Consent Updates – Research Sample Repository and Research Database

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Outline

• Consent form changes
  – Research Sample Repository
  – Research Database

• Drivers of the consent form changes
  – NIH Genomic Data Sharing Policy
  – HRSA requirements to post publication analysis files
  – NIH Certificate of Confidentiality
  – Revised Common Rule consent form requirements
Consent Form Changes

• Research Sample Repository
  – Genome sequencing may be done on the sample
  – Data may be broadly shared in other scientific databases
  – Research results will not be shared
  – Potential to use samples in commercial projects, no sharing profits

• Research Database
  – Data are protected by a Certificate of Confidentiality
  – Data may be broadly shared in other scientific databases
NIH Genomic Data Sharing Policy

• Effective January 25, 2015
• Ensures the broad and responsible sharing of genomic research data
• Applies to all NIH funded human and non-human genomic projects
  – Must submit data generated to NIH database of Genotypes and Phenotypes (dbGAP)
  – Application must include a data sharing plan
  – Includes NIH funded studies that analyze samples from the Research Sample Repository
NIH Genomic Data Sharing Policy

• Controlled-access database
  – NIH must approve the secondary research project

• Unrestricted-access database
  – Publically available to anyone; no approval needed to access data

• IRBs required to review informed consent document prior to submission to determine
  – If broad data sharing and secondary research is allowed
  – Which database is most appropriate for submission
NIH Genomic Data Sharing Policy

• After effective date consent form must explicitly state
  – Genotypic and phenotypic data will be generated
  – Data will be shared broadly for future research

• Prior to effective date IRB can determine if “submission is not inconsistent with the consent form”
NMDP IRB Process

• IRB reviewed all versions of the Research Sample Repository and Research Database consents forms to determine if
  – Broad sharing of data for secondary research allowed
  – Genetic research allowed

• Review Conclusions
  – All but most recent versions of consents meet policy requirements
  – Consents versions dated after January 25, 2015 didn’t meet policy requirements – data can’t be submitted
  – Data can only be placed in controlled access database and used for transplant and cellular therapy-related studies
NMDP IRB Data Sharing Policy

• Review conclusions formalized into policy
• Policy shared with investigators accessing CIBMTR research samples for NIH genomic research
• Data sharing plans reviewed and approved by the CIBMTR Director of Immunobiology & Observational Research prior to submission to NIH
• Institutional certifications must rely on the NMDP IRB assessment of informed consent compliance with NIH Genomic Data Sharing policy
HRSA Requirement for Publication Analysis File

• Proposal still under development but will address
  – Posting de-identified datasets for CIBMTR published studies
  – Making datasets available to the public to recreate and validate the analysis for specific studies

• Changes to research database consent form are in support of proposal
NIH Certificate of Confidentiality

• CoCs protect researchers and institutions from being compelled to disclose information in response to legal demands that would identify research subjects
• NIH has issued CoCs for many years but investigators were required to apply for one
• As of October 1, 2017, NIH automatically issued CoCs to all funded research projects
• Research Database is funded by NIH, so issued a CoC
• Added the CoC language to the database consent form
NIH Certificate of Confidentiality

• Research Sample Repository not NIH funded so not automatically issued a CoC

• Exceptions
  – NIH funded projects that use CIBMTR samples
  – Data from CIBMTR samples submitted to dbGAP

• Within in the coming year, CIBMTR will apply for a CoC

• Increasingly important as more genetic data being generated from samples

• Will update repository consent form when CoC is issued
Revised Common Rule – Consent Form

• Include statement in the consent form addressing if
  – Potential for identifiers to be removed from biospecimens and used for future research without additional consent
  – Biospecimens might be used for commercial purposes and if subject would share in any profits
  – Research results will be returned to the subject
  – Genome sequencing might be done on biospecimens

• Added to the Research Sample Repository consent form in anticipation of the new rule implementation
QUESTIONS