



Purpose

The purpose of this guidance is to inform researchers about the requirements related to reportable diseases and to provide template language for inclusion in the consent form to inform subjects of these reporting requirements.

Identifying and Reporting Infectious Diseases

Please carefully review your research protocol and determine what reportable diseases will be tested for as part of a subject's participation in the research. Please ensure any testing for reportable diseases required for the research is specifically identified as a research procedure in the protocol and consent form.

If your research protocol involves initial or ongoing testing for any of the communicable diseases identified as reportable by the City of Philadelphia's Department of Public Health or Pennsylvania's Department of Health's you are responsible for reporting positive test results as outlined in the applicable reporting requirements.

- City of Philadelphia Department of Public Health's list of notifiable diseases and conditions: <https://hip.phila.gov/ReportDisease/WhatToReport>
- Pennsylvania Department of Health list of notifiable diseases and conditions: <http://www.health.pa.gov/Your-Department-of-Health/Offices%20and%20Bureaus/epidemiology/Pages/Reportable-Diseases.aspx#.V7YE400rIdV>

Please see the Philadelphia City of Philadelphia Health Department's guidance on how to report: <https://hip.phila.gov/ReportDisease/HowToReport>.

If you're testing for HIV/AIDS, please review the PA Department of Health's information for reporting AIDS, HIV, CD4 T-lymphocyte counts and perinatal exposure of newborns to HIV: <http://www.pacode.com/secure/data/028/chapter27/s27.32a.html>.

Consent Form

The consent form needs to inform subjects which tests are being performed for research purposes that are considered reportable to the City/State Departments of Health. To assist researchers with appropriately informing subjects about reportable diseases and the applicable notification requirements, the IRB has developed template language for the consent form. This language is required for all studies that include testing for reportable diseases specifically for research purposes.

In order to adequately inform subjects please ensure your consent form includes the following:

- A listing of all reportable tests in the "Procedures" section of the informed consent form
- The required language related to notification of reportable tests in the "Confidentiality" section of the consent form

Template Language for the Consent Form

***Please Note: This language is also available in the IRB's biomedical consent form template located on the IRB's website at the following link: <http://www.upenn.edu/IRB/forms>.*



University of Pennsylvania – Institutional Review Board
Reportable Diseases: Requirements for Reporting & Informing Subjects

If you test positive for <add any reportable infectious diseases for which testing will be performed specifically for research>, by law we have to report the positive test results to the City of Philadelphia Health Department and/or the PA Department of Health. Personal identifiers such as name, sex, date of birth, address, and phone number will be reported. For more information about the requirements reporting infectious diseases to the City of Philadelphia Health Department, please visit <https://hip.phila.gov/ReportDisease>. For more information about the requirements reporting infectious diseases to the PA Health Department, please visit <http://www.health.pa.gov/Your-Department-of-Health/Offices%20and%20Bureaus/epidemiology/Pages/Reportable-Diseases.aspx#.V620aZ3D9eU>.