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HCPHES Comment Regarding the Interim Final Rule to 21 CFR 50: Medical Devices; Exception from General Requirements for Informed Consent

In June 2006 the Food and Drug Administration (FDA) issued an interim final establishing a new exception to informed consent requirements. This exception would allow the use of investigational in vitro diagnostic devices intended to identify chemical, biological, radiological or nuclear agents without informed consent under limited circumstances. This exception was developed due to concerns that during a potential public health emergency or terrorism event, delaying the testing of specimens while obtaining informed consent may threaten the life of the individual as well as others who may have been exposed to the agent. Also, because clinical studies involving diagnostic devices for chemical, biological, radiological or nuclear agents cannot easily (or often ethically) be conducted, the diagnostic devices at the center of this rule change remain investigational.

In general, Harris County Public Health and Environmental Services (HCPHES) supports the exception described in the interim final rule to 21 CFR 50. However, HCPHES has concerns regarding language relating to reporting to public health authorities. Section 50.23(e)(4) requires the investigator to provide the institutional review board with certain information "at the time the test results are provided to the subject's health care provider and the public health authorities." Further, this section requires the investigator to disclose the investigational status of the in vitro diagnostic device and what is known about the performance characteristics of the device "in the report to the subject's health care provider and in any report to public health authorities."

However, there is no explicit language regarding notifying and/or reporting to public health authorities. In FDA's analysis of the interim final rule, it is stated that "FDA expects that in accordance with routine clinical practice, the investigator will provide the test results obtained using the investigational in vitro diagnostic device to the subject's health care provider.... It is possible that, in certain circumstances, the test results will also be reported to the appropriate public health authorities. This reporting will occur when appropriate and/or required by State or Federal law."

Public health agencies maintain primary responsibility for ensuring a rapid and effective response to a potential threat such as bioterrorism or other large-scale public health emergency. Therefore, timely notification to public health agencies regarding potential threats is key to planning, mobilizing and enacting appropriate surveillance and disease control measures. **HCPHES requests that section 50.23(e)(4) explicitly require investigators to notify the jurisdictional public health authority upon suspicion of need for testing for the chemical, biological, radiological or nuclear agent with the investigational device. Further, the language should reinforce that investigators must provide test results to the jurisdictional public health authority in accordance with State and/or Federal law.**

Specifically, HCPHES requests that a statement such as the following be added at the beginning of section 50.23(e)(4): **“As soon as feasible without delaying the performance of testing, an investigator must notify the jurisdictional public health authority upon suspicion of need for testing for the chemical, biological, radiological or nuclear agent with the investigational device. An investigator must report test results to the jurisdictional public health authority in accordance with State and/or Federal law.”**