**IRB Frequently Asked Questions**

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11. **Do oral history activities require IRB review?**

In September, 2003, the Office of Human Research Protections (OHRP) issued a letter to the Pennsylvania Historical and Museum Commission concerning the need for review of oral history being collected by the Commission. This letter has led some investigators who make use of oral history in research to ask for clarification of OHRP's position as it affects the need for investigators to apply to for IRB approval.

In response to an inquiry on this topic from Northeastern Illinois University, Dr. Michael Carome of the OHRP issued, on Dec. 1, 2003, a [clarification of the Pennsylvania decision](http://www.nyu.edu/content/nyu/en/research/resources-and-support-offices/getting-started-withyourresearch/human-subjects-research/forms-guidance/clarification-on-oral-history/michael-caromes-email.html) as it might apply to other situations. This clarification maintains that if oral history activities meet the federal definition of research according to 45 CFR 46.102(d), then they are subject to IRB review. Most oral history activities are either a) systematic investigations designed to draw conclusions/generalize findings or b) designed to produce materials for permanent archiving in the library. The following excerpt from Dr. Carome's response to NIU details the circumstances under which oral history does or does not need IRB review and approval:

* Oral history activities, such as open ended interviews, that ONLY document a specific historical event or the experiences of individuals without an intent to draw conclusions or generalize findings would NOT constitute "research" as defined by HHS regulations 45 CFR part 46.

Example: An oral history video recording of interviews with holocaust survivors is created for viewing in the Holocaust Museum. The creation of the video tape does NOT intend to draw conclusions, inform policy, or generalize findings. The sole purpose is to create a historical record of specific personal events and experiences related to the Holocaust and provide a venue for Holocaust survivors to tell their stories.
* Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions, inform policy, or generalize findings) WOULD constitute "research" as defined by HHS regulations at 45 CFR part 46.

Example: An open ended interview of surviving Gulf War veterans to document their experiences and to draw conclusions about their experiences, inform policy, or generalize findings.
* Oral historians and qualitative investigators may want to create archives for the purpose of providing a resource for others to do research. Since the intent of the archive is to create a repository of information for other investigators to conduct research as defined by 45 CFR part 46, the creation of such an archive WOULD constitute research under 45 CFR part 46.

Example: Open ended interviews are conducted with surviving Negro League Baseball players in order to create an archive for future research. The creation of such an archive would constitute research under 45 CFR part 46 since the intent is to collect data for future research.

Until the regulations governing the use of human subjects in research are revised or OHRP changes the policies cited above, investigators at Lehigh University must continue to apply to the LU IRB for review and approval of all activities that meet the definition of human subjects research. Investigators requiring advice on whether IRB review is required for a particular project involving oral history should contact the IRB.

1. **My project is finished. Do I need to tell anyone?**

IRB approval must be maintained as long as a project continues to involve human subjects. IRB protocols may be closed if:

*Investigators have finished obtaining data through interaction or intervention with subjects or obtaining identifiable private information about the subjects, including using, studying, or analyzing identifiable private information.*

To close a protocol, email confirmation that the above conditions apply to inors@lehigh.edu. Include your protocol title and your IRBNet numbers. The email must come from directly from the PI or the PI must be cc’d on the email.

1. **Who can serve as PI?**

The Principal Investigator (PI) has the primary responsibility for protecting the welfare, rights, and privacy of individual subjects in a research project. Those with the academic rank of Professor, Associate Professor, or Assistant Professor at Lehigh University may serve as PI on an IRB protocol application.

Professors of Practice, Research Engineers, or Research Scientists holding an appointment from an academic department or research center of the University may serve as a PI or co-PI with the written approval of the chair of the academic department or director of the research center in which he or she holds an appointment.

In some cases, a research proposal may be submitted by an individual who does not qualify as PI under the policy, or by a non-academic department of the University under the following conditions: a) the individual proposing to conduct the research is a full-time University employee with the requisite qualifications and research experience necessary to conduct such research; and b) the research proposal has been approved in writing by the Vice President or Dean to whom such individual or department reports, with such approval i) indicating that such research is in furtherance of University objective, and ii accepting responsibility for ensuring that such research will be conducted in compliance with University research policies and procedures.

1. **Can my study be approved retroactively?**

No. The federal regulations do not allow for IRB approval of research that has already been conducted. If data was collected for purposes that the IRB determines to be non-research (e.g. program evaluation not initially intended to be used for research), IRB approval can be sought for the data analysis going forward.

1. **How long does it take to obtain IRB approval?**

The length of time from application submission to approval depends on a few factors. It depends upon the nature of the study and the characteristics of the population that you intend to recruit. Research projects that are minimal risk are eligible for expedited review, which means they are reviewed by a sub-committee of three IRB members rather than by the full committee. Applications that may qualify for exempt or expedited review should be submitted at least six weeks in advance of the anticipated start date. Research that is greater than minimal risk need to be reviewed by the full committee in a convened meeting. Meetings are scheduled for the second Tuesday of each month. Applications requiring full committee review are required to be submitted to the IRB at least four weeks in advance of the meeting date. After reviewing, the IRB will often send the investigator a letter that details “Modifications Required to Secure Approval”, which are changes that must be made to the study in order for the IRB to approve. The investigator must take the time to make and submit those modifications, which must be reviewed in turn by the IRB. This process of back-and-forth communication between the investigator and the IRB takes some time.

1. **When can I start working on my study?**

Investigators must receive written approval from the IRB before beginning participant recruitment, data collection, or data analysis. An official approval notice will be sent via IRBNet once a protocol is approved.

1. **When do I need to submit an Amendment/Modification to the IRB to make changes to my study?**

Investigators with approved projects must submit an Amendment/Modification application in IRBNet when any study design, informed consent procedures, or the investigator team within an IRB approved research protocol is revised. There is only one exception to this rule, specifically where the change is necessary to eliminate apparent immediate hazards to the subjects. In such cases, the investigator must submit a report to the IRB explaining the protocol deviation.

Amendments/Modifications involving minor changes that pose no more than minimal risk to subjects will be reviewed on an expedited basis. Amendments/Modifications involving changes that pose more than minimal risk will be reviewed by the full committee, at the next available IRB meeting. In general, amendments to protocols considered to be more than minimal risk, are reviewed by the full committee. Similarly, amendments to protocols considered to involve no more than minimal risk, are reviewed via an expedited review process.

**Changes may not be implemented until the Principal Investigator receives final written IRB approval for the change**
Some examples of situations that require that an amendment application be submitted for IRB review:

* Changes in the content of a previously-approved personal interview, telephone interview, or self-administered questionnaire – new or substantially rewritten questions (you do not need to report typos and minor wording changes)
* Review of the final interview or questionnaire for a previously approved study
* Addition of new consent or assent forms
* Changes to any of the consent forms or scripts
* Changes to the aspect of the informed consent process, including oral consent
* Changes in the population studied, e.g. including minors as well as adults
* Changes in study recruitment procedures, e.g. changing from telephone to email recruitment
* For focus groups, major changes in recruitment procedures or aims
* Changes in the mode of administration of a study, e.g. from mail or telephone to web or Internet access
* Change in the amount of compensation or method of providing compensation
* Changes in the leadership of a research project, e.g. change in the principal investigator, adding a co-investigator, changing faculty adviser.
* Addition of personnel who will interact with human participants or have responsibility for research data
* Data set enhancements, such as merging community, company, or neighborhood level data into survey records
* Any changes in research design
* Addition of study locations
1. **What is the difference between “privacy” and “confidentiality”, and why are they relevant to research with human subjects?**

Per HHS and FDA Regulations, 45 CFR 46.111(a)(7) and 21 CFR 56.111(a)(7)), the IRB shall determine that where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of data in order to approve human subjects research. The committee must consider the sensitivity of the information collected and the protections offered the subjects. Privacy and confidentiality are also supported by two principles of the [Belmont Report](http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/):

**Respect for persons** – Individuals should be treated as autonomous agents able to exercise their autonomy to the fullest extent possible, including the right to privacy and the right to have private information remain confidential.

**Beneficence** - Maintaining privacy and confidentiality helps to protect participants from potential harms including psychological harm such as embarrassment or distress; social harms such as loss of employment or damage to one‘s financial standing; and criminal or civil liability.

Maintaining privacy and confidentiality helps to protect participants from potential harms including psychological harm such as embarrassment or distress; social harms such as loss of employment or damage to one‘s financial standing; and criminal or civil liability. Especially in social/behavioral research, the primary risk to subjects is often an invasion of privacy or a breach of confidentiality.

**Privacy** is the control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. For example, persons may not want to be seen entering a place that might stigmatize them, such as a pregnancy counseling center clearly identified by signs on the front of the building. The evaluation of privacy also involves consideration of how the researcher accesses information from or about potential participants (e.g., recruitment process). IRB members consider strategies to protect privacy interests relating to contact with potential participants, and access to private information.

**Privacy is:**

* About people
* A sense of being in control of access that others have to ourselves
* A right to be protected
* Is in the eye of the participant, not the researcher or the IRB.

**Confidentiality** pertains to the **treatment of information** that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

During the informed consent process, if applicable, subjects must be informed of the precautions that will be taken to protect the confidentiality of the data and be informed of the parties who will or may have access (e.g., research team, FDA, OHRP). This will allow subjects to decide about the adequacy of the protections and the acceptability of the possible release of private information to the interested parties.

**Confidentiality:**

* Is an extension of privacy
* Is an agreement about maintenance and who has access to identifiable data
* In regards to HIPAA, protects patients from inappropriate disclosures of Protected Health Information (PHI).

***Privacy is about people. Confidentiality is about data.***

1. **How can researchers protect participants’ privacy?**

The IRB decides on a protocol-by-protocol basis whether there are adequate provisions to protect the privacy of subjects at each segment of the research from recruitment to maintenance of the data.

In regards to **privacy**, researchers should consider and address following issues in their IRB application:

* The proposed subject population?
	+ What are the cultural norms of the proposed subject population? Some cultures are more private than others.
	+ What are the ages of the proposed subject population? There may be age differences in privacy preferences (e.g., teenagers less forthcoming than older adults)
* The proposed recruitment methods: How are potential participants identified and contacted?
Acceptable methods:
	+ advertisements, notices, and/or media
	+ introductory letter to colleagues to distribute to eligible individuals – interested individuals contact researcher
	+ primary care staff contact those patients that qualify to determine interest
* Unacceptable methods:
	+ search through medical records for qualified subjects or existing database (e.g., registry); then have a researcher with no previous contact with potential subject recruit; this method violates the individuals' privacy
	+ recruit subjects immediately prior to sensitive or invasive procedure (e.g., in pre-op room)
	+ retain sensitive information obtained at screening without the consent of those who either failed to qualify or refused to participate for possible future studies participation
* Sensitivity of the information being collected – the greater the sensitivity, the greater the need for privacy
* Method of data collection (focus group, individual interview, covert observation)
	+ Will subjects feel comfortable providing the information in this manner?
	+ If passively observing the subject; could the individual have a reasonable expectation of privacy (e.g., chat room for breast cancer patients)?
	+ Will the researcher collect information about a third party individual that is consider private (e.g., mental illness, substance abuse in family)? If yes, informed consent should be obtained from third party?
* Privacy is in the eye of the participant, not the researcher or the IRB
1. **What must researchers know about maintaining confidentiality?**

The IRB also decides on a protocol-by-protocol basis whether there are adequate provisions to maintain the confidentiality of the identifiable data at each segment of the research from recruitment to maintenance of the data. Protocols should be designed to minimize the need to collect and maintain identifiable information about research subjects. If possible, data should be collected anonymously or the identifiers should be removed and destroyed as soon as possible and access to research data should be based on a “need to know” and "minimum necessary" standard.

When it is necessary to collect and maintain identifiable data, the IRB will ensure that the protocol includes the necessary safeguards to maintain confidentiality of identifiable data and data security appropriate to the degree of risk from disclosure.

In regards to when it is appropriate to require provisions to maintain confidentiality of data, the following issues should be considered:

* Will confidentiality of identifiable data be offered?
* Are there additional legal/ethical requirements (e.g., HIPAA)?
* Will the release of data cause risk of harm?