

Guidance Document: Needlestick and Splash Events in Clinical Research. March 25, 2010

Just as in clinical medicine, needlesticks and splash of biological materials may occur when biological samples are obtained during clinical research. (These will be referred to as needlestick exposures going forward, but the comments apply to other mechanisms of unintentional inoculation as well). Although in general, these occupational exposures are handled similarly to those that occur in clinical care, there are some important issues raised by the identification status and consent status of research samples.

Identification Status

In many instances, research samples are coded (i.e., labeled with a number, linked elsewhere to a specific human subject) or fully de-identified/anonymized (i.e., no link to a human subject from whom the sample was obtained exists anywhere, or should not exist, per IRB approval of the project).

Consent Status

Most fully anonymized samples and some coded samples may be used in research *pursuant to a waiver of informed consent granted by the IRB*. This means that the person from whom the sample was obtained was not explicitly asked whether that sample could be used for research purposes. The IRB must follow specific federal regulations and ensure that specific criteria are met in order to grant a waiver of informed consent for use of identifiable samples in research under a waiver of consent. Though surgical consent forms reference use of excess material for research, patients may not remember this. Additionally such forms are not used for most phlebotomy. Patients may not be aware that there is a possibility that their excess samples may be used for research prior to disposal. When human materials are used for research, the “consent status” of the sample is the major factor to consider when deciding whether it is acceptable to contact source patients to ask about infectious disease testing.

Reporting to the IRB

An occupational exposure that occurs when using research samples usually meets the criteria for an “unanticipated problem involving risks to human subjects or others (insert link to policy)” and must be reported to the IRB by the principal investigator. There may be other institutional reporting requirements as well (e.g. safety reports).

Management of Needlestick Exposures Related to Samples Used in Research

Should an employee sustain a needlestick exposure related to a “consented sample”, i.e. ,one in which a human subject signed a consent form and understands that their sample was being used in research, the following points are germane.

1. The principal investigator of the study should be informed and should report the incident to the IRB.
2. With the assistance of an investigator known to the research subject, a source subject may be contacted and asked to undergo infectious disease testing just as would occur in a clinical setting. The IRB need not be contacted first, in order for

- that to proceed, if all involved in managing the situation are in agreement that this is a reasonable approach.
3. There may be occasional situations in which, despite the fact that the person has consented to participate in the research project, the principal investigator believes it is not appropriate to contact the subject. Should this occur, the matter should be discussed with occupational health specialists and an IRB chairperson. The IRB may elect to seek counsel from the Office of General Counsel and others.

Should an employee sustain a needlestick exposure related to a sample used in research under a waiver of informed consent, the following points apply.

1. The principal investigator of the study should be informed and should report the incident to the IRB.
2. In general, the source subject should not be contacted. The employee should be counseled and treated as if their exposure was from an unknown source, i.e. similar to an injury that occurred while emptying a needle collection box.
3. Should there be extraordinary or compelling reasons why someone believes efforts should be made to attempt to identify and contact a source subject where that individual did not explicitly consent for use of their materials in research, *the IRB must be consulted*. Please contact Elizabeth Hohmann MD, IRB Chair and Director, by pager 28390 through Partners paging. In her absence contact the IRB offices and request that an available IRB chairperson contact you, or page another IRB physician chair at your institution (see <https://partnershealthcare.sharepoint.com/sites/phrmDepartments/poc/irb/Pages/About-the-PHRC.aspx>). The IRB may also seek advice from the office of general counsel and others such as CMO, or Employee Health directors in such situations.