

# Criteria For Approval

45 CFR 46.111

25 CFR 56.111

- Minimized risks
- Reasonable risk/benefit ratio
- Equitable subject selection
- Informed consent process
- Informed consent documentation
- Data monitored for safety
- Confidentiality/privacy maintained
- Vulnerable populations protected

# Review Criteria

45 CFR 46.111

21 CFR 56.111

- (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

# Belmont Principles

- **Respect for persons**
- Beneficence
- Justice

# Declaration of Helsinki 2000

## Principle 21

“The right of research subjects to safeguard their **integrity** must always be respected. Every precaution should be taken to respect the **privacy** of the subject, the **confidentiality** of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.”

# Privacy

- **1 a** : the quality or state of being apart from company or observation
- **b** : freedom from unauthorized intrusion <one's right to *privacy*>
- Doing something to a person or seeing their information



# Clinical Research Times 5/04

- *Privacy* is the freedom from unauthorized intrusion – the right to be left alone. In many research settings, privacy translates to the right of a person to control who has access to information about him or her. In clinical research, this usually means that the researcher may not perform any procedures or access any personal information about a person without that person's consent.

# Identifiable Private Information

- *Identifiable private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place, and information which has been provided for specific purposes by an individual and which the **individual can reasonable expect will not be made public** (for example, a medical record)

# Confidentiality

- Confidential → secret:
- 1 a : kept from knowledge or view
- Telling someone's information to others





# Clinical Research Times 5/04

- *Confidentiality* is the ability to keep something secret. In IRB terms, this relates to an investigator's responsibility to **prevent the unauthorized disclosure of information** without permission of the research subject. A breach of confidentiality will harm the trust relationship between the subject and the researcher that will be difficult to mend.

# HIPAA

- Mostly redundant with IRB requirements
- Formalizes and standardizes information provided to subjects
- Research HIPAA has different requirements than clinical HIPAA ([www.bumc.bu.edu/hipaa](http://www.bumc.bu.edu/hipaa))

# INSPIR: Section K

1. Will research data include elements which will allow the subjects to be **identified**? [**master code list**?]
2. **Where** will research data be kept? **How** will such data be secured? **How long** will it be kept? **How and when** will it be destroyed?
3. **Who**, besides the PI, the study staff, the IRB and the sponsor, will have access to identifiable research data?
4. State what **steps** will be taken to maintain confidentiality of data and privacy (or anonymity) of subjects.
5. Will you obtain a **Certificate of Confidentiality** for this study?
6. Research is exempt from the Privacy Rule if there will be no collection of protected health information and/or the PI is not a member of a HIPAA covered workforce. Is this research subject to the **HIPAA Privacy Rule**?

# Certificates of Confidentiality

The screenshot shows a Microsoft Internet Explorer browser window. The address bar contains the URL <http://www.hhs.gov/ohrp/humansubjects/guidance/certconf.htm>. The page content includes a note that the guidance replaces the 9/1998 OHRP guidance, followed by the title "Guidance on Certificates of Confidentiality" and a date of February 25, 2003. The page also defines the scope, target audience, and background of the guidance.

**NOTE: THIS GUIDANCE REPLACES THE 9/1998 OHRP GUIDANCE: "Privacy Protection for Human Research Subjects, Certificates of Confidentiality"** [CLICK HERE](#). **THIS GUIDANCE HAS BEEN UPDATED IN FORMAT, PROVIDES EMPHASIS ON LIMITATIONS OF THE CERTIFICATES OF CONFIDENTIALITY, AND PROVIDES LINKS TO RELEVANT MATERIALS ON THE NATIONAL INSTITUTES OF HEALTH (NIH) WEBSITE.**

**Office for Human Research Protections (OHRP)**  
**Department of Health and Human Services (HHS)**

**Guidance on Certificates of Confidentiality**

**Date:** February 25, 2003

**Scope:** The purpose of this document is to provide guidance about Certificates of Confidentiality and assistance in locating resources for obtaining a Certificate of Confidentiality to protect the privacy of research subjects.

**Target Audience:** Institutions, institutional review boards (IRBs), and investigators.

**Background:** The Public Health Service Act §301(d), 42 U.S.C. §241(d), "Protection of privacy of individuals who are research subjects," states:

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.

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.

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# Section E – Vulnerable Subjects?

- Vulnerable populations require special protections. How will you obtain informed consent, **protect subject confidentiality**, and prevent undue coercion?

# Reviewers' Template

http://www.bumc.bu.edu/www/bumc/irb/images/IRBReview\_NewApp.doc - Microsoft Internet Explorer

File Edit View Insert Format Tools Table Go To Favorites Help

Back Forward Stop Home Search Favorites Refresh Print Mail New Tab

Address http://www.bumc.bu.edu/www/bumc/irb/images/IRBReview\_NewApp.doc Go Links >>

7. If requesting waiver of documentation of the Informed Consent process, does the study meet one of the two CFR criteria?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Is the consent form in lay language (i.e., 8 <sup>th</sup> grade level or below)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Is the informed consent form correctly formatted and include all basic elements per the BUMC Consent Form Checklist?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Comments:</b>			
<b>SECTION K: CONFIDENTIALITY</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>
1 Will the investigator(s) collect sensitive information about the subject?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Are adequate provisions in place to protect privacy/confidentiality?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Will participation be documented in subject's institutional medical record (including a copy of the consent/assent form(s)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Are issues related to the Privacy Rule adequately addressed in the protocol, consent/assent form(s) and the IRB application?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Comments:</b>			
<b>SECTION L: COST/PAYMENT</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>
1. Are costs/potential costs to be incurred by the subject or the subject's insurance clearly described?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. If subjects are to be paid (money, gift certificates, coupons, etc) is the method of disbursement clearly described and equitable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Is there a plan for reimbursement should a subject withdraw from the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Comments:</b>			
<b>SECTION M: GENETICS</b>	<b>YES</b>	<b>NO</b>	<b>N/A</b>
1. Does the research involve genetic testing?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Unknown Zone

# Clinical Research Times 5/04

Does the researcher have the subject's permission to invade the subject's privacy by performing a research procedure or accessing private information?

Why is it necessary to obtain an identifier?

Are there subtle identifiers in this study due to the design and sample size?

Where will the identifiers be stored? What is the security at this storage site?

Who has access to the coding list? How is that list protected?

Who might monitor the research data and thus may see identified private information?

With whom are the data being shared? What data are being shared? What is the security of the data during transmission to another site?