SESSION 3

CONSENT PROCESS

SPECIAL POPULATIONS

CONSENT

Common Rule

- Current provisions of the Common Rule provide only basic information about the elements of informed consent and how consent documents should be written. Many consent forms are too long and hard to understand, and fail to include some of the most important information.

ANPRM

- The regulations would be revised to provide greater specificity about how consent forms should be written and what information they should contain. The goal would be consent forms that are shorter, more readily understood, less confusing, that contain all of the key information, and that can serve as an excellent aid to help someone make a good decision about whether to participate in a study

BIOSPECIMENS AND RICH DATA SOURCES

Common Rule	ANPRM
• Research using existing biospecimens (clinical or from prior research) can be done without consent by stripping the specimens of identifiers	• Reforms would require written consent for research use of biospecimens, even those that have been stripped of identifiers. Consent could be obtained using a standard, short form by which a person could provide open-ended consent for most research uses of a variety of biospecimens (such as all clinical specimens that might be collected at a particular hospital). This change would only apply to biospecimens collected after the effective date of the new rules