



**SOUTHERN UTAH UNIVERSITY**  
**Policies and Procedures**

**Policy # 6.20**  
**Date Approved: 12/15/94**  
**Date Amended: 05/03/2013**  
**Reviewed w/no Changes:**  
**Office of Responsibility: Prov**  
**Page 1 of 33**

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**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

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**I. INTRODUCTION:**

Southern Utah University (SUU) supports Institutional Review Boards (IRBs) for research on human participants. It has established policies and procedures to protect the rights, well-being, and personal privacy of individuals, and to assure a favorable climate for the conduct of scientific inquiry at SUU. Investigators who receive IRB approval for their research are protected from unwarranted legal action and are protected from personal liability.

Policies, definitions and guidelines, where applicable, are taken or modified from The Code of Federal Regulations (CFR) Title 45 (Public Welfare), Part 46 (Protection of Human Subjects Subparts A,B,C,D):

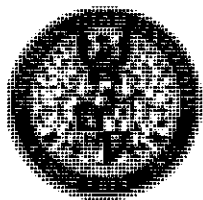
<http://www.hhs.gov/ohrp/policy/ohrpreulations.pdf> and <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html> and are referred to throughout this policy. Some policies related to human subjects research are included in the above sited sources, but do not appear in this policy, for the sake of parsimony. If not included in this policy, the SUU IRB adheres to Health and Human Services written policies for decisions and guidance, if warranted.

The IRB is guided by the ethical principles regarding research involving humans as participants as set forth in the "Belmont Report" (Ethical Principles and Guidelines for the Protection of Human Subjects of Research, by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979).

The IRB acknowledge three basic principles which are particularly relevant to the ethics of research involving human participants: the principles of respect for persons, beneficence (including minimization of harms and maximization of benefits), and justice. The IRB acknowledges and accepts responsibilities for protecting the rights and welfare of human research participants.

The following policies and procedures apply to all research involving human participants, as defined in Section H III.C of this policy. All human subjects research performed by Southern Utah University faculty, students, or staff under University auspices, whether carried out solely with University resources or with assistance of outside funds, are required to adhere to procedures in this policy. Research is considered to be under University auspices if it involves one or more of the following:

A. The research is sponsored by the University



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**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

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- B. The research is conducted by, or under the direction of, any employee or agent of the University in connection with his or her employment with the institution, including the use of institutional letterhead.
- C. The research is conducted by, or under the direction of, any employee or agent of the University using any property or facility of the institution.
- D. The research involves the use of this institution's non-public information to identify or contact human research participants or prospective participants.

The (IRB) recognizes three categories of reviewable human subjects research:

1. Exempt, as defined in Section II.A of this policy;
2. Expedited, as defined in Section II.B of this policy;
3. Full-Board Reviews, as defined in Section II.C of this policy.

No investigator may *solely* decide whether *the* research *to be conducted* needs to be submitted to the IRB *for review*. Investigators must complete the Request for IRB Exemption form, and submit this to the chairperson of *the* IRB. The chairperson will notify the investigator in writing of *the* decision to approve or deny the request.

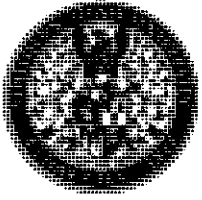
## II. TYPES OF HUMAN PARTICIPANTS RESEARCH

The Southern Utah University IRB recognizes multiple categories of human subjects research. Specifically, categories of Exempt, Expedited and Full-Board Reviews are recognized by the IRB, and thus, subject to the review processes described in Section IV of this policy.

### A. Exempt Status

The SUU IRB, guided by the CFR (Title 45, Part 46.101), recognizes 8 types of human participants research which may qualify as Exempt. The following activities, though research, do not require *full* submission to the IRB for approval but do require documentation and IRB approval as described in Section IV of this policy:

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



**SOUTHERN UTAH UNIVERSITY**  
**Policies and Procedures**

**Policy # 6.20**  
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**Office of Responsibility: Prov**  
**Page 3 of 33**

---

**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

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2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (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 subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under item 2 of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, 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.
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
7. Research required by students in a course, for completion of the course requirements, where only non-sensitive information is collected from



**SOUTHERN UTAH UNIVERSITY**  
**Policies and Procedures**

**Policy # 6.20**  
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**Reviewed w/no Changes:**  
**Office of Responsibility: Prov**  
**Page 4 of 33**

---

**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

---

participants, or all foreseeable risk are minimized or eliminated (see IRB Approval of Student Research document on the following website: <http://suu.edu/academics/provost/grants/irb-animal-care.html>).

8. Research for Internal Agency Use: Research done by or at the request of an internal agency for their own use, and which is not intended to contribute to generalizable knowledge (i.e. knowledge shared by professionals in a given field which is designed to contribute to that field).

The IRB retains final judgment as to whether a particular activity is exempt or whether it requires another category status (i.e., Expedited Review or Full-Board Review).

**B. Expedited Status**

SUU guided by the CFR (Title 45, Part 46.110) recognizes that some types human participants research need not be reviewed by *all* members of the IRB. These types of research may qualify as Expedited. The following criteria may qualify a research proposal to be categorized as having Expedited Status. Required documentation and proposal processes are described in Section IV of this policy:

Expedited review procedures can be approved for certain kinds of research involving (1) no more than minimal risk, and (2) no inclusion of vulnerable populations (as defined in Section III of this policy) as participants, or for minor changes in approved research.

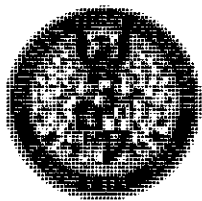
Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not reject the research proposal. A research activity may be rejected only after review in accordance with the non-expedited procedure as described in Section IV of this policy.

**C. Full-Board Review Status**

If the proposed research does not qualify for Exempt Status or Expedited Status, it shall hereafter be referred to as a Full-Board Review. Procedures for Full Board Reviews are described in Section IV of this policy.

**III. DEFINITIONS:**





**SOUTHERN UTAH UNIVERSITY**  
**Policies and Procedures**

**Policy # 6.20**  
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**Office of Responsibility: Prov**  
**Page 5 of 33**

---

**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

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Institutional Review Board (IRB): IRB means an institutional review board established in accord with, and for the purposes expressed in this policy. An Institutional Review Board's (IRB's) function is to review proposed research to insure that participants' rights are protected and that the risk of harm to participants and researchers is minimized.

Research is defined as a systematic investigation, whether carried out by faculty, staff, or students, designed to develop or contribute to generalizable knowledge (i.e. knowledge shared by professionals in a given field which is designed to contribute to that field). Included in the definition are student research projects (e.g. theses, dissertations, group research projects), regardless of whether they will be submitted for presentation and/or publication in a professional venue. Activities that meet this definition constitute research for the purposes of this policy, whether or not they are supported under a program that is considered research for other purposes. In-class demonstrations of research using students enrolled in the class as participants are not considered research and as such are not regulated by policy 6.20. The course instructor is nevertheless obligated to be familiar with this policy and to adhere to its principles to respect the rights and welfare of the students involved.

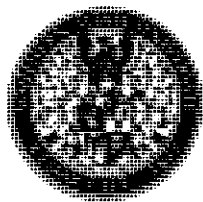
A human participant is defined as a living individual about whom an investigator (professional or student) conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information.

An intervention includes any manipulation of the subject, the subject's environment or stimuli to which the subject is exposed.

An interaction includes any communication with a subject, whether orally or in writing, whether in person (e.g. face-to-face) or not (e.g. via mail, email, telephone)

Identifiable private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place. Also included is information provided for specific purposes by an individual, which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e. the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily



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**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

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encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Harm may take any of the following forms: physical, psychological, social, legal, or economical. The investment of time required from the participant is also considered harm, though it may be minimal if the time requirement is negligible.

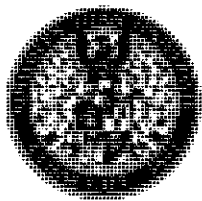
Vulnerable Populations include but are not limited to individuals who cannot give legal consent (e.g. minors), physically handicapped individuals, prisoners, pregnant women, non-English speakers, students (if the investigator is also someone who is responsible for assigning grades to the participants), and individuals with impaired cognitive functions.

Signed Informed Consent must be sought under circumstances where there is more than minimal risk and/or vulnerable populations are tested. For research which poses no more than minimal risk and which does not test a vulnerable population, unsigned informed consent is generally required. Informed consent is used to minimize risks and the possibility of coercion or undue influence. Information must be presented in language understandable to the participant or the participant's legally authorized representative. Signed informed consent must be documented with a written form approved by the IRB and signed by the participant or the participant's legally authorized representative.

Legally Authorized Representative means an individual, judicial or other body authorized under applicable law to consent on behalf of the prospective participant to the participant's participation in the procedures(s) involved in the research.

Exempt Status is given to proposals which pose no more than minimal risk, test only participants who belong to the SUU campus community and who are not considered vulnerable, and where there is no intent to publish/present the results off campus. Only an IRB can assign a protocol exempt status. Protocols with this status are not subject to continuing reviews, audits, or project closure requirements, as long as no material changes are made to the protocol. Initial review and status determination of these proposals are made by a college IRB.

Expedited Status is given to proposals which pose no more than minimal risk, test participants who do not belong to the SUU campus community and who do not constitute a vulnerable population. Whether the results of these studies are published/presented off campus is not a consideration. Protocols which pose no more than minimal risk, test only participants who belong to the SUU campus community



**SOUTHERN UTAH UNIVERSITY**  
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**Office of Responsibility: Prov**  
**Page 7 of 33**

---

**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

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and who are not considered vulnerable, and where there is an intent to publish/present the results off campus are given expedited status as well. Only an IRB can assign a protocol expedited status. Proposals assigned this status are reviewed by a college IRB.

Full Board Review Status is given to a proposal if more than minimal risk is involved or a vulnerable population(s) is tested. Only an IRB can assign a protocol full board review status. Proposals assigned this status are initially assessed by a college IRB but are reviewed by the University IRB.

Office of Sponsored Projects (OSP) is charged with assisting faculty and other university personnel to achieve funding for research and other scholarly activity and to provide oversight on issues of federal, state and university compliance, laws and regulations.

Office for Human Research Protections (OHRP) is a federal office charged with ensuring compliance with the Code of Federal Regulations, 45 CFR 46, for federally funded research.

Human Research Protections Program (HRPP) is an SUU sponsored program charged with protecting the rights and welfare of human research participants, as well as training, administering, and overseeing SUU's institutional review boards.

**IV. POLICIES AND PROCEDURES:**

A. The IRB uses the Code of Federal Regulations, 45 CFR 46, Protection of Human Subjects (Effective July 14, 2009). The following policies and procedures serve to operationalize and summarize relevant aspects of the Code.

B. IRB Membership:

1. The IRB will consist of at least eight members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by SUU. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants. In addition to possessing



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**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

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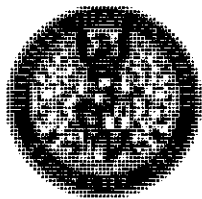
the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If the IRB regularly reviews research that involves a vulnerable category of participants, such as children, prisoners, pregnant women, handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these participants.

2. Every nondiscriminatory effort should be made to ensure that the IRB does not consist entirely of men or entirely of women, and that no selection is made to the IRB on the basis of gender. The IRB shall not consist entirely of members of one profession or academic discipline.
3. The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
4. The IRB shall include at least one member who is not otherwise affiliated with SUU and who is not part of the immediate family of a person who is affiliated with the institution.
5. No IRB member shall participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
6. The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

**C. IRB Training**

1. With the exception of members from the community, each member of an IRB will complete the computer based training program sponsored by NIH (<http://phrp.nihtraining.com/users/login.php>) prior to





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**Office of Responsibility: Prov**  
**Page 9 of 33**

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**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

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conducting any IRB business. Proof of completion certificates will be kept on file with SUU's OSRG.

2. IRB members will receive continued training at the beginning of their meetings on an as needed basis. This training will be provided by SUU's Director of the HRPP.

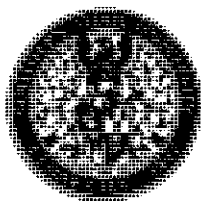
**D. Southern Utah University's IRB**

1. The University will establish and maintain one University IRB with at least one member from each individual college. The number of committee members per college IRB will be justified by the volume of proposals that each receives.
2. Membership for the University IRB will adhere to the requirements described in Section IV.B of this document
3. Typically, IRB members will review protocols for all research activities which involve human research participants submitted by faculty, staff, or students from their own college after being assigned to a review by the IRB chairperson. In the event that the IRB member determines that a protocol involves more than minimal risk and/or involves one or more vulnerable populations, the protocol will be sent to the IRB chairperson for a Full-Board review. In addition to these reviews, the IRB will review protocols submitted by an investigator not affiliated with Southern Utah University (SUU) who wishes to conduct research on the campus of SUU.

**E. Appointment of Members to the University IRB**

1. The Institutional Official appoints members to the IRB at the beginning of each academic year. Members of the University IRB serve up to a three term. IRB members can serve additional three year terms, if warranted.
2. Faculty who serve on the IRB shall not be required to serve on any other University level committee.

**F. Review of Research Proposals**

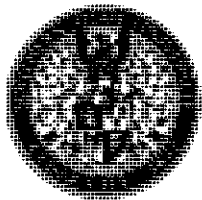


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**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

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1. Researchers seeking IRB approval must complete and submit an *IRB Proposal Submission* form to the IRB. All proposals must be received by the IRB chairperson electronically by the 7<sup>th</sup> day of the month during the fall and spring semesters to be considered for review in the same month. Proposals received after the 7<sup>th</sup> day of the month will be considered in the subsequent month. Within one week of its receipt, the chairperson of the IRB will disseminate the proposal submission form to one of the members of the IRB for an initial assessment of minimal risk and vulnerable population status. The member who conducts this initial review will typically be the board member associated with the college from whence the proposal originated. The IRB member assigned to the initial review will complete the *Initial Assessment of Minimal Risk and Vulnerable Population Status* form. This form must be submitted to the IRB chairperson within one week of receipt of proposal.
2. Proposals determined to involve more than minimal risk and/or use of vulnerable population(s) will be forwarded to the IRB chairperson and will be distributed to members of the IRB for a Full-Board Review.
3. Proposals determined to pose no more than minimal risk AND which do not involve a vulnerable population(s) will be assigned either *Exempt* or *Expedited* status by the initial reviewer. The initial reviewer will complete either the *Documentation of Exempt Review* or *Documentation of Expedited Review* form. The completed form must be returned to the IRB chairperson along with, and at the same time as the *Initial Assessment of Minimal Risk and Vulnerable Population Status* form.
  - i. The initial reviewer will consult the OHRP website for a current list of research categories permissible for expedited review.
  - ii. The initial reviewer will document which category(ies) permissible for expedited review apply.
4. IRB members who review protocols which receive exempt or expedited status will duly consider each of the following in their assessment of the protocol:



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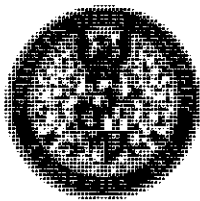
**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

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- i. Minimization of risks and maximization of benefits
  - ii. Required elements for informed consent
  - iii. Method for obtaining informed consent
  - iv. Method of subject selection and recruitment
  - v. Privacy and confidentiality
5. In the event a protocol is approved by the initial reviewer, the IRB chairperson will notify the primary investigator (PI) or faculty/staff supervisor (if PI is a student) of this decision in writing.
6. In the event the protocol is NOT approved by the initial reviewer, the IRB chairperson, solely or along with other members of the IRB, will review the protocol. In the event that the protocol is rejected, the IRB chairperson will notify the primary investigator (PI) or faculty/staff supervisor (if PI is a student) of this decision in writing. Included in the documentation will be a description /explanation of the reason(s) for its non-approval. The PI will be given an opportunity to resubmit the protocol after making any and all revisions requested by the initial reviewer, or request an IRB Full-Board review of the protocol as is. Revised protocols are to be submitted to the IRB chairperson, who will forward them on to the initial reviewer for reconsideration. Submission of revised protocols can occur on a rolling basis during the fall and spring semesters. The reviewer will notify the chairperson of his/her decision (in writing and with adequate explanation if again the proposal is not accepted) within one week of receiving the resubmission.
7. IRBs will NOT conduct *ex post facto* reviews of protocols. Conducting human subjects research without prior IRB approval is in violation of SUU Policy 6.14, and infractions will result in written notification to the SUU Research Integrity Officer.

**G. IRB Full-Board Review of Research**

1. For proposals which have been assessed as more than minimal risk or which involve the use of one or more vulnerable populations, a Full-



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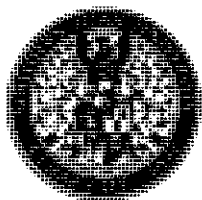
**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

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Board review will occur. The IRB member assigned to review the initial protocol submission will forward a copy of the completed *Initial Assessment of Minimal Risk and Vulnerable Population Status* form for said proposal.

2. Within one week of its receipt, the IRB chairperson will disseminate copies of these materials to each member of the IRB. The IRB will meet between the 15th and end of each month as needed during the fall and spring semesters to conduct Full-Board review(s).
3. IRB meetings require that a majority of its members be present including at least one non-scientist member (i.e., a quorum). IRB Full-Board reviews require that all members of the committee receive a copy of the proposal no less than one week prior to a scheduled meeting. Approval of the protocol is by a majority vote of this quorum. Should the quorum fail during a meeting, the IRB may not take further actions or votes unless the quorum can be restored.
4. All IRB meetings will be open to the PI and the general public in accordance with Utah state law. The PI and any other individual affiliated with a proposal being reviewed may not be present during voting on said proposal.
5. IRB members will duly consider each of the following in their assessment of a protocol:
  - i. Risk/benefit analysis
  - ii. Informed consent
  - iii. Selection of subjects
  - iv. Privacy and confidentiality
  - v. Monitoring and observation
  - vi. Additional safeguards
  - vii. Incentives for participation





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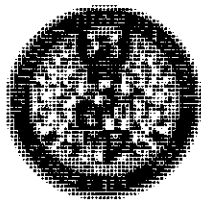
**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

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6. In the event a proposal is NOT approved through the IRB review, the PI or faculty/staff supervisor (if PI is a student) must be notified in writing of this decision. Included in the documentation will be a description/explanation of the reason(s) for its non-approval. The PI will be given an opportunity to respond in person or in writing at the next IRB meeting.
7. IRB members will document their reviews by completing the *Documentation of Full Board Review* form. This form will solicit protocol specific information in each of the categories listed in Section IV of this policy.
8. In the event that investigators not affiliated with Southern Utah University wish to conduct research on the SUU campus, those investigators must submit a copy of a) the IRB proposal they submitted to their own institution, and b) a copy of their IRB's approval letter. The chairperson of the IRB will forward these materials to each of the IRB members. Concerns will be reviewed at the next meeting, with the minutes of the meeting serving as the review. A letter of acknowledgement will then be sent to the PI and any SUU affiliates.

**H. Continuing Reviews of Approved Research**

1. Proposals assigned expedited or Full-Board review status and approved by the IRB will be subject to continuing review by the IRB.
2. The IRB will establish how often the research will be reviewed. All research which requires continuing review must be reviewed no less than once annually. The frequency with which a protocol will undergo continuing review will be proportionate to the level of risk involved in the research and the extent to which a PI or faculty/staff supervisor (if PI is a student) has a history of infractions to policy 6.20.
3. Continuing reviews must be substantive and meaningful. Within two weeks prior to the established deadline for a continuing review, the PI must complete and submit the *Continuing Review of Approved Research* form to the chairperson of the IRB.

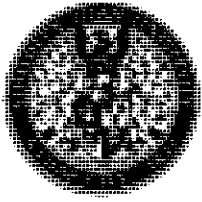


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**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

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4. The *Continuing Review of Approved Research* form will consist of a protocol summary and a status report on the progress of the research. The form will solicit information on the following:
  - i. the number of subjects accrued;
  - ii. a summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
  - iii. a summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
  - iv. any relevant multi-center trial reports;
  - v. any other relevant information, especially information about risks associated with the research; and
  - vi. a copy of the current informed consent document and any newly proposed consent document.
5. The IRB member who originally approved the protocol will conduct the continuing review within two weeks of receiving the *Continuing Review of Approved Research* form. In the event the reviewer determines that the research should be discontinued or revised, the *Continuing Review of Approved Research* form will be disseminated to all members of the IRB and discussed at the next convened meeting, after receiving the review form.
6. If the research was initially approved through a Full- Board-review, the chairperson will submit the review form to all members of the IRB. Assessment of the continuing review information will be conducted at the next IRB meeting, after receiving the review form.
7. IRB members/chairpersons who conduct continuing reviews will receive a copy of the initial protocol including any modification previously approved by the IRB. Upon request, members will have access to the complete IRB protocol file and relevant IRB minutes.

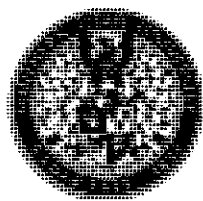


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**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

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8. Decisions based on assessment of the *Continuing Review of Approved Research* form will be conveyed in writing to the PI or faculty/staff supervisor (if PI is a student).
- I. Request for an Extension of an Approved Protocol
  1. IRB approval for a specific protocol (Expedited or Full-Board review status only) will in most cases terminate within one year of its approval date.
  2. It is at the discretion of the IRB member who reviewed the protocol to establish the expiration date for the protocol's approval. Consideration will be given to the nature of the risks and benefits associated with the research.
  3. Requests for an extension of the project's approval expiration date will require the PI to submit a completed *Approved Protocol Extension* form to the chairperson of the IRB that initially approved the protocol. This form should be submitted no later than four weeks prior to the project's expiration date to avoid any disruption in research activities.
  4. If an extension is requested for a protocol approved by the IRB, the chairperson of the IRB will forward the request to all members of the committee, who will review and decide on the request at a meeting to be convened after all members have received the request.
  5. Final decisions to grant or refuse a request for extension will be conveyed to the PI or faculty/staff supervisor (if PI is a student.) If the decision is made to not grant an extension, the reason(s) why will be detailed in writing.
- J. Project Closure
  1. All approved protocols with expedited or Full-Board review status require the PI or faculty/staff supervisor, if the PI is a student, to complete and submit a *Project Closure* form within 30 days of the project's completion. This form is to be submitted to the chairperson of the IRB.



**SOUTHERN UTAH UNIVERSITY**  
**Policies and Procedures**

**Policy # 6.20**  
**Date Approved: 12/15/94**  
**Date Amended: 05/03/2013**  
**Reviewed w/no Changes:**  
**Office of Responsibility: Prov**  
**Page 16 of 33**

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**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

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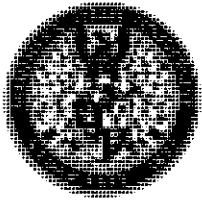
**K. Random and Selected Audits of Approved Research**

1. Once in the fall and once in the spring semester, one previously approved and on-going research protocol will be randomly selected by the IRB chairperson for a random audit.
2. Investigators with a history of infractions to policy 6.20 may be targeted for selected audits of approved and on-going research activities. The chairperson of the IRB will decide whether to require an audit, which he/she will conduct. Investigators with several infractions or severe infractions are more likely to be subjected to a selected audit.
3. An audit's purpose is to ensure that no material changes to the protocol have been made since the previous IRB review. The auditor will examine the PI's materials and apparatus, speak to one or more research assistants (if applicable), and review raw data records. Where participants' contact information is known, and the PI has a history of infractions to policy 6.20, the auditor will contact 1-5 participants to verify the PI's adherence to the approved research protocol. The auditor may also contact participants in the event that inconsistencies/infractions appear in the course of the audit.

**L. Amendments to Previously Approved Protocols**

1. Primary investigators who wish to amend and/or revise a previously approved protocol must complete and submit the *Proposed Changes to a Previously Approved Protocol* form to the chairperson of the IRB.
2. *Proposed Changes to a Previously Approved Protocol* form submitted to the IRB chairperson will be reviewed or forwarded to the IRB member who approved the research initially. The IRB member will be required to review and decide whether to approve the changes within one week of receiving the form. The reviewer will complete his/her section of the form and return it to the IRB chairperson (if not self), who will notify the PI in writing.
3. In the event an IRB member has concerns with regards to the proposed changes, the original *Proposal Submission* form and the *Proposed Changes to a Previously Approved Protocol* form will be disseminated





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**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

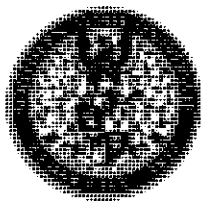
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to all members of the IRB. Concerns will be addressed at the next IRB meeting.

4. *Proposed Changes to a Previously Approved Protocol* form submitted to the IRB chairperson will be forwarded to all the members of the IRB. The IRB members will be required to review and decide whether to approve the changes within one week of receiving the form. The reviewer will complete the form and return it to the IRB chairperson. Should one or more IRB members have any concerns with respect to the proposed changes, these will be discussed at the next IRB meeting after the chairperson receives the *Proposed Changes to a Previously Approved Protocol* forms from the IRB members.
5. Proposed changes to a previously approved protocol may not be initiated prior to receiving IRB approval, except when necessary to eliminate apparent immediate hazards to the participant. Instructions to this effect will be clearly printed on the *Proposed Changes to a Previously Approved Protocol* form and the initial *Proposal Submission* form.

M. Reports of Unanticipated Problems, Risks, and Hazards to Participants

1. The investigator will notify the chairperson of any unforeseeable risks or hazards to participants, as soon as they become evident. Initial contact will be made wither in person or by phone. The investigator must complete and submit the *Incident Report* form to the IRB chairpersons within two days of the incident.
2. The IRB chairperson, will report the incident immediately to the OSP, the director of HRPP, the Institutional Official, and the Provost. In cases where the research is supported by a federal grant, OSP will immediately notify OHRP and the Federal agency that awarded the grant. Initial contact will be made either in person or by phone. Copies of the *Incident Report* form filed by the investigator will be sent to the above mentioned people and offices immediately upon receipt of the form.
3. The IRB will meet as soon as possible to discuss the implications of the incident and what, if any, action(s) need to be taken. A representative from OSP, HRPP, the University Official, the Provost,



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**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

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and the University's legal consultant will be invited or requested to attend. Proposed actions from this meeting will not supersede those required by OHRP and/or the federal granting agency, to the extent required by law.

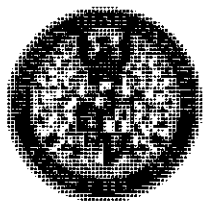
**N. Notification of IRB Decisions and Actions**

1. All IRB decisions pertaining to a protocol will be conveyed in writing (electronically) to the PI or faculty/staff supervisor (if PI is a student)
2. All IRB decisions and actions will be documented at their respective meetings. The minutes of these meetings will be e-mailed to each IRB members, OSP, the Director of the HRPP, and the Provost, as soon as they become available.

**O. Nature and Retention of IRB Records**

1. The chairperson of the IRB is responsible for keeping adequate records of its members, the minutes of IRB meetings, correspondence with researchers, and all completed IRB forms.
2. IRB records must be retained for at least 3 years, and records relating to research that is conducted must be retained for at least 3 years after completion of the research.
3. All records will be kept by the SUU Director of the OSP. Files must be accessible for inspection and copying by authorized representatives of the University and of the HHS, and by the public in accordance with Utah state law, at reasonable times and in a reasonable manner.
4. The minutes of IRB meetings will record the members who attended the meeting, actions taken at the meeting, the outcome of the vote on research protocols including the number of members voting for or against approval and abstaining, the basis for requiring any modifications or revisions in research procedures or the informed consent process or forms, documentation of any specific findings required by the federal regulations, and a written summary of the discussion of issues and their resolution.

**P. Noncompliance with Policy 6.20**

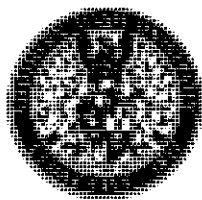


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**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

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1. All faculty, students, and staff named individually or collectively (e.g. students enrolled in courses where human subjects research is conducted) in an approved research protocol must adhere strictly to policy 6.20.
2. All reports of non-adherence to the policy will be investigated by the chairperson of the IRB who initially approved the protocol.
3. The IRB chairperson will present the evidence to the IRB members. Should the IRB decide that a preponderance of the evidence support one or more infractions to policy 6.20, the IRB chairperson is authorized to take one or more of the following actions voted on by the IRB members (which one will depend on the severity and frequency of the infraction):
  - i. A letter describing the infraction(s) and cautionary statements may be sent to the PI or faculty/staff supervisor (if PI is a student).
  - ii. A letter describing the infraction(s) and IRB actions in response to the infractions(s) may be sent to the chairperson of the PI's or faculty/staff supervisor's (if PI is a student) department.
  - iii. A letter describing the infraction(s) and IRB actions in response to the infraction(s) may be sent to the OSP, director of HRPP, and the Provost.
  - iv. A letter describing the infraction(s) and IRB actions in response to the infraction(s) may be sent to OHRP and/or the federal Agency which funded the project.
  - v. The PI or faculty/staff supervisor (if PI is a student) may be required to suspend or discontinue the research project for which IRB approval was granted.
  - vi. The PI or faculty/staff supervisor (if PI is a student) may be required to suspend or discontinue all research activities for which IRB approval has been granted.



**SOUTHERN UTAH UNIVERSITY**  
**Policies and Procedures**

**Policy # 6.20**  
**Date Approved: 12/15/94**  
**Date Amended: 05/03/2013**  
**Reviewed w/no Changes:**  
**Office of Responsibility: Prov**  
**Page 20 of 33**

---

**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

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- vii. The PI or faculty/staff supervisor (if PI is a student) may be prohibited from participating in any research activity while remaining at SUU.
- viii. A formal report to be sent to the Research Integrity Officer with a request to be considered as an act of research misconduct.

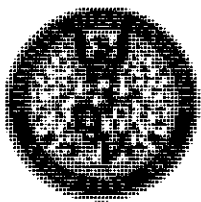
**Q. Responsibilities and Rights of the Institution**

- 1. The institution will encourage and promote constructive communication among the institutional officials, research administrators, department chairs, research investigators, clinical care staff, human participants, and all other relevant parties as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the participants, recognizing the ethical codes of behavior operating within the various academic disciplines.
- 2. The institution will support the principle of free inquiry, and provide an atmosphere favorable for research and supportive of academic freedom.
- 3. The institution will exercise appropriate administrative overview carried out at least annually to assure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied.
  - i. The University will staff, maintain, and support the HRPP.
  - ii. HRPP is responsible for:

**Communication & Education**

- a. Promoting communication among the research administrators, department heads, investigators, clinical care staff, human subjects, and institutional officials, as a means of maintaining a high level of awareness regarding the ethical conduct of research, and safeguarding the rights and welfare of subjects.





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**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

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- b. Maintaining access to the institution's Assurance, copies of pertinent Federal regulations, policies and guidelines related to the involvement of human participants in research, as well as institutional policies and procedures.
- c. Educating the members of its research community in order to establish and maintain a culture of compliance with Federal regulations and institutional policies relevant to the protection of human participants.

Record-keeping & Reporting

- a. Ensuring that IRB records are being maintained appropriately and that the records are accessible, upon request, to authorized Federal officials.
- b. Ensuring that the certification of IRB approval of proposed research to the appropriate Federal department or agency for federally supported research.

Monitoring & Oversight

- a. Ensuring that appropriate oversight mechanisms to ensure compliance with the determinations of the IRB have been implemented.
- b. Ensuring that all cooperating performance sites in Federally supported research have appropriate OHRP-approved assurances and provide Certifications of IRB review to the appropriate Federal authorities.
- c. Ensuring that performance sites cooperating in non-Federally supported research have, and can document, appropriate mechanisms to protect human participants.
- d. Ensuring that cooperative IRB review arrangements are documented in writing in accordance with OHRP guidance.



**SOUTHERN UTAH UNIVERSITY**  
**Policies and Procedures**

**Policy # 6.20**  
**Date Approved: 12/15/94**  
**Date Amended: 05/03/2013**  
**Reviewed w/no Changes:**  
**Office of Responsibility: Prov**  
**Page 22 of 33**

---

**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

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- e. Ensuring that all independent investigators, who rely on the institution's IRB, have documented, in accordance with OHRP guidance, their commitment to the institution's human participants protection requirements and to the IRB's determinations.
  - 4. The institution will provide for meeting space and sufficient staff to support the IRBs' review and record-keeping duties.
  - 5. Research covered by this policy may be subject to further appropriate review by officials of the institution. However, those officials may not approve research if it has not been approved by an IRB.
- R. Responsibilities and Rights of the Investigator
- 1. The primary investigator (and supervisor if applicable) must complete the NIH sponsored training course, currently located at: <http://phrp.nihtraining.com/users/login.php>. The primary investigator or supervisor (if PI is a student) is responsible for ensuring that all other investigators involved with the project are appropriately and adequately trained in the protection of human research participants.
  - 2. Proof of completion certificates will be kept on file with SUU's OSP. No protocol will be approved by an IRB until all required certificates are on file with OSP.
  - 3. The PI and faculty/staff supervisor (if PI is a student) must read and understand SUU Policy 6.20, and all instructions provided by the IRBs for securing and maintaining IRB approval.
  - 4. Should investigators wish to appeal an IRB decision, they must first do so internally. That is, the appeal must be presented initially to the chairperson of the IRB the appeal was not resolved, the investigator may then appeal to the director of HRPP. Note that no individual or office at the University may approve a protocol which was not approved by the IRBs.

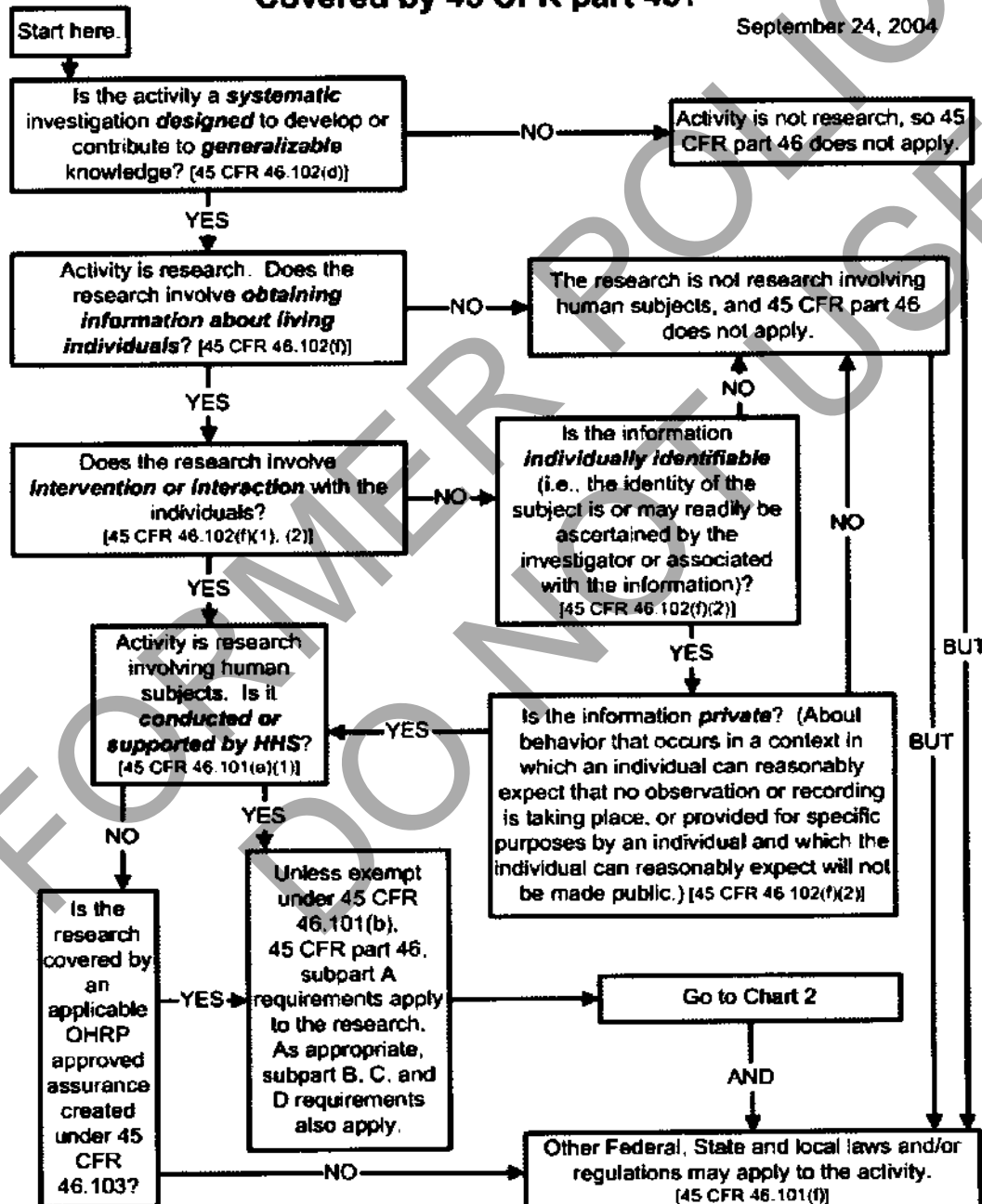
V. Decision Charts

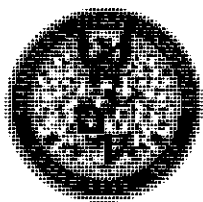


**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

**Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?**

September 24, 2004

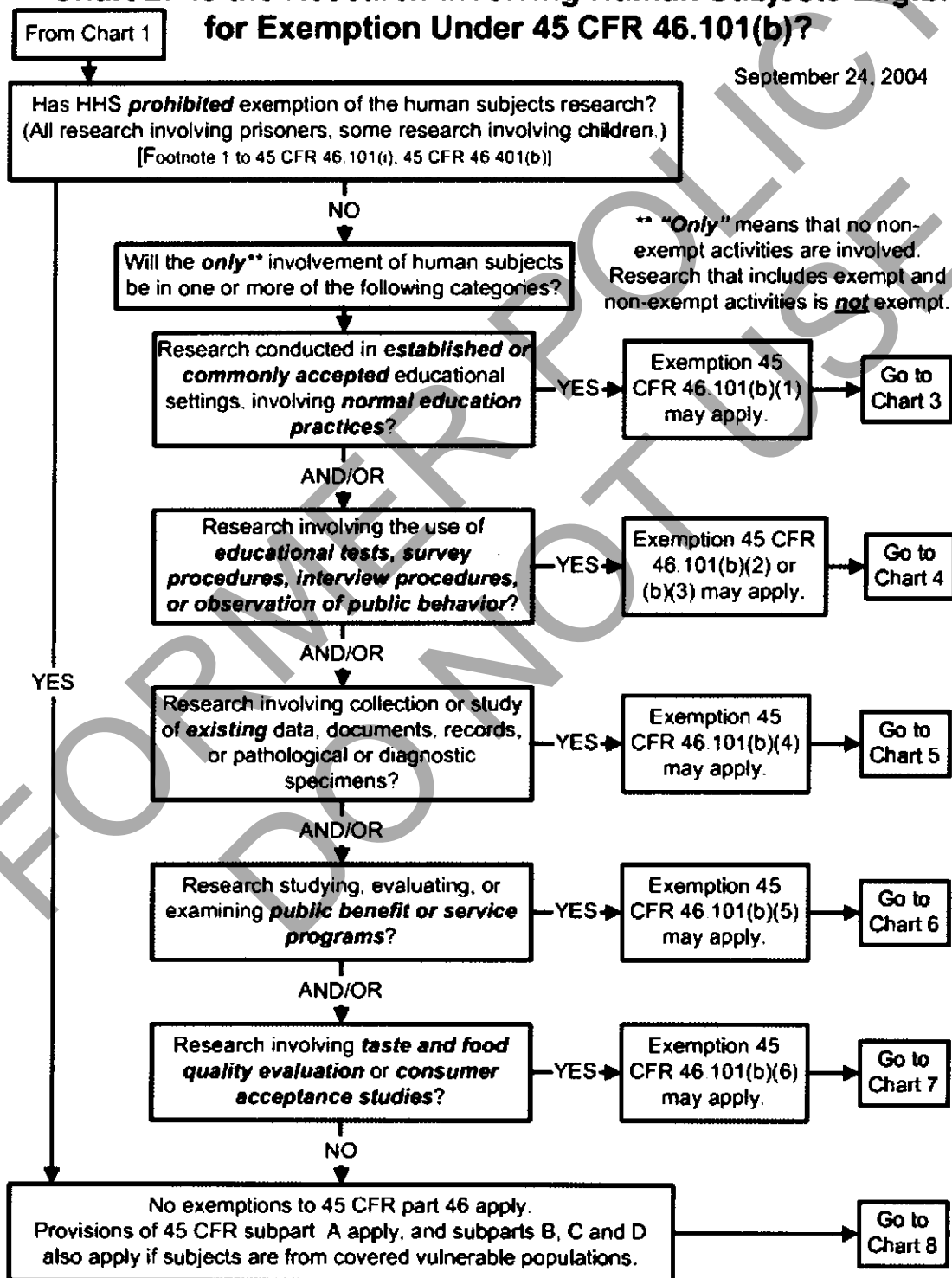


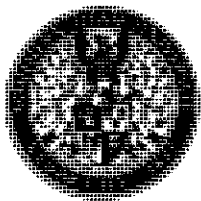


SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS

Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

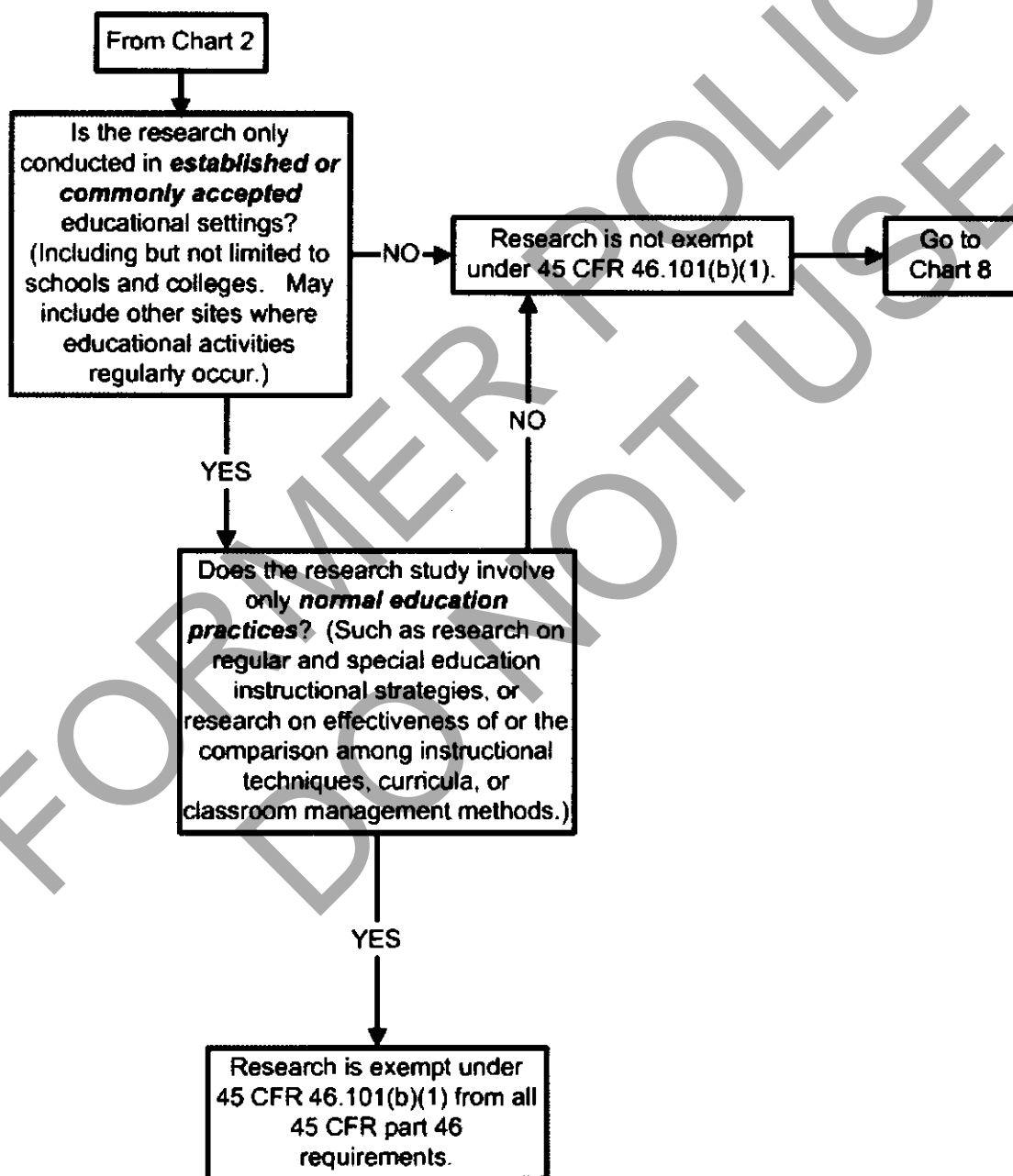
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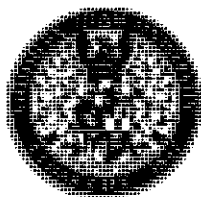




SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS

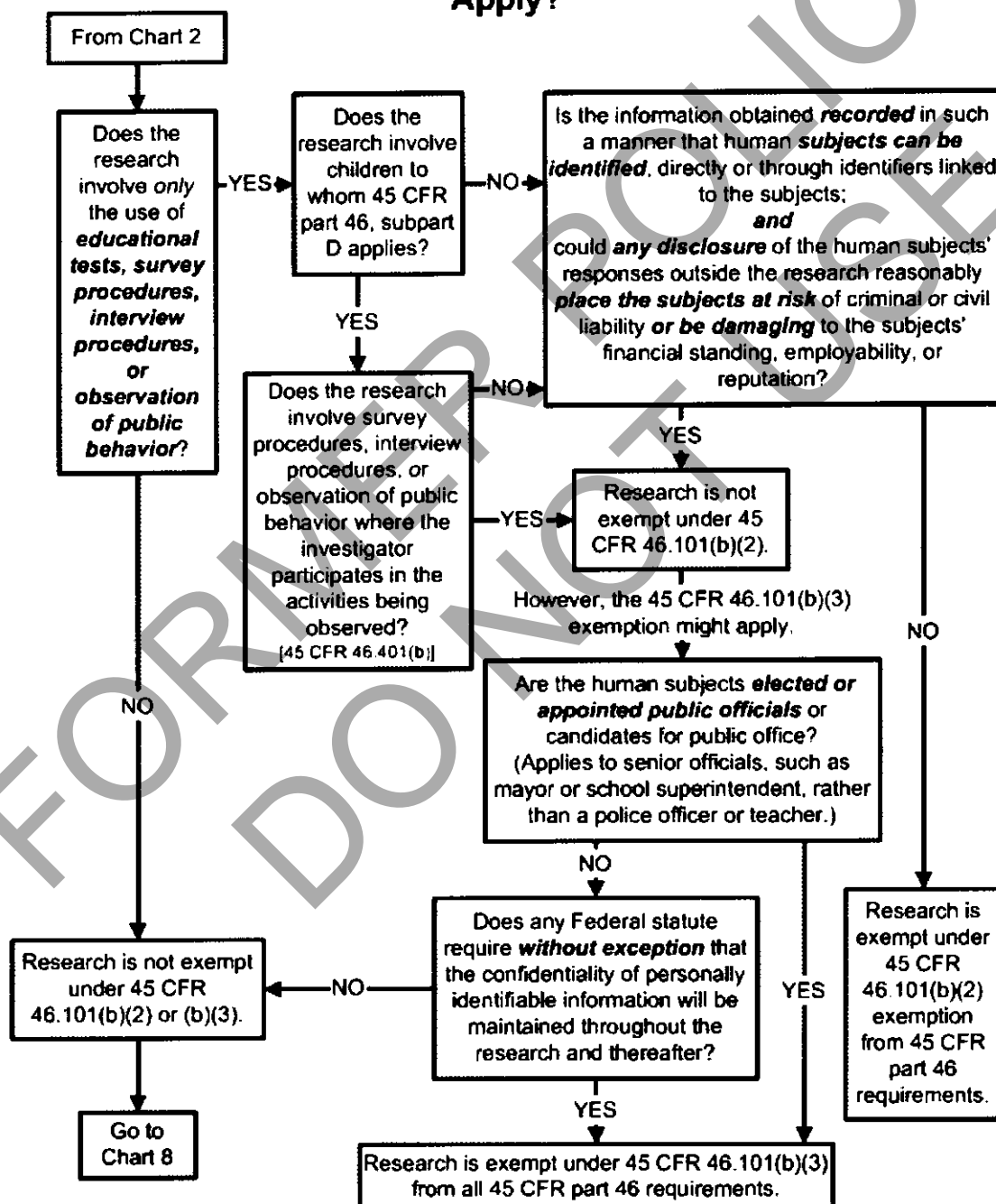
**Chart 3: Does Exemption 45 CFR 46.101(b)(1)  
(for Educational Settings) Apply?**



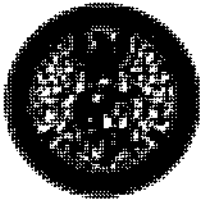


**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

**Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3)  
(for Tests, Surveys, Interviews, Public Behavior Observation)  
Apply?**

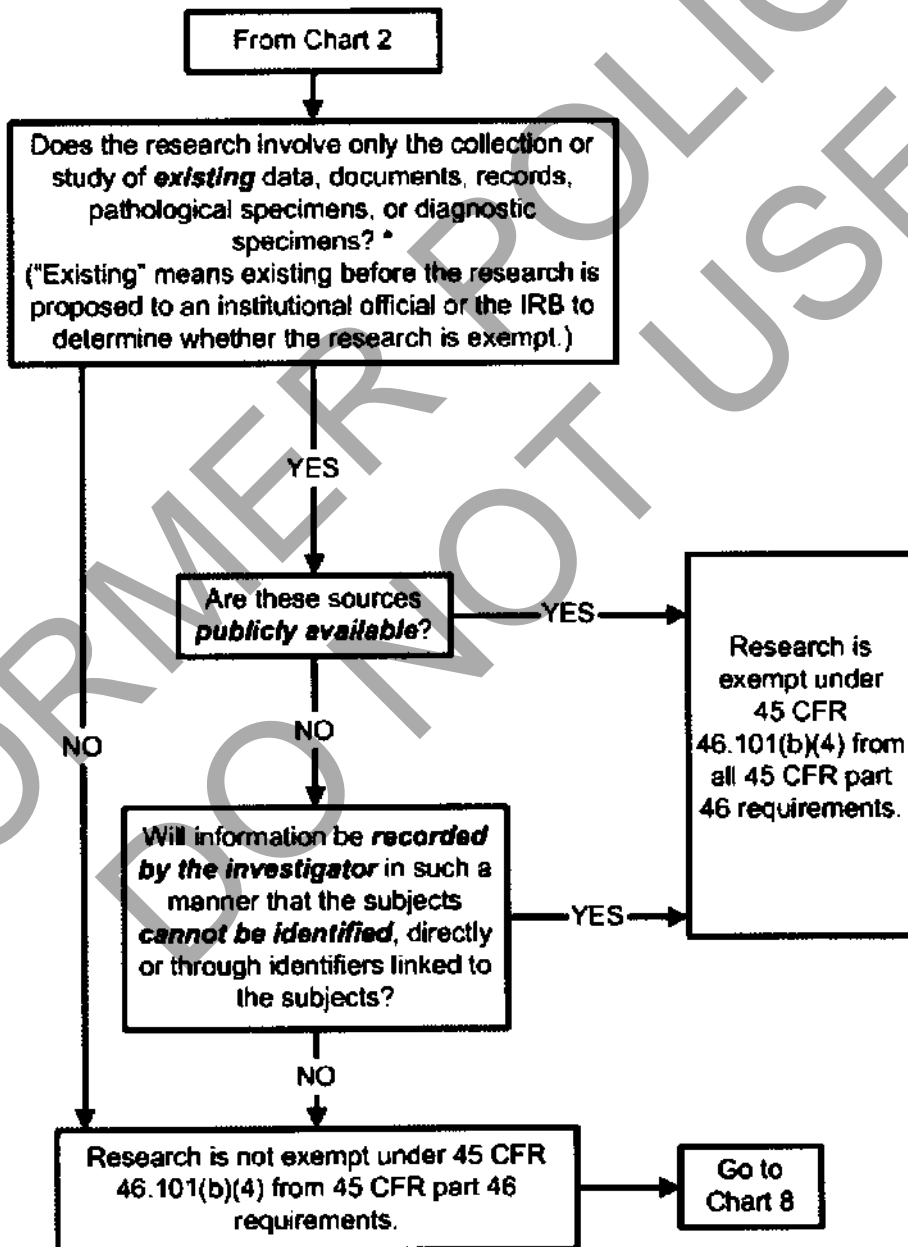




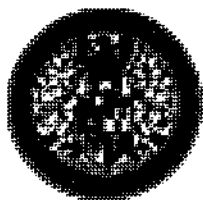


SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS

**Chart 5: Does Exemption 45 CFR 46.101(b)(4)  
(for Existing Data Documents and Specimens) Apply?**

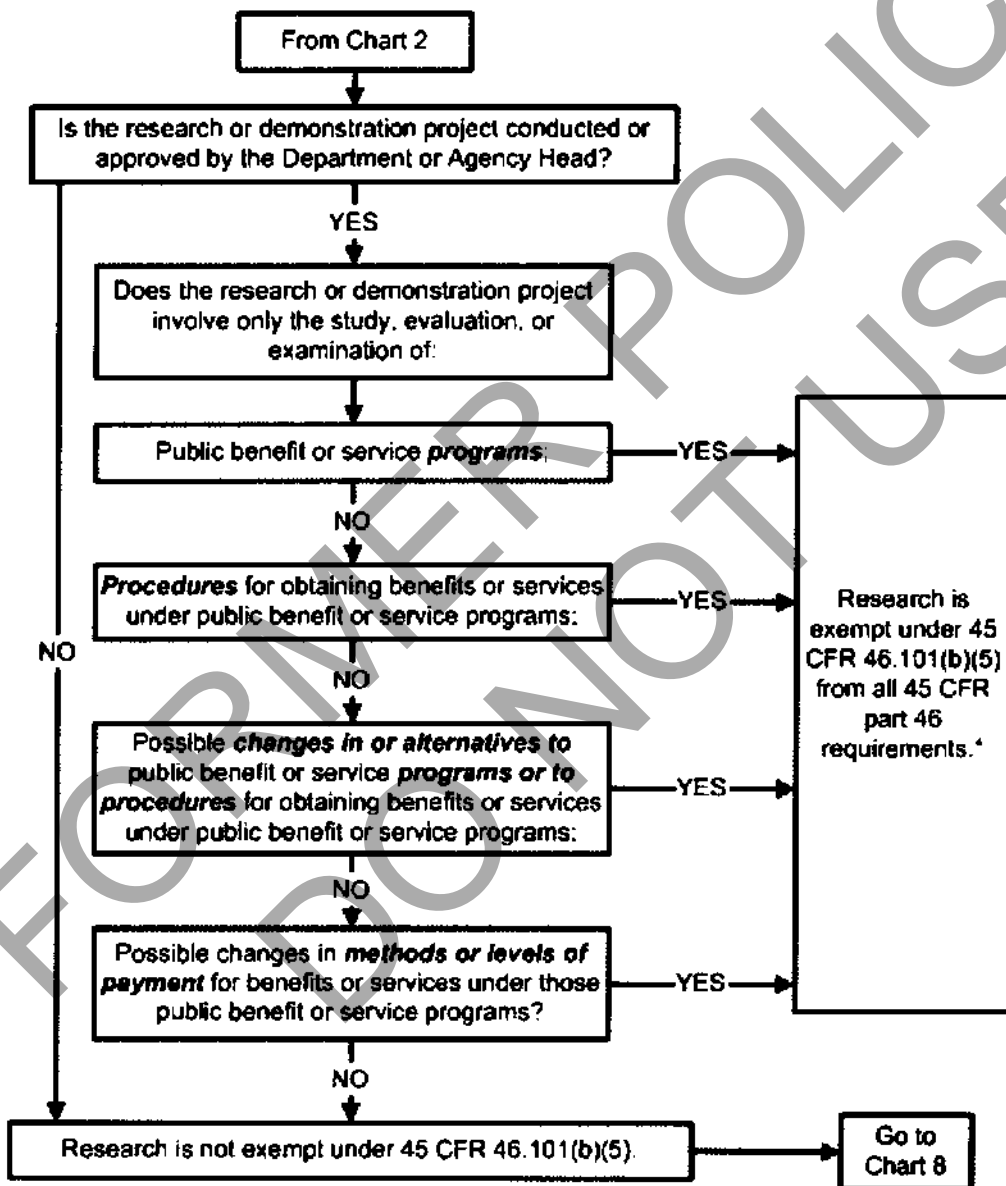


\* Note: See OHRP guidance on research use of stored data or tissues and on stem cells at <http://www.hhs.gov/ohrp/policy/index.html#tissues> and <http://www.hhs.gov/ohrp/policy/index.html#stem>, and on coded data or specimens at <http://www.hhs.gov/ohrp/policy/index.html#coded> for further information on those topics.



**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

**Chart 6: Does Exemption 45 CFR 46.101(b)(5)  
(for Public Benefit or Service Programs) Apply?**

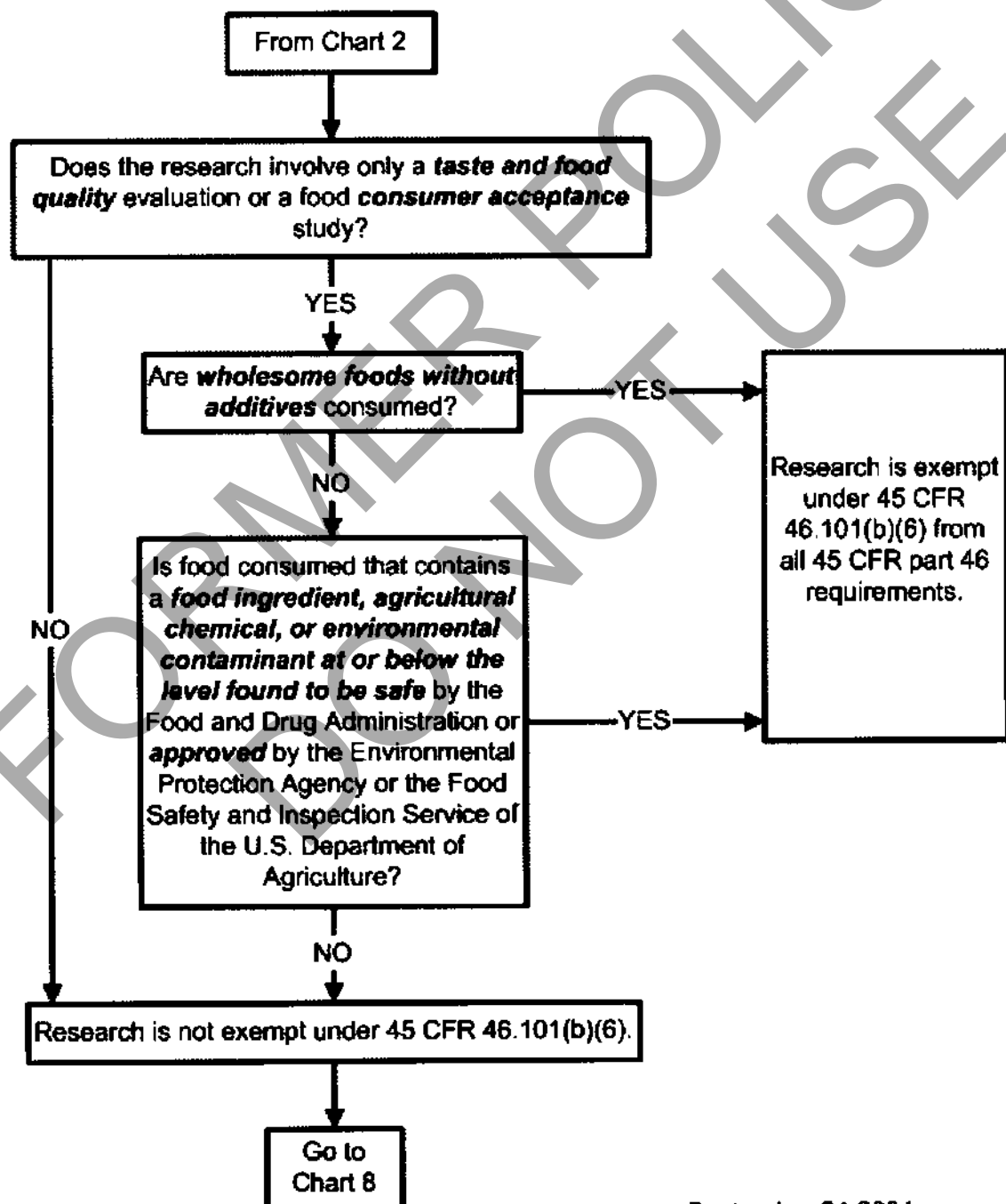


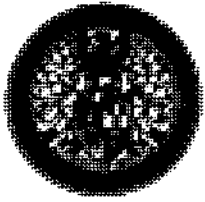
\* Note: See OHRP guidance on exemptions at <http://www.hhs.gov/ohrp/policy/index.html#exempt> for further description of requirements for this exemption.



SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS

**Chart 7: Does Exemption 45 CFR 46.101(b)(6)  
(for Food Taste and Acceptance Studies) Apply?**

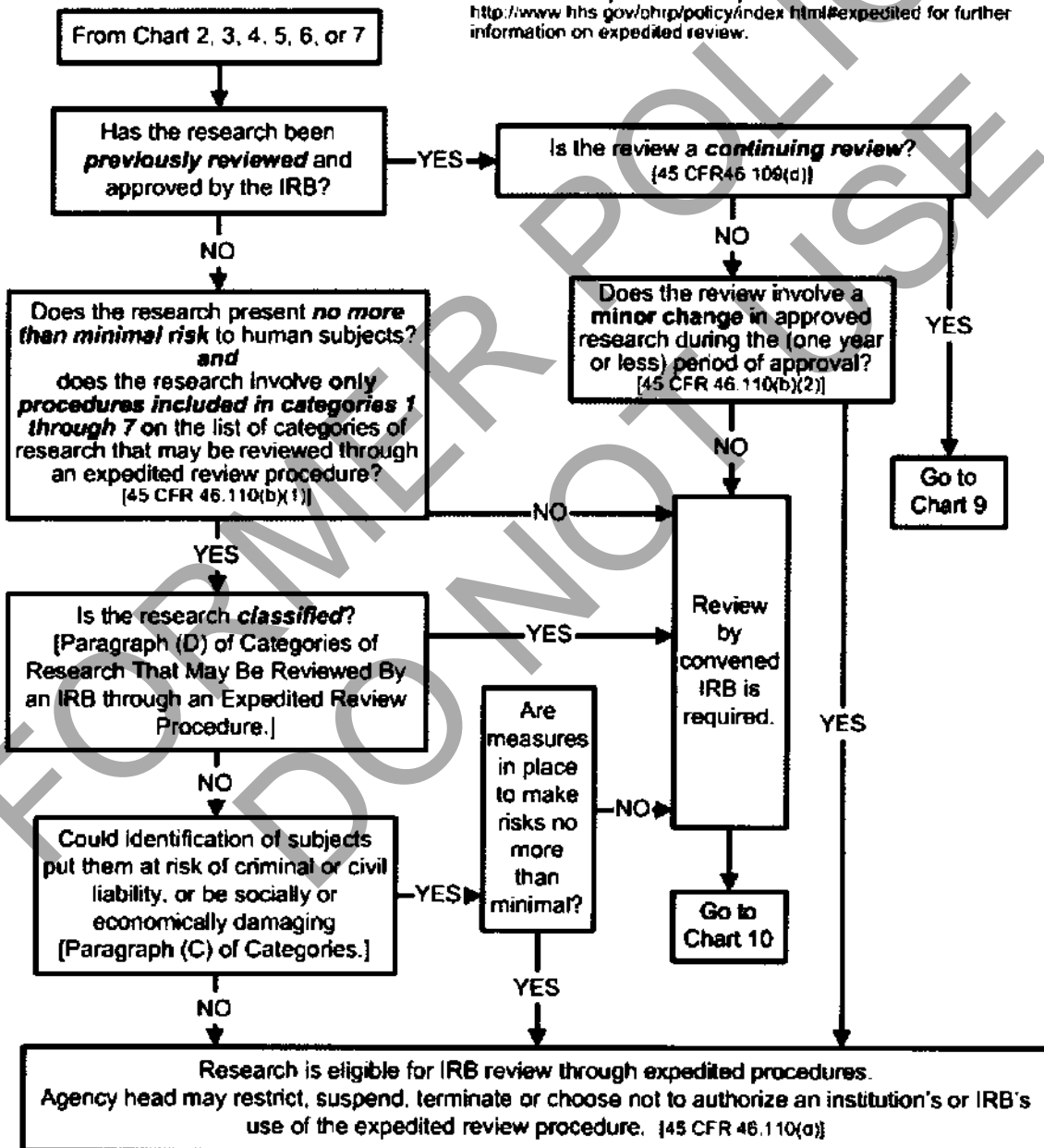


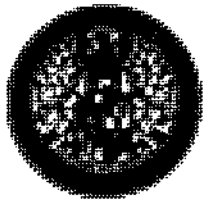


SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS

Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?\*

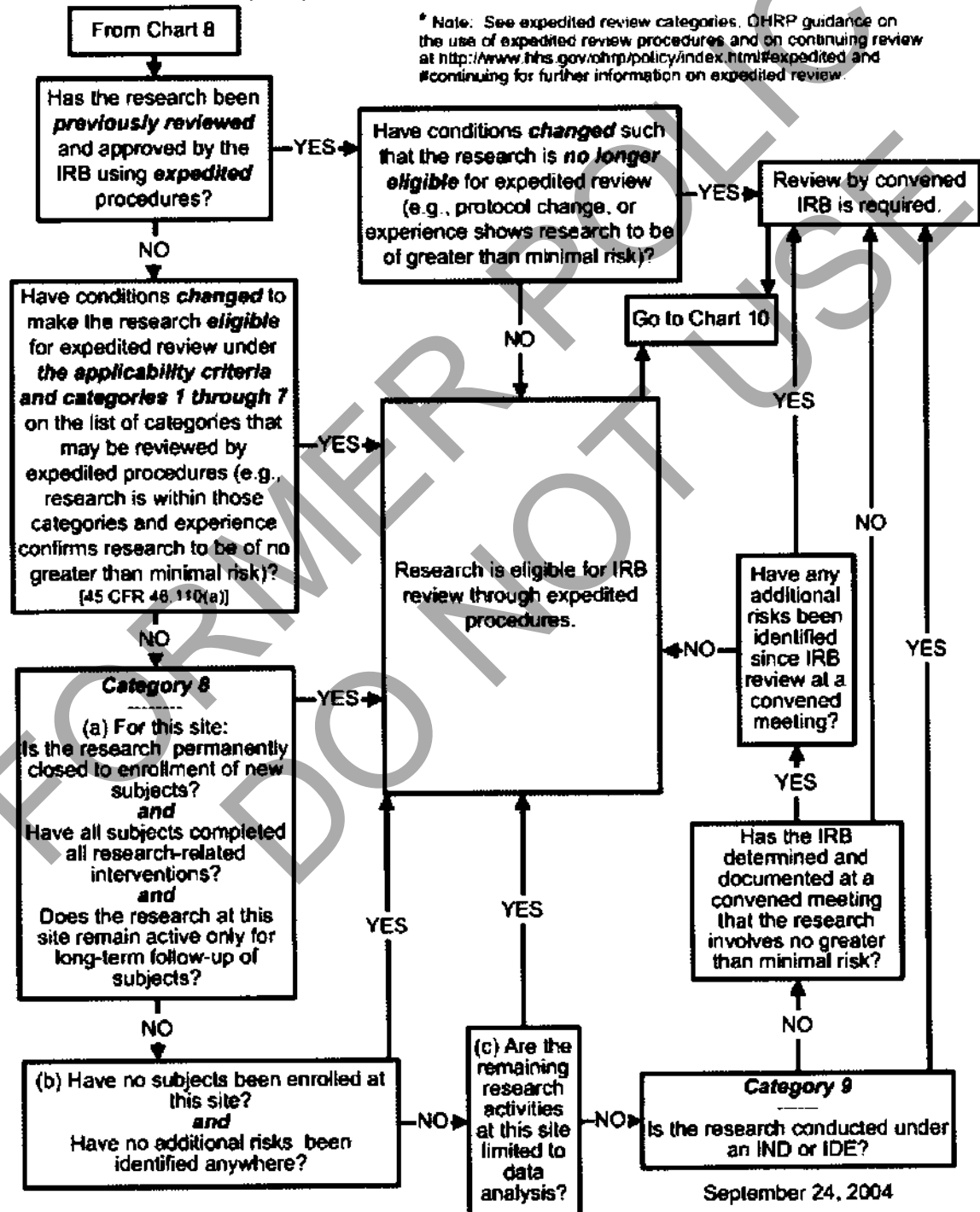
\* Note: See expedited review categories and OHRP guidance on the use of expedited review procedures at <http://www.hhs.gov/ohrp/policy/index.html#expedited> for further information on expedited review.





SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS

**Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?**



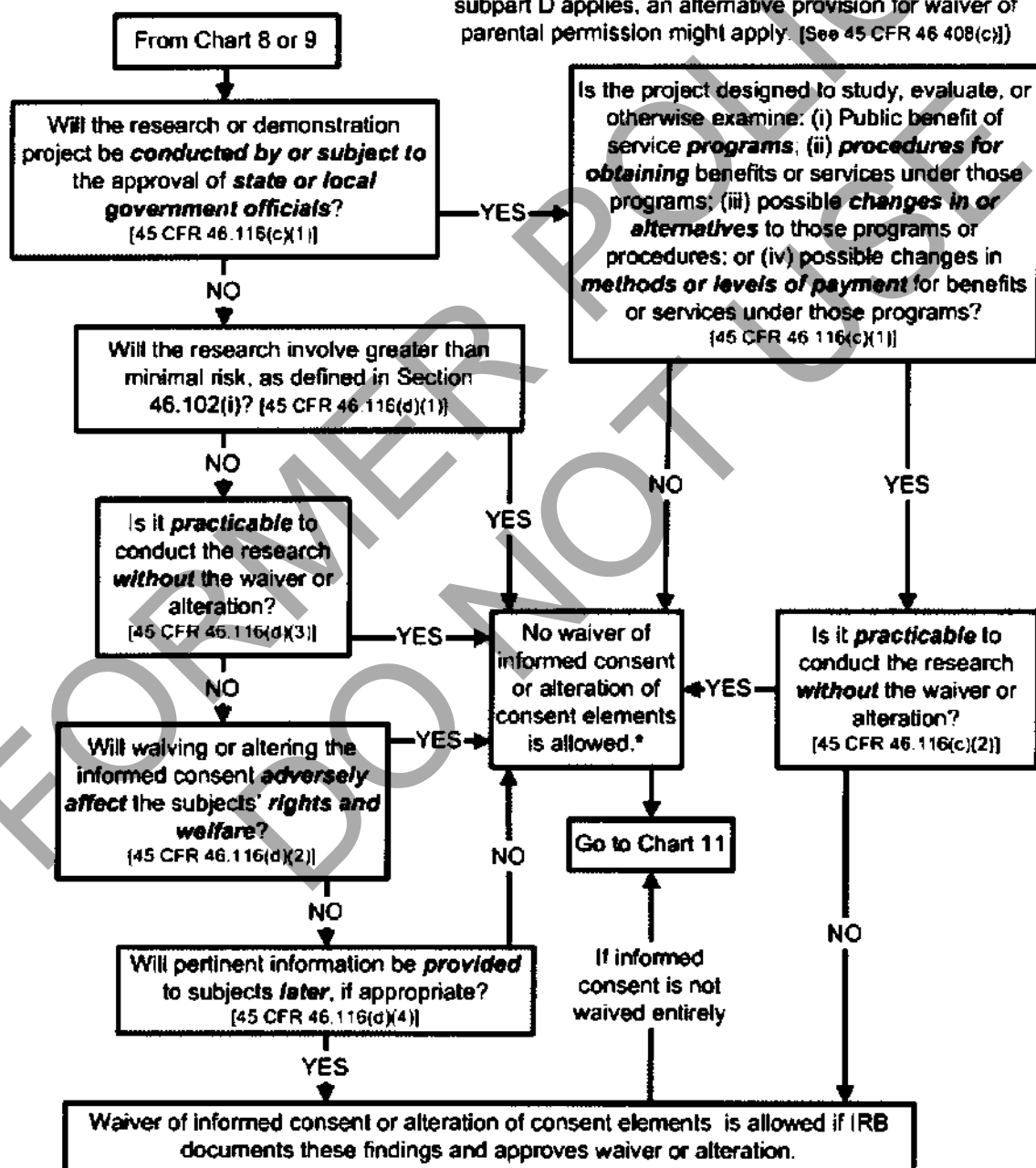
September 24, 2004



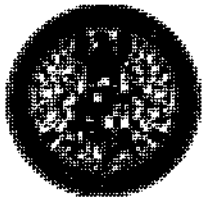
SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS

Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?\*\*

\*\*(Note: If subjects include children to whom 45 CFR part 46, subpart D applies, an alternative provision for waiver of parental permission might apply. [See 45 CFR 46.408(c)])



\* Note: See OHRP guidance on informed consent requirements in emergency research at <http://www.hhs.gov/ohrp/policy/index.html#emergency> for further information on emergency research informed consent waiver



**SUBJECT: INSTITUTIONAL REVIEW BOARD FOR RESEARCH ON HUMAN PARTICIPANTS**

**Chart 11: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?**

