Researcher Handbook

Human Subject Protection Program

April 2024

Message from the Director

The Office of Research Compliance has several sections that support a culture of research integrity with university policies and federal regulations for the conduct of research. The Institutional Biosafety Committee (IBC), Institutional Animal Care and Use Committee (IACUC), and Institutional Review Board (IRB) staff are available to assist in guiding you in conducting your research within the established norms of CMU and U.S. Federal Regulations governing research.

We are here to assist so your research goes as smoothly as possible. My staff along with the committee chairs are available for consultation if you have any questions concerning your research. Please feel free to contact me directly or visit our office for assistance.

Belinda

Belinda Adamson, MEd, CIP, CHRC, CCRC
adams1bs@cmich.edu
Office: 989.774.3477

The Researcher Handbook serves as a roadmap for researchers as they navigate the Human Subject Protection Program (HRPP) and the IRB process at Central Michigan University. This handbook is designed as a *resource* to guide investigators and study team members. It will provide information for getting started, applying for the appropriate approvals, and conducting research that is compliant with relevant government laws and regulations and CMU policies and procedures. For more detail information on CMU HRPP program and specific topics, refer to the *CMU HRPP Policy Manual.*

If you have a concern, question or suggestion regarding the CMU's HRPP, contact the Director of Research Compliance and/or the IRB Chair via a phone call or email ComplianceQuestions@cmich.edu.

Table of Content

Introduction

Mission Statement

Central Michigan University conducts research designed to create new knowledge and promote an improved quality of life for the state of Michigan citizens, the nation, and the world. The IRB furthers the University research mission by:

- Safeguarding and promoting the health and welfare of human research subjects by ensuring that their rights, safety and well-being are protected.
- Providing guidance and support to the research community in the conduct of research with human subjects.
- Assisting the research community in ensuring compliance with relevant federal, state, and local laws and regulations.
- Provide timely and high-quality education, review and monitoring of human research projects.
- Facilitate excellence in human subjects' research.

Authority and Responsibility of the IRB

CMU's IRB operates under a Federal Wide Assurance (FWA). A FWA is a document, which formalizes an institution's commitment to protect human participants and is required by any institution that participates in federally supported human subject research. This is an agreement between the IRB and the Department of Health and Human Services (DHHS) outlining the responsibilities of the IRB in upholding the ethical principles of research involving human subjects. These principles are outlined in the report of the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research entitled, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, also known as "The Belmont Report". Research activities are overseen for DHHS by the Office for Human Research Protections (OHRP). Other agencies that the IRB reports to include: the Office of Research Integrity, funding agencies, and CMU's Institutional Official.

The Institutional Review Board is responsible for the review and approval, or modifications for approval, or disapproval of all human subjects research projects. In applying for approval of your project, written protocols are provided to the IRB via an electronic application system.

IRB policies and procedures applies to all activities which, in whole or in part, involves research with human subjects if:

- The research is sponsored by Central Michigan University, **or**

- The research is conducted by or under the direction of faculty, staff, or students of Central Michigan University in connection with their institutional responsibilities, **or**
- The research is conducted by or under the direction of faculty, staff or students of Central Michigan University using any property or facility of the University, **or**
- The Central Michigan University researcher is engaged in collaborative research with another institution or institutional representative; **or**
- The research involves the use of Central Michigan University's nonpublic information to identify or contact human research subjects or prospective subjects.

Graduate and undergraduate student research projects, which meet the definition of research and are intended for generalization (poster, abstract, conference) beyond the classroom, are covered by this policy. Student projects designed to provide research training, but do not produce generalizable data and are not intended for dissemination beyond the classroom are not treated as research projects under our policy.

Institutional Official

The Institutional Official (IO) is CMU's signatory official on the FWA and on all IRB authorization agreements. The IO has the authority to review decisions of the IRB. In the case of an approval decision, if the IO determines that a project does not fully comply with policies or obligations of the University, the IO may disapprove, suspend, or terminate the project on behalf of CMU. However, the IO does not have the authority to approve research disapproved by the IRB. CMU's IO is the Vice President for Research and Innovation. The IO is responsible for administering the program, ensuring compliance with the Public Health Service Act, Protection of Human Participants, and 45 CFR 46.

IRB Members

The Vice President for Research and Innovation appoints members of the IRB in consultation with the IRB Chair and Director of Research Compliance. Appointments are one to three year terms. Federal requirements mandate that the IRB have a minimum of five members with varying backgrounds to adequately review research activities commonly conducted at CMU. IRB members must be knowledgeable about institutional commitments and regulations, applicable laws, standards of professional conduct, and practice. The IRB membership must be diverse in race, gender, and cultural background. IRBs must include at least one person in each of the following categories:

- A scientific member,
- A non-scientific member,

- A community member, which must be someone who is not affiliated with the institution, nor an immediate family member of a person who is affiliated with the institution.

It is important to note, that no member of the IRB may participate in the review of any project with which that member has a conflict of interest, except to provide information requested by the IRB.

CMU Human Research Protections Program

The HRPP is a comprehensive system to ensure the protection of human subjects participating in research. It involves various individuals and committees with responsibilities to oversee the system, and includes the Institutional Official, Director of Research Compliance, Office of Research Compliance/IRB staff, the IRB, Institutional Biosafety Committee, Radiation Safety Committee, Sponsored Program Director and staff, Clinical Research Institute administration and staff, clinical research staff, legal counsel, investigators, and others. The objective of this system is to assist the institution in meeting ethical principles and regulatory requirements for the protection of human subjects in research.

CMU joins an elite group of organizations in achieving full accreditation from the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP). In achieving full AAHRPP accreditation, CMU has demonstrated its commitment to rigorous standards that help protect research participants while ensuring that society continues to realize the benefits of scientific research.

Communicating Information to Research Community

When new and relevant information needs to be disseminated to the research community, the Office of Research Compliance has several methods available to communicate this information. The dashboard in the electronic application system is an area that researchers enter on a routine basis. Emails and emails containing departmental newsletters are another way HRPP provides information. CMU Today is a university driven notification system that is used for general information communications.

Research

Federal Regulations define research as

> "*a systematic investigation, including development, testing and evaluation, designed to develop or contribute to generalizable knowledge*" [§45CFR46.102(d)].

A systematic investigation is a process that involves the formulation of a hypothesis, exploration of a theme, or establishment of research questions, and the collection and/or analysis of data that will lead to a conclusion that either proves or disproves the

hypothesis, addresses the themes, or that answers the research question.

Research generally does not include operational activities such as defined practice activities in psychology or social work, or studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, marketing studies or contracted-for services. It also does not include certain public health surveillance activities done in partnership with a public health authority, collection and analysis efforts for certain criminal justice purposes, or authorized operational activities in support of intelligence/homeland security/defense/national security missions. However, even some of these activities may include or constitute research in circumstances where there is a clear intent to contribute to generalizable knowledge.

Sometimes the issue of whether or not the study will contribute to generalizable knowledge is unclear. For example, some qualitative studies, which may not directly "contribute to generalizable knowledge," are still research. In addition, course research assignments conducted by students may be research even if they are limited in scope.

For the purpose of determining the need for IRB review (per the above definition of research), *generalizable knowledge* is knowledge that is "expressed in theories, principles, and statements of relationships" that can be widely applied to our experiences. Generalizable knowledge is usually created to share with other people, such as through presentations and publications. For example, Masters theses and Ph.D. dissertations are generally considered to present generalizable knowledge.

Criteria used for review of research follow basic principles and guidelines for the protection of participants, established in The Belmont Report. These principles outline the acceptable conduct of research involving human subjects. The criteria are summarized below.

- **Respect for persons**, or autonomy, requires recognizing the personal dignity and autonomy of individuals, and provides special protection for persons with diminished autonomy.
- **Beneficence** creates an obligation to protect people from harm by maximizing anticipated benefits and minimizing possible risks.
- **Justice** requires that the benefits and burdens of research be distributed fairly.

All research conducted by or at CMU that includes human participants is reviewed using these principles, in conjunction with regulatory requirements at 45 CFR 46. Central Michigan University promotes each principle with policies and procedures overseen by the IRB. For example the principle of:

- "*respect for persons*" requires researchers to obtain informed consent,
- "*beneficence*" requires a risk/benefit analysis of the research to minimize risks and maximize benefits to the research participants, **and**
- "*justic*e" requires that participants be fairly selected.

In determining whether a proposed activity is research, the following criteria are applied:

- Does the activity meet the definition of "research" as defined above?
- If yes, does the research involve "human participants" as defined below?
- If both of the above criteria are answered "yes" the protocol must be reviewed and approved by the IRB.

To avoid potential regulatory consequence(s), researchers should consult the IRB if they are uncertain whether or not a study qualifies as research with human subjects.

Human Subjects/Participants

While the regulatory language refers to "human subjects," the CMU IRB recognizes the autonomy of prospective participants. Humans are not "subject" to research or researchers' requests but are rather participants in expanding knowledge.

Human subject is defined by Federal Regulations as:

> *"A living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens;* ***OR*** *(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."* [§45CFR46.102(e)(1)]

About whom: A human participant research project requires the data received from the living individual to *be about* the person.

Intervention: includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

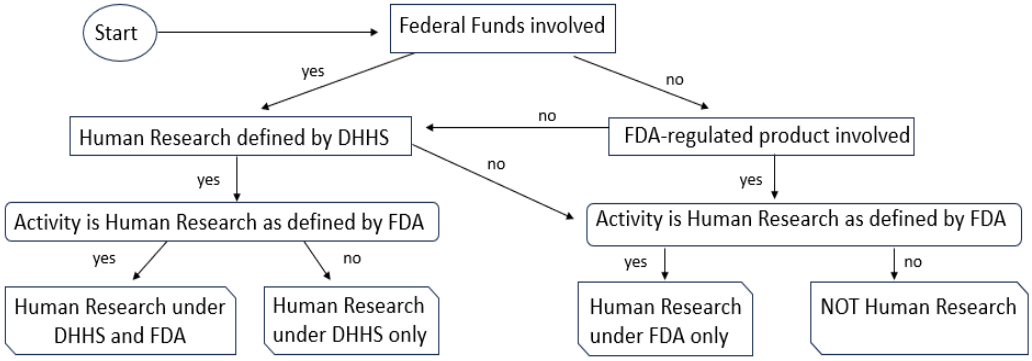
Interaction: Includes communication or interpersonal contact between the investigator and the participant. This includes in-person, *on-line surveys*, mail, and phone interaction as well as other methods of communication.

Private: 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public.

Minimal Risk: 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.

IRB Determination and Method of Review



Case Report

Under HIPAA, a case report is an activity to develop information to be shared for medical/educational purposes. Although the use of protected health information to prepare the paper and/or poster does not require IRB review, the author(s) of a **case report** must comply with **HIPAA**.

If all HIPAA identifiers (including unique patient characteristics) have been removed but the publication is requesting patient consent, this is the responsibility of the investigator to obtain. A case report for IRB purposes is a retrospective analysis of one, two, or three clinical cases. If more than three cases are involved in the analytical activity, the activity may constitute "research".

If HIPAA identifiers OR photo/video images ARE to be included in the report, a HIPAA-compliant authorization form must be signed by the patient(s) involved. IRB review on the form is not required; however, the signed release form should be scanned into the patient's medical record prior to any presentation of the case report.

If no HIPAA identifiers or images are to be included, but a "unique characteristic" is discussed, that might suggest the patient's identity, additional steps need to be considered to protect the patient's identity. Contact the IRB Coordinator or Director of Research Compliance to discuss steps to be taken prior to presentation or publication of the case report.

Not Human Subjects Research Determination

All human subjects research must undergo review by the CMU's IRB. Activities that do not meet the definition of human research do not require review and approval. An IRB application is required when investigators are unsure whether their research project meets the definition of Human Subjects Research. To obtain a formal "Not Human Subjects Research" determination from the IRB, submit a "*Does My Project Need IRB Review*" form in the electronic submission system.

Be aware that many journals are requiring an IRB determination if the project involves human participants. The IRB will not retrospectively review a request after it has been submitted to a journal. Review the journal's requirements for submission verifying if an IRB determination is necessary. This should be known at the start of your project so you have the IRB determination in place prior to the start of any research-related activities (e.g., participant recruitment, data collection, and writing the manuscript).

OHRP Decision Charts were designed to provide guidance on whether the proposed activities constitute human research. (https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html)

Exempt Determination

Certain categories of human research may be exempt from some of the federal regulations that govern protection of participants in Human Subjects Research. Investigators may not determine whether their proposed human research is exempt. Instead, a formal determination is required from the CMU IRB prior to implementation the project. Submit a "*IRB Exempt Application*" form in the electronic submission system.

When conducting exempt human research internationally, the Principal Investigator is required to comply with applicable local laws, legislation, regulations, and/or policies. Additionally, if local ethics review is required, it must be obtained before any human research activities are conducted. If assistance with applicable local requirements is needed, contact Office of the IRB.

Exempt Categories	
1	Research conducted in establish or common accepted educational settings
2	Research that only includes interactions involving educational tests, survey procedures, interview procedures or observation of public behavioral (adults only)
3	Research involving benign behavioral interventions in conjunction with the collection of information through verbal or written responses (some restrictions & adults only)

4	Secondary research for which consent is not required. Secondary research use of identifiable private information or identifiable biospecimens. (specific requirements)
5	Research and demonstration projects that are conducted or supported by a Federal department or agency
6	Taste and food quality evaluation and consumer acceptance studies.
7.	Storage or maintenance for secondary research for which *broad consent* is required.
8.	Secondary research for which *broad consent* is required.

Expedited Review Procedure

Certain categories of non-exempt human research may qualify for review using the expedited procedure, meaning that the project may be approved by one or more designated reviewers, rather than by the convened IRB. Minimal risk protocols eligible for review using the expedited procedure do not require continuing review unless the IRB member determines otherwise. Submit a "*IRB Application to Conduct Research Involving Human Subjects*" form in the electronic submission system.

Expedited Categories (Non-Exempt Research)	
1	Clinical studies of drugs and medical devices with specific conditions. (no IND/IDE needed)
2	Collection of blood samples by finger stick, heal stick or venipuncture (restriction on amount)
3	Prospective collection of biological specimens for research purposes by noninvasive means.
4	Collection of data through noninvasive procedures routinely employed in clinical practice.
5	Research involving materials that have been collected, or will be collected solely for nonresearch purposes
6	Collection of data from voice, video, digital, or image recordings made for research purposes.
7	Research on individual or group characteristics or research employing survey, interview, oral history, focus groups, program evaluation, human factor evaluations or quality assessment. (This list refers only to research that is NOT exempt.)

Convened IRB Review ("Full Board")

Non-exempt human research that does not qualify for expedited review and/or present greater than minimal risk to participants must be reviewed at a fully convened IRB meeting. The CMU IRBs meets monthly. A convened board protocol needs to be received by the IRB three (3) weeks before a monthly meeting. Submit a "*IRB Application to Conduct Research Involving Human Subjects*" form in the electronic submission system.

Protocol Submission

The CMU IRB is responsible for the review and oversight of Human Subjects Research conducted by CMU faculty, staff, and students. Its oversight applies regardless of whether the Human Subject Research is conducted at CMU, another institution, in another country, and/or in collaboration with non-CMU affiliates. If it's unclear what is required for collaborative research, contact the IRB coordinator. Some activities do not require IRB review. Activities that do not meet the definition of "Human Subjects Research" do not fall under the HHS Protection of Human Subjects Regulations. Examples are oral history, scholarly and journalistic activities specifically about an individual, public health surveillance, and use of certain type of de-identified data.

IRB applications may be submitted at any time via the electronic submission system. Applications are entered in the queue for review in the order they are received. Most research with human participants does not need the convened board's review. As soon as a protocol application is received by the IRB office, the IRB staff will determine if the application can be reviewed under the regulations for Expedited Review and, if so, the review process will begin *without waiting* for a convened board meeting. Applications that require Convened Board Review, from the *pediatric faculty*, must be received 3 (three) weeks before a monthly IRB meeting. Protocols that require convened board review but are not received by the deadline will be held over for consideration until the next meeting. Applications that require Convened Board Review, from the *Mt. Pleasant* campus, will have an ad hoc convened board meeting scheduled.

Documents to facilitate IRB Review

For any Human Subject Research that is does not qualify for an exempt category review, the following documentation are requested to assist IRB members in doing their review. For initial review, the documents are distributed by IRB staff to all IRB members who will be charged with reviewing the protocol. For review by the convened IRB, the following documents (if applicable) are *distributed to all members* of the IRB:

- The IRB Application
- A protocol
- The proposed Informed Consent document or Letter of Information
- Any privacy authorization from participant (HIPAA)
- Any advertisement to be used for recruitment
- Any brochures to be used during the study
- Any survey or questionnaire instrument to be administered
- Data Collection tools or documents (e.g., data collection sheet, spreadsheets)
- Approval or Letter of Support from entities, facilities, schools, etc.
- Approval or Letter of Support from international site's ethic boards or institutions
- The Reviewer's Checklist, to be used by primary reviewers and reviewers assigned to conduct reviews under expedited procedures.

- Supplemental HIPAA summary form for reviewer evaluation.

Any ancillary review (e.g., IBC, radiation, institutional local review, etc.) necessary for the conduct of the study needs to be going through a concurrent review process. The IRB cannot make a final determination on a study without the ancillary review approval. Their review and concerns need to be considered in the risk to benefit evaluation to the human participants. Prior to final determination of the study, the risk in relationship to the benefits is an important factor to protect human participants that is considered by the IRB.

Informed Consent Process

It is the researcher's responsibility to educate prospective participants about the purpose of the project and its risks and benefits, to obtain their consent before involving them in research, and to keep them informed as the research proceeds. This is the informed consent process. Information may be provided to the potential participant as:

- a document/information sheet that may or may not require a signature,
- a script that is read to the participant prior to proceeding with a telephone survey, on-line interview or focus group,
- a paragraph to be read prior to completing an online survey **or**
- a hybrid of the above.

Creating a Consent Script for Exempt Human Research

Exempt Human research does not usually require a long signed consent form. However, the ethical principles outlined in The Belmont Report, namely, respect for persons, emphasizes the importance of ensuring that participants are fully informed. Therefore, a consent process is required when exempt research involves an interaction with human subjects. At a minimum, this process must disclose the following:

- That the activities involve research,
- The procedures to be performed,
- That participation is voluntary, **and**
- The name and contact information for the investigator.

Creating Consent Forms for Non-Exempt Research

Consent documents must contain all the required elements and, as appropriate, additional elements of informed consent. No informed consent (oral or written) can include exculpatory language whereby the participant or their representative is made to waive, or appear to waive, any of the participant's legal rights, or releases or appears to release the Investigator, sponsor, Institution or its agents from liability for negligence.

On the CMU website in the *Office of Research Compliance*, *Human Subject Protection* sections have templates to assist in creating consent documents.

Compensation of Participants

The IRB will review the amount and schedule of incentives/compensation to assess the appearance or fact of undue influence or coercion for participants who may be overly influenced due to their economic insecurity or vulnerability. All information concerning participant compensation should be stated in the IRB protocol and informed consent document(s), including amount, method, and timing of disbursement. If compensation is mentioned in recruitment materials, the recruitment materials should also include a brief description of project procedures.

For researchers who would like to offer course credit/extra credit to the study participants or utilize lotteries/raffles refer to the *CMU HRPP Policy Manual* for more detailed information.

Research using Student Information

There are several regulations that protect student and parent information maintained in an Education Record. Family Educational Rights and Privacy Act (FERPA) and Protection of Pupil Rights Amendment (PPRA) afford certain rights to students and parents about the use of educational records or conducting research with children. Researchers must obtain signed and dated permission from the parent/legal guardian and/or eligible student for the release of their records or obtain information through interactions with students.

HIPAA Privacy Protections

Permitted Access/Disclosure

There is no need for patient HIPAA authorization if accessing or disclosing records for:

- Treatment: any activity related to patient care
- Payment: activities to pay or get paid for healthcare services
- Operations: day to day core activities (audits, **quality improvement projects**)

Access/Disclosure for Research

Releasing information for research purposes requires authorization from research subjects. In certain circumstances, the Privacy Rule permits Covered Entities to use and disclose Research PHI without patient authorization as follows:

- If the IRB has granted a waiver or an alteration of the authorization.
    - If the IRB approves a waiver, the receipt of the requisite documentation of the approval/determination letter permits a covered entity to use or disclose PHI in connection with a particular research project without Authorization.

- If the Covered Entity has entered into Data Use Agreement for sharing a limited data set.
- Activities are preparatory to research.
- Research on decedents' information.

Data Use Agreement for use of PHI

The purpose of a Data Use Agreement (DUA) is to set out the permitted uses and disclosures of the Protected Health Information (PHI) in the "limited data set". A "limited data set" is a limited set of identifiable patient information as defined in the Privacy Regulations issued under the Health Insurance Portability and Accountability Act, better known as "HIPAA". A "limited data set" of information may be disclosed to an outside party without a patient's authorization if certain conditions are met.

The health information that may be in a limited data set are:

- dates such as admission, discharge, service, DOB, DOD;
- city, state, 5 digit or more zip code; and
- ages in years, months or days or hours.

The recipient of the health information will ensure:

- Properly safeguard the data;
- Not use the information in a manner inconsistent with the DUA;
- Report any improper uses or disclosures to the covered entity;
- Not use the information to attempt to identify or contact individuals based on the information in the "limited data set"; **and**
- Require all agents and subcontractors to comply with the terms of the DUA.

The Office of Sponsored Projects needs to be contacted if you wish to share a "limited data set" so a DUA can be established.

Review Process

After the appropriate board members have completed the application review, the IRB makes determinations that are consistent with federal criteria for IRB approval of research, whether or not the research has federal funding.

Criteria for IRB Approval of Research Expedited or more than Minimal Risk Research (non-exempt studies)

IRB must determine all of the following requirements are met:

1. Risks to participants are minimized
   (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and

(ii) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes (such as a blood draw, or diagnostic behavioral interview).

2. Risks to participants are reasonable in relation to both the anticipated benefits, if any, to participants, and to the importance of the knowledge that may reasonably result.
3. Selection of participants is equitable.

   In making this assessment the IRB will consider the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the unique problems of research that involves vulnerable populations.
4. Informed consent is sought from each prospective participant or the participant's legally authorized representative, in accordance with relevant policies or federal regulations (all required elements, ongoing consent, in a language understandable to the participants, etc.).
5. Informed consent is appropriately documented, in accordance with relevant policies and federal regulations, unless there is a credible justification to waive such documentation.
6. When appropriate, the research plan makes adequate provision for monitoring data collected to ensure the safety of participants.
7. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

Review Outcomes

Approved: The IRB approves a project when all criteria for approval are met. No further action is required from the researcher and research may begin. Researchers must not begin research (new proposals) or continue research (amendments or continuing review) until the researcher has received a letter documenting IRB approval.

Approved with Conditions: The protocol and/or supporting documents require specific changes in order to meet the criteria for approval. The **Approved with Conditions letter** will list the changes and/or modifications required by the IRB. The researcher must revise and submit the changes to be able to receive an approval letter from the IRB before the project may begin or continue.

Deferred: If the IRB was unable to approve a project because one or more of the *IRB criteria for approva*l regulations were not met or there was insufficient detail in the submission to make a determination, the PI will be asked for additional information or modification. In this case, a **deferred letter** is sent indicating what additional information needs to be provided or changes that need to be made. If originally reviewed by the full board, the full board must subsequently review the project at a monthly meeting.

Disapproved: A fully convened board determines that it is unable to approve the research and cannot describe modifications that might make the research approvable. When making this determination, the IRB will describe its reasons for this decision and

give the researcher an opportunity to respond to the IRB's concerns. If disapproved, the research cannot be conducted.

Acknowledged: The IRB staff can acknowledge certain types of submissions, including but not limited to minor administrative corrections to certified translations of approved documents. These submissions do not require formal review by an IRB member.

Protocols that spend an excessive amount of time with the PI for modifications will be returned to the PI and must be submitted as a new protocol. This generally is 60 (sixty) days for any outstanding modification requests. Contact the IRB if issues arise in being able to complete the modifications within that time frame.

A determination letter will be issued via the electronic submission system once the review is complete. System notifications are sent to the Principal Investigator and study contact when all institutional approvals have been completed. If you have questions about the status of your study during the IRB review process, contact the IRB office.

Expiration of IRB Approval

The PI must submit a renewal request at least 30 days in advance of the IRB expiration date. The expiration date is the last date that the protocol is approved (i.e. IRB approval expires at midnight on the expiration date). If the PI fails to do so, and *IRB approval expires, all human research activities, including data analysis, must stop*. Failure to have a project approved or closed prior to the IRB approval expiration date is considered noncompliance. The electronic application system, as a courtesy, sends out expiration date reminders 90, 60 and 30 days before the study's expiration date. However, it is the investigator's responsibility to prevent a study lapsing in IRB approval.

For studies reviewed by a convened board, renewal applications must be submitted at least 30 days before the study's expiration date. Plan accordingly so the study is reviewed at a scheduled convened board meeting prior to the expiration date.

Non-Compliance

Conducting human subjects research without IRB approval, an exemption determination, or lapse in IRB approval is noncompliance. Non-compliance is *defined* as failure to adhere to federal, state, or local regulations governing human subject research, institutional policies related to human subject research, or the requirements or determinations of the IRB. Non-compliance may be minor or sporadic or it may be serious or continuing.

Finding of non-compliance is defined as an allegation of non-compliance that is proven true or a report of non-compliance that is clearly true. For example, a finding on an

audit of an unsigned consent document, or an admission of an investigator that the protocol/research plan was willfully not followed, represent reports of non-compliance that would require no further action to determine their truth and would therefore represent findings of non-compliance. Once a finding of non-compliance is proven, it must be categorized as non-compliance, serious non-compliance, or continuing non-compliance.

Principal Investigator

Office of Research Compliance follows the Office of Sponsor Project's policy "*Eligibility to serve as CMU Principal Investigator/Project Director on Sponsored Projects*" which has designated individuals in the following categories as being eligible to serve as PI:

- All CMU tenure or tenure-track faculty
- All non-tenure College of Medicine faculty with a CMU paid appointment
- All professional staff with CMU permanent appointments
- CMU Medical Education Partners (CMEP) employees: submissions must also include a project Lead who is a paid CMU employee or faculty member, who meets the PI eligibility criteria. See the first three bullet point above.

This requirement does not preclude any non-paid faculty member from being listed as a Co-Investigator on the project, or having certain research responsibilities delegated to them, but they may not be named as PI nor assume ultimate responsibility for the assurances conduct of the study.

Responsibilities

For each application submitted to the IRB, The PI must acknowledge their role and responsibilities in the research. When the application is submitted by the PI, they are assuring that:

- *The trainee(s) is/are sufficiently knowledgeable about the regulations and policies governing research with human subject, and has/have sufficient training and experience, to conduct this particular study according to the approved protocol.*
- *I have reviewed the application and all associated materials with the trainee(s).*
- *I will meet with the trainee investigator(s) as necessary to monitor study progress.*
- *I will assist and advise the trainee(s) in reporting immediately to the CMU (specific board name) Institutional Review Board any changes in the procedure; injury to a research participant; or any problems that involve risk or the possibility of risk to participants or others.*

Human Subjects Research Training

CMU and federal regulations *require* that Principal Investigators, Co-Investigators and any research personnel who performs any of the following research activities

- *Designing the research*
- *Conducting the research*
- *Obtains informed consent*
- *Collects data*
- *Performs data analysis*

receive training in the ethical protection of human participants. CMU uses Collaborative Institutional Training Initiative (CITI) to fulfill this requirement. The IRB review may be delayed if CITI training has not been completed or is not current for all study personnel. Recertification is required every *three* years. PIs are also responsible to adequately train personnel under their responsibility, whether or not they are directly involved in the conduct of Human Subject Research, concerning participant safety, privacy and preserving the confidentiality of research data associated with participants.

NOTE: When Principal Investigators, Co-Investigators and any research personnel receive notification of that their CITI training is due to be re-certified, CMU modules MUST be completed. The CMU IRB will not accept re-certification from the affiliated institution that was provided with the initial study review. The person will be required to complete the CMU modules prior to approval even though they have just re-certified under another institution's CITI modules.

Training is verified by the IRB staff at time of initial application submission and continuing review/status update.

Reporting Financial Interests to the IRB

To minimize the actual or potential conflicts of interest in Human Subject Research, the IRB requires that all individuals involved in the design, conduct, or reporting of a clinical trial or federally funded research disclose financial interests related to non-exempt research. Of note, individuals involved in the design, conduct, or reporting of the research may also include study coordinators, research nurses, and data coordinators.

Investigators must report any change(s) to this disclosure within 30 business days of discovering or acquiring (e.g., through purchase, marriage, inheritance, filing a patent application, etc.) a new financial interest.

Collaborating with non-CMU individuals

When engaging in human research, all CMU investigators need to have an IRB approved study. Individuals not associated with CMU must inquire with their home/affiliated institution to determine if local IRB review and oversight is required. Federal regulation changes now require a single IRB oversight of a study if federal funds are involved. To avoid duplicating IRB reviews between multiple institutions, investigators may ask the IRB to consider entering into a reliance agreement between institutions. Ceding review allows one institution to serve as the Reviewing Institution/IRB while the others serve as the Relying Institution/IRB.

If a collaborator does not have a home/affiliated institution, it may be appropriate to add the collaborator as an Individual Investigator on the CMU study. This is done through executing an *Individual Investigator Agreement* (IIA) allowing them to work under the oversight of the Principal Investigator. The collaborator will be required to complete appropriate CITI training modules. Contact the Office of Research Compliance for assistance for this type of an agreement.

Relying on another IRB

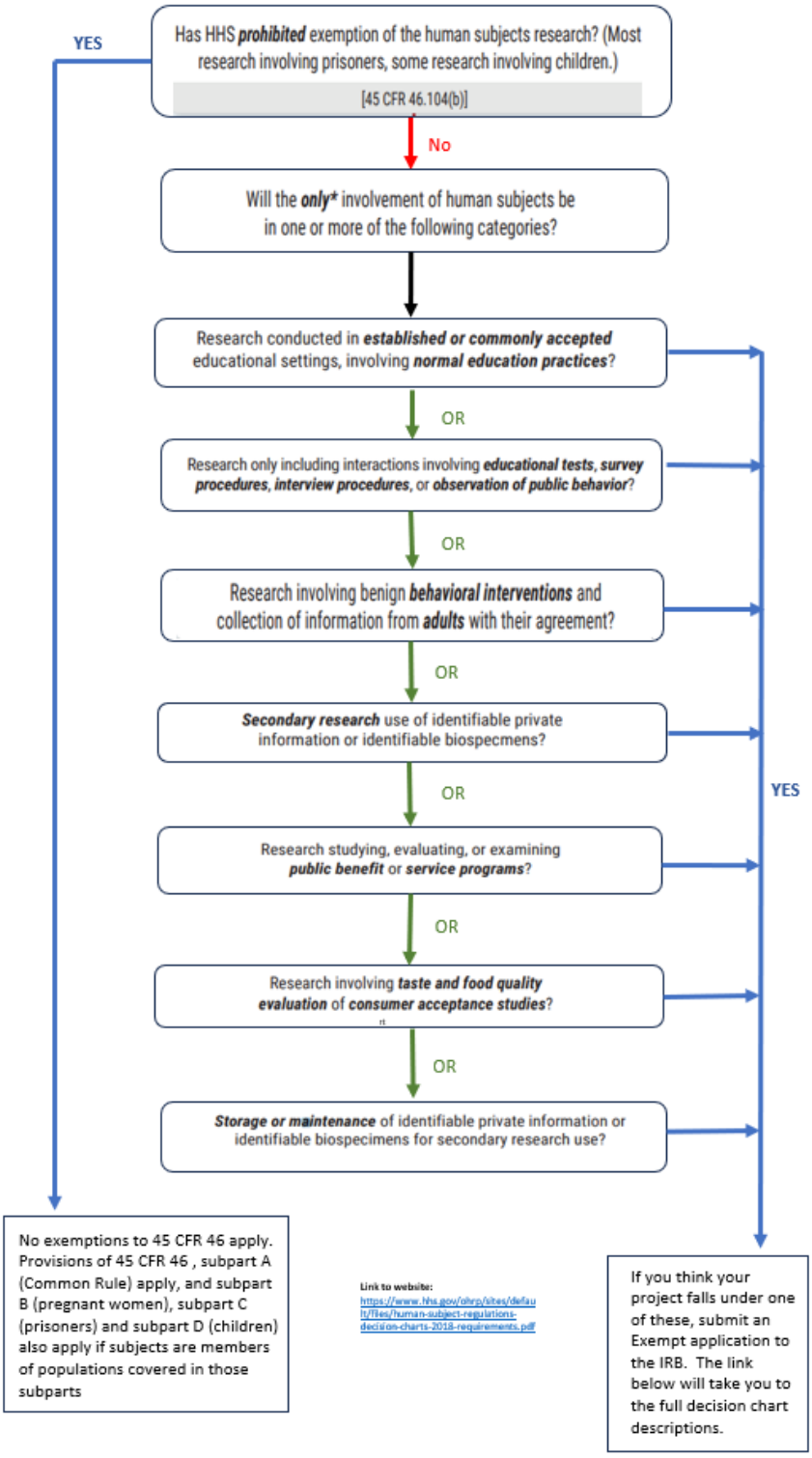
When two or more institutions are involved in a research study, one institution will serve as the Reviewing Institution/IRB while the other is the Relying Institution/IRB. This is done through a reliance agreement which is also known as an *Institutional Authorization Agreement* (IAA). The Reviewing institution is responsible for the conduct of the study and the Relying institution cedes review and is known as a participating site.

Non-exempt human subject research (expedited or a convened board review) can be considered for a Reliance Agreement. Contact the IRB coordinator to discuss the need for such an agreement. Studies that qualify for exemption or is considered not human subject research must be reviewed by the CMU IRB; they do not qualify for a Reliance Agreement.

The CMU IRB may cede review of a project to an external IRB if we believe another IRB is better suited in expertise to oversee the project or as part of the requirement by NIH for single IRB review. If the external IRB requires review fees, the researcher is responsible for payment of those fees.

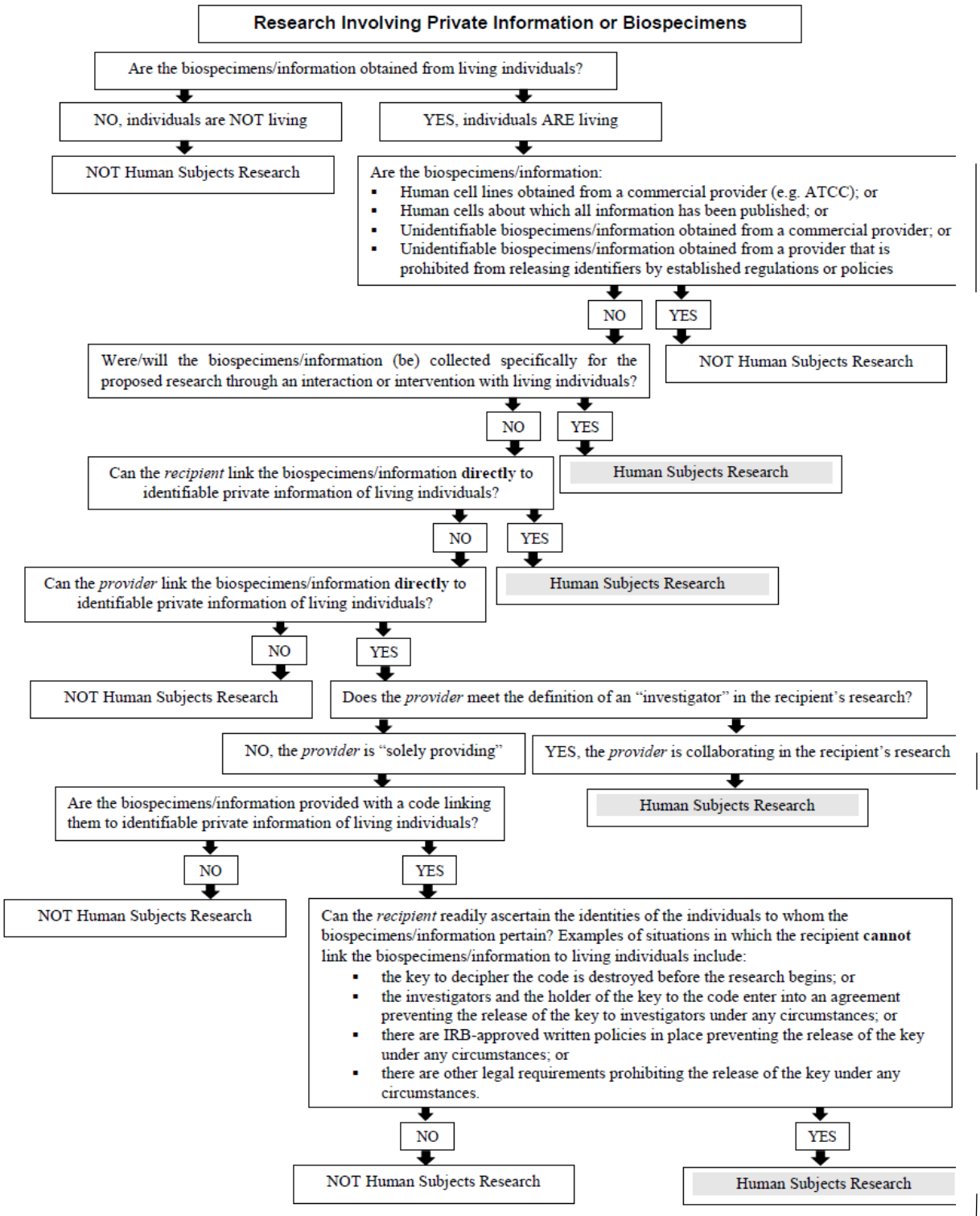
Researchers may also request that a collaborator's institution, that is engaged in non-exempt research, defer oversight to the CMU IRB. Contact the IRB coordinator **prior to delegating** the CMU IRB to be the Reviewing IRB so we can be determined if CMU IRB is qualified or can take on the responsibility of the conduct of the study.

Appendix A: Exempt Decision Tree



OHRP website:
https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html

Appendix B: Research Involving Private Information or Biospecimens



Please note: this document is intended to be a resource only. Final decisions should be made in accordance with 45 CFR 46.

NIH Office of Extramural Research - June 25, 2019

Appendix C: Comparison Chart- Human Research, QA/QI, Program Evaluation

Comparison: Characteristic of Different Types of Projects
(Human Subject Research, QA/QI, Program Evaluation)

*Determining whether a project requires IRB Review depends on if it constitutes **HUMAN SUBJECT RESEARCH** Confirm with IRB staff at cmuirb@cmich.edu, if any questions.*

	HUMAN SUBJECT RESEARCH	QUALITY ASSURANCE/ QUALITY IMPROVEMENT	PROGRAM EVALUATION
INTENT	Develop or contribute to generalizable knowledge (e.g., testing hypothesis)	**Improve a practice or process** within a particular institution or ensure it confirms with expected norms	**Improve a specific program**, only to provide information for and about the setting in which it is conducted
MOTIVATION FOR PROJECT	Projects occurs in large part as a result of individual professional goals and requirements (e.g., seeking tenure, obtaining grants, completing a thesis or dissertation)	Project occurs regardless of whether individual(s) conducting it may benefit professionally from conducting the project	Project not initiated by the evaluator and occurs regardless of whether individual(s) conducting it may benefit professionally from conducting the project
DESIGN	Designed to develop or contribute to generalizable knowledge; may involve randomization of individuals to different treatments, regimens, or processes; novel research ideas supported by literature search	Not designed to develop or contribute to generalizable knowledge; generally does not involve randomization to different practices or processes	Not designed to develop or contribute to generalizable knowledge; does not involve randomization of individuals, but may involve comparison of variations in program
MANDATE	Activities not mandated by institution or program	Activity mandated by the institution or clinic as part of its operation	Activity mandated by the program, usually its funder, as part of its operations
EFFECT ON PROGRAM OR PRACTICE EVALUATED	Findings of study are not expected to directly or immediately affect institutional or programmatic practice	Findings of the study are expected to directly affect institutional practice and identify corrective action(s) needed	Findings of the evaluation are expected to directly affect the conduct of the program and identify improvements
SUBJECT POPULATION	Usually involves a subset of individuals; universal participation of an entire clinic, program, or department is not expected for sample size is used to ensure endpoints can be met	Information on all or most receiving a particular treatment or undergoing a particular practice or process expected to be included; exclusion of information from some individuals significantly affects conclusions	Information on all or most participants within or affected by receiving a particular treatment of undergoing a particular practice or process expected to be used; exclusion of information from some individuals significantly affects conclusions
BENEFITS	Participants may or may not benefit directly-benefit, if any, to individuals is incidental or delayed	Participants expected to benefit directly from the activities	No benefit to participants expected; evaluation concentrates on program improvements or whether the program should continue
DISSEMINATION OF RESUTS	Intent to published or present generally presumed at the onset of project as part of professional expectations, obligations; dissemination of information usually occurs in research/scientific publications, grant proposals, or other research/scientific forum; results expected to develop or contribute to generalizable knowledge by filling a gap in scientific knowledge or supporting, refining, or refuting research from other studies	Intent to publish or present generally not presumed at the outset of the project; dissemination of information often does not occur beyond the institution evaluated; dissemination of information may occur in quality improvement publications/forums; when published or presented to a wider audience, the intent is to suggest potentially effective models, strategies, assessment tools, or provide benchmark or base rates rather than to develop or contribute to generalizable knowledge	Intent to publish or present generally presumed at the outset of the project; dissemination of information to program stakeholders and participants; may be publicly posted (e.g. website) to ensure transparency of results; when published or presented to a wider audience, the intent is to suggest potentially effective models, strategies, assessment tools or provide benchmarks or base rates rather than to develop or contribute to generalizable knowledge

Appendix D: Comparison Chart- Human Research, Class/Student Projects, Oral History

Comparison: Characteristic of Different Types of Projects
(Human Subject Research, Class/Student Project, Oral History)

*Determining whether a project requires IRB Review depends on if it constitutes **HUMAN SUBJECT RESEARCH** Confirm with IRB staff at cmuirb@cmich.edu, if any questions.*

	HUMAN SUBJECT RESEARCH	CLASS/STUDENT PROJECT	ORAL HISTORY
INTENT	Develop or contribute to generalizable knowledge (e.g., testing hypothesis)	Intent of project is to provide an educational experience about the research process or methods	Project is to explain a particular past; does not create generalizable explanations about all that has happened in that topic, nor does it predict the future of that topic; interviews are a conscious intention of creating a permanent record to contribute to an understanding of the past
MOTIVATION FOR PROJECT	Projects occurs in large part as a result of individual professional goals and requirements (e.g., seeking tenure, obtaining grants, completing a thesis or dissertation)	Project occurs as part of assigned course/class work or requirement of an educational program in order to learn a new technique or pass a course/fulfill an assignment	The purpose is to create a historical record of specific personal events and experiences related to a topic at hand; project may also occur as part of individual professional goals and requirements
DESIGN	Designed to develop or contribute to generalizable knowledge; may involve randomization of individuals to different treatments, regimens, or processes; novel research ideas supported by literature search	Not designed to develop or contribute to generalizable knowledge; design is often an example or template provided by a professor or course book	Interview or series of interviews gives a unique perspective on the topic; story or collection of stories to be a variety of particular perspectives; may involve open ended questions that are tailored to the experiences of the individual narrator; content of interviews is grounded in reflections on the past as opposed to commentary on purely contemporary events; analysis of the stories and/or conclusions drawn about the stories are not part of the design
MANDATE	Activities not mandated by institution or program	Activity mandated by regularly assigned coursework or educational program	Activities not mandated by institution or program
EFFECT ON PROGRAM OR PRACTICE EVALUATED	Findings of study are not expected to directly or immediately affect institutional or programmatic practice	Findings of project are not expected to directly affect the program; the project will mainly generate raw data, not generalizable knowledge	Collection of stories are not expected to affect the narrator group, as any conclusions, trends, judgments, or general findings about the stories are not part of the project
SUBJECT POPULATION	Usually involves a subset of individuals; universal participation of an entire clinic, program, or department is not expected for sample size is used to ensure endpoints can be met	Can either include all, most, or a subset of individuals; statistical justification may be used in the context to understand the process of subject selection; however, recruitment often utilizes convenience sampling Narrators are not anonymous individuals or selected as part of a random sample; narrators are specific individuals selected because of their unique relationship to the topic at hand; it is the practice in oral history for narrators to be identified by name	Narrators are not anonymous individuals or selected as part of a random sample; narrators are specific individuals selected because of their unique relationship to the topic at hand; it is the practice in oral history for narrators to be identified by name
BENEFITS	Participants may or may not benefit directly- benefit, if any, to individuals is incidental or delayed	Participants may or may not benefit directly; benefit is primarily for the investigator conducting project for his/her own knowledge or fulfillment of educational requirements	Narrators will not benefit directly, as the purpose is not to inform policy, control outcomes, or direct conclusions
DISSEMINATION OF RESUTS	Intent to published or present generally presumed at the onset of project as part of professional expectations, obligations; dissemination of information usually occurs in research/scientific publications, grant proposals, or other research/scientific forum; results expected to develop or contribute to generalizable knowledge by filling a gap in scientific knowledge or supporting, refining, or refuting research from other studies	No intent to present or publish results beyond the classroom, campus, or educational program; any presentations, posters, or publishing (such as on UTA website) is simply to document completed work/raw data for educational or programmatic requirements and/or to obtain experience	Intent to publish or present generally presumed at the outset of project; oral history interviews are historical documents that are often preserved and made accessible to future historians and members of the public; dissemination typically occurs through presentations, historical publications, or oral history archives (including centers and collections), as opposed to research/scientific publications, grant proposals, or other research/scientific forum