

## Facilitating Collaboration with Informed Consent and IRB Approval: Lessons from the Candidate-gene Association Resource (CARE)

- ✓ CARE combines nine cohorts to create a shared resource comprising 50,000 person cohort genotyped for candidate gene SNPs and merged with harmonized phenotype data
- ✓ Studies were older and consent was variable from fairly restrictive to unrestricted
- ✓ Lessons learned:
  1. The most useful informed consent provides unrestricted use/sharing of data/samples
  2. Layered consent requires heavy documentation, tracking and inefficiencies
  3. IRB approval for older studies depends almost completely on the letter from OHRP to the NIH Director of Science Policy (10-23-06) that states “NIH will not be considered engaged in human subjects research under the HHS regulations at 45 CFR part 46 for its creation and maintenance of the GWAS repository... based upon ... the data submitted to the GWAS Data Repository will not be collected specifically for inclusion into the database, and will be coded in such a way that the data would not be individually identifiable to the investigators maintaining the repository.”
  4. Some studies will request additional assurances including
    - ✓ application approval process
    - ✓ data access agreements
    - ✓ computer security requirements
    - ✓ restricted use terms (time, variables)
    - ✓ IRB approval for accessing investigator
    - ✓ manuscript administrative review
    - ✓ certificates of confidentiality for data sharing resource
    - ✓ legislation to make genetic discrimination illegal
  5. Study ethics boards or other mechanism may be needed for some communities