

Institutional Review Board
Penn State College of Medicine
Penn State Milton S. Hershey Medical Center

Assessing the Need for a Certificate of Confidentiality

Certificates of Confidentiality

Certificates of Confidentiality (CoC) are obtained for research in order to protect from compulsory disclosure by:

- Protecting investigators and institutions from being compelled to release information that could be used to identify research study participants;
- Allowing the investigator and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

CoCs are coordinated by various centers of the National Institutes of Health and the FDA. The research does not need to be sponsored or funded by a federal agency to apply for a certificate. More information about CoCs may be found on the NIH Kiosk, accessible from the IRB website, www.pennstatehershey.org/irb, under Links.

A CoC assessment should be made for research that proposes to collect identifying information that if released could have adverse consequences for the subjects, such as damage to financial standing, employability, insurability, or reputation. For example, this may include:

- Collecting genetic information
- Collecting information on psychological well-being of subjects
- Collecting information on sexual attitudes, preferences or practices
- Collecting data on substance abuse or other illegal risk behaviors
- Studies where participants may be involved in litigation related to exposures under study (e.g., breast implants, environmental or occupational exposures)

Framework for a Structured Assessment of the Risk of Compulsory Disclosure

First, identify the potential privacy risks associated with participation in the research. Next assess each of these risks for two factors, the magnitude of potential harm from compulsory disclosure and the probability of forced disclosure. It may help to rank the magnitude [or probability] on a scale from the least to greatest harm [or least to greatest likelihood]. These will be subjective judgments based on your own perceptions. Use this information to help you decide if the overall risk associated with compulsory disclosure is greater than minimal risk, as defined in the regulations. Finally, when determining if a CoC is necessary, consider what existing protections may already apply.

1. Identify the potential privacy risk(s) (e.g., disclosure of a positive test result)

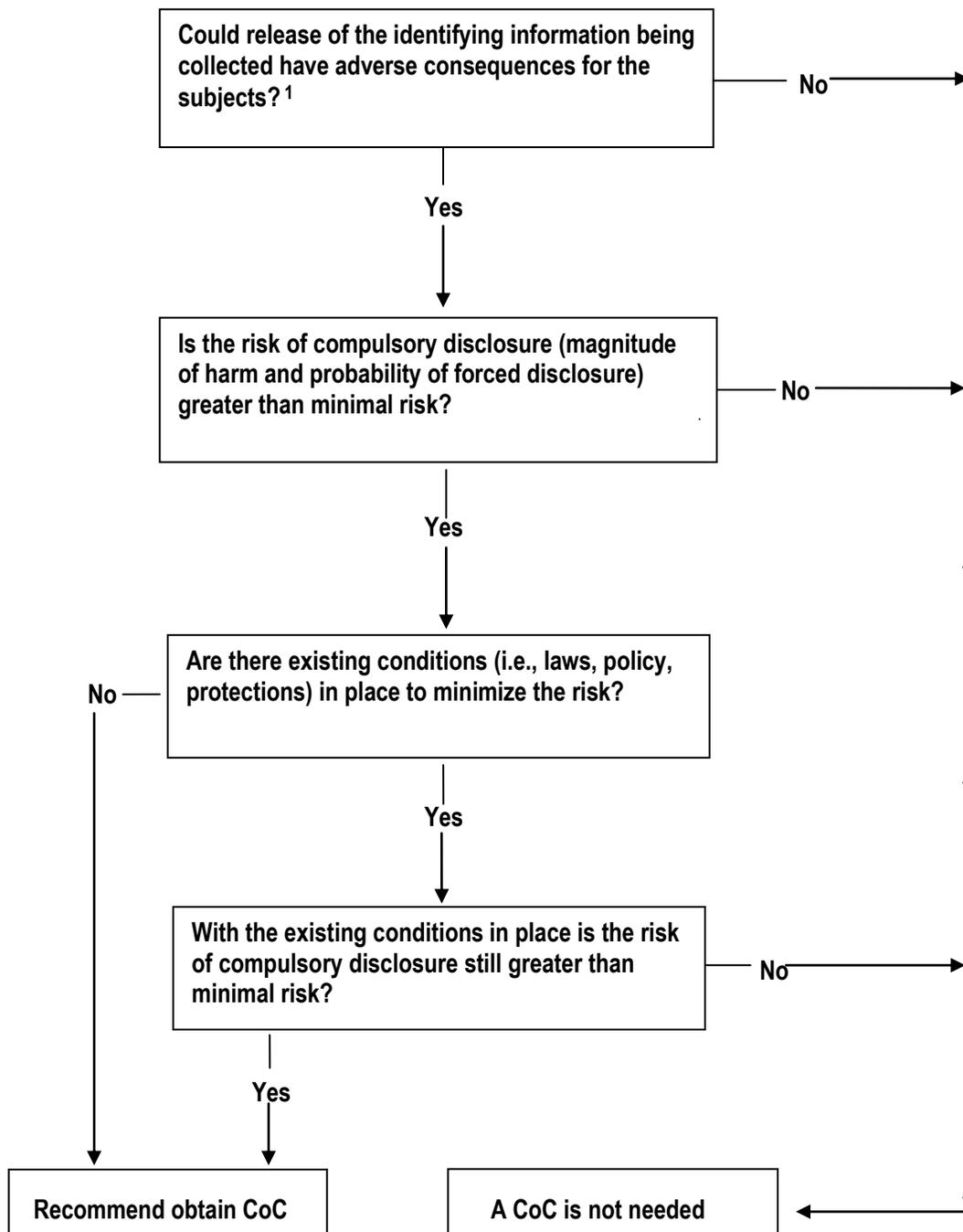
2. Assess the risk(s) relative to the potential harm and likelihood of compulsory disclosure

- **Assess the magnitude of potential harm caused by compulsory disclosure**
(i.e., amount of damage caused, duration of harm, permanency of consequences, affect on subject's lifestyle)
- **Assess the probability of compulsory disclosure**
- **Evaluate the overall risk of compulsory disclosure** – Is it greater than minimal risk?

2. Consider Existing Protections

Identify what existing legal protections are in effect and what types of information are eligible for those protections. Considering the protections already available can the research be practicably carried out without a CoC?

Structured Risk Assessment



Footnote: 1 Examples include: Research involving genetic testing for inherited diseases for research purposes and not clinical care; research that involves setting up a tissue/data repository; research that collects sensitive information.

EXAMPLE CASES

CASE 1

Collection of urine drug screens (including illicit drug use) in a therapeutic trial

The IRB reviews a protocol designed to assess the safety and efficacy study of a new chemotherapy agent in patients with breast cancer. The therapeutic study will be conducted at a university medical center and subjects will be recruited from throughout the U.S. At various points during the study, subjects' urine will be collected to screen for a variety of exclusionary criteria, including illicit drug use. Data will be recorded in identifiable form and will be in subject's medical records.

Structured Risk Analysis

- Privacy Risk = Compelled disclosure of a positive test result
- Magnitude of harm - Great; disclosure could include loss of employment or criminal prosecution
- Probability - Low probability that such harms will occur; in a therapeutic trial the protection of patients medical data (and protection from subpoena) are supported by existing law and policy.
- Risk level - This does not exceed minimal threshold.

Existing protections- Privacy for medical records is supported by law and institution policy. The hospital may have legal staff to assist in quashing subpoena.

Routine exams collect sensitive information, drug testing occurs regularly in daily life (i.e., by employers). Existing protections are in place. The IRB could choose to approve the research without requiring a CoC.

CASE 2-

Survey and urinalysis in IV drug users

Investigators plan to study the effectiveness of a needle exchange program on disease transmission among intravenous drug users (IDUs). Subjects will be recruited from homeless shelters and through word-of-mouth advertising. Among other procedures, subjects will be asked to complete a self-report survey on drug use and will undergo a urinalysis. The study is non-therapeutic, although subjects will be assisted in gaining access to rehabilitation programs.

Structured Risk Analysis

- Privacy risk = disclosure of data on illegal activity (purchase and use of drugs)
- Magnitude of harm - Great; could include criminal prosecution
- Probability - Great; primarily homeless individuals that engage regularly in illegal activity; subject population may be a target for law enforcement
- Risk level - Circumstances raise the risk of participation above those encountered in daily life

Existing protections - Non-therapeutic study; legal protections for research data are virtually nonexistent
Compelling rationale for the IRB to require a CoC; or the combination of high privacy risks and insufficient protection might preclude IRB approval of the hypothetical study

CASE 3-

Sample collection and Survey

Investigators plan to study sources of exposure to certain industrial chemicals, including dioxins, furans, and polychlorinated biphenyls or PCBs, by comparing data from subjects who reside in the flood plain of [named] river, 3 neighboring counties not in the flood plain, as well as elsewhere in the state. Subjects will be asked to complete a questionnaire /interview and provide a blood sample (less than 3 ounces), and to allow collection of house dust and soil samples. The consent form lists the physical risk of the blood sample and indicates that the interview will include questions about residential history, occupational history, recreational activities (e.g., fishing), and diet, and clarifies that nothing potentially embarrassing (e.g., use of illegal drugs or other criminal behavior) will be asked.

Structured Risk Analysis

- Privacy risk = disclosure of industrial chemicals in subjects blood or associated with their property
- Magnitude of harm - Great; could impact their employment, health insurance, ability to sell property
- Probability - Great; results of the study may be of interest to local industries for litigation purposes
- Risk level - Circumstances raise the risk of participation above those encountered in daily life

Existing protections - Not a therapeutic study, so existing legal protections for the research data don't apply
Compelling rationale for additional protection and a CoC was required by the IRB in this real life case