

OHRPP Updates

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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:
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Thank you!

❖ For questions:

- **North & South General IRBs**
 - ❑ x57122
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