# 17 Special Topics

## 17.1 Certificate of Confidentiality (CoC)

The privacy of the research subjects referred to in §301(d) is protected through the issuance of Certificates of Confidentiality. These certificates of Confidentiality provide protection against compelled disclosure of identifying information about subjects enrolled in sensitive biomedical, behavioral, clinical, or other research. This protection is not limited to federally supported research.

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) and other HHS agencies to protect identifiable research information from forced or compelled disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in civil, criminal, administrative, legislative, or other proceedings, whether federal, state, or local. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects, such as damage to their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help to minimize risks to subjects by adding an additional level of protection for maintaining confidentiality of private information.

Certificates of Confidentiality protect subjects from compelled disclosure of identifying information but do not prevent the voluntary disclosure of identifying characteristics of research subjects. Researchers, therefore, are not prevented from voluntarily disclosing certain information about research subjects, such as evidence of child abuse or a subject's threatened violence to self or others.

However, if a researcher intends to make such voluntary disclosures, the consent form should clearly indicate this. Furthermore, Certificates of Confidentiality do not prevent other types of intentional or unintentional breaches of confidentiality. As a result, investigators and IRBs must ensure that other appropriate mechanisms and procedures are in place to protect the confidentiality of the identifiable private information to be obtained in the proposed research.

### 17.1.1 Statutory Basis for Protection

Protection against compelled disclosure of identifying information about subjects of biomedical, behavioral, clinical, and other research is provided by the Public Health Service Act 301(d), 42 U.S.C. 241(d):

"The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any federal, state or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

### 17.1.2 Usage

Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to subjects.

Any investigator engaged in research in which sensitive information is gathered from human subjects (or any person who intends to engage in such research) may apply for a Certificate of Confidentiality. Research can be considered "sensitive" if it involves the collection of

1. information about sexual attitudes, preferences, practices;
2. information about personal use of alcohol, drugs, or other addictive products;
3. information about illegal conduct;
4. information that could damage an individual's financial standing, employability, or reputation within the community;
5. information in a subject's medical record that could lead to social stigmatization or discrimination; or
6. information about a subject's psychological well-being or mental health.

This list is not exhaustive. Researchers contemplating research on a topic that might qualify as sensitive should contact the IRB Office for help in applying for a certificate.

In the Informed Consent form, investigators should tell research subjects that a Certificate is in effect. Subjects should be given a fair and clear explanation of the protection that it affords, including the limitations and exceptions noted above. Every research project that includes human research subjects should explain how identifiable information will be used or disclosed, regardless of whether a Certificate is in effect.

### 17.1.3 Limitations

The protection offered by a Certificate of Confidentiality is not absolute. A Certificate protects research subjects only from legally compelled disclosure of their identity. It does **not** restrict voluntary disclosures.

For example, a Certificate does not prevent researchers from voluntarily disclosing to appropriate authorities such matters as child abuse, a subject's threatened violence to self or others, or from reporting a communicable disease. However, if researchers intend to make such disclosures, this should be clearly stated in the Informed Consent form that research subjects are asked to sign.

In addition, a Certificate of Confidentiality does **not** authorize the person to whom it is issued to refuse to reveal the name or other identifying characteristics of a research subject if

1. the subject (or, if he or she is legally incompetent, his or her legal guardian) consents, in writing, to the disclosure of such information;

2. authorized personnel of the Department of Health and Human Services (DHHS) request such information for audit or program evaluation, or for investigation of DHHS grantees or contractors and their employees; or
3. release of such information is required by the federal Food, Drug, and Cosmetic Act or regulations implementing that Act.

Here are the limitations as outlined by UCLA:

- Required by other Federal, State, or local laws, such as for reporting communicable diseases; OR,
- The subject has consented to such disclosure; OR,
- The disclosure is for the purposes of scientific research that is compliant with human subjects regulations

### 17.1.4 Application Procedures

Any person engaged in research collecting sensitive information from human research subjects may apply for a Certificate of Confidentiality.

NIH will automatically issue CoCs to all research funded by NIH that is collecting or using identifiable, sensitive information. Compliance requirements are outlined in the NIH Grants Policy Statement, which is a term and condition of all NIH awards.

If the PI is conducting a sensitive research project that is covered by the AHRQ confidentiality statute (42 U.S.C. section299a-1(c) entitled "limitation on use of certain information") or the Department of Justice confidentiality statute (42USC section 3789g), then a CoC is not required.

If there is an Investigational New Drug Application (IND) or an Investigational Drug Exemption (IDE), the sponsor can request a CoC from the FDA.

For more information, see the NIH Certificates of Confidentiality Kiosk. (http://grants.nih.gov/grants/policy/coc/index.htm).

## 17.2 Mandatory Reporting

While any person may make a report if they have reasonable cause to believe that a child or elder was abused or neglected, Michigan law mandates that certain persons who suspect child or elder abuse or neglect report this to the Michigan Department of Social Services or relevant county social service office.

CMU policy requires the solicitation of informed consent from all adult research subjects and assent from children involved as research subjects, in addition to the consent of their parents. In situations where conditions of abuse or neglect might be revealed, mandated reporters should make themselves known as such to parents of children under age 18, to subjects who are children, and to subjects who are potential victims of abuse or neglect.

Michigan's Mandatory reporting Law can be found at MCL 722.623 et seq.

Investigators should consult these sources to determine if potential subjects should be advised of mandatory reporting requirements during the informed consent process.

## 17.3 CMU Students and Employees as Subjects

When CMU students and/or employees are being recruited as potential subjects, researchers must ensure that there are additional safeguards for these subjects. The voluntary nature of their participation must be primary and without undue influence on their decision. Researchers must emphasize to subjects that neither their academic status or grades, or their employment, will be affected by their participation decision.

To minimize coercion and undue influence, investigators should avoid, whenever possible, the use of their students and employees in procedures that are neither therapeutic nor diagnostic. In these latter situations, investigators should solicit subjects through means such as bulletin board notices, flyers, advertisements in newspapers, and announcements in classes or laboratories **other than their own**. When entering a classroom to recruit students and conduct research (e.g. administer a survey), investigators should do so at the end of the class period to allow non-participating students the option of leaving the classroom, thereby alleviating pressure to participate.

## 17.4 Student Research

### 17.4.1 Human Subjects Research and Course Projects

Learning how to conduct ethical human subjects research is an important part of a student's educational experience. Research activities that are designed as part of a course requirement for purposes of learning experience only and are **NOT *designed to develop or contribute to generalizable knowledge* will generally NOT** require IRB review and approval

**Responsibility of the Course Instructor:** The course instructor is responsible for communicating to the students the ethics of human subjects research, for ensuring the protection of human subjects (including a process is in place for obtaining voluntary informed consent from research subjects when appropriate), and for monitoring the students' progress.

When designing a project, students should be instructed on the ethical conduct of research and on the preparation of the IRB application when such is required. In particular, instructors and students should

1. understand the elements of informed consent;
2. develop appropriate consent documents;
3. plan appropriate strategies for recruiting subjects;
4. identify and minimize riskrisks to subjects;
5. assess the risk-benefit ratio for the project;
6. establish and maintain strict guidelines for protecting confidentiality; and
7. allow sufficient time for IRB review (if necessary) and completion of the project.

In determining whether a class research project requires IRB review, the instructor is encouraged to err on the side of caution and to contact the IRB office for assistance.

### 17.4.2 Individual Research Projects Conducted by Students

Senior theses, masters and advanced degree research, and similar activities must be independently submitted for IRB review. It is important to keep in mind that any human subjects research activity that will ultimately contribute to part or all of a thesis, dissertation, or other type of publication or presentation must go through the IRB review process prior to enrolling subjects and collecting data. **IRB review cannot occur after a study has begun.**

Students and advisors should contact the IRB Office with any questions.

Students should also check with their department, program advisor, and the College of Graduate Studies to determine if there are additional requirements to be met that are not covered in this document.

### 17.4.3 Theses and Dissertations

These research activities are generally considered to meet the federal definition of human subjects research and must be independently submitted to the IRB by the student-researcher's faculty advisor. However, when students conduct research as part of a course of study, *a faculty member ultimately is responsible for the protection of the subjects*, even if the student is the primary researcher and actually directs the project. Advisers assume the responsibility for students engaged in independent research, and instructors are responsible for research that is conducted as part of a course.

Students may not serve as PIs. They must have a faculty sponsor who fulfills the PI eligibility criteria and who will serve as PI and faculty advisor on the study.

## 17.5 Pilot Studies

Pilot studies serve various purposes such as determining whether a research project is feasible given available resources, and it is often not clear whether they meet the regulatory definition of research, namely a systematic investigation designed to develop or contribute to generalizable knowledge. Investigators should consult the IRB Chair or the DRC. Pilot studies that do not meet the regulatory definition yet pose greater than minimal risk to subjects may be referred for separate review.

## 17.6 Case Reports Requiring IRB Review

In general, an anecdotal report on a series of patients seen in one's own practice and a comparison of these patients to existing reports in the literature is not research and would not require IRB approval. Going beyond one's own practice to seek out and report cases seen by other clinicians creates the appearance of a systematic investigation with the intent to contribute to generalizable knowledge and, therefore, would be considered research and would require IRB approval.

**Single Case Report** – The external reporting (e.g., publication or poster/verbal presentation) of an interesting clinical situation or medical condition of a single patient. Case reports normally contain detailed information about an individual patient and may include demographic information and information on diagnosis, treatment, response to treatment, follow-up after treatment, as well as a

discussion of existing relevant literature. The patient information used in the report must have been originally collected solely for non-research purposes as the result of a clinical experience.

**Case Series** – The external reporting (e.g., publication or poster/verbal presentation) of an interesting clinical situation or medical condition in a series of patients (i.e., more than one patient). Case series usually contain detailed information about each patient and may include demographic information and information on diagnosis, treatment, response to treatment, follow-up after treatment, as well as a discussion of existing relevant literature. The information used in the report must have been originally collected solely for non-research purposes as the result of a clinical experience.

## 17.7 International Research

For international research where CMU is responsible for the conduct of the research in foreign countries, the IRB will review the research to assure adequate provisions are in place to protect the rights and welfare of the participants.

Approval of research is permitted if "the procedures prescribed by the foreign institution afford protections that are at least equivalent to those provided in 45 CFR 46."

All policies and procedures that are applied to research conducted domestically should be applied to research conducted in other countries, as appropriate.

The CMU IRB must receive and review the foreign institution's or site's IRB review and approval of each study prior to the commencement of the research at the foreign institution or site.

For federally-funded research, approval of research for foreign institutions or sites "engaged" in research is only permitted if the foreign institution or site holds an Assurance with OHRP and local IRB review and approval are obtained.

Approval of research for foreign institutions or sites "not engaged" in research is only permitted if one or more of the following circumstances exist:

1. When the foreign institution or site has an established IRB/IEC, the PI must obtain approval to conduct the research at the "not engaged" site from the site's IRB/IEC or provide documentation that the site's IRB/IEC has determined that approval is not necessary for the PI to conduct the proposed research at the site.
2. When the foreign institution or site does not have an established IRB/IEC, a letter of cooperation must be obtained demonstrating that the appropriate institutional or oversight officials are permitting the research to be conducted at the performance site.
3. IRB approval to conduct research at the foreign institution or site is contingent upon receiving documentation of the performance site's IRB/IEC determination or letter of cooperation, as applicable.
4. It is the responsibility of the CMU PI and the foreign institution or site to assure that the resources and facilities are appropriate for the nature of the research.

5. It is the responsibility of the CMU PI and the foreign institution or site to confirm the qualifications of the researchers and research staff for conducting research in that country(ies).
6. It is the responsibility of the CMU PI and the foreign institution or site to ensure that the following activities will occur.
    a. Initial review, continuing review, and review of modification
    b. Post-approval monitoring
    c. Handling of complaints, non-compliance, and unanticipated problems involving risk to subjects or others.

The IRB will not rely on a local ethics committee that does not have policies and procedures for the activities listed above.

7. It is the responsibility of the CMU PI and the foreign institution or site to notify the IRB promptly if a change in research activities alters the performance site's engagement in the research (eg, performance site "not engaged" begins consenting research participants, etc.).
8. The IRB will consider local research context when reviewing international studies to assure protections are in place are appropriate to the setting in which the research will be conducted.
9. In the case where there is no local IRB review, the IRB may require an expert consultant, either from the local country where the research is conducted or from an international organization, with the expertise or knowledge required to adequately evaluate the research in light of local context.
10. The informed consent documents must be in a language understandable to the proposed participants. Therefore, the IRB will review the document and a back translation of the exact content contained in the foreign language informed consent document which must be provided by the PI, with the credentials of the translator detailed in the IRB application or amendment form. Verification of the back translation should be made available for the IRB file.

### 17.7.1 Monitoring of Approved International Research

The IRB is responsible for the ongoing review of international research conducted under its jurisdiction through the continuing review process in accordance with all applicable federal regulations.

When the IRB and a local ethics committee will both be involved in the review of research, there is a plan for coordination and communication with the local ECs.

The IRB will require documentation of regular correspondence between the CMU PI and the foreign institution or site and may require verification from sources other than the CMU PI that there have been no substantial changes in the research since its last review.

## 17.8 Community-Based Research (CBR)

Community-based research is research that is conducted as an equal partnership between academic investigators and members of a community. In CBR projects, the community participates fully in all aspects of the research process. *Community* is often self-defined, but general categories of community include geographic community, community of individuals with a common problem or issue, or a community of individuals with a common interest or goal.

Where research is being conducted in communities, PIs are encouraged to involve members of the community in the research process, including the design and implementation of research and the dissemination of results when appropriate. The HRPP Office will assist the PI in developing such arrangements.

The following are some questions that PIs should ask as they develop CBR. These are also the questions that the IRB should consider when reviewing CBR.

*Background, purpose, objectives*

1. How was the community involved or consulted in defining the need?
2. Who came up with the research objectives and how?
3. Is this research really justified with respect to community concerns?
4. Are there concrete action outcomes?
5. Who benefits? How?

*Research methodology*

6. How will the community be involved in the research? At what levels?
7. What training or capacity-building opportunities will be built in?

*Procedures*

8. Will the methods used be sensitive and appropriate to various communities (consider literacy issues, language barriers, cultural sensitivities, etc.)?
9. How will scientific rigor and accessibility be balanced?

*Participants*

10. Are the appropriate people being included to get the questions answered (e.g., service providers, community members, leaders etc.)?
11. How will the research team protect vulnerable groups?
12. Will the research process include or engage marginalized or disenfranchised community members? How?
13. Is there a reason to exclude some people? Why?

*Recruitment*

14. What provisions have been put in place to ensure culturally-relevant and appropriate recruitment strategies and materials?

15. Have "power" relationships been considered in the recruitment strategies to minimize coercion?
16. Who approaches people about the study and how?

*Risks and potential benefits*

17. What are the risks and potential benefits of the research for communities? For individuals?
18. Are the risks (including risks to the community) being presented honestly?
19. How will risks be minimized?

*Privacy and confidentiality*

20. Where will data be stored? Who will have access to the data? How?
21. What processes will be put in place to be inclusive about data analysis and yet maintain privacy of participants?
22. What will be the rules for working with transcripts or surveys with identifying information?
23. How will boundaries between multiple roles (e.g., researcher, counselor, peer) be maintained?

*Compensation*

24. How will people be reimbursed for their time and honored for their efforts without it becoming coercive?
25. How will compensation be approached?
26. What provisions have been made for minimizing barriers to participation (e.g., providing for food, travel, childcare)?
27. Who is managing the budget? How are these decisions negotiated?

*Conflicts of interest*

28. What happens when the PI/research staff is the friend, peer, service provider, doctor, nurse, social worker, educator, funder, etc.?
29. How will power differentials be appropriately acknowledged and negotiated?

*Informed consent process*

30. What does informed consent mean for "vulnerable" populations (e.g., children, mentally ill, developmentally challenged)?
31. What processes are in place for gathering individual consent?
32. Is written informed consent being obtained? If not, explain why.
33. What processes are in place for gathering community consent?
34. Where minors are to be included as participants, how will assent be obtained?
35. Are the consent processes culturally sensitive and appropriate for the populations being included?

*Outcomes and results*

36. How will the research be disseminated to academic audiences?
37. How will the research be disseminated to community audiences?
38. What are the new ways that this research will be acted upon to ensure community/ policy/social change?

*Ongoing reflection and partnership development*

39. Is there a partnership agreement or memorandum of understanding to be signed by all partners that describes how they will work together?
40. What internal process evaluation mechanisms are in place?
41. When plans change to accommodate community concerns (as they invariably do in CBR), how will this be communicated to the IRB?