



Human Subjects

Office of Research

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Reporting HIV



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OHRP AIDS Research, Guidance for IRBs

- IRBs should consider what information will be recorded in the subjects medical records, and may wish to minimize the recording of data from AIDS related studies in the medical records.
- Some states or other jurisdictions may require AIDS to be reported and may require follow-up.
- Participation in research does not exempt compliance with those laws, but potential study participants must be fully informed of laws requiring disclosure of information before they volunteer for the studies.

Georgia HIV/AIDS Epidemiology Section

- All health care providers diagnosing and/or providing care to a patient with HIV have the obligation to report them.
- All laboratories certified and licensed by the State of Georgia are required to report laboratory test results indicative of HIV infection, such as positive antigen/antibody tests, type differentiating tests, viral load tests (detectable and undetectable), CD4 counts, and viral nucleotide sequence results.
- Both lab-confirmed and clinical diagnoses are reportable within 7 days

HIV Testing Laws for Clinicians – Georgia

- Informed Consent is Required
- Pre-test counseling and post-test medically appropriate counseling with confirmed HIV positive test result are required
- Physician may notify spouse, sexual partner or any child of the patient, spouse, or sexual partner of possible HIV exposure
- Physicians may, but are not required to, notify the parents of the HIV test result.

Georgia Department of Public Health – Rapid HIV Testing Protocols and Quality Control

- Counselors should explain the difference between “confidential” and “anonymous”
 - Confidential test positive – must report
 - Anonymous – no report
- Counselors must explain that if they test confidentially, a positive HIV test result is reported to the state and/or local county health department.

Rapid Screening Testing

- After a positive HIV test result, a follow-up test is conducted. If the follow-up test is also positive, it means you are HIV positive.
- Question – are investigators providing the follow-up test?

Summary

- IRBs must evaluate researcher and collaborator (if any) roles and determine if reporting is required by law.
 - If reporting is required by law, the IRB must review and approve the process and materials, if any.
- IRBs should assess plans regarding return of results in context of the reporting requirements and other ethical considerations