IV. Framework for Analysis

[***to be written after full Commission discussion***]

This chapter will describe the framework used by the Commission to help it formulate recommendations. This includes consideration of the distinctions between the collection of tissue samples in routine clinical care versus research, previously collected samples versus those to be collected in the future, anonymized versus identifiable tissues, the consent process, the role of Institutional Review Boards, the appropriateness of community consultation, and measures to ensure confidentiality and restricted access to tissue samples. (See tables.)

Tissue Samples Collected in Clinical Care or with No Known Research vs. Research Studies

Distinction Between Previously Collected Samples and Samples Collected in the Future

Distinctions Between Anonymized versus Identifiable Tissues

Informed Consent and Disclosure

Federal consent requirements for medical treatment and human research

Physician/patient and researcher/subject relationships

Necessary components of informed consent

Scope of consent
- description of intended use of samples
- anonymized/identifiable
- identifiable harms
- possible research/clinical outcomes (therapeutic expectations)
- access to tissues
- duration and storage of tissues
- fully informed, general informed, implied, opt out
- freedom to withdraw from research

recontact - NHANES/CDC example

Disclosure in the research setting

HIV example - OPRR mandate that all research subjects tested for HIV infection must be informed of their results if the result an be lined to the subject.

Community consultation

The Role of Institutional Review Boards

Provision of Confidentiality and Privacy

general issues concerning medical records

DHHS report on "Confidentiality of Individually-Identifiable Heath Information"

identifiability/security issues

"Two-way" track

"One-way" track

Research Using Previously Collected Samples

(boxes 1A,1B,2A,2B,3A,3B)

(discuss why purpose at time of sample collection is not an issue)
- to be used in an anonymous manner vs. to be used so identification is possible
- individual vs. community
- no potential harms versus potential harms

Research Using Samples Collected in the Future

(boxes 1C,1D,1E,1F,2C,2D,2E,2F,3C,3D,3E,3F)

- purpose at time of collection (clinical care or no known research vs. research) vs. to be used so identification is possible
- individual vs. community

- no potential harms versus potential harms