Updates

- webIRB
- NIH Genomic Data Sharing
webIRB

- Two upcoming deployments
- Usual information & guidance
- Integration with CRMS
webIRB

- Re-ordering of some questions
- Changes to some choices
  - e.g. Clinical Trial Phase
- Additional questions
  - IND/IDE
  - Attachments on amendments
- Back end changes
  - Administrative Closure
webIRB

- Next deployments
  - HIPAA
  - Chart Review
  - Reliances
NIH GDS

- Replaces prior Genome-Wide Association Studies policy
- Detailed UCLA guidance coming soon
NIH GDS

- Applies to:
  - NIH-funded projects generating large-scale genomic data
  - Any project involving genotypic/phenotypic data for submission to NIH repositories (such as dbGaP)
NIH GDS

- For new grant proposals
- PI needs to include:
  - Basic plan for GDS compliance OR
  - Explanation why broad sharing not possible

- Just-In-Time documentation:
  - IRB approval
  - Institutional Certification
    - With authorizing signature
NIH GDS

- Informed Consent
  - Needed
  - To include broad sharing
  - Mentions NIH databases
  - Describes confidentiality protections
NIH GDS

- Detailed guidance coming
- SOM work on consent
- Questions- contact me directly:
  - Kip Kantelo
  - x55855
  - kip.kantelo@research.ucla.edu
Thank you!

❖ For questions:
  • North & South General IRBs
    ❖ x57122
    ❖ gcirb@research.ucla.edu
  • Medical IRBs
    ❖ x55344
    ❖ mirb@research.ucla.edu