Florida State University Policy 7-IRB-27

Title of Policy: HIV Testing

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

Effective Date: Readopted –January 1, 2015

Revision History: New August 13, 2003

Revised _____

I. INTRODUCTION

This policy states that investigators must comply with applicable federal and state laws and local policies concerning the study of the human immunodeficiency virus (HIV). The policy also outlines the responsibility of the IRB during the review of HIV-related research protocols.

II. POLICY

1. Investigators at Florida State University must comply fully with all applicable federal and state laws, and local policies and guidelines, including those concerning notification of seropositivity, counseling, and safeguarding confidentiality and privacy where research activities directly or indirectly involve the study of human immunodeficiency virus (HIV).

2. During its review of an application, the IRB should consider and the Investigator's protocol must address issues of obtaining informed consent, confidentiality, the notification process, the timeliness of informing individuals, and counseling of the individuals and others designated by the individual (i.e. sexual partners).

3. General Policy: Where HIV testing is conducted or supported by the Public Health Service, including both research and health services activities, domestic and foreign, individuals whose test results are associated with personal identifiers must be informed of their own test results and provided the opportunity to receive appropriate counseling unless the situation calls for an exception.

4. Exceptions to General Policy:

    a) Pertaining to an individual. Where there are compelling and immediate reasons that justify not informing a particular individual that he or she is seropositive (i.e.

indication that an individual might attempt suicide), the particular individual need not be informed of HIV test results. When this exception is utilized, the details of the exception must be documented by the Investigator or another responsible person at the testing facility. The principal investigator must promptly report the exception to the IRB Office without identifying the individual. It will be presented to the next scheduled IRB Committee meeting for review and approval of the exception.

b) Pertaining to Protocol Design. Because circumstances may exist in which extremely valuable knowledge might be gained from research involving subjects who would be expected to refuse to learn their HIV antibody results, an exception included in the protocol design may be proposed to the IRB reviewing the research protocol. The IRB shall consider the particular circumstances of the research study, the characteristics of the target research subjects, and other factors, and may approve a testing procedure that would allow research subjects to participate without being informed of their individual results. In proposing such an exception, the investigator must demonstrate to the satisfaction of the IRB that:

- research subjects will be informed of their risk of infection;
- research subjects will receive risk reduction counseling whether they receive test results;
- there is sound reason to believe that a requirement for test notification counseling whether or not they receive their test results;
- there is sound reason to believe that a requirement for test result notification would significantly impair collection of study information that could not be obtained by other means;
- the risk/benefit ratio to individuals, their partners, and society will be periodically reevaluated by the IRB so that the study might be revised or terminated it if is determined that it is no longer justifiable to allow subjects to continue to participate without receiving their HIV test results.

c) Foreign Sites. Activities conducted at foreign sites should be carefully evaluated for account for cultural norms, the health resource capabilities and official health policies of the host country. The IRB Committee must consider if any modification to the policy is justified by the risk/benefit evaluation of the research.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.116