POLICY AND GENERAL INFORMATION ON THE
GLSEN RESEARCH ETHICS REVIEW COMMITTEE
Policy on Review of Research Involving Human Participants
August 20, 2006

All human subjects research (sponsored or non-sponsored) at the Gay, Lesbian, & Straight Education Network (GLSEN), conducted by agents of the organization, or involving non-public information held by the organization will be reviewed and approved by the Research Ethics Review Committee (RERC) using criteria similar to those applied to federally-funded research and consistent with the principles outlined in the Belmont Report. The formation and operation of this committee has been approved by the GLSEN Board of Directors.
GLSEN’s Research Ethics Review Committee: General Information
August 20, 2006

Goals of the Research Ethics Review Committee (RERC):

The primary goal of the RERC is to assure that the rights and welfare of human subjects participating in research are adequately protected.

Three ethical principles serve as the moral foundation for the review and conduct of research involving human participants: respect for persons, beneficence, and justice. Respect for persons requires attention to informed consent (information, comprehension, and voluntariness), surrogate permission, assent, maximization of choice, protection of privacy and confidentiality, and the protection of vulnerable populations (e.g., children). Beneficience requires examining the research design, evaluating the risks and benefits of the research, minimizing the risks of research participation, and ensuring that the principal investigator is qualified to conduct the research. Justice requires attending to participant recruitment procedures, the equitable distribution of the burdens and benefits of research, and the criteria for selecting participants.

The RERC reviews all planned research involving human subjects prior to initiation of the research, approves research that meets established criteria for protection of human subjects, and monitors approved research to ascertain that human subjects are indeed protected.

Definitions for the Use of Human Subjects in Research

The following federal definitions apply to all research reviewed by GLSEN’s RERC:

Human Subject (45 CFR 46.102(f)): Human subject means a living individual about whom an investigator (whether professional or student) conducting research
obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

*Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and 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 subject 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 subjects.

Research (45 CFR 46.102(d)):
*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes (for example, some demonstration and service programs may include research activities).

Minimal Risk (45 CFR 46.102(i)):
*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 encountered in daily life or during the performance of routine physical or psychological examinations or tests.
Monitoring of Research

GLSEN’s RERC is authorized and organized to review any and all types of research in which human subjects are involved, including projects that are not subject to federal oversight.

Authority of GLSEN’s RERC:

GLSEN’s RERC employs a review process in conformity with the Federal Policy for the Protection of Human Subjects (45 CFR 46).

The review process is the same for all research involving human subjects supported or otherwise subject to regulation by any federal department or agency, sponsored by any other extramural entity, or initiated and funded within GLSEN.

The authority conveyed to the GLSEN RERC includes decisions to approve, disapprove, require modifications, monitor, suspend and terminate research projects involving human subjects. Under no circumstance may a decision of the RERC to disapprove a project be reversed by another office, individual, or committee of GLSEN.

Certain populations of human subjects may be particularly vulnerable in a research setting: children, prisoners, pregnant women, fetuses, mentally disabled persons, economically or educationally disadvantaged persons. In undertaking its review of these subject populations, the RERC will apply additional protective safeguards as required by federal and state law, institutional guidelines, and any other applicable agency/entity regulations.
GUIDE TO SUBMITTING PROPOSALS TO THE GLSEN RESEARCH ETHICS REVIEW COMMITTEE
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I. Introduction

This guide to submitting proposals to the Research Ethics Review Committee is designed to help you:

- Determine if your work must be reviewed and approved by the GLSEN Research Ethics Review Committee (RERC);
- Understand federal regulations and GLSEN policies concerning human subjects in research;
- Prepare an application for review and approval to the RERC;
- Respond to any concerns or revisions the RERC may request after the initial review.

At GLSEN, all research involving human subjects (whether externally funded or not) must be reviewed and approved by the Research Ethics Review Committee (RERC) before the research project begins.

To get started with the application process, including whether your proposed work requires RERC review and approval, please review the section on How to Apply.

It is GLSEN’s policy that all RERC applicants must take the Human Participant Protections Education for Research Teams web-based course. The two-hour tutorial is designed for people conducting research using human participants. All researchers must complete the course before submitting an RERC application. A copy of the certificate of completion, which you can print from your computer upon completing the course, must accompany your application for RERC approval.

The Director of Research and the RERC members expect that investigators will make use of the materials in this guidebook and the educational chapters of the online tutorial. These references explain most human subjects issues and they should be the first stop for information in the human subjects review and approval process. For additional questions and guidance, please contact:

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II. Review Process

Principal investigators planning to conduct research with human subjects must first obtain approval for their research and its methods from GLSEN’s Director of Research. Furthermore, investigators should plan to allow at least two months from the initial Research Ethics Review Committee (RERC) meeting date before beginning any research in the event that the RERC requests revisions or additional information before granting final approval. No research activities may begin until the project has been approved by the RERC.

At least one month prior to the deadline for a given RERC meeting, all principal investigators (other than the Director of Research) must submit all materials for review to the Director of Research. This will allow the Director to review the application and provide feedback in time for submission of all materials to the RERC. Furthermore, all investigators, including the Director of Research, must pass the online course, Human Participant Protections Education for Research Teams, prior to submitting their application and materials to the RERC. This course is available online at http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp.

Contact the Director of Research for the dates of RERC meetings and RERC application submission deadlines.

Notification in writing of the RERC’s decision will be sent to applicants approximately ten business days after the meeting. This letter will either:

- Detail the reasons that approval was not granted and what must be done (e.g., requests for revisions or additional information) to allow the proposal to receive final approval;
- Grant approval to proceed with the proposed work.
III. Does Your Research Need Review?

Human subjects research means any activity intended to obtain and record information from or about individuals for research purposes. Some examples are:

- questionnaires,
- in-person and telephone surveys,
- internet-based surveys,
- educational tests,
- observation of public or private behavior, including classroom observation,
- interviews and focus groups,
- evaluation and research components of demonstration and training programs,
- the collection or study of existing data (e.g., school records).

Research Requiring Approval

All research activities involving human subjects (funded or non-funded) must be approved by the RERC prior to the commencement of the research, if:

- the research is sponsored by GLSEN; or
- the research is conducted by or under the direction of any GLSEN employee or agent (e.g., paid staff or volunteer) in connection with his/her other institutional responsibilities, no matter where the research is conducted; or
- the research is conducted by or under the direction of any GLSEN employee or agent using any GLSEN property or facility; or
- the research involves the use of GLSEN’s information or records to identify or contact human research subjects (or prospective subjects) or to provide data for the research; or
- the research involves the use of GLSEN’s facilities.

The need for RERC approval applies to both funded and non-funded research, including research for:

- dissertations,
- master’s theses,
- class projects,
- pilot studies.

Office of Human Research Protections Decision Charts

The federal Office for Human Research Protections (OHRP) of the U.S. federal government provides decision charts to assist investigators and others in deciding if an activity is research involving human subjects that must be reviewed by an Institutional Review Board (IRB) under current federal regulations. See the Appendix. The charts will assist investigators in determining:

- whether an activity is research that must be reviewed by an IRB,
- whether the review may be performed by expedited procedures, and
- whether informed consent or its documentation may be waived.

If the decision charts do not provide enough information or a clear-cut answer to any of the above criteria, please consult the Director of Research for a determination.
IV. Can You Apply for Exempt Status?

Principal investigators may apply to the Research Ethics Review Committee (RERC) for Exempt status if their research falls within certain categories of research considered very low risk under federal regulations. The designation of “Approved as Exempt” may only be made by the RERC chair, not by the principal investigator.

If granted Exempt status, a project will no longer be under RERC oversight as long as no changes are made to the protocol as “Approved as Exempt.” If changes are planned, those changes must be submitted to the RERC for review and approval prior to being initiated.

Exempt Research Categories

Categories of research which are exempt include:

- the study of normal educational practices in commonly accepted educational settings, including research on:
  - regular and special education instructional strategies;
  - the effectiveness of or the comparison of instructional techniques, curricula or classroom management methods.

Note: The fact that the research takes place in the school does not necessarily mean that Exempt status is appropriate. Activities introduced for the purpose of a study do not constitute normal educational practice.

- The use of educational tests, surveys, interviews, or observation of public behavior where:
  - identifiers are not recorded; or
  - there is neither a risk of harm to subjects nor information sought concerning sensitive aspects of the subject’s behavior (this does not apply to research involving surveys and interviews with children); or
  - there is neither a risk of harm to subjects nor observation of sensitive aspects of the subject’s behavior (this does not apply to research with children when the investigator(s) participate(s) in the activities being observed); or
  - subjects are public officials or candidates for public office; or
  - federal statute(s) require(s) without exception that confidentiality of personally identifiable information will be maintained throughout the research and thereafter.

- The collection or study of existing data (all work with subjects has been completed), documents, records, pathological or diagnostic specimens, where publicly available or where the information is private but identifiers are not recorded by the Principal Investigator.

Note: Research (except some projects using existing data, see section on Secondary Analysis of Public-Use Data below) is not eligible for Exempt status if it involves:

- minors (under 18 years of age), except in cases of studies of normal educational practice or collection/study of existing data;
- prisoners,
• institutionalized mentally disabled people.

Secondary Analysis of Public-Use Data

Secondary analysis of public-use survey data is one of the most common forms of research conducted by social scientists. At present, the research involving secondary data analysis of data from the data sources listed below may qualify for exempt status. NOTE: The designation of Approved as Exempt may only be made by the RERC, not by the principal investigator. A full application must be submitted for an announced deadline in order for the Committee to determine whether a project should be granted Exempt status.

Currently Approved Sources of Public-Use Data are:

• Inter-University Consortium for Political and Social Research (ICPSR);
• U.S. Bureau of the Census;
• National Center for Health Statistics
• National Center for Education Statistics
• Bureau of Labor Statistics

This policy does not apply to restricted-use forms of secondary data that may be provided under special agreements by the above agencies or similar organizations. Such secondary datasets typically include potentially identifying information, unusually sensitive and/or private data, etc. The distinction between public-use and restricted-use data is generally very clearly stated by the primary source, and use of restricted data requires a clearance process and a confidentiality agreement. Projects that use restricted data must be approved by the RERC through the regular application process.

Researchers who wish to propose that an additional agency or data set be approved for exempt secondary data analysis should contact the Chair of the RERC.
V. Required Materials for Submission

You should plan to submit your RERC application at least 3 months before data collection is to begin.

All submissions for Committee review must include:

- original, fully completed Application for Review, unstapled. This includes:
  - principal investigator's signature;
  - signature of the Director of Research indicating his/her approval of the research,
  - certificate that you have completed the Human Participant Protections Education for Research Teams course (available at [http://cme.cancer.gov/clinicaltrials/learning/humanparticipant‐protections.asp](http://cme.cancer.gov/clinicaltrials/learning/humanparticipant‐protections.asp));
- all applicable attachments (recruitment materials, consent or permission forms, institutional approval letters, research instruments, and any other additional materials).
- 1 copy of the full research proposal if funding is being sought from an outside sponsor.

Incomplete submissions will be returned un-reviewed to the researcher for revision and resubmission. Contact the Director of Research for a copy of the current application form.

Recruitment Materials

Any materials used to inform potential participants of the opportunity to participate as a subject (e.g. flyers, letters, etc.) should clearly identify the investigator, the Director of Research, and GLSEN.

Materials should give a brief idea of the purpose of the research, what participation entails (including any important subject inclusion/exclusion criteria), and a way for potential participants to contact the investigator if interested in participating.

Recruitment materials should also include sample letters to potential subjects and applications to organizations that are being asked to take part (or are taking part) in the project effort. This includes:

- assisting in the recruitment of subjects;
- providing space for meeting with potential/actual subjects;
- access to records of individuals or the organization.
Statement to Subjects

This statement is provided by the investigator to potential participants prior to obtaining informed consent and carrying out the proposed work. It explains in more detail (than the recruitment materials) the purpose(s) of the research and what the subject will be asked to do if s/he agrees to participate.

The statement is generally provided as a response by the investigator to interest generated through a recruitment effort. It may be written or verbal and may be delivered in person, by phone, by mail, or by email. In some cases, the recruitment material and statement to the subjects may be combined in one document.

Informed Consent and Permission Forms and Assent Scripts

Informed consent is designed to provide potential subjects, or those who must give permission for potential subjects, all the information they need to decide whether or not to participate in a research project.

Consent, permission, and assent materials must be written in language appropriate to the intended subjects. If an investigator plans to recruit subjects from non-English speakers, or those who do not speak it well, translations should be provided.

The RERC strongly advises that the principal investigator consult one of the publicly available consent language generators to learn about the appropriate language for consent and parental permission forms, as well as the language in obtaining child assent. These language generators are designed to help investigators construct forms that include all appropriate language and information. An example of an available language generator is the New York University consent form generator (http://www.nyu.edu/ucaihs/forms/consent). The University of Michigan’s Behavioral Science IRB website also has a page that provides consent form language guidelines, including specific examples of appropriate language (http://www.irb.research.umich.edu/IRB_HSBS_Shared/consent.html).

Consent and assent forms must be on GLSEN letterhead or contain the GLSEN logo (e.g., if online). The consent language used with research participants must be identical to that approved by the RERC.

The following information must be included in all consent forms and permission forms:

- a statement that the study involves research and an explanation of the purpose(s) of the research;
- names and contact information of the investigator(s) and of the Director of Research (contact information must include address, phone number, and e-mail address);
- a description of the procedures to be followed, what the subject will be expected to do, and whether there are any procedures which are experimental;
- how long participation will take, including how many sessions will be held if more than one will be needed;
• a description of any benefits to the subject or to others which may reasonably be expected from the research or, more commonly, since the benefits of research to the subjects are usually tenuous at best, a statement that there will be no direct benefit to the subjects;
• a description of any reasonably foreseeable risks or discomforts to the subject, including any intervention which may be offered, OR the statement that there are no risks beyond those of everyday life;
• a description of any incentives (monetary or otherwise) that may be available to the subject for participation, and information on what the subject will be entitled to, if anything, if they do not complete the study;
• a statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits (if the subjects are in an educational setting, a statement that non-participation, participation, or withdrawal from the study will have no effect on the academic status or grades of the subject);
• a statement describing how and to what extent the confidentiality of subjects' identity and any information about them will be protected and how records identifying the subjects will be maintained so as to preserve that confidentiality;
• an explanation of any limits of confidentiality, for example
  o for participation in a focus group,
  o for mandated reporting to the appropriate authorities of indications of harm to self, children, or others; or
  o from any chance that identification of subjects might be possible because of the context of the research, a small sample size or the like;
• an offer by the investigator to answer questions concerning the study at any time during or after the study;
• whom to contact to report a research-related problem or injury to the subject (usually the investigator and the Director of Research);
• a statement, including contact details, that information on subject’s rights as a research participant may be obtained from the RERC;
• if audio- or videotaping is involved, a statement that the subjects will be taped and that they have the right to review the tape and request that all or any portion of the tape be destroyed (parental permission forms, however, should not offer parents the right to review their child’s tapes);
• if subjects might be quoted by name or in any way that might make them identifiable, an attribution statement authorizing (or refusing) this use of their names and/or verbatim responses;
• if the research is sponsored by or associated with a commercial enterprise, e.g. product evaluations or clinical trials, the name(s) of the research sponsors.

* It is expected that most GLSEN research will involve minimal risk to participants. However, if you believe that the research you are considering may involve more than minimal risk, contact the Director of Research early in the planning stages of the study to discuss the proposed research and methods involved.
Research Instruments

Surveys, questionnaires, demographic data sheets, interview questions, and observation guides are among the instruments commonly used by researchers at GLSEN. All surveys, questionnaires, and other data collection instruments must be submitted to the RERC for review.

If the investigator will be using proprietary instruments (those that affiliated with, owned by, or copyrighted by an author or organization), the instruments should be named and briefly described in the Application.
VI. Avoiding Common Mistakes

**Missing Exempt Request Justification**

Requests to have proposals classified as Exempt must include a justification detailing which category of exemption is being claimed and why the researcher believes the activity falls into this category. Read the Exempt Status section (page 4) for details.

**Inappropriate Referrals to Other Documents**

The Application for Review must be complete and include all requested information. Do not include statements such as, "Refer to Research Proposal."

**Complicated or Technical Language**

The language in the recruitment materials and consent forms should be age appropriate, and not above a 10th grade level (circumstances frequently dictate a lower level). Do not use technical language or terms specific to a discipline. If the consent forms may be best understood in another language, that version must be submitted along with an English translation.

**Lack of Investigator Identifiers**

The recruitment materials, consent forms, and permission forms must indicate that the research is being conducted by GLSEN and include the names of the researcher and the Director of Research, along with the address and telephone number where the researcher and the Director of Research can be reached.

**Overstatement of Possible Benefits**

In most research, expected results are tenuous at best. If no direct benefits to the subjects due to participation are foreseen, it is appropriate to state this. Payments or course credit are not benefits; they are incentives and should be listed separately from benefits and risks.

**Insufficient Explanation of Confidentiality Protection and Its Limits**

Methods for maintaining confidentiality of the data (e.g., coding procedures, who has access to the files, how long the data will be kept, etc.) should be described in detail in the RERC application. There are limits to confidentiality when others may directly know the identity of participating individuals (group interviews or focus groups, etc).

**Inappropriate Guarantees of Anonymity**

If there is any possibility of linking the information from or about a subject with the subject’s identity, then anonymity cannot be promised.

**Failure to Explain Impact of Non-Participation**

When treatment or services are involved (e.g., when participants are recruited from a community center), an affirmation should be included indicating that a decision not to participate will not affect the availability of services to which the individual is entitled. When
students are involved, an affirmation should be included indicating that non-participation will not affect grades or academic standing.

**Lack of Taping Statement**

When video or audio taping is involved, a subject must be told that they may review the completed tape and ask that any or all parts in which they appear or are heard may be destroyed. Parental permission forms should not offer the parent(s) access to their child’s tape.

**Failure to Obtain Permission from Cooperating Institutions**

When cooperating institutions are involved, a letter from an institutional official authorized to give permission should be included.

**Absence of Translations**

Translations of recruitment materials, consent forms, and permission forms into the native language may be appropriate to ensure comprehension for subjects whose native language is not English. Investigators must provide the RERC with the recruitment and consent documents in both English and the alternative language(s).

**VII. Submitting Your Application**

Applications should be submitted to GLSEN’s Director of Research, who will forward the materials to the RERC for review. Applications will be reviewed at the RERC meeting following receipt of all required materials.
VIII. Additional Information

A. What are the current regulations concerning human subjects research?


Part 46 embodies the actual regulations governing activities with human subjects, and is usually referred to as the “Common Rule.” These regulations are supplemented by policies and regulations of other branches of government.

The policies put forth in the Common Rule apply to all research with human subjects that is conducted, supported or otherwise subject to regulation by a federal department or agency. At GLSEN the requirements of the Common Rule are applied to all research with human subjects.

The Common Rule, along with the body of precedent and interpretation based on it, establishes the requirements for approval of research with human subjects, including:

- categories of research that may receive Exempt Status;
- procedures for working with minors and other protected populations;
- the content and documentation of informed consent;
- ongoing review policies.

All of these topics are presented in detail in other sections of this guide.

The Common Rule also:

- establishes the functions and operations of the IRB and the criteria for IRB approval of research;
- sets requirements for IRB membership to ensure diversity of its members, appropriate expertise, and inclusion of a nonscientist and a public member who has no other association with the organization;
- identifies vulnerable subject populations;
- establishes the categories of IRB approval and the ongoing requirements for each;
- establishes the general requirements for informed consent and its documentation.

Federal regulations as expressed in the Common Rule and administered by individual agencies, are not, however, the only source of policies and requirements for research involving human subjects.

In addition, GLSEN may institute policies affecting the requirements for approval that extend federal, state or local requirements to nonfunded projects as well.
For example, effective October 1st, 2000, the National Institutes of Health requires that, for all NIH-funded projects:

- principal investigators, co-investigators and all key personnel complete a formal education program in the regulations governing research activities involving human subjects, and that
- an organization certifies, in order for an award to be made, that the principal investigator and key personnel in the project have successfully received that education (key personnel includes all individuals responsible for the design and conduct of the study and are labeled as such in the proposal).

As a matter of institutional, educational and research policy, GLSEN has made the decision that all researchers must take and pass a human research participants educational tutorial, whether their research project is funded or not.

B. What are the Investigator’s Responsibilities

While the regulations for research involving human subjects are established by the government, GLSEN is responsible for their implementation through the development of internal policies and procedures.

However, primary responsibility for incorporating and adhering to the regulations and policies rests with the principal investigator. In carrying out any research work with human subjects, it is the responsibility of the principal investigator to:

- Know, understand and adhere to the ethical principles and applicable federal, state, local and institutional regulations, relating to research activities with human subjects.
- Consider and incorporate these principles and regulations and the welfare of potential subjects in all aspects of the design and execution of research projects.
- Fully complete the Application for Review by the Research Ethics Review Committee, including all necessary documentation and associated information (for example, interview schedules and questionnaires, consent and permission forms)
- Submit the Application for Review to the RERC at the appropriate point in the research development process. Timing may be particularly important if external support is being sought for the project since most federal and many other sponsors require IRB approval as a condition of award. Sponsors may delay or withdraw an award if approval is not available at the appropriate time. The RERC, therefore, strongly recommends that all researchers applying for external support submit an Application for Review to the RERC within 60 days after submission of the proposal for funding.
- Respond to any requests for revisions, additional information, or clarification as part of the approval process.
- Receive full approval from the RERC before initiating any research activities with human subjects and do only such work with human subjects as has been approved by the RERC.
- Train and supervise research staff in all aspects of the ethics and individual responsibilities of research involving human subjects and ensure that key personnel complete and pass this tutorial.
• Fully inform potential subjects of the purpose and nature of the research work in which they are being asked to participate (what will be involved in participation, that under all circumstances participation is fully voluntary, and that participants are entitled to protection of their privacy) and ensure appropriate consent for all subjects.
• Submit changes in the project to the RERC for review and approval prior to their initiation.
• If the project has not received Exempt Status, complete and submit an annual Continuing Review Progress Report before the end of the current approval period
• Notify the RERC immediately of any adverse outcomes or effects involving human subjects and of the steps taken to remedy such outcomes or effects.
• Notify the RERC immediately if any changes in research methods already approved by the RERC are planned, and obtain RERC approval before implementing any changes.
APPENDIX:

HUMAN SUBJECTS REGULATIONS DECISIONS CHARTS FROM THE OFFICE OF HUMAN RESEARCH PROTECTIONS (OHRP) OF THE U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Appendix

Human Subject Regulations Decision Charts
from the
Office of Human Research Protections (OHRP)

**Chart 1:** Is an Activity Research Involving Human Subjects?

**Chart 2:** Is the Human Subjects Research Eligible for Exemption?

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

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

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

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

**Chart 7:** [Not included, as it does not apply: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?]

**Chart 8:** May the IRB Review Be Done by Expedited Procedures?

**Chart 9:** May the IRB Continuing Review Be Done by Expedited Procedures?

**Chart 10:** May Informed Consent Be Waived or Consent Elements Be Altered under 45 CFR 46.116(d)?

**Chart 11:** May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?
Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

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- **Start here.**
  - Is the activity a **systematic** investigation **designed** to develop or contribute to **generalizable** knowledge? [45 CFR 46.102(d)]
    - **NO** → Activity is not research, so 45 CFR part 46 does not apply.
    - **YES** → Activity is research. Does the research involve **obtaining information about living individuals**? [45 CFR 46.102(f)]
      - **NO** → The research is not research involving human subjects, and 45 CFR part 46 does not apply.
      - **YES** → Does the research involve **intervention or interaction** with the individuals? [45 CFR 46.102(f)(1), (2)]
        - **NO** → Is the information **individually identifiable** (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)? [45 CFR 46.102(f)(2)]
          - **NO** → **BUT**
          - **YES** → Is the information **private**? (About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.) [45 CFR 46.102(f)(2)]
            - **NO** → Go to Chart 2
            - **YES** → Unless exempt under 45 CFR 46.101(b), 45 CFR part 46, subpart A requirements apply to the research. As appropriate, subpart B, C, and D requirements also apply.
              - **NO** → Other Federal, State and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]
              - **YES** → Go to Chart 2

- **Start here.**
  - Is the research covered by an applicable OHRP approved assurance created under 45 CFR 46.103?
    - **YES** → Go to Chart 2
    - **NO** → Other Federal, State and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]
Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

Has HHS prohibited exemption of the human subjects research? (All research involving prisoners, some research involving children.) [Footnote 1 to 45 CFR 46.101(i), 45 CFR 46.401(b)]

**NO**

Will the only** involvement of human subjects be in one or more of the following categories?

- Research conducted in established or commonly accepted educational settings, involving normal education practices?
  - YES
  - Exemption 45 CFR 46.101(b)(1) may apply.
  - Go to Chart 3

- Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior?
  - YES
  - Exemption 45 CFR 46.101(b)(2) or (b)(3) may apply.
  - Go to Chart 4

- Research involving collection or study of existing data, documents, records, or pathological or diagnostic specimens?
  - YES
  - Exemption 45 CFR 46.101(b)(4) may apply.
  - Go to Chart 5

- Research studying, evaluating, or examining public benefit or service programs?
  - YES
  - Exemption 45 CFR 46.101(b)(5) may apply.
  - Go to Chart 6

- Research involving taste and food quality evaluation or consumer acceptance studies?
  - YES
  - Exemption 45 CFR 46.101(b)(6) may apply.
  - Go to Chart 7

- NO

No exemptions to 45 CFR part 46 apply. Provisions of 45 CFR subpart A apply, and subparts B, C and D also apply if subjects are from covered vulnerable populations.

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**"Only"** means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.
Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

From Chart 2

Is the research only conducted in *established or commonly accepted* educational settings? (Including but not limited to schools and colleges. May include other sites where educational activities regularly occur.)

- NO: Research is not exempt under 45 CFR 46.101(b)(1). Go to Chart 8

- YES

  Does the research study involve only *normal education practices*? (Such as research on regular and special education instructional strategies, or research on effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.)

    - NO

    - YES: Research is exempt under 45 CFR 46.101(b)(1) from all 45 CFR part 46 requirements.
Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

From Chart 2

Does the research involve only the use of educational tests, survey procedures, interview procedures, or observation of public behavior?

- **YES**
  - Does the research involve children to whom 45 CFR part 46, subpart D applies?
    - **YES**
      - Is the information obtained recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and could any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation?
    - **NO**
      - Research is not exempt under 45 CFR 46.101(b)(2). However, the 45 CFR 46.101(b)(3) exemption might apply.

- **NO**
  - Research is not exempt under 45 CFR 46.101(b)(2) or (b)(3).

Go to Chart 8

Are the human subjects elected or appointed public officials or candidates for public office? (Applies to senior officials, such as mayor or school superintendent, rather than a police officer or teacher.)

- **NO**
  - Does any Federal statute require without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter?
    - **YES**
      - Research is exempt under 45 CFR 46.101(b)(2) exemption from 45 CFR part 46 requirements.
    - **NO**
      - Research is exempt under 45 CFR 46.101(b)(3) from all 45 CFR part 46 requirements.

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

From Chart 2

Does the research involve only the collection or study of *existing* data, documents, records, pathological specimens, or diagnostic specimens? * (*Existing* means existing before the research is proposed to an institutional official or the IRB to determine whether the research is exempt.)

YES

Are these sources *publicly available*?

YES

Research is exempt under 45 CFR 46.101(b)(4) from all 45 CFR part 46 requirements.

NO

NO

Will information be recorded *by the investigator* in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects?

YES

Research is not exempt under 45 CFR 46.101(b)(4) from 45 CFR part 46 requirements.

NO

Go to Chart 8

* 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 #stem, and on coded data or specimens at #coded for further information on those topics.

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

From Chart 2

Is the research or demonstration project conducted or approved by the Department or Agency Head?

YES

Does the research or demonstration project involve only the study, evaluation, or examination of:

YES

Public benefit or service programs;

NO

Procedures for obtaining benefits or services under public benefit or service programs;

YES

Research is exempt under 45 CFR 46.101(b)(5) from all 45 CFR part 46 requirements.*

NO

Possible changes in or alternatives to public benefit or service programs or to procedures for obtaining benefits or services under public benefit or service programs;

YES

NO

Possible changes in methods or levels of payment for benefits or services under those public benefit or service programs?

YES

NO

Research is not exempt under 45 CFR 46.101(b)(5).

Go to Chart 8

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

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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.

From Chart 2, 3, 4, 5, 6, or 7

Has the research been previously reviewed and approved by the IRB?

YES

Is the review a continuing review? [45 CFR 46.109(d)]

NO

Does the research present no more than minimal risk to human subjects? and does the research involve only procedures included in categories 1 through 7 on the list of categories of research that may be reviewed through an expedited review procedure? [45 CFR 46.110(b)(1)]

YES

Does the review involve a minor change in approved research during the (one year or less) period of approval? [45 CFR 46.110(b)(2)]

NO

NO

Review by convened IRB is required.

YES

Are measures in place to make risks no more than minimal?

NO

NO

Go to Chart 9

NO

Could identification of subjects put them at risk of criminal or civil liability, or be socially or economically damaging [Paragraph (C) of Categories.]

YES

Research is eligible for IRB review through expedited procedures. Agency head may restrict, suspend, terminate or choose not to authorize an institution’s or IRB’s use of the expedited review procedure. [45 CFR 46.110(d)]

September 24, 2004
Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?

From Chart 8

Has the research been previously reviewed and approved by the IRB using expedited procedures?

- YES
  - Have conditions changed such that the research is no longer eligible for expedited review (e.g., protocol change, or experience shows research to be of greater than minimal risk)?
  
  - NO
    - Go to Chart 10

- NO
  - Review by convened IRB is required.

Have conditions changed to make the research eligible for expedited review under the applicability criteria and categories 1 through 7 on the list of categories that may be reviewed by expedited procedures (e.g., research is within those categories and experience confirms research to be of no greater than minimal risk)? [45 CFR 46.110(a)]

- YES
  - Research is eligible for IRB review through expedited procedures.

- NO
  - NO
    - Have any additional risks been identified since IRB review at a convened meeting?
      
      - YES
        - Has the IRB determined and documented at a convened meeting that the research involves no greater than minimal risk?
          
          - NO
            - Is the research conducted under an IND or IDE?

Category 8

(a) For this site:
Is the research permanently closed to enrollment of new subjects? and
Have all subjects completed all research-related interventions? and
Does the research at this site remain active only for long-term follow-up of subjects?

- YES
  - (c) Are the remaining research activities at this site limited to data analysis?
    
    - NO
      - NO
        - YES
          - YES

(b) Have no subjects been enrolled at this site? and
Have no additional risks been identified anywhere?

- NO
  - NO

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

- From Chart 8 or 9
  - Will the research or demonstration project be conducted by or subject to the approval of state or local government officials? [45 CFR 46.116(c)(1)]
    - YES
    - Is the project designed to study, evaluate, or otherwise examine: (i) Public benefit of 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? [45 CFR 46.116(c)(1)]
    - YES
    - Is it practicable to conduct the research without the waiver or alteration? [45 CFR 46.116(d)(3)]
      - YES
      - No waiver of informed consent or alteration of consent elements is allowed.*
      - NO
    - Will waiving or altering the informed consent adversely affect the subjects' rights and welfare? [45 CFR 46.116(d)(2)]
      - YES
      - Will pertinent information be provided to subjects later, if appropriate? [45 CFR 46.116(d)(4)]
        - YES
        - Go to Chart 11
        - NO
      - NO
    - NO
  - NO
  - Will the research involve greater than minimal risk, as defined in Section 46.102(i)? [45 CFR 46.116(d)(1)]
    - YES
    - No waiver of informed consent or alteration of consent elements is allowed.*
    - NO
  - NO
  - Is it practicable to conduct the research without the waiver or alteration? [45 CFR 46.116(c)(2)]
    - YES
    - If informed consent is not waived entirely:
      - NO
      - Waiver of informed consent or alteration of consent elements is allowed if IRB documents these findings and approves waiver or alteration.
    - NO
      - Go to Chart 11

*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.

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

From Chart 10

Would the consent document be the only record linking the subject and the research and would the principal risk be potential harm resulting from a breach of confidentiality? [45 CFR 46.117(c)(1)]

NO

Does the research present no more than minimal risk and involve no procedures for which written consent is normally required outside the research context? [45 CFR 46.117(c)(2)]

YES

IRB may waive the requirement for a signed consent form for some or all subjects.

AND

IRB may require investigator to provide subjects with a written statement regarding the research. [45 CFR 46.117(c)]

IF IRB Allows Waiver of Documentation Under 45 CFR 46.117(c)(1)

Investigator will ask each subject if he or she wants documentation linking the subject with the research. [45 CFR 46.117(c)(1)]

NO

Subject’s wishes will govern whether informed consent is documented. [45 CFR 46.117(c)(1)]

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APPENDIX:

APPLICATION FOR REVIEW BY THE GLSEN RESEARCH ETHICS REVIEW COMMITTEE
**INSTRUCTIONS**

Applicants must take and pass the Human Participant Protections Education online course at http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp before submitting their application. All applications must be typed or word processed (single-spaced). Do not write or type on the back. Applicants should refer to the online education course for guidance, as well as the Guide to Submitting Proposals to the Research Ethics Review Committee.

**RESEARCH AND INVESTIGATOR INFORMATION**

<table>
<thead>
<tr>
<th>Principal Investigator</th>
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<tbody>
<tr>
<td>Name:</td>
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<td>Tel.:</td>
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<th>Co-Investigator</th>
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<td>Address:</td>
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(if necessary, attach a list of the names, institutions, and addresses of additional investigators)

**Project Title:**  

**Grant Title if different from Project Title:**

**Has this study been previously approved by the RERC?** Yes ☐ No ☐

If yes, what was the most recent approval date?

Have the procedures changed since the most recent RERC approval? Yes ☐ No ☐

If yes, provide details as part of this application as appropriate.

**Project start date:**

**Anticipated end date:**

Note: RERC approval is always for one year (or less). If you need more time, you will need to submit a request for continuation of approval.

**Is this research funded by (or an application to) an external funding agency?** Yes ☐ No ☐

If yes, complete the following:

- **Funding Source:**
- **Date of Award (or proposed date):**

**Study Location:**
REQUEST FOR EXEMPT STATUS FROM FULL RESEARCH ETHICS COMMITTEE REVIEW

Certain categories of research deemed very low risk under Federal regulations may be granted Exempt Status once the appropriate review has been conducted by the RERC. If Exempt Status is granted, the study will not require continuing or other review unless procedures are revised which deviate from those originally approved by the RERC.

NOTE: Only the RERC may grant Exempt Status. Therefore, applications for Exempt Status must include the completed remainder of the application in addition to the information requested below.

Part 1
Exempt status may be claimed under the following categories. Please check all that apply.

☐ 1. Research is a study of normal educational practices in commonly accepted educational settings.
   
   Note: This exemption does not apply to research with children when the investigator[s] participate in the activities being observed; for example, in classroom situations where the Investigator is taking part in the classroom activities being studied, or if activities are introduced for the purpose of the proposed project and are not part of the usual curriculum or activities.

☐ 2. Research involves:
   
   a. The use of educational tests, surveys, or interviews where identifiers are not recorded by the Investigator or where there is neither a risk of harm to subjects nor information sought concerning sensitive aspects of the subject’s own behavior. (Note: This exemption does not apply to research involving surveys and interviews with children or to experiments such as computer simulations of decision making or laboratory tests of group interactions or to activities involving deceit or manipulation of beliefs); or
   
   b. Observation of public behavior where identifiers are not recorded by the Investigator or there is neither a risk of harm to subjects nor observation of sensitive aspects of the subjects’ own behavior.

☐ 3. Research involves the use of educational tests, surveys, interviews, or observation of public behavior that is not exempt under the above category if:
   
   a. subjects are elected or appointed public officials or candidates for public office;
   
   b. 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 involves only:
   
   a. the collection or study of existing data, documents, records, pathological or diagnostic specimens, where publicly available; or
   
   b. the information is private but identifiers are not recorded by the Investigator.

Note: Recent Office of Human Research Protections guidance on types of data that do and do not require review and approval has changed the interpretation of category 4a. Please see the section on applying for exempt status in the GUIDE.

Part 2
Please complete the following Exempt Justification Statement: I believe my research qualifies for exempt status under one or more categories indicated above, for the following reason(s):
**HUMAN SUBJECT INFORMATION**

**Number of subjects expected to participate:**

Briefly describe any foreseeable risks or discomforts and discuss attempts to minimize such risk to subjects:

**How and where will recruitment of subjects take place?**

Describe procedures used to maintain confidentiality of responses:

Describe procedures used to protect anonymity of data:

**Are any vulnerable populations to be recruited for this project?** (Check all that apply.)

- Children (under 18 years of age)
- Prisoners
- Pregnant Women

If children, please specify age range:

**Will subjects be compensated?** Yes: ☐ No: ☐

If yes, how?

**Is Investigator requesting waiver of documentation of informed consent?** Yes: ☐ No: ☐

If yes, explain:

**If subjects are children, is Investigator requesting waiver of documentation of parental consent?**

Yes: ☐ No: ☐

If yes, explain:

**Is Investigator requesting waiver of any of the elements of informed consent?** (see checklist on the following page)

Yes: ☐ No: ☐

If yes, check appropriate boxes for waiver requested

☐ (#5) This proposal does NOT involve more than minimal risk, so basic element #5 (see next page) does not apply.

**Will the project involve more than minimal risk to the participants (i.e., risk greater than that of everyday life)?** Yes: ☐ No: ☐

**Is the application for a Pilot Study?** Yes: ☐ No: ☐
## Consent Form Checklist

Check boxes on the left to certify that each element of informed consent is contained in the consent form (or oral consent briefing, if a waiver of documentation is requested). The text in the right column (except that in brackets) comes directly from the federal regulations (45CFR46.116(a) and (b)). **If you do not check all boxes in Section a (basic elements), you must request a waiver of informed consent elements on the previous page of this proposal form.**

### (a) Basic elements of informed consent.

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<table>
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<tr>
<td></td>
<td>(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental;</td>
</tr>
<tr>
<td></td>
<td>(2) A description of any reasonably foreseeable risks or discomforts to the subject;</td>
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<td>(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;</td>
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<td>(4) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;</td>
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<tr>
<td></td>
<td>(5) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;</td>
</tr>
<tr>
<td></td>
<td>(6) An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, [Suggested text: <em>If you have further questions about the research or your rights as a research participant, please contact (your name and contact information). You may also address any concerns to Peggy Clements, chairperson of GLSEN's Research Ethics Review Committee (a committee with oversight over human subject research).</em>]</td>
</tr>
<tr>
<td></td>
<td>(7) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.</td>
</tr>
</tbody>
</table>
**Description of Project**

Briefly describe the project (in language understandable to the lay reader) and the procedures to be used in the research. Indicate whether any of these procedures have been approved by GLSEN’s RERC in the past. If the project is being carried out in the context of a course, briefly describe the educational objective of the research exercise. Attach any questionnaires, consent forms or other relevant materials used in the study to this application form.

1. **Purpose of Study:** Briefly state the purpose of the proposed research, clearly stating the research question(s) the study is attempting to address. Your explanation must be clear to those unfamiliar with your field. References are not necessary.

2. **Subject Selection and Recruitment:**
   a. What is the expected sample size?
   b. What are your criteria for inclusion of potential subjects (e.g., age range, country of birth, membership in a particular organization)?
   c. What are the criteria for subject exclusion?
   d. How will investigators identify potential subjects (how will they know whom to recruit)?
   e. Where and how will potential subjects be informed of the opportunity to participate? (Include copies of recruitment letters, flyers, or advertisements, and/or a copy of the oral and written statements to be used at the time.)
ASSURANCES

List all collaborating agencies.

If the research involves a cooperating agency, institution, school district, etc., a letter of agreement to participate in the research (on letterhead) is required. If the cooperating agency has an IRB, a copy of that agency's IRB approval is required.

List all independent investigators (investigators that are not affiliated with GLSEN).

Researchers collaborating with independent investigators who are not affiliated with GLSEN must sign a formal written agreement of commitment to follow the human subject protection policies of this Institution.

Investigator’s Agreement

I agree to use procedures with respect to safeguarding human subjects in this activity that conform to federal, state, local, and GLSEN policy. If significant change in the investigative procedure involving human subjects is called for during the activity covered by this application, I shall seek prior approval for such change from the RERC and agree to follow the advice of the RERC. If this activity is a continuation or renewal of an ongoing program, I affirm that the procedures followed during the current period conform to this policy.

Any unanticipated problems involving risks to human subjects or others will be reported to the RERC immediately.

Signature: ___________________________  date: __________________
Principal Investigator or Sponsor

Signature: ___________________________  date: __________________
Co-investigator (if applicable)