

Certificate of Confidentiality

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Research Compliance Office



Confidentiality and Research

- Criteria for IRB Approval of Research
 - Privacy of subjects and confidentiality of data is protected
- General Requirement of Informed Consent
 - Confidentiality of records



The IRB is charged with ensuring adequate protections to subjects and their information

HIPAA

which involves...

- **Privacy rule** : covered entities and disclosure of PHI
- **BUT permits** disclosure in response to judicial orders
- **Informed Consent** lets subjects know who could access their information

Certificate of Confidentiality moves....

Beyond →



CoC (Certificate of Confidentiality)

What is it?

How is it obtained?

What type of research is it used for?

NIH/IRB considerations?

What is a Certificate of Confidentiality (CoC)?

Document obtained from the National Institutes of Health (NIH) that:

- **Protects institutions/investigators** from being forced to disclose sensitive information
- May be needed to **protect participants** from the risks of external investigative or judicial processes



Note : CoC is NOT an endorsement by the DHHS or NIH

How are CoCs obtained?

- Issued based on applications (from PD) for specific research projects
- May/may not be federally funded research
- Awarded to institutes/universities where research is conducted

For multi site projects lead institution obtains CoC on behalf of all sites



A CoC is used for research that is...



Research that could have adverse legal consequences for subjects or damage their financial standing, employability, insurability or reputation

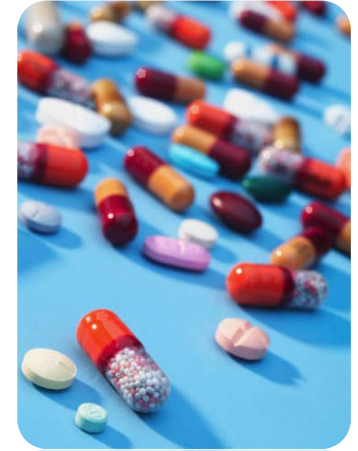
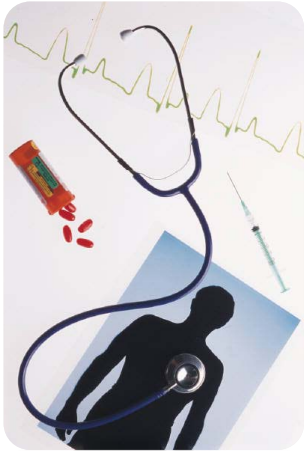
CoCs can be used for

Research that involves the gathering of sensitive information, on topics such as:



- Psychological well-being of subject
- Sexual attitudes, preferences or practices (e.g., impact of “Don’t Ask, Don’t Tell” on military personnel)
- Substance abuse or illegal risk behaviors
- Involvement in litigation related to exposures under study (e.g., exposure to cigarette smoke)

Research that involves, cont.

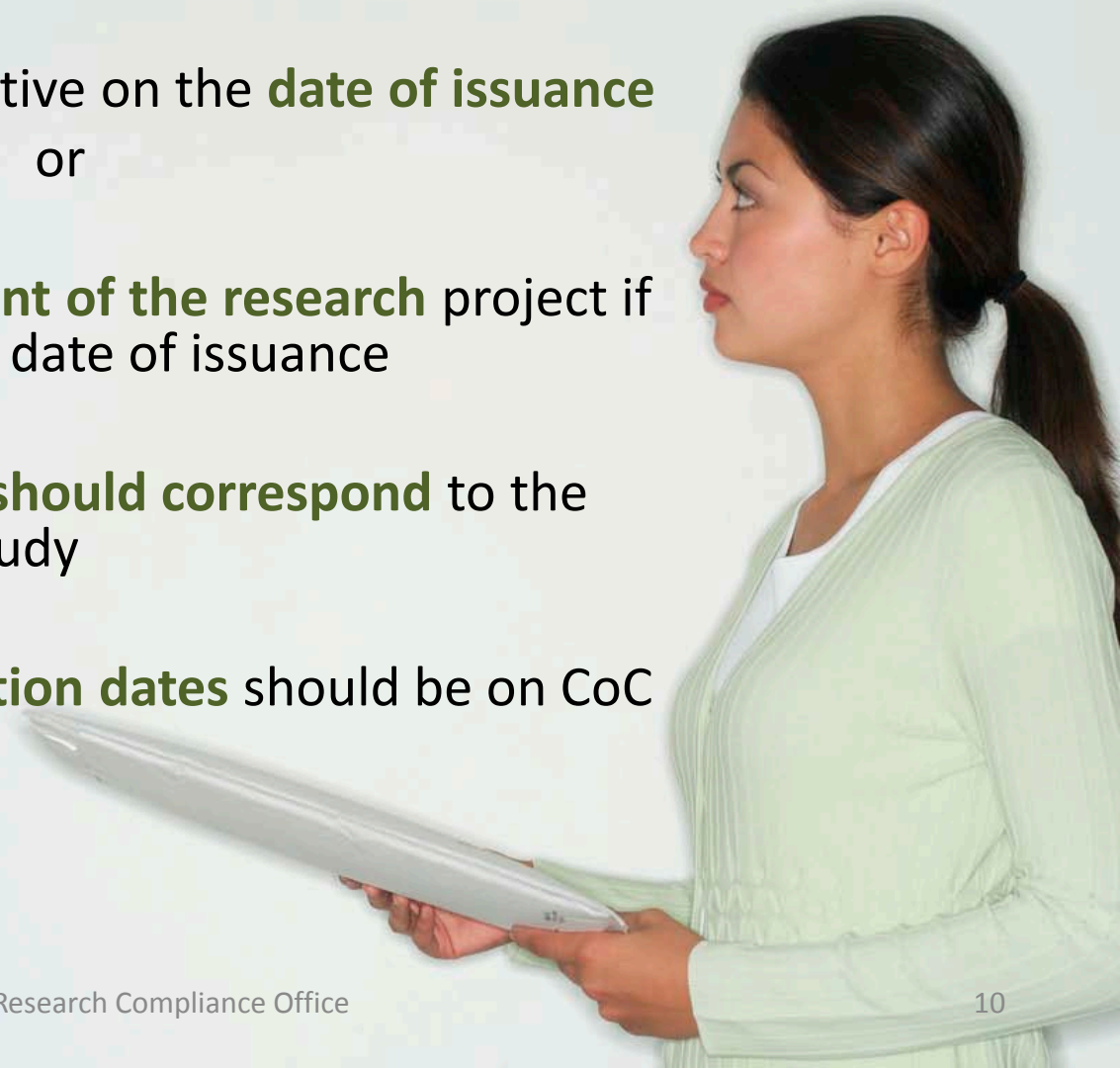


- HIV, AIDS and STD's
- Genetic information and studies
(including collected/stored samples that may be used for future studies)
- Behavioral interventions
- Epidemiological studies
- Use of alcohol, drugs or other addictive products



How long does protection last?

- Certificates are effective on the **date of issuance** or
- **Upon commencement of the research** project if that occurs after the date of issuance
- The expiration date **should correspond** to the completion of the study
- **Effective and expiration dates** should be on CoC





How long does protection last?

Protection afforded for the data by the certificate **is permanent** (protected in perpetuity)

Applies even if the subject gave the researcher data **before** the Certificate was issued

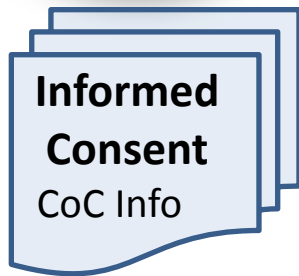




NIH requires:



- IRB approval
(or IRB approval conditioned upon issuance of a CoC)



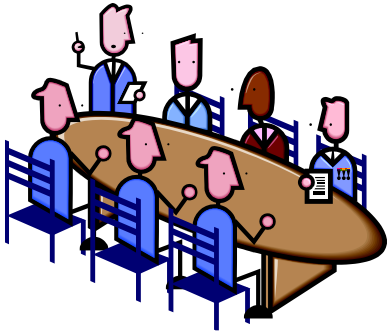
- Copy of informed consent form as it would read if a CoC is obtained



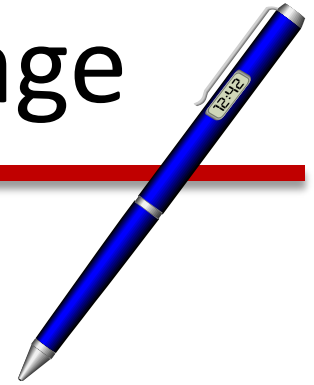
- Signature of Institutional Official

IRB Requirements - Panel

- Consider if study may require CoC
- Consider language that is in the informed consent:
 - Ensure the participants **understand the limitations and protections** of a CoC
 - Language in the CoC should **not appear to be an endorsement** by the DHHS
 - **Look for language** consistent with NIH's recommended language



NIH Recommended Language



- “To help us protect your privacy, we have obtained a Certificate of Confidentiality from the NIH...”*
- “ Researchers cannot be forced to disclose information that may identify you, even by a court subpoena...”*
- “...Cannot be used to resist a demand for info from the U.S. Government that is used for auditing/evaluation of Federally funded projects or FDA”*
- “...Does not prevent you or a member of your family from voluntarily releasing information...”*
- “...disclosure about things such as child abuse, intent to hurt self or others...”*

http://grants.nih.gov/grants/policy/coc/appl_extramural.htm

PD: I'm collecting data from subjects recruited in a foreign country. Can I get a Certificate of Confidentiality?



<http://www.google.com/imgres?imgurl=http://www.lindacifford.com/images/KiltGuys.jpg>

Yes, if the data are maintained within the U.S.
If the data are maintained only in the foreign country, a Certificate of Confidentiality would not be effective.

Is the NIH required to give all who apply a Certificate of Confidentiality?

No. The NIH uses its discretion regarding issuance of CoCs.

Ineligible studies can include projects that:

- ▶ are not research based
- ▶ do not collect sensitive information
- ▶ do not collect personally identifiable information



Has a CoC ever been legally challenged?



There have been very few reported cases.

In 1973 the certificate's authority was upheld in the NY Court of Appeals. The U.S. Supreme Court declined to hear the case.