



# SUFFOLK UNIVERSITY

INSTITUTIONAL REVIEW BOARD

<b>SUBJECT:</b> Certificates of Confidentiality	<b>POLICY #:</b> 0008
<b>APPROVED BY:</b> <i>D. H. [Signature]</i> IRB Chair	<b>PAGE:</b> 1 of 3
<i>S. [Signature]</i> Institutional Official	<b>EFFECTIVE DATE:</b> 02/26/09

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## I. PURPOSE

To establish Suffolk University policy regarding the IRB approval process for human subjects research that necessitates obtaining a Certificate of Confidentiality, in accordance with the Public Health Service Act, §301(d), 42 USC 241(d), "Protection of privacy of individuals who are research subjects."

## II. APPLICABILITY

This policy shall apply to all human subjects research directed or performed by any Suffolk University faculty or staff member, student, volunteer, or other agent in connection with his or her institutional responsibilities or educational program, whether or not the research is carried out on Suffolk University premises.

## III. POLICY

- A. All human subjects research investigators that are planning to obtain identifiable sensitive information as part of the research protocol, **and have a reasonably foreseeable risk of being subpoenaed**, must apply for a Certificate of Confidentiality from the appropriate issuing organization, regardless of funding status or agency.
- B. Sensitive information includes, but is not limited to the following:
  1. Information regarding sexual attitudes, practices, or preferences;
  2. Information relating to the use of drugs, alcohol, or other addictive substances;
  3. Information about illegal conduct;

4. Information that, if released, might be damaging to an individual's financial standing, employability, or reputation within the community;
5. Information that might lead to social stigmatization or discrimination;
6. Information pertaining to an individual's psychological well-being or mental health; and
7. Genetic information or tissue samples.

C. The protocol must contain additional mechanisms and procedures for protecting the privacy and confidentiality of participants besides a Certificate of Confidentiality, in accordance with the requirements set forth in 45 CFR §46.110. A protocol that plans to apply for a Certificate of Confidentiality may be eligible for expedited review, provided that the protocol is in compliance with the criteria listed in both 45 CFR§ 46.110(b) and the Office for Human Research Protections document "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure."

D. The IRB Submission Process

1. Any Principal Investigator (PI) who plans to apply for a Certificate of Confidentiality must have his/her protocol reviewed and approved by the Suffolk University IRB before the application can be submitted to the issuing agency.
2. Once the research protocol is reviewed and approval is finalized, the IRB will approve the protocol contingent upon the issuance of a Certificate. The PI and research team may not begin data collection until a Certificate has been issued.
  - a) If the research is under a deadline or time constraint, the PI should include a statement in their RAR Form detailing the risks and difficulties to the study of waiting to begin until after the Certificate has been issued.
3. The protocol will be given a continuing review date of four months from the date of approval, to accommodate the Certificate application submission requirements as set out by the National Institutes of Health. At that time, the following options are available to the IRB:
  - a. If the Certificate has been issued, the PI will provide a copy to the IRB Administrator for the protocol records. The protocol will be approved for renewal and given a new continuing review date.
  - b. If the Certificate application is still in process or undergoing revision, the protocol status will remain as is. The IRB will set a new continuing review date at one month, and the protocol will be reviewed again at that time.
  - c. If the Certificate application has been denied, the PI may choose to either withdraw the protocol, or submit a modification to the

study protocol and consent form removing the language regarding the Certificate, and specifically stating that any sensitive information is confidential within the limits of the law, and will be disclosed if subpoenaed by a court of law. The IRB will then review the protocol again, considering the denial's impact on the risk-benefit analysis of the protocol.

E. The Suffolk University IRB **requires that the PI include in the consent form all exceptions** to the Certificate of Confidentiality. These include:

1. Voluntary disclosure by research participants themselves, or any disclosure that the participant has consented to in writing, such as to insurers, employers, or other third parties;
2. Voluntary disclosure by the PI in accordance with Massachusetts state law regarding mandated reporting (MGL c. 19C, §10; MGL c. 19A, §15; MGL c. 119, §51A; MGL c. 111, §3 and c. 111B; MGL c. 111, §6; MGL c. 112, §12A; MGL c. 111, §67A; MGL c. 111, §202; 29 CFR., Part 1910; 42 U.S.C. §300aa.25) and duty to warn (MGL c. 123, §36B).
3. Release of information by the PI to the Department of Health and Human Services as required for audits or program evaluation; and
4. Release of information to the FDA as required under the Food, Drug, and Cosmetic Act (21 USC§301 et seq.).