

Guidelines for Determination of Need for IRB Review

IRB review and approval is required for any research involving research volunteers that: is conducted by University faculty, staff, students; is performed on the premises of the University (even if conducted by persons not affiliated with MSU); is performed with or involves the use of facilities or equipment belonging to the University (even if conducted by persons not affiliated with MSU); or involves University, students, staff, or faculty (even if conducted off-campus).

Some types of research may not require IRB review, or some research may not involve human research volunteers.

- Normal Educational Practices
- Research for University Courses
- Pilot Studies
- Oral History
- Secondary Analysis of Existing Data
- Content Experts / Consultants / Key Informants
- Research done at another institution
- Research that does not require IRB review

Normal Educational Practices Considered Exempt from Full Committee Review

Kinds of Data

- students' curriculum-related written work, test scores, grades, artwork and other work samples produced by children
- students' curriculum-related oral and non-verbal communicative responses individually, such as in an interview, in small groups and with the whole class
- students' responses (written, oral or behavioral) to curriculum-related activities
- students' level of active participation in curriculum-related activities
- "a normal educational setting" means preschool, elementary, secondary, and higher educational facilities, and after-school programs (if the project relates to tutoring, or homework help.)
- in Special Education, normal educational practices correspond to the Individualized Educational Program (IEP), which is tailored to each student with an identified disability and may be implemented in diverse settings (e.g., school, home, work, community).

Collection Methods

- videotapes and photographs of curriculum-related classroom activities
- audio tapes of teacher-student and student-student discourse related to the assignment
- teacher's non-participant observation of curriculum-related activity of individual children or groups of children, noting what will be observed and how it will be analyzed, or whether it will be used as anecdotal evidence in the study
- teacher's commentary on students' curriculum-related written work, artwork and other artifacts produced by children
- student journals and communication books related to the curriculum
- student grades and test scores
- teacher journals, notes and reflective comments on student responses and participation in curriculum-related activities
- questionnaires or interviews with students, parents and family members, teachers and administrators

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- non-participant classroom observations by colleagues, with the class teacher's permission, stating what will be observed and how it will be used, i.e. how data will be analyzed or whether it will be used as anecdotal evidence.
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Research for University Courses

Research conducted solely for pedagogical purposes may not need IRB review, under the following conditions.

- the instructor's intention is to teach professional research methods such as interviewing, surveying, or experimental design
- the data are gathered solely for the purposes of teaching how to analyze them
- the results will remain in the classroom.

These data can be presented at the end of the semester within the confines of the institution, for instance, at the MSU Scholarship Colloquium. However, if the results will be published, presented at a larger conference off-campus (such as the CUR Research Competition) or generalized in some other way, it will be necessary to obtain IRB approval.

If a class project evolves into a research project that the student/instructor wishes to publish or generalize, then the research will need to undergo IRB review. This should occur as soon as it is known that the data will be used for research. If this is not determined until after the research is completed, it may be possible to submit a protocol to the IRB, requesting permission to use existing data.

Pilot Studies

Pilot studies with human research volunteers, no matter how small, must also get IRB approval. You can include the pilot study as a smaller section of the complete protocol, or you can get approval for the pilot study first, then come through the IRB again for a review of the full "parent" study. At this stage, you may have modified your research to take into account the results of the pilot study. (For example, you may decide to change the survey questions as a result of the pilot study, or change inclusion/exclusion criteria.)

Oral History

The researcher's intention plays a large part in determining whether research is an oral history or not. If the intention is to interview informants who have a unique perspective on a particular historical event or way of life, and the researcher also intends to let the informant's stories stand on their own as a "testimonio" or in an archive, with no further analysis, the research is most likely oral history.

However, if the surveys or interviews are conducted with the intention of comparing, contrasting, or establishing commonalities between different segments or among members of the same segment, it is safe to say your research will be regular survey/interview procedures, because you will be generalizing the results.

Historians explain a particular past; they do not create general explanations about all that has happened in the past, nor do they predict the future.

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Moreover, oral history narrators are not anonymous individuals, selected as part of a random sample for the purposes of a survey. Interviewees are selected because of their personal relationship to the topic under investigation. An oral history interview provides one person's unique perspective. A series of oral history interviews offers up a number of particular, individual perspectives on the topic, not information that may be generalized to all research volunteers in the event or time under investigation.

Oral history interviews are not analyzed as qualitative data is generally analyzed. No content analysis, discourse analysis, coding for themes or other qualitative analysis methods of data analysis are performed on the interviews. They stand alone as unique perspectives.

It is primarily on the grounds that oral history interviews, in general, are not designed to contribute to "generalizable knowledge" that they are not subject to the requirements of 45 CFR part 46 and, therefore, can be excluded from IRB review.

Secondary Analysis of Existing Data

Projects that use an existing data set which includes identifiable data gathered in earlier research projects may require a new IRB protocol for review. Secondary analysis of existing data may include the review of medical records, student records, data collected from previous studies, audio/video recordings, etc. that were initially collected for another purpose. In order to be existing, the information must be "on the shelf" (i.e., it has already been collected) at the time that the current research is proposed.

In addition to being identifiable, the existing data must include "private information" in order to constitute research involving human subjects. Private information is defined as information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical or school record). Information that contains identifiers and can be accessed freely by the public (without special permission or application) is not "private" and the research therefore does not therefore involve human subjects. For example, a study involving only analysis of the published salaries and benefits of public university presidents would not need IRB review since this information is not private.

Research involving the secondary analysis of existing data **may be reviewed by the IRB** to ensure that the original data were properly and ethically obtained and to ensure that the objectives of the secondary analysis are in keeping with those for which consent was obtained. Data analysis activities that meet the definition of research with human subjects may qualify for an exemption or require expedited or even full committee review. Any such project must receive IRB approval or a determination of exemption *before* the investigator accesses the data.

When is the secondary use of existing data exempt?

There are six categories of research activities involving human subjects that may be exempt from the requirements of the Federal Policy for the Protection of Human Subjects (45 CFR 46). However, only one category (Category 4) applies specifically to existing data. In order to qualify for an exempt determination, an Application for IRB Review must be submitted. The application is reviewed and if determined exempt, registered for a period of 3 years.

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Research involving collection or study of *existing* data, documents, and records can be exempted under Category 4 of the federal regulations if: (i) the sources of such data are publicly available; or (ii) the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

The latter condition of this category applies in cases where the investigators initially have access to identifiable private information but abstract the data needed for the research in such a way that the information can no longer be connected to the identity of the subjects. This means that the abstracted data set does not include direct identifiers (names, social security numbers, addresses, phone numbers, etc.) or indirect identifiers (codes or pseudonyms that are linked to the subject's identity). Furthermore, it must not be possible to identify subjects by combining a number of characteristics (e.g., date of birth, gender, position, and place of employment). This is especially relevant in smaller datasets, where the population is confined to a limited subject pool.

The following do not qualify for exemption: Research involving prisoners, research involving collecting protected health information from HIPAA-covered entities and FDA-regulated research.

When does the secondary use of existing data not require review?

In general, the secondary analysis of existing data does not require IRB review when it does not fall within the regulatory definition of research involving human subjects, as referenced above.

In order for the committee to evaluate research which includes secondary analysis, the researcher will need to provide:

1. A complete protocol for the secondary study;
2. The details of primary data collection (which may include the original protocol, consent and approval, if research), or the source of publicly available data; and
3. If the data are not publicly available, a letter from the source authorizing access to the data or, if the data were purchased commercially, a copy of the contract authorizing the use of the data.

After these documents are submitted, the committee will be able to decide if the research is exempt, non-exempt, requires a new consent, or does not need to be reviewed further.

Terms useful in discussing Secondary Analysis of Existing Data:

Existing data are data that exist at the time the research is proposed.

Existing samples must already be "on the shelf" (meaning, they must have already been gathered) at the time the research is proposed. For example, existing blood samples, existing tissue samples, completed surveys, existing interview notes, and existing audio- and video-tapes.

Public data: Public use data sets (such as portions of U.S. Census data, data from the National Center for Educational Statistics, National Center for Health Statistics, etc.) are data sets prepared with the intent of making them available for the public. The data available to the public are not individually identifiable and therefore their analysis would not involve human subjects.

De-identified data are data from which all identifiers have been removed. Identifiers include obvious information such as name, address, social security or medical record numbers, photographs, address, telephone number, etc. as well as things such as biometric identifiers (voice and finger prints) and even zip code, if there are less than 20,000 people in the geographic area. A birth date coupled with a diagnosis may be sufficient to identify an individual in many research populations.

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Non-exempt review

Existing data containing identifiers may need to be reviewed as non-exempt research.

Exempt review

Existing data that are publicly available or are recorded by the researcher in such a manner that the research volunteers cannot be identified (de-identified data, or data for which the key to identities will not be provided the secondary researcher) may qualify for exempt review.

When New Consent is required

If the purpose of the secondary data analysis is found to differ significantly from the purpose of the original study, the IRB may require that informed consent for secondary data analysis is obtained from the research volunteers.

Some research may not have to be reviewed by the IRB because the data are so anonymous that they no longer implicate human research volunteers. For example, some public health data, amalgamations of median income and average longevity, statistics from the U.S. Census Bureau are pooled such that anonymity is ensured.

Content Experts/Consultants/Key Informants

It may not necessary to get IRB approval if interview questions are with experts about a particular policy, agency, program, technology, technique, or best practice. The questions are not about the interviewee themselves, but rather about the external topic. For instance, questions will not include demographic queries about age, education, income or other personal information.

IRB review *will be* required when a researcher is interviewing individuals about content, but there is a research question or hypothesis involved. The researcher intends to analyze and generalize the results, that is, look for common themes in the collected data, try to universalize the interviewees experiences, or quantify the results in some way.

Examples of content expert projects that may not require human research volunteer review:

In all the following examples, the questions are focused on the facts about the program, policy, software, curriculum, procedures or project. The researcher will simply report the facts as they are related by the content experts. You may not need to submit a protocol or an informed consent form for IRB approval if:

- you are interviewing managers in a company about their billing procedures, or their use of a particular software program, or
- you are interviewing or surveying teachers about what should be included in the development of a particular curriculum unit, or
- you are interviewing entrepreneurs about the obstacles they faced in starting their own businesses, and how they overcame them, or
- you are asking a panel of nurses and doctors to review your antismoking program for teens for correct medical content, or
- you are interviewing social agency directors about their client intake procedures.

Research Done at Another Institution

To conduct research at another institution, MSU faculty, staff or students who are not the sole Principal Investigator on a project must receive approval from the MSU IRB before research may begin. If the

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researcher is the sole Principal Investigator on the project, the MSU IRB will review the other institution's approved protocol.

Non-Principal Investigators must submit:

- A signed Protocol Approval Form, with signatures from the MSU faculty, (not faculty from the institution where research will be carried out.)
- A copy of the application to the research institute's IRB. (If the institution has no IRB, indicate this and MSU can serve as the IRB of record.)
- A copy of the research institution's IRB approval letter.
- An MSU protocol detailing the researcher's role in the overall project, and the part of the research that he/she will be conducting.
- A letter from the PI giving you permission to use the data generated for your research.

Research that may not need IRB Review

The IRB office has identified several categories that may not need IRB review, such as:

- a supervised internship or field practicum/field study
- a community health needs assessment
- an Instructional Technology web design evaluation
- a Design and Industry product design assessment
- a field study designed to improve one's own teaching practice
- a program evaluation, model curriculum, or a needs assessment, which does not lead to research activities such as field testing, and is not generalizable to the larger community (meaning that the results will be delivered only to one school or agency for the purpose of quality improvement, and will not be compared with other assessments, etc.
- a quality improvement project
- an interview with content experts or consultants about factual issues only, in which no personal information is obtained from the interviewees.
- an oral history project which collects personal stories about particular events or periods of time, to let them stand on their own as testimonials or archived historical documents. The stories will not to be compared with each other, analyzed in any way, or used to prove an agenda or hypothesis.
- a case study that reports on treatment strategies that have already been applied to one patient in the course of treatment and are not meant to be generalizable to all patients. A report that "tells a story" of what has already been tried in the course of treatment is considered a case study.