IRB COMMITTEE POLICIES AND PROCEDURES

XAVIER UNIVERSITY OF LOUISIANA

VERSION 7 (February 22, 2010)

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I. INTRODUCTION

Committee Structure

The Xavier University Institutional Review Board (Committee for the protection of Human Subjects) is an appointed committee consisting of at least five members. The members of the Committee and the chairperson, selected from those members, are jointly appointed by the Associate Vice President for Research and Sponsored Programs and the Associate Vice Presidentfor Academic Affairs of Xavier University of Louisiana. The chairperson reports directly to the Associate Vice President for Research and Sponsored Programs.

Authority

Xavier University of Louisiana has adopted the principles of the World Medical Association's Declaration of Helsinki and the Belmont report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. These ethical principles and the Good Clinical Practice guidelines will be the standard utilized to assist the Institutional Review Board (IRB) in the discharge of its responsibilities for protecting the rights and welfare of human subjects involved in research.

Xavier University has adopted the policies and procedures as indicated above and below regarding the rights and welfare of human subjects involved in research activities, including those supported by grants and contracts from the Department of Health, Education and Welfare, the Food and Drug Administration (FDA) 21 CFR Part 56, *et seq*., the Office of Human Research Protection (OHRP), 45 CFR Part 46, *et seq*., and other agencies providing funds to support investigations involving human subjects.

Ethical Principles and Responsibilities

The Xavier University IRB (Committee for the Protection of Human Subjects) will review all research involving humans at Xavier University and shall determine whether all the following conditions are met [21 CFR §56.111(a)(1)-(7)(b)] prior to the actual conduction of the research:

(1) Risks to subjects are minimized by using sound research procedures that do not unnecessarily expose subjects to risk, and by using procedures already being used to diagnose or treat the subjects, whenever possible;

(2) Risks to subjects are reasonably balanced with any anticipated benefits and with the importance of the knowledge that may result from the study.

In evaluating these risks, the regulations suggest that IRBs consider only those risks and benefits that may result from the research (as opposed to those that could result from therapies given to patients not participating in the study). However, the FDA cautions in the regulations that the IRBs not consider long-range effects of applying knowledge gained in the study as risks that they should evaluate (such as the possible effects on public policy);

(3) Selection of subjects is equitable. The regulations suggest that IRBs take into account the purposes and settings of the research, and any special problems of "vulnerable" study populations, such as pregnant women, children, prisoners, handicapped or mentally disturbed persons, or economically or educationally disadvantaged persons;

(4) Informed consent is obtained from each subject or the subject's legal representative [21 CFR Part 50, Subpart B];

(5) Informed consent is documented [21 CFR *§50.27*];

(6) Monitoring of the research to ensure the safety of subjects occurs;

(7) Privacy of subjects is provided for and confidentiality of the data are maintained; and

(8) Additional safeguards are included to protect the rights and welfare of any vulnerable subjects (see number (3), above) participating in a study.

In addition, research reviewed and approved by the Xavier University IRB may be subject to review by official representatives of the institution at which the study is taking place (see also the section labeled "Full Review" in this document). Although these representatives may disapprove research approved by an IRB, they may not approve research already <u>disapproved</u> by an IRB [21 CFR §56.112].

<u>IRB Organization and Personnel</u>

FDA regulations require that an IRB consist of a minimum of five members who possess varying backgrounds and diversity in race, gender, culture, and sensitivity to such issues as community attitudes [21 CFR §56.107]. An IRB's membership should be tailored to meet the specifics of the research involved. For example, a study involving a cardiac drug would suggest that a cardiologist should be included as a member. In addition, each IRB must have

at least one member whose primary interest is non-scientific, such as law, ethics, or religion, as well as one member whose primary interest is in the scientific arena. Moreover, if an IRB regularly reviews research involving a vulnerable category of subjects -- children, prisoners, pregnant women, handicapped or mentally disabled persons -- the board must include one or more individuals who are knowledgeable about, and experienced in, working with such subjects. Each IRB must include one member who is not affiliated with the institution where studies will be conducted or not part of the immediate family of someone who is so affiliated. The non-scientist member must be present in order to maintain a quorum.

An IRB member is permitted to be involved in research being reviewed by the IRB, but that member may not vote on approving or disapproving their own research or be involved in the continuing review of that research [21 CFR §56.107(e), (f)]. NOTE: <u>The minutes of the meeting at which the vote took place must indicate that the member with the conflict did not vote, and must reflect that the non-scientist was present at all material times.</u>

The Xavier University Institutional Review Board (IRB) shall consist of at least seven appointed members. Two members should come from the health sciences (at least one must be a practitioner licensed by law to administer drugs). One to two members should come from the basic sciences (not licensed to administer drugs), and two members should be of varying backgrounds (i.e., lawyers, clergymen, laymen, or consumers). At least one member must not be directly affiliated with Xavier University or have a family member so affiliated. Two members of the Committee must be experienced, (i.e., have at least one year of service on the Committee). The Xavier University Safety Officer and the Compliance Specialist serve as *ex officio* members of the Xavier University IRB.

The IRB must be sufficiently qualified through the maturity, experience, and expertise of its members, and through the diversity of its membership, to ensure respect for its advice and council in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the Committee must be able to ascertain the acceptability of applications and proposals in terms of institutional commitments and regulations, applicable law, standards of professional conduct and practice, and community attitudes.

All Committee business shall emanate from the President of Xavier University, who will authorize the Associate Vice President for Research and Sponsored Programs and the Senior Vice President for Academic Affairs to carry out certain specific functions, such as appointing the chairperson and any new members to serve on the Committee.

Frequency of Meetings

The Xavier IRB will meet as required to review studies involving human participation. However, if a period of three months has passed with no studies to evaluate, the chairperson will, at his or her discretion, call a meeting of the full Committee to discuss general issues related to the Committee's functions. Such "general issue" meetings are unlikely to be called during the summer. The chairperson may, at times, phone and/or email individual members of the Committee to request input on studies that, by their nature, do not require a full meeting of the Committee.

Quorum

Except for expedited review, which is permitted under section 56.110 of FDA regulations, review of research must be at a convened meeting at which a majority of the members is present, including one member whose concerns are non-scientific. The research must receive approval of the majority of the members present at any meeting [21 CFR §56.108(c)]. A quorum of the Committee for conducting official review actions shall be a majority of the duly appointed total membership and must include a non-scientist member.

When the grant, contract or study involves the use of drugs (clinical trial), one member must be licensed to administer drugs and two members may not be so licensed. At least two members must be drawn from a discipline that does not overlap that of the investigator. Every effort shall be made to insure that members reviewing proposals have scientific and other competencies pertinent to the judgments that need to be made.

If a quorum of Committee members is not available for any specified meeting, as might occur during the summer, a qualified replacement may be appointed to the Committee for that meeting. Such a replacement must be chosen from among the Committee's "Alternate Members" and will be indicated in the minutes of that meeting (See section on "Alternate Members.")

APPENDIX I lists the current composition of the Xavier University IRB by name and contains resumes for each member that indicates earned degrees (if any), position or occupation, representative capacity, board certification, licensure, and relationship to Xavier University (i.e., full-time employee, part-time employee, member of governing panel or board, paid consultant, unpaid consultant), if any.

Relationship to other University Committees

If appropriate, the IRB Committee will be guided by the recommendations of other existing or ad Hoc Committee(s) or panel(s) formed for considering special applications for research projects involving human subjects. No member of the Xavier IRB shall be involved in review of an activity in which he or she has a conflicting interest except to provide information requested by the Committee [21 CFR 56.107(e)]. Examples of other committees might include "The Animal Care Committee," "The Biohazards Committee," and "The Radiation Safety Committee."

Orientation and Training of Committee Members

Xavier has purchased a membership in the Collaborative Institute Training Initiative (CITI) that can be found at www.citiprogram.org. Each IRB member should register with the CITI program and complete the course for IRB members. Available for additional training is the Office of Human Subjects Research program found at http://ohsr.od.nih.gov (click on "Computer-Based Training" and then on "IRB Members"). Upon completion of the courses, the certificates should be given to the Chairperson. The Chairperson will give new members IRB Summary Sheets and samples of informed consents; they are asked to "sit in" on one or two reviews before voting. FDA regulations and OHRP regulations can be found onlinehttp://grants.nih.gov/grants/policy/hs/ohrp_fda.htm. Xavier's Office of Research and Sponsored Programs' website contains this manual, as well as forms, guidelines and a sample of an informed consent.

Compensation

There will be no compensation paid to Committee members for serving on the Xavier University of Louisiana's Committee for the Protection of Human Subjects (IRB). However, the chairperson of the Committee receives one-quarter release time from his or her teaching load in order to allow sufficient time for handling Committee related work.

In addition, compensation may be paid to a designated individual, such as a secretary, for taking minutes and assisting with filing. *If it becomes necessary for a member of the IRB to take minutes at a meeting, that member will be compensated at the same rate as a secretary who might take such minutes.*

Alternate Members

In order to assure that a quorum is available for all IRB meetings, alternate members may be added to the roster. These members will not routinely be required to attend meetings, but may do so on an as-needed basis. Alternate members must substitute only for equivalently qualified primary members. For example, a non-scientist alternate could substitute for a non-scientist primary member but not for a scientist primary member. ***Alternate members must be listed in the IRB Roster.***

II. IRB Functions and Procedures

Initial Application and Review

All applications for review by the Xavier University IRB must be submitted in hardcopy form to the chairperson of the IRB Committee. Applications must be submitted to the IRB directly by the Principal Investigator or, if submitted through the auspices of the Xavier University Clinical Trials Unit, must be accompanied by a letter from the Principal Investigator.

The following documents must be submitted:

1. **IRB Summary Sheets (see Appendix II)**
2. **Protocol**
3. **Consent form(s) (see Appendix III)**
4. **Questionnaires/surveys (if applicable)**
5. **Advertising (Brochures, Flyers, Radio, TV)**
6. **Investigator CV**
7. **Federal form 1572 (if applicable)**
8. **A copy of medical licensure (if applicable)**

NOTE: It is recommended that copies of any approvals granted by other institutions be included in the submission package.

The Committee requires use of the "Check List For Protection of Human Subjects" (Appendix II) as a guide in preparation of protocols submitted for review. At the discretion of the IRB Committee, further documentation might be required beyond the Principal Investigator's CV, such as research experience or copies of previously approved projects. The IRB Committee may determine

that special circumstances exist and that the proposed project and/or the investigator require verification from sources other than the Principal Investigator.

Full Review

A full review consists of a review, in committee, of a quorum of the members of the IRB. Project Directors and Principal Investigators will be asked to be available for questions during the last fifteen minutes to one-half hour of the meeting. No vote of approval can be taken without an appropriate quorum present.

The applicant is to submit his or her materials to the Committee well in advance of the deadline for submission to a granting source, and at least two weeks before the next meeting of the IRB Committee. By so doing, he or she will have the benefit of the review before the final preparation of the application, thus insuring that any procedural revisions that might be indicated by the Committee can be incorporated in the proposal. If it is impossible for the applicant to submit the protocol to the IRB in advance of the date of submission to a funding source, a "Pending Review Letter" can be attached to the proposal and the review carried out at the next Committee meeting. However, a copy of the IRB Summary sheets and all other available materials should be submitted to the IRB Committee for consideration prior to the issuing of a "Pending Review Letter."

The Principal Investigator must report to the Committee, promptly and in writing, any proposed changes in research procedures not included in the original submission, including a prompt reporting of unanticipated problems involving risks to subjects [CFR 56.108(b)(1)] . No changes, except those necessary to eliminate apparent, immediate hazards, can be made without prior approval by the Committee [CFR 56.108(a)]. (If problems or proposed procedural changes are reported to the Committee through the auspices of the Clinical Trials Unit, then a letter from the Principal Investigator must accompany the report.) (See Appendix IV.)

In those instances when an applicant is unsatisfied with the Committee's decisions, he or she may again appeal to the IRB Committee. If still unsatisfied, the applicant may appeal to the Associate Vice President for Research and Sponsored Programs, and from there to the President of Xavier University who may, if he or she wishes, request a special hearing for reconsideration by the full Committee membership. However, neither the President nor the Associate Vice Presidentmay override the Committee's decision except for disapproval of an

approved project or adding restrictions to an approved project.

Investigational Device Reviews

The FDA [CFR part 812] recognized two types of studies utilizing medical devices. These are significant risk devices and non-significant risk devices. Significant risk devices [CFR part 812.3(m)] are those, such as implants (e.g., a pacemaker) or devices meant to prolong or maintain human life, which are potentially injurious to research participants.

Any investigational device study that involves significant risk must be accompanied by an "Investigational Device Exemption (IDE), which is filed with the FDA by the study sponsor. Investigational device studies involving non-significant risk can begin after approval by the Xavier University IRB. Note, however, that any investigational device study must be approved by a quorum of the Xavier University IRB, and that informed consent must be obtained in all such studies.

The Xavier University IRB will defer to the FDA in its decisions as to whether an investigational device study poses a significant or non-significant risk. If the level of risk is judged as being significant or unclear to the members of the Xavier University IRB, the Committee will require a notice from the sponsor to indicate that the device was submitted to the FDA and what decision was made by the FDA regarding it. The criteria applied for both significant and non-significant risk studies are specified by the FDA [21 CFR 56.111]. Approved studies must also comply with "abbreviated IDE requirements" [21 CFR 812.2(b)] and informed consent approval criteria [21 CFR parts 50 and 56].

Expedited IRB Review Criteria

FDA regulations allow IRBs to review certain categories of research through an expedited procedure [21 CFR §56.110]. In the January 19, 1981 *Federal Register, the FDA published* a list of the categories of research that can be reviewed using expedited review (see ¶814-A). The agency updates this list through publication of additional listings in the *Federal Register,* whenever necessary.

IRBs may use the expedited review process for research appearing on the list if the research involves no more than minimal risk to the subjects, and for review and approval of minor changes to research approved in the previous year [21 CFR §56.110(b)]. Note, however, that the FDA and the OHRP reserve the right to "restrict, suspend, or terminate an institution's or an IRB's use of the expedited review procedure when necessary to protect the rights or welfare of the subjects" [21 CFR §56.110(d) and 45 CFR § 110(c).

The expedited review may be carried out by the Chairperson of the IRB or by one or more designated experienced reviewers from among the IRB membership. The reviewer has all the authority of the full IRB except that he or she cannot disapprove the research without going through the review procedures set forth in section 56.109 of FDA regulations for non-expedited reviews. A filed record must be maintained of this review and the approval must be in writing.

FDA and OHRP regulations require that IRBs using the expedited review process adopt procedures for informing the remaining IRB members of the research reviewed under this process and the results of this review [21 CFR §56.110(c)]. In accordance with the OHRP, all IRB members will received copies of the approval letters sent to investigators. However, <u>all</u> IRB files, whether for full review or expedited review, and whether involving surveys or clinical trials, will be available in the chairperson's office at any time for examination by any member of the Committee. These files are also available to the Associate Vice President for Research and Sponsored Programs of Xavier University, and to any other official of the University appointed to examine them by the President or the Associate Vice President for Research and Sponsored Programs.

<u>When an amendment, change or modification of a protocol that was previously reviewed by the full Committee is reviewed and approved via expedited review, the IRB members will be notified at the next full IRB meeting and the minutes should reflect this</u>.

The expedited review procedure may not be used where the identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to the invasion of privacy and breach of confidentiality are no greater than minimal.

FDA's List of Research Activities Allowed Expedited IRB Review

(This list is excerpted from an FDA Federal Register notice issued Jan.19, 1981 (46 FR 8960).]

(1) Collection of hair and nail clippings in a non-disfiguring manner; of deciduous teeth; and of permanent teeth if patient care indicates a need for extraction.
(2) Collection of excreta and external secretions including sweat and uncannulated saliva; of placenta at delivery; and amniotic fluid at the time of rupture of the membrane before or during labor.
(3) Recording of data from subjects who are 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This category includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, electrocardiography, thermography, electroencephalography, and detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. This category does not include exposure to electromagnetic radiation outside the visible range (for example, X-rays or microwaves).
(4) Collection of blood samples by venipuncture in amounts not exceeding 450 milliliters in an eight-week period and no more than two times per week, from subjects who are 18 years of age or older and who are in good health and not pregnant.
(5) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth, and the process is accomplished in accordance with accepted prophylactic techniques.
(6) Voice recording made for research purposes such as investigations of speech defects.
(7) Moderate exercise by healthy volunteers.
(8) The study of existing data documents, records, pathological specimens or diagnostic specimens.
(9) Research on drugs or devices for which an investigational new drug exception or an investigational device exemption is not required.

NOTE 1: For expedited reviews, <u>NO</u> study that had to be approved by the full Committee is eligible for an expedited approval for the purposes of "continuing" that study past the one year period.

NOTE 2: Surveys that involve no manipulation of an independent variable and do not ask invasive questions (such as those concerning illegal activities or sexual activity) would normally be eligible for expedited review.

NOTE 3: Studies approved via expedited review at other academic institutions would normally be eligible for expedited review.

NOTE 4: Studies involving participants under the age of 18 would normally NOT be eligible for expedited review.

Consent(s)

As part of the research review, Xavier's IRBs requires documentation of the informed consent [21 CFR §56.109(c)]. FDA regulations require that IRBs review and approve, require modifications in (to secure approval), or disapprove of all research activities covered by Part *56* of FDA regulations [21 CFR §56.109]. This includes information given to research subjects as part of their informed consent.

No project involving human subjects will be approved unless evidence is presented that legally effective informed consent to participate in the study has been given, or unless the requirement for informed consent has been waived under consideration by the IRB (See Appendix II for a copy of the "Request for Waiver of Informed Consent" form). "Informed Consent" means the knowing consent of an individual or of his or her legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The Committee will employ the following basic elements of information regarding such consent:

All required elements of informed consent, as set forth in FDA regulations, are included; The IRB must review this information to determine the following [21 CFR §50.25]; (NOTE: Xavier reserves the right to review the consent forms at any time by reviewing investigators' records.)

(a) A fair explanation of the procedures to be followed and their purpose, including duration of the subject's participation and identification of any procedures that are experimental;

(b) A description of any attendant discomforts and risks reasonably to be expected;

(c) A description of any benefits reasonably to be expected;

(d) A disclosure of any appropriate alternative procedures that might be advantageous for the subject;

(e) A statement describing the extent to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the FDA may inspect the records or be required by law in some cases to release records to a third party.

(f) An offer to answer any inquiries concerning the procedures, with appropriate contact names and numbers included;

(g) A notice that the person is free to withdraw his or her consent and to discontinue participation in the project or activity at any time without prejudice to him or her;

(h) For research involving more than minimal risk, an explanation as to whether compensation and/or medical treatments are available if injury occurs, and who to contact in case of such an event;

(i) The consent does not imply that the study material is approved by the FDA (or other government agency) or is safe and effective;

(j) The consent correctly indicates protocol requirements;

(k) The language in the consent is not coercive; and

(l) Payments or other compensation to subjects are indicated and are not coercive;

Approval/Disapproval/Modification Notice

The IRB will notify an investigator directly in writing of the following [21 CFR §56.109(e)]:

(1) A decision to approve or disapprove the research study;

(2) Any IRB-required modifications or changes to the research study to secure approval of the study, including changes in advertising; and,

(3) The reason(s) for a decision to disapprove a study. With this

decision, an IRB must allow the investigator an opportunity to respond in person or in writing. Any appeal of the decision must be presented in writing. (See section labeled "Full Review" in this document.)

(4) The IRB approval letter directs that the investigator must submit in writing any changes to the study. These changes must be approved by the IRB committee at its next meeting.

Continuing Review

IRBs are required by FDA regulations to conduct continuing review of all approved clinical trials research at least annually [21 CFR §56.109(f)]. IRBs may require sponsors to conduct more frequent reviews for complicated or large-scale studies. The Xavier University IRB applies the standard of annual review to clinical trials studies carried out at Xavier University.

When the element of risk sufficiently warrants, as judged by the frequency of reported averse events, more frequent reviews will be requested of the Project Director and Principal Investigator at the discretion of the Committee. Through distribution of information concerning the review, Xavier University encourages a continuing, constructive communication between the Committee and Project Directors, particularly the Principal Investigator and the director(s) of Xavier's Clinical Trials Unit.

For the Xavier IRB, a master list of all open projects is kept and is checked periodically by the chairperson of the IRB, or by a secretarial assistant, to see what projects are nearing time for review/renewal. Although records are kept of the need for review/renewal by the IRB chairperson, it is the responsibility of the Principal Investigator to notify the chairperson one month prior to any request for such a review/renewal. Studies are never approved for a period of longer than one year.

Advertising/Recruiting of Participants

According to the FDA's IRB Information Sheet, "Advertising for Study Subjects," IRBs also must review and approve all advertisements used to recruit subjects into those research studies that are subject to FDA approval. (The Xavier University IRB requires that all projects submitted to the Committee

include advertisements and recruiting materials, if any are being used.) Any advertisements are considered by the FDA to be extensions of the consent process. The "Information Sheet" also indicates that advertisements recruiting subjects for research studies should be limited to include only the following information:

(1) Name and address of the clinical investigator;

(2) Purpose of the research and a summary of the eligibility criteria that will be used to admit subjects into the study;

(3) Straightforward and truthful description of the benefits to the subject from participation in the study (for example, payments or free treatments); and

(4) Location of the research centers and the name and phone numbers of the person to contact for further information.

NOTE: As with changes in research protocol or informed consent, any changes to study advertising must be submitted to the IRB for consideration and approval.

Minutes and Record Retention

Minutes of all meetings and records for all studies, including summary sheets, protocols, questionnaires, informed consent forms, advertising, notifications to investigators concerning recommendations following reviews, and all other communications between research directors, Principal Investigators, and the IRB shall be kept in the office of the chairperson of the Xavier IRB. The records for each proposal to the Committee shall be available for audit at any time. All minutes, directives, and recommendations shall also be made available to the members of the IRB Committee, and to University officials upon request.

Note: Minutes must reflect the precise makeup of the vote taken in all approval/disapproval actions. The term "unanimous" is typically not used to indicate that all members present voted for approval. If five members are present at the meeting and all vote to approve, the vote should be reported as:

Five members voted to approve the study.
No members voted to disapprove the study.
No members abstained.

Reporting Findings and Actions to the Institution

The actions of the Xavier University IRB will be reported to the institution via copies of all minutes and of all approval/disapproval letters and/or request-for-change letters to the Associate Vice President for Research and Sponsored Programs, the institutional agent to whom the chairperson of the Xavier IRB reports.

Reporting Adverse and Significant Adverse Events

For Clinical Trials studies, adverse events are normally reported directly from the Principal Investigator to the chairperson of the Xavier IRB. However, the Director of the Clinical Trials Unit at Xavier may provide the IRB chairperson with these reports, as long as a note is attached from the Principal Investigator to indicate that he or she is aware of the reports. Typically, a large number of such reports are received for major clinical trials. All such adverse events must be acknowledged by the chairperson of the IRB. Unusual events or unusually numerous events are reported by the chairperson to the Committee members and appropriate actions are taken as needed. Such actions may involve a request for explanation from the Principal Investigator, a requirement for more frequent reviews of the study, or termination of approval for the study.

Unanticipated problems that increase the risks for human participants in research, and any instances of serious and continuing noncompliance with FDA regulations or with the procedures of the Xavier University IRB, will be reported by letter from the chairperson of the Xavier IRB to the Associate Vice President for Research and Sponsored Programs of Xavier University, and to the FDA.

Suspension or Termination of Approved Research

Any required suspension or termination of already approved research will be indicated in writing from the chairperson of the Xavier University IRB, and will be signed by the chairperson, the Associate Vice Presidentfor Academic Affairs, and the Associate Vice President for Research and Sponsored Programs of the University.

As required by 21 CFR 56.113, the Principal Investigator, Xavier institutional officials such as the Associate Vice President for Research and Sponsored Programs, and the FDA will be notified within ten working days of any suspension or termination of already approved research.

Completion of Data Collection

It is the responsibility of the Principal Investigator and of the Director of the Clinical Trials Unit to inform the Xavier IRB, through a letter to the chairperson, that data collection for a study has been completed and that the study is "closed."

III. SUBJECT'S RIGHTS TO VOICE CONCERNS

If subjects wish to voice complaints or concerns about their treatment as human subjects, they should contact the chairperson of the Xavier University IRB Committee. (A contact phone number for the chairperson should be provided on the informed consent form.) If not satisfied with the chairperson's response, a complaint may be submitted to the Associate Vice President for Research and Sponsored Programs, and then to the President of Xavier University.

APPENDIX I
IRB MEMBERSHIP LIST

SEE ATTACHED:

APPENDIX II (Also available via email)
IRB SUMMARY SHEETS,
INFORMED CONSENT CHECKLIST,
REQUEST FOR WAIVER OF INFORMED CONSENT

SEE ATTACHED:

APPENDIX III
SAMPLE CONSENT FORM

SEE ATTACHED: