Penn
University of Pennsylvania
Human Research Protections Program

Reportable Diseases Guidance: Guidance for Protocol Required Testing, Informed Consent Language, and Requirements for Reporting Positive Cases

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.

Exclusion of Patients with Infectious Diseases

The Penn IRB does not support the blanket exclusion of participants with infectious diseases from research protocols. Exclusion of these patients slows development of effective, generalizable therapies, and restricts a population from receiving potential benefit from new trials.

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

In alignment with the ethical principle of justice, research inclusion/exclusion criteria should be centered around:

- Mechanism of action of the drug;
- Targeted disease or patient population;
- Anticipated safety of the investigational drug;
- Ability to recruit trial participants from the population.

If it is vital to exclude patient populations with infectious diseases for safety or scientific reasons, testing should be implemented. This is because some patients are unaware of their positivity. Additionally, absence of results from the medical record is not a confirmation that the patient does not have an infectious disease. Namely, if there is a scientific reason for exclusion on protocols with small sample sizes, the results could be contaminated if an individual with an infectious disease was included on the protocol. Moreover, if the rationale for exclusion is due to participant safety reasons, a participant could be exposed to the risks of the study unnecessarily, and the risk benefit ratio of their inclusion on the study could be unacceptable.

Identifying and Reporting Infectious Diseases

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, 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, and Guidance on How to Report: https://hip.phila.gov/report-a-disease.
- Pennsylvania Department of Health list of notifiable diseases and conditions: www.health.pa.gov/topics/Reporting-Registries/Pages/Reportable-Diseases.aspx

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: 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, and
- 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 template located on the IRB's Forms and Templates webpage: https://irb.upenn.edu/forms.*

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/report-a-disease. For more information about the requirements reporting infectious diseases to the PA Health Department, please visit www.health.pa.gov/topics/Reporting-Registries/Pages/Reporting-Registries.aspx.

References

- Amdur, R., & Bankert, E. (2011). *Institutional Review Board Member Handbook* (3rd ed.). Sudbury, MD: Jones & Bartlett Publishers.
- Schiller, L. J.: Food and Drug Administration, HHS.; *Cancer Clinical Trial Eligibility Criteria: Patients With Human Immunodeficiency Virus, Hepatitis B*

Virus, or Hepatitis C Virus Infections; Draft Guidance for Industry; Availability. Dated 3/13/2019