FDA Requirements for IVD Device Studies

Special requirements from the US Food and Drug Administration (FDA) apply when human research studies involve investigational in vitro diagnostic (IVD) products.

In vitro diagnostic (IVD) products – those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. IVD products are defined as devices according to FDA regulations. An **investigational IVD** is one that is not FDA-approved.

Unless an IVD meets FDA exemption criteria, the IRB must determine whether the use of an investigational IVD represents a significant risk device or a non-significant risk device. The sponsor must provide its rationale if a claim is being made that the device is non-significant risk. IRBs must determine whether they agree with the sponsor's rationale. If the IRB does not agree, the sponsor will be required to obtain an NSR determination or an IDE from FDA.

In determining whether the investigational IVD is a significant risk device, the IRB can consider these factors:

- Does the specimen collection present a risk?
- Is the investigational IVD being used to make treatment decisions apart from corroboration from another FDA-approved test?
- Are the results of the IVD being used for enrollment or assignment to a treatment arm?
- Will the results of the IVD be used for monitoring or dose adjustment during the study?
- Are eligible subjects placed in the clinical trial based solely on the results of the investigational IVD? If yes,
    - Will they experience greater risk than standard therapy?
    - Can the risks of the study therapy be lessened through medical monitoring?
    - Are the risks of the study therapy reversible?
- How do the risks associated with the clinical trial compare to the risks of disease progression, alternative standard care or palliative care?

Once the risk determination is made, the IRB must verify that the investigational IVD is appropriately described in the consent form.

- Subjects must understand they are being placed in the trial based upon the results of a test that has not yet been approved by the FDA.
- Subjects should be told that researchers do not know how well the test works.
- Subjects should be told there may be risks if the test is not accurate; those risks are currently unknown.
- If the risks of the IVD are determined to be non-significant, the rationale should be presented in the consent document.