV-positive individuals, non-English-speaking individuals, or employees and students of the institution who may participate as research subjects, in accordance with the criteria found at 45 CFR 46.111 and the federal guidelines for involvement of such individuals in research.

[If the research being submitted to a Yale IRB for review involves a class of subjects that could be identified as requiring additional protections given the specific nature of the research and/or the recruitment process you must include a specific policy statement that identifies the additional protections the Institution will apply to research involving such subjects. This policy statement must be inserted into Section III. “Special Topic Policy Statement”. You may choose to adopt one of the individual policy templates provided to you or you can create your own.]

B. Operation of the Human Subject Protection Program

1. This Institution’s Signatory Official (SO) will have ultimate responsibility for ensuring ethical conduct of research involving human subjects.
2. This SO will appoint a Human Protections Administrator (HPA) to oversee the administration and daily operations of human subject protection matters including the implementation of these policies. The HPA should have demonstrated experience in human subjects protections, federal regulations and, when possible, research with human subjects. The HPA shall report to the SO for matters related to the protection of human subject.

C. Authority of IRB(s)

1. All human subject research conducted by this Institution will be in accordance with the decisions of the IRB(s) that review this Institution’s research as well as that IRB’s policies and procedures.
2. The designated IRB(s) that review this Institution’s research have the authority to 1) approve, 2) require modifications to secure approval, 3) disapprove, and 4) terminate or suspend all such research. All IRB decisions will be accepted as binding on this Institution and no human subject research will take place without documented IRB approval.
3. In addition, the designated IRB(s) have the authority to 1) require research progress reports, 2) audit and/or monitor the research, and 3) report suspensions, terminations and non-compliance to IRB officials, this Institution and the federal government.

D. Training and Education

1. All researchers and pertinent staff (including the HPA and SO) will receive initial and ongoing education in the general concepts of ethical conduct of research and the protections of human subjects.
2. Only those researchers and study personnel who have completed all necessary training and who are qualified to perform the specific research interventions identified in the protocol will participate in the conduct of human subject research.

E. Research Compliance and Oversight

1. This Institution will maintain and manage an oversight system to ensure that research by its staff or within its facility complies with the terms of the approved protocol, federal regulations and state law, IRB decisions and IRB policies and procedures.
2. This Institution will conduct procedural and record keeping audits for the purpose of detecting, correcting and reporting (as required) administrative and/or material breaches in protecting the rights and welfare of human subjects.
3. A climate free of fear of sanction is required to foster appropriate reports and ensure a fair review of allegations, therefore, any individual who reports an incident of non-compliance will remain confidential and be protected from retaliation. Retaliation against good faith "whistle blowers" is illegal and will not be tolerated at this Institution.

F. Informed Consent

Informed consent will be obtained from all individuals enrolled as research subjects. No investigator or staff person may enroll a human subject into a research protocol without having obtained the informed consent of the subject or his/her legally authorized representative using an IRB-approved consent document. The only exception to this policy is for studies in which the cognizant IRB has waived the requirement for investigators to obtain signed consent or waived the informed consent process pursuant to federal regulations.

G. Adverse Events

All adverse events, both anticipated and unanticipated, will be reported to the HPA. Adverse events should be reported to the cognizant IRB pursuant to that IRB's policies and procedures.

H. Confidentiality of Subjects Participating in Research

This Institution will ensure that information related to an individual subject's participation in research is protected and maintained in a confidential manner. No such information will be released beyond the scope of the research staff, the IRB, sponsor or the appropriate Institutional officials without the individual subject's permission, unless otherwise required by law or in response to emergent situations which require such disclosure to minimize harm to the subject or others.

In some studies, subject information may remain confidential and not be disclosed even to the subjects or may be disclosed to the subject only after some period of time. In such studies, the consent form will explain the confidentiality requirements to the subjects.

I. Document Retention

1. The Institution will ensure that all research-related documents will be maintained for the duration of the research study and after the study has been terminated as required by the applicable grant, contract, or local, state, or federal law or federal regulation. Such documents include, but are not limited to, copies of individual research protocols, IRB decisions and correspondences, annual reports. All protocol and IRB-related records will be available for inspection in accordance with federal regulations. HIPAA-related documentation such as HIPAA authorizations, waiver of authorization, accounting for disclosure logs, must be maintained for six years from the completion of the study.
2. This Institution will ensure that all investigators will be given ready access to:
 - a. This Institution's FederalWide Assurance (FWA)
 - b. The IRB Authorization Agreement (IAA) entered into with the cognizant IRB and its parent institution
 - c. Copies of pertinent federal regulations and state laws
 - d. *The Belmont Report*
 - e. Other pertinent federal policies and guidelines related to the involvement of human subjects in research
 - f. IRB forms and guidelines

J. Conflict of Interest

This Institution will take steps to identify actual or potential sources of conflict of interest in human subject research and either eliminate, reduce or manage such conflict.

Investigators are required to disclose actual or potential research related conflicts of interest and this Institution will abide by the conflict of interest policies and procedures of the cognizant IRB.

The IRB will evaluate such conflicts and, if necessary, determine (1) whether the conflict is permissible in the context of the protocol, and, if so, (2) whether the conflict warrants disclosure to potential subjects as part of the informed consent process or (3) warrants further management to reduce or eliminate the interest. The IRB will notify the HPA when it determines that an interest must be disclosed and/or further managed.

[All applicants must include a Conflict of Interest policy statement specific to the Institution. This policy statement must be inserted into Section III. "Special Topic Policy Statements". You may choose to adopt the template policy provided to you or you can create your own.]

II. Practices

A. Training

1. The core curriculum of human subject protection training for all researchers and pertinent staff should include:
 - a. The terms and conditions of this Institution's FederalWide Assurance (FWA)
 - b. The terms and conditions of the IRB Authorization Agreement (IAA) this Institution entered into with the cognizant IRB and its parent institution.
 - c. *The Belmont Report*
 - d. Federal regulations found at 45 CFR 46 and all its Subparts
 - e. Cognizant IRB's policies and procedures
 - f. The HIPAA Privacy Rule, if appropriate
 - g. Other applicable state law and federal regulations

1. All researchers and pertinent staff may complete the National Institutes of Health (NIH) on-line tutorial on human subject protections to meet training requirements (found at <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>). Copies of the training certifications for Institutional personnel will be submitted to the IRB with the research protocol application.

2. The HPA and SO will complete the Office of Human Research Protections (OHRP) Assurance Training Modules (found at <http://137.187.172.153/CBTs/Assurance/login.asp>).

3. When possible, the SO and HPA will attend human subject protections training initiatives offered by appropriate sponsors.

4. The HPA will monitor federal regulatory websites and other research-related resources so as to stay current with regulatory changes in human subject protection guidelines and policies. The HPA will ensure that regulatory changes or other pertinent information is communicated to staff in a timely manner.

5. Completion of all training requirements will be documented and recorded for each individual and will include a) individual's name, b) date, c) topic, and d) instructor (source). Copies of all such documents will be available for review by cognizant IRB personnel when necessary.

B. Research Review/Conduct of Research

1. All research protocols involving the direct or indirect interaction or interventions with human subjects must obtain IRB approval before the research project may be initiated.

2. The Principal Investigator (PI) is responsible for ensuring continuing approval of research protocols at the time intervals deemed appropriate by the IRB. The PI will inform the HPA should the protocol approval expire. Such notification must be made

no later than 5 days after the protocol expiration date or 5 days after the protocol expiration has been discovered.

3. All changes to approved research protocols will be submitted to the designated IRB for review and approval before being initiated, except when such changes are necessary to eliminate immediate hazards to subjects. In such cases, when modification or deviation of the approved protocol is necessary, it will be reported to the IRB and HPA within 48 hours of occurrence.

C. Adverse events

1. All research protocols must contain a Data and Safety Monitoring Plan (DSMP) appropriate to the nature of the proposed research.
2. Adverse event reporting must be conducted in accordance with the DSMP as specified in each individual protocol.
3. In addition to adverse event reporting specified in the protocol's DSMP, adverse events must be reported as follows:
 - a. Both **anticipated and unanticipated serious adverse events** must be reported to the designated IRB and the Institutional HPA and SO within 48 hours of the occurrence becoming known to the Principal Investigator. All such reports must be made using the appropriate IRB form provided for that purpose.
 - b. Whenever a **serious adverse event form** is submitted to an IRB, the reporting individual shall maintain in the protocol file at the Institution a copy of all correspondence between the principal investigator and the IRB relating to the serious or unanticipated adverse event. All documents must be date stamped. Correspondence and documentation associated with serious or unanticipated adverse events will also be maintained in an Institutional adverse event file. The Institutional file will be made available, upon request, to authorized IRB personnel or other persons as authorized in the protocol.
 - c. All **unanticipated adverse events** must be reported to the designated IRB and Institutional HPA whenever the unanticipated event is thought to be directly related to the subject's participation in research and involves risks to subjects or others. The reporting of this type of event to the HPA and IRB must take place within five working days of knowledge of such event (unless it is an **unanticipated serious event**, see A above). Investigators are required to fully describe and explain the event(s) on the form provided for that purpose and to take prompt action, when necessary, to preclude further adverse events.
 - d. Non-serious anticipated adverse events must be reported to the IRB whenever their seriousness or frequency exceeds that which was forecasted in the protocol submission.

- e. All adverse events must be retained by the principal investigator and reported to the research sponsor as required. A summary of all events may be required when requesting continuing review of a protocol by an IRB.

D. Research Compliance and Oversight/Non-compliance

1. Non-compliance means conducting research involving human subjects in a manner that disregards or violates regulations governing such research. This can include, but is not limited to, failure to obtain IRB approval for research involving human subjects, inadequate or non-existent procedures for informed consent, inadequate supervision in research involving novel interventions or procedures, failure to follow recommendations made by the IRB or Institution to ensure the safety of subjects and failure to report appropriate adverse events or proposed protocol changes to the IRB and the Institution.
2. This Institution will review all allegations of non-compliance with human subject regulations. Any individual or organization may submit a written complaint or allegation of non-compliance to the HPA and IRB. The Institution may also initiate a complaint based on information available to the Institution (e.g., deficiencies noted in IRB files, media or scholarly reports of research activity subject to committee jurisdiction).
3. The Institution will review the allegation of non-compliance, the response from the researcher and any other information necessary to conduct its investigation.
4. Based on its investigation, this Institution will prepare a report summarizing the information it considered and outlining its conclusions and recommended actions. The report will be reviewed by the IRB, HPA and SO.
5. This Institution is required to report to the Institutional Official and the appropriate Federal Department or Agency any “serious or continuing noncompliance” with the regulations governing the protection of human subjects or the requirements or determinations of the IRB Committee. Whenever possible, the Institution will coordinate with the IRB before submitting such reports.
6. When the IRB or this Institution makes a decision to suspend or terminate approval of research for any reason, the following individuals, in addition to the investigators listed on the protocol and the departments/Institutions involved in the research, will be notified, where applicable:
 - a. SO
 - b. IRB Chair(s) of Institutions participating in the research under a Cooperative Agreement or Inter-Institutional Agreement to the FWA
 - c. Appropriate federal departments or agencies
 - d. Food and Drug Administration
 - e. The funding agency

7. Notice will be given within five working days of such suspensions or terminations.
8. All investigators are required to report to the Institutional HPA and to the IRB as soon as possible but no later than 48 hours after discovery:
 - a. Serious or continuing noncompliance with the federal regulations or IRB requirements (e.g., not adhering to the procedures in the approved protocol and/or conducting research activities not listed in the approved protocol), and/or
 - b. Suspension of termination of IRB approval.

E. Protocol Confidentiality Protections

1. Provisions for protecting the confidentiality and privacy of information gathered in research protocols must be described in the Confidentiality section of each protocol. Provisions must be appropriate to the risks associated with study participation. Methods for protecting confidentiality could include coding data, instituting computer passwords and firewalls for data stored electronically or assigning pseudonyms to protect subject identity.
2. Subjects should not be promised anonymity unless the research data is truly anonymous. Anonymity cannot be guaranteed unless there is no method by which the investigator can connect the research results with individual subjects providing the data. If there are codes, a master list or sufficient demographic information that would enable the investigator to identify subjects, the research is not anonymous even though the subject names do not appear in the research data. In this case the data would be considered to be confidential.

III. Special Topic Policy Statements

[Insert individual policy statements here as appropriate to the nature of the Institution's research. In addition, all applicants must include in this section a Conflict of Interest policy statement specific to the Institution. You may choose to adopt the template policy provided to you or you can create your own.]

Signature Page

This Policy Document was adopted by _____ effective _____.

By: _____

Title:

Date: _____