

Human Research Protections Newsletter

Updating IRB records: exempt protocols

Principal investigators, please watch your mail box for a notice regarding exempt protocols certified prior to May 1, 2006, currently listed as 'active' in IRB records. It is likely that many of these projects have been completed, and the protocols can be closed in the IRB database.



Unless you notify Kristy by July 15th, protocols will be considered inactive and closed in our records. Active protocols that continue to qualify for exempt status, with a consent process conforming to current standards, will be re-certified for a period of 3 years.

IRB membership composition

IRB members serve an important role in the review and oversight of human research. Federal regulations require the IRB to be *'...sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.'* **Ref: 45CFR46.**

Focus on: In Vitro Diagnostic Devices and FDA Regulations

In vitro diagnostic products, such as general purpose lab equipment, reagents, and test kits for use in the collection, preparation and analysis of human specimens (ie, blood, cells, tissue) are considered a type of **'medical device'** by the Food and Drug Administration. 'Medical devices' include, among other things, instruments and reagents used to diagnose disease or other conditions in man or other animals.

'Investigational' medical devices are those studied for the purpose of determining their effectiveness and/or safety. Investigational device studies, including research on in vitro diagnostic devices (IVDs), must comply with applicable FDA regulations. If the research will involve human subjects, IRB review and approval is also required.

FDA defines **'human subject'** to include those individuals *on whose specimen* an investigational device will be used. Therefore, device studies using any human specimens require IRB review, as well as the informed consent of donors. While use of some types of specimens (ie, existing, de-identified) in non-FDA regulated research may sometimes not require review, or qualify for a waiver of consent, FDA regulations are typically more stringent. To facilitate research in this area, FDA has recently published guidance, **'Informed Consent for IVD studies using left-over specimens without identifiers'**. The guidance specifies conditions under which device studies may utilize de-identified repository specimens or remnants of specimens collected for routine clinical care without donor consent. Such studies would, however, still require IRB review.

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New IRB procedures

Comments welcome on new draft SOPs: More draft standard operating procedures (SOPs) have been posted for public comment on the IRB Updates **Blackboard course**.

Approved SOPs: Additional SOPs have now been approved for implementation. See the **IRB website 'Guidelines'** page for a complete list.

