IRB Handbook

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ETHICAL PRINCIPLES	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	1.0
	Approval: Vice President for Academic Affairs, IRB Administrator/Manager, Office of Human Subjects Research/Manager Human Subjects Research Office, IRB Chairperson	

The primary goal of the Institutional Review Board (IRB) is to protect the safety and welfare of human research subjects by ensuring that the physical, psychological, and social risks to them as participants in research and scholarly projects are minimized. In addition, the IRB seeks to protect the University and the investigator(s) from possible adverse consequences of research with human subjects. In an effort to achieve these goals, the IRB will ensure compliance with the exacting federal requirements that govern ALL research with human subjects unless they meet specific criteria for exemption.

All Dillard University research using living humans as subjects or samples or data obtained from living subjects directly or indirectly, with or without their consent must be approved in advance by the Dillard University IRB. Review or approval by another IRB does not negate the requirement for review and approval by the Dillard University IRB.

1. Ethical Principles

The Dillard University IRB is guided by ethical principles established by the World Medical Association and its adoption of the Declaration of Helsinki, the Belmont Report, and by the Ethical Guidelines of Behavioral Research of the American Psychological Association. These principles are implemented in concurrence with applicable university, state and federal laws and regulations and provide the ethical foundation for these written policies and procedures.

1.1 The Nuremberg Code

The discovery of experimentation atrocities committed by WW II Nazi physicians on war captives led to the development of the Nuremberg code. The Nuremberg Military Tribunal developed ten principles (standards) to facilitate the judgment of the Nazi physicians charged with crimes against humanity. The fundamental principle of the code is the necessity to require the voluntary consent of research participants and that any individual who "initiates, directs, or engages in the experiment" must bear personal responsibility for the quality of the consent.

1.2 The Declaration of Helsinki

The World Medical Association's Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects

(2000, 1996, 1989, 1983, 1975, 1964) calls for prior approval and ongoing monitoring of research by independent ethical review committees.

1.3 The Belmont Report

A major impetus for the development of this 1974 legislation calling for human protection regulations and the creation of a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was the 40-year United States Public Health Service Syphillis Study at Tuskegee.

2. Respect, Beneficence, & Justice

The Belmont Report emphasizes three principles that are central to the ethical treatment of human research subjects that should guide human studies.

2.1 Respect for Persons

Individuals should be treated as autonomous agents and those persons with diminished autonomy should be entitled to protection. This principle is applied by obtaining informed consent with due consideration of privacy, confidentiality, and additional protections for vulnerable populations

2.1.1 In applying this principle, potential study participants should be given information about a study without undue influence or coercion, so that they can make a reasoned decision on their own. However, there are certain individuals who are particularly subject to influences that may limit their ability to make decisions freely (e.g., children and prisoners). They are considered to be vulnerable and are entitled to additional protections. Respect for persons is particularly relevant to the consent process.

2.2 Beneficence

Individuals should be treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. This principle is applied by appropriately weighing risks and benefits.

2.2.1 In applying this principle, investigators should attempt to seek alternative ways of investigating hypotheses that would lead to a more favorable risk-benefit ratio.

2.3 Justice

All individuals should equally share the burdens and benefits of research. This principle applied by the equitable selection of research subjects.

2.3.1 In applying this principle, care should be taken to avoid performing studies that might cause excessive risks or benefits for one group over another group. In other words, to the extent possible, risks and benefits should be equally distributed. Justice is highly relevant to the selection of research subjects for a study.

3. Ethical Principles & IRB Review Process

3.1 Considerations

In reviewing research protocols, Institutional Review Boards must consider all of the following:

3.1.1 The rights and welfare of the individual or group involved

3.1.2 The minimization of risks to human subjects by using procedures consistent with sound research design

3.1.3 The appropriateness of the procedures and methods employed to the aims, underlying hypotheses and goals of the research

3.1.4 The adequacy and appropriateness of the consent form and the process by which consent would be obtained

3.1.5 The medical, social or psychological risks to the subject and the reasonableness of these risks in relation to the anticipated medical and/or psychosocial benefits of the investigation, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result

3.1.6 The fairness and equitability of the inclusion of individuals according to race, ethnicity, gender, and age

REGULATORY STATUTES	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	1.1
	Approval: Vice President for Academic Affairs, IRB Administrator/Manager, Office of Human Subjects Research/Manager Human Subjects Research Office, IRB Chairperson	

In addition to the ethical tenets underpinning the protection of human subjects, federal, state, and University regulations mandate specific protections for human subjects. To assure these protections Dillard University's IRB must review all human subjects research conducted (a) at Dillard University or (b) by Dillard University faculty, staff, and students.

1. Department of Health and Human Services (DHHS)

DHHS regulations outlined in 45 CFR Part 46, Subpart A constitute the Federal policies (Common Rule) for the protection of human subjects. Also included are additional protections for pregnant women, human fetuses, and neonates (subpart B), prisoners (subpart C), and children (subpart D). All human subject research at Dillard University must comply with all subparts of these regulations. Regulatory enforcement is through the DHHS and the Office of Human Research Protections (OHRP).

2. Food and Drug Administration (FDA) Regulations

Generally, FDA human subjects regulations apply to investigatory research involving products regulated by the FDA (i.e.. drugs [investigational and routine], medical devices [investigational and routine], food, color additives, biologics, electronic products). *Due to the nature of research currently conducted at Dillard University and or by Dillard University employees and or agents; the incorporation of FDA regulations has been excluded at this time within this policies manual.*

3. Applicable State of Louisiana Law

Under federal law a **"Legally Authorized Representative"** means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to that subject's participation in the procedures involved in the research. [45 CFR §46.402(c)]. The individuals authorized under Louisiana law to consent on behalf of a prospective participant to participation in the procedures involved in the research are the parent or legal guardian if the patient is a child, a legal guardian if the individual has been adjudicated incapacitated to manage the individual's personal affairs, an agent of the individual authorized under a durable power of attorney for health care, an attorney ad litem appointed

for the individual, a guardian ad litem appointed for the individual, or an attorney retained by the individual.

Under federal law "**children**" are persons who have not attained the legal age for consent to treatments or procedures involved in research or clinical investigations, under the applicable law of the jurisdiction in which the research or clinical investigation will occur. In Louisiana, individuals under the age of 18 are children unless emancipated by filing a petition and meeting the statutory requirements, or they have been adjudicated to be an adult for the purpose of criminal prosecution.

FEDERAL SUPPORT & THE COMMON RULE	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	1.2
	Approval: Vice President for Academic Affairs, IRB Administrator/Manager, Office of Human Subjects Research, IRB Chairperson	

Federal departments and agencies that conduct, support, or regulate research have adopted as regulation a common Federal Policy for the protection of human research subjects. These rules and regulations are contained in DHHS Code of Federal Regulations 45 CFR 46 ("the Common Rule") and its subparts B, C and D*. The Federal Policy applies to research involving human subjects that is conducted, supported, or otherwise subject to regulation by any of the federal departments and agencies listed below:

- Department of Agriculture
- Department of Energy
- National Aeronautics and Space Administration
- Department of Commerce
- Consumer Product Safety Commission
- International Development Cooperation Agency
- Agency for International Development
- Department of Housing and Urban Development
- Department of Justice
- Department of Defense
- Department of Education
- Department of Veterans Affairs
- Environmental Protection Agency
- Department of Health and Human Services
- National Science Foundation

**Although all federal agencies have adopted the Common Rule, some federal agencies have yet to adopt all subparts. The FDA has concurred with the Federal Policy, but has additional requirements found in 21 CFR 50, 54, 56, 312, 600, and 812. Due to the nature of research currently conducted at Dillard University (i.e., social/behavioral) the incorporation of FDA regulations does not apply and as such have been excluded at this time within this policies manual.*

FEDERAL WIDE ASSURANCE (FWA)	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	1.3
	Approval: Vice President for Academic Affairs, IRB Administrator/Manager, Office of Human Subjects Research, IRB Chairperson	

Every institution that receives federal funds for human subjects research must have a "Federalwide Assurance" (FWA) of Compliance for the protection of human subjects (45 CFR 46.103). The Dillard University Office of Academic Affairs is responsible for the coordination of IRB registration and Assurance filing. The Federal Wide Assurance that Dillard University has adopted can be viewed at the DHHS OHRP web site.

Dillard University has adopted Subparts B, C, and D of 45 CFR 46 and that the University has extended its assurance to include all human subjects research independent of the sponsor of the activity.

1. The Assurance

Dillard University requires review and approval by the IRB of all research involving human subjects, whether conducted by its faculty, staff, or students, ***before*** the involvement of human subjects may begin. The review of research at Dillard University is conducted in accordance with its FWA, which is a binding written agreement with the federal government that is approved by the Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP) affirming that the University is in compliance with DHHS regulations contained within 45 CFR 46.

The FWA states that the University is guided by the ethical principles of the Belmont Report and will comply with federal regulations. The FWA also stipulates that Dillard University authorizes its IRB to review, approve or disapprove all research projects involving human subjects regardless of funding source. In addition, the IRB has the responsibility and authority to review and take appropriate actions regarding conflict of interest.

The FWA is effective for 3 years and must be renewed at the end of that period of time. The FWA describes the responsibilities of the institution, institutional officer, the Institutional Review Board, and the investigator.

All investigators at Dillard University are expected to conduct research in accordance with the provisions of the FWA. Primary responsibility for assuring that the rights and welfare of human subjects involved in research are protected rests with the Principal Investigator conducting the research. Faculty members who assign or supervise research conducted by students have an obligation to

consider carefully whether those students are qualified to safeguard adequately the rights and welfare of human subjects.

2. Office of Human Research Protections (OHRP)

2.1. Compliance

The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP helps ensure this by providing clarification and guidance, developing educational programs and materials, maintaining regulatory oversight, and providing advice on ethical and regulatory issues in biomedical and behavioral research.

2.2. Oversight

OHRP's Division of Compliance Oversight evaluates all written substantive indications of noncompliance with HHS regulations—Title 45, Part 46, Code of Federal Regulations (45 CFR part 46). OHRP asks the institution involved to investigate the allegations and to provide OHRP with a written report of its investigation. The Office then determines what, if any, regulatory action needs to be taken to protect human research subjects.

DETERMINATION OF HUMAN SUBJECTS RESEARCH	Effective Date	02/01/2007
	Revisions Date	06/10
	IRB Policy Number	1.4
	Approval: Vice President for Academic Affairs, IRB Administrator/Manager, Office of Human Subjects Research, IRB Chairperson	

All protocols involving both "research" or *"clinical investigations" and* "human subjects" must be reviewed and approved by the IRB before recruitment and data collection may start. If the proposed activity *clearly* does not involve "research" *or "clinical Investigations" and* "human subjects", it does not require submission to the IRB.

For some protocols, however, it might be difficult to tell whether they qualify as human subject research. Consult the OHRP chart (reprinted below) to assist with the determination of whether a proposed activity involves human subjects. (*Note: If in any doubt, contact the IRB Administrator/Manager, Office of Human Subjects Research, or submit a Determination of Human Subject Application).*

In circumstances where an investigator has need for a written determination from the IRB that an activity does not constitute "human subject research" and is not subject to IRB review, a Determination of Human Subject Application must be submitted.

1. Defining Human Subjects Research (Definitions)

1.1 ***Research:*** "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge".

1.2 ***Systematic Investigation:*** Research development, testing and evaluation, i.e., the gathering and analysis of information.

1.3 ***Designed:*** Implies intent to engage in research. If the intent of the activity is to do programmatic evaluation, quality assurance, or quality improvement, you may not be engaged in research. *Intent to publish* is not automatically an indication of intent to do research, but will be taken into consideration when making a determination of research.

1.4 ***Generalizable:*** You intend to draw conclusions from your research which will develop or contribute to a general body of knowledge.

1.5 ***Human subject:*** A living individual about whom an investigator (whether professional or student) conducting research obtains: (1) Data through intervention or interaction with the individual or (2) Identifiable private information.

1.6 ***Intervention:*** Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes (including interviews and surveys).

1.7 ***Interaction:*** Includes communication or interpersonal contact between investigator and subject.

1.8 ***Obtaining:*** Receiving or accessing identifiable private information or identifiable specimens for research purposes. OHRP interprets *obtaining* to include an investigator's use, study, or analysis for research purposes of identifiable private information or identifiable specimens already in the possession of the investigator. *(Note: If private individually identifiable information is received by the researcher and subsequently de-identified, the study is still considered to involve human subjects).*

1.9 ***Private information:*** Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record, school grades, or height and weight measurements). Private information must be ***individually identifiable*** (i.e., the identity of the subject is or may be ascertained by the investigator or associated with the 2 of 2 information) in order for obtaining the information to constitute research involving human subjects. Examples of studies using private information include chart reviews, obtaining lab studies on identifiable tissues and specimens, or using identifiable information from data or tissue repositories, obtaining school grades, private interviews, or surveys of opinions and attitudes.

1.10 ***Coded (Identifiable)***: Identifying information (such as name, social security number, or medical record number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e. the code); and that a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

2. Process

Investigators seeking a determination about whether an activity is human research should submit a Determination of Human Subject Application to the IRB Administrator/Manager, Office of Human Subjects Research with a copy of the research proposal. The IRB Administrator/Manager, Office of Human Subjects Research and IRB Chair will meet and reach consensus regarding whether the activity represents human subjects research and then the IRB chair formally approves this action.

Determinations are based on the regulations, policies, and guidance as outlined in section 3 of this policy. An official IRB determination letter will be forwarded to the PI – project leader, final determination and recommended course of action.

3. Procedure for Determination

3.1 Determinations shall be based on the following regulations, policies and the guidance provided by the OHRP in Chart 1 (reprinted below). Such guidance is based on three questions which are:

3.1.1 Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge?

Pursuant to 45 CFR 46.102(d), research is defined as a systematic investigation including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge. A key to this definition is that there is a systemic design generally utilizing a scientific approach or protocol for the defined purpose of contributing to generalized knowledge. By this definition, research can encompass studies that are experimental or observational, surveys, tests and recordings whether or not they are conducted or supported under a program which is considered research for other purposes.

The definition of research may or may not include public health monitoring activities, internal management studies such as program evaluation, quality assurance or improvement, fiscal or program audits or marketing studies. These activities must be considered on a case-by-case basis to determine if they involve research and require IRB review. Research generally does not include journalism or political polls unless there is clear intent to contribute to generalized knowledge with a scientific protocol. However, the intent to publish may be an indication of intent to contribute to generalizable knowledge.

It is important to distinguish between "research" and the practice of accepted therapy since these may often occur together (such as when research is designed to evaluate the safety and/or efficacy of a therapy). The term "practice" usually refers to interventions designed solely to enhance the well-being of an individual patient or client. Such interventions are carried out with a reasonable expectation of success for purposes of diagnosis, preventive treatment or therapy to a particular individual. In contrast, "research" designates an activity designed to test a hypothesis, permit conclusions to be drawn and thereby to develop or contribute to generalizable knowledge which is usually expressed in theories, principles and statements of relationships. Research is usually described in a formal protocol that contains an objective and a set of

procedures designed to reach that objective. If there is any element of research in an activity involving human participants, that activity shall undergo IRB review for the protection of human subjects.

If the activity is not definable as research, then 45 CFR 46 does not apply; but if the activity is definable as research, then a second question should be:

3.1.2 Does the research involve obtaining information about living individuals?

Within this definition, "Private Information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). "Identifiable Private Information" is that which contains one or more data elements that can be combined with other reasonably available information to identify an individual.

The "obtaining" of identifiable private information or identifiable specimens for research purposes constitutes human subject research. Conversely, research is not considered to involve human subjects when such research involves only coded private information or specimens if both of the following conditions are met:

a. Private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; **AND**

b. Investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain.

If an investigator unexpectedly learns the identity of one or more living individuals or now believes that identifying the individuals is important, then the research activity previously considered not to involve human subjects would now involve human subjects and IRB review and informed consent of the subject are required.

If the research does not involve human subjects, then 45 CFR 46 does not apply; but if the research does involve human subjects, then a third question should be:

3.1.3 Does the research involve intervention or interaction with human subjects?

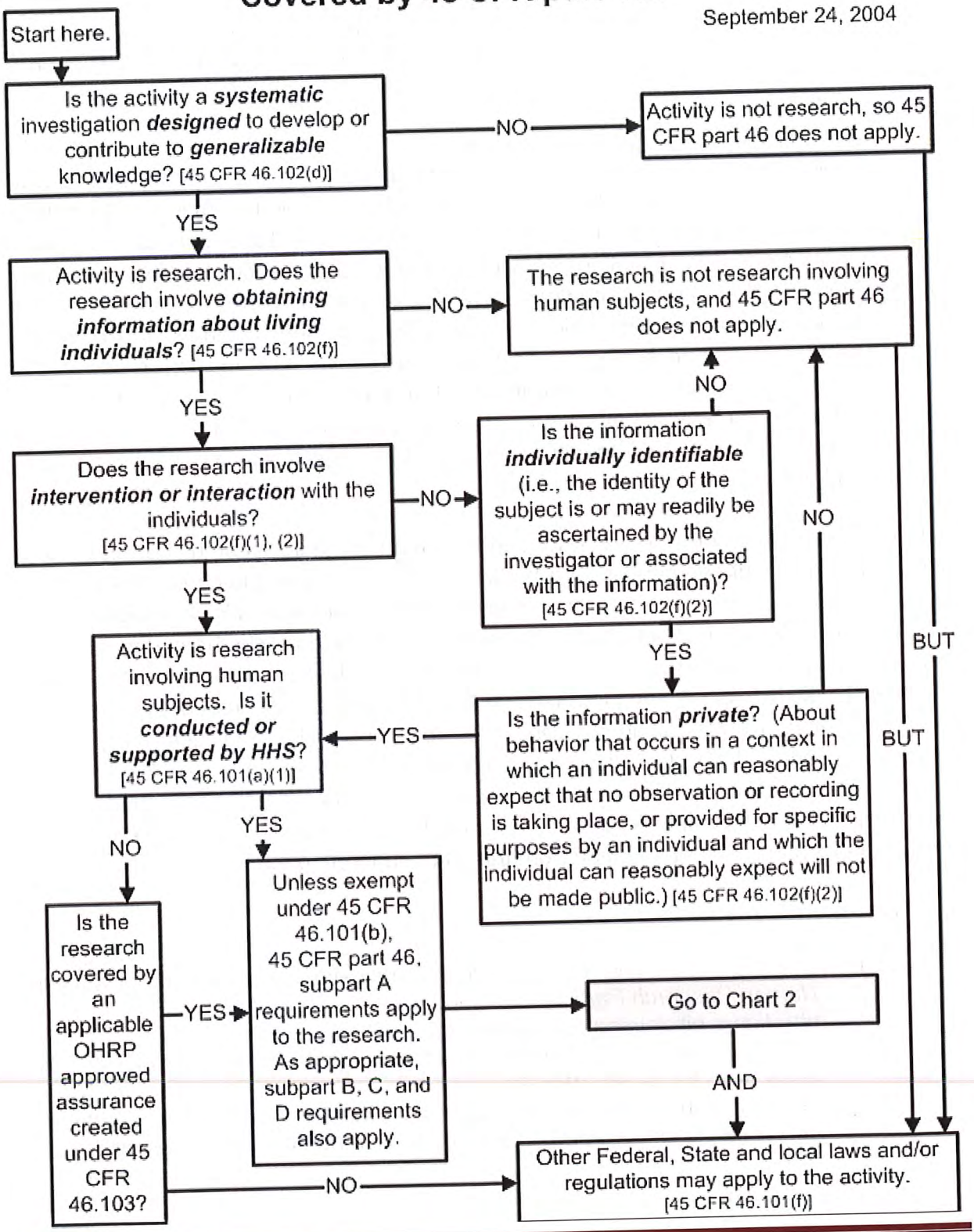
Pursuant to federal regulation 45 CFR 46.102(f)(1),(2), human subjects research is defined as research involving a living individual about whom an investigator (whether professional or student) conducting research obtains

data through intervention or interaction with the individual or from whom an investigator obtains identifiable private information. Within this definition, "intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subjects' environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between investigator and subjects.

Since the University is covered by an approved FWA, all human subject research (as defined above) shall require review and approval by the IRB.

Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

September 24, 2004



TRAINING REQUIREMENTS	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	1.5
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

Although the human subjects protections training mandate from the HHS applies only to NIH grants and contracts, the Dillard University policy extends this mandate to include all human subjects research under the Dillard University IRB's purview. As such, Federal regulations and guidelines require documented evidence that IRB members, principal investigators, co-investigators, collaborators, study coordinators and/or other individuals involved in human subject research are qualified and have the expertise needed to protect human subjects. To meet this requirement and University ethical standards, Dillard University policy requires that all IRB members and those individuals considered to be engaged study personnel receive and maintain certification in human subject protection prior to their involvement in human subject research. This applies to existing and new personnel.

Individuals are considered to be "engaged in human subject research" if they make a direct and significant contribution to a particular study and/or to the conduct of protocol requirements or who contribute in a substantive way to the scientific development of a project. This definition includes (but is not limited to) individuals who have direct contact with subjects, identifiable subject data, identifiable subject records, protected health information or biological samples collected and/or tested for research purposes. Engaged personnel also includes clinical professionals who administer any study-related intervention being tested or evaluated under a research protocol. Students are considered engaged personnel if they meet any of the criteria described in this paragraph. The definition of engaged personnel is not dependent upon whether or not the personnel receive compensation from the grant supporting the project.

1. Training Requirements

1.1 Complete the online human subjects certification modules titled *Protecting Human Research Participants* found at: http://phrp.nihtraining.com/users/login.php

1.2 Submit training certificates for all members of the research team with initial application for review (IRB-A).

1.3 For research team members that are TBA, items should be forwarded upon completion and prior to engagement in human subject research.

1.4 Training need not be renewed unless specifically required by the Dillard University IRB or outside institution. However, the IRB may require additional training.

IRB DUTIES & SCOPE OF AUTHORITY	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	2.0
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

Federal regulations at 45 CFR Part 46 require that institutions engaging in human subjects research funded, in part or in totality, by the Department of Health and Human Services (DHHS), or its entities, develop mechanisms for the protection of human subjects. Regulations require that (a) a written "Assurance of Compliance" for the protection of human subjects is filed and (b) one or more Institutional Review Boards (IRBs) be established to review its human subjects research.

The filing of the Federal Wide Assurance and the registration of the University IRB are coordinated by the Dillard University Office of Academic Affairs (i.e,, Signatory Official and IRB Administrator/Manager, Office of Human Subjects Research). The University IRB operates under a Federal wide Assurance (FWA) from the Office of Human Research Protections (OHRP) in the Department of Health and Human Services (DHHS). IRB policies and procedures have been developed according to the regulations and or criteria stipulated for all research involving human subjects, regardless of funding source, if any.

1. Institutional Authority of the IRB

The Vice President for Academic Affairs is the official signatory and ultimately responsible for all research activities conducted under the auspices of Dillard University.

2. Purpose of the IRB

The primary responsibility of the IRB is to protect the rights and welfare of prospective and current participants involved in human subjects' research. As such, the IRB monitors (a) the ethical implementation of research and (b) compliance with Dillard University's policies and procedures, federal regulations, and applicable law through the prospective and continuing review of human subjects' research. This includes the review of all research protocols and/or proposals, the informed consent process, prospective subject enrollment methodology, and any adverse events or unanticipated problems reported to the IRB.

3. Designation of the IRB

Dillard University has one IRB responsible for conducting initial and continuing reviews and providing oversight for all social and behavioral research activities

involving the use of human subjects performed on the campus or at any location under the purview of Dillard University. The IRB will conduct initial and continuing reviews of research activities. All review procedures will meet or exceed the requirements set forth in 45 CFR 46.

4. Scope of IRB Authority

All research conducted with human subjects at Dillard University or by Dillard University faculty, staff, students, and agents must be prospectively reviewed and approved by the University IRB. The University designated IRB is empowered to take any action necessary to protect the rights and welfare of human subjects in research conducted at Dillard University or by Dillard University faculty, staff, students, and agents.

The IRB is authorized to review and to approve, defer and/or require modifications to secure approval, table, or disapprove all human subject research overseen and conducted by the Dillard University and its agents and covered by the University's Federal-wide Assurance. This responsibility extends to all human subject research including pilot studies and feasibility studies, even if such studies include only one subject; and it includes all research involving human subjects performed under the auspices of Dillard University regardless of whether the studies are extramurally funded, funded by University sources or non-funded.

IRB authorities include but are not limited to:

4.1 Authority to Require Progress Reports and to Oversee the Study

The IRB has the responsibility and the authority to review the progress of human subject research studies, to monitor the activities in approved studies including regularly scheduled continuing review at least annually and to require verification of compliance with approved research protocols and informed consent procedures through means such as audit, observation or third party review. The authority to review the progress of studies includes the authority to require prompt reporting to the IRB of any planned changes in approved projects prior to the implementation of those changes and the authority to require prompt reporting to the IRB of any unanticipated problems (including adverse events) occurring in, or related to, approved protocols.

4.2 Authority to Suspend or Terminate Approval of Research

The IRB, the Vice President for Academic Affairs and/or the IRB chair have the responsibility and the authority to suspend or revoke approval of any study that was originally reviewed and approved for reasons such as unanticipated problems involving risks to human subjects, serious or continuing non-compliance with any federal regulation or serious or continuing non-compliance with the requirements or determinations of the IRB [*45 CFR 46.113*]. Such actions by the IRB shall be determined at a

convened meeting of the IRB with a quorum present and shall be incorporated into the minutes of the meeting. The IRB shall consider the rights and welfare of current research subjects when suspending or terminating approval of active studies.

4.3 Authority to Restrict Research

The IRB has the responsibility and the authority to restrict any study that it has originally reviewed and approved if it determines that such action is warranted. Under this policy, 'restrict' is defined as suspending or terminating a portion of a study found in non-compliance either permanently or until it is brought into compliance. One example of this may be if an aspect of a study fails to comply with federal regulations or IRB requirements or determinations. In this circumstance, the IRB may suspend or terminate approval of the entire study pursuant to the policy on suspending or terminating approval of research (see above) or the IRB may place restrictions on one or more portions of the study. The IRB may also request that a study audit be conducted.

4.4 Authority to observe, or have a third party observe, the consent process

If an IRB panel approves a study, that IRB panel has sole authority for oversight of the study including the consent process. To carry out this responsibility, the IRB may observe or have a third party observe the consent process and/or it may seek information on this process from the principal investigator or others [*45 CFR 46.109(e); 21 CFR 56.109(e)*].

4.5 Authority to observe, or have a third party observe, the conduct of the research

If an IRB panel approves a study, that IRB panel has sole authority for oversight of the study including the conduct of the research under the approved protocol [*45 CFR 46.109(e); 21 CFR 56.109(e)*].

4.6 Authority to obtain additional expertise when reviewing a specific study

If the IRB chair or designee reviewing an exempt or expedited study, or a member of the convened IRB reviewing an initial or continuing study, determines that additional expertise is required for this review, the chair or member has the authority to contact one or more experts within or outside of the University by whatever means he/she believes appropriate or to request that the IRB Administrator/Manager, Office of Human Subjects Research arrange for this additional expertise. Review of the specific study requiring this consultative input shall be deferred until the expert advice is received and considered by the IRB.

5. Decisions of the IRB

IRB approval is always necessary before a research project involving research participants may begin. An IRB decision to not approve a human research project, or require modifications as a condition for approval, cannot be overturned by any Dillard University official or Dillard University committee.

SHARED RESPONSIBILITIES: THE IRB & OTHERS	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	2.1
	Approval: Vice President for Academic Affairs, IRB Administrator/Manager, Office of Human Subjects Research, IRB Chairperson	

The ethical conduct of research is a shared responsibility. A clear delineation of the responsibilities for all parties involved in protecting human subjects volunteering for research is delineated.

1. The Institution

Dillard University will promote the physical, psychological, spiritual, and social well-being of those we serve. Dillard University is dedicated to defending and promoting human dignity, health, and well-being. All components of this mission apply to the subjects who volunteer to participate in research.

The institution is committed to assuring all regulatory agencies that it will comply with all of the regulations governing the protection of human subjects. As part of this assurance, the institution has developed policies and procedures for conducting human subjects' research in a responsible and ethical fashion, including how research will be reviewed by the IRB, the reporting of unanticipated problems to the IRB and appropriate regulatory bodies.

The Vice President for Academic Affairs serves as the Institutional Signatory Official for Dillard University's Assurance and is ultimately responsible for overseeing the protection of human subjects within the institution. The Signatory Official will also maintain open channels of communication between the IRB, research investigators and staff, and administration, and provide the IRB with sufficient meeting space and access to staff to support its review and record keeping responsibilities.

2. The Principal Investigator

The principle investigator bears direct responsibility for protecting every research subject. Principle investigators have the following responsibilities:

2.1 To ensure that all human subjects' research conducted at Dillard University or by employees and or agents of Dillard University receives prospective review and approval by the University IRB.

2.2 To ensure continuing review and approval has been secured in a timely manner.

2.3 To ensure that the research is conducted, at all times, in compliance with all applicable federal and state regulatory requirements and the determinations of the University IRB.

2.4 To ensure no changes are made to the approved research without IRB approval (except to eliminate immediate hazards to participants) nor will research continue beyond the IRB approval period.

2.5 To ensure prompt notification to the IRB of any unanticipated problems or adverse events involving risks to others.

2.6 To ensure the adequacy of the informed consent document and process regardless of which members of the research team actually obtain and document the consent.

2.7 Submit continuing reports in a timely manner to avoid suspension of a study as a result of its expiration.

2.8 Know expiration dates, to submit continuing review applications with sufficient time for IRB review, and to make necessary changes per regulations if a study is suspended for lapse in approval.

2.9 Ensure that he/she, co-investigators, study coordinators, student investigators and all key personnel have completed the human subject training program and hold current certification from that program before they participate in the human subject research

2.10 Ensure that the study is conducted by qualified personnel following the approved IRB protocol

2.11 Maintain research files for a minimum of five years from the date of study completion

2.12 Fully inform the IRB of all locations in which human participants will be recruited for the study and ensure that current IRB approvals/letters of cooperation are obtained and maintained when applicable

2.13 Ensure prompt and complete compliance with any IRB or administrative decision to suspend or withdraw approval for the study

Failure to comply with IRB requirements for active studies is considered serious misconduct and may be subject to sanctions including possible termination of approved research. Serious misconduct shall be reported to the School Dean, the Vice President for Academic Affairs.

3. Research Team Members

Every member of the research team is responsible for assuring the protection of human subjects. Nurses, research assistants, study coordinators, co-investigators, and all other research staff have a moral and regulatory responsibility to comply with all IRB edicts and procedures, adhere rigorously to all protocol requirements, inform investigators of all adverse subject reactions or unanticipated problems, manage the adequacy of the informed consent process, and take the appropriate steps necessary to protect the safety and welfare of study participants. Researchers at every level are responsible for notifying the IRB promptly of any noncompliance with applicable regulatory requirements or

determinations made by the IRB of which they become aware, regardless of their involvement in the research.

4. Student Team Members

The Undergraduate Research Program is designed to provide students the opportunity to become engaged in the research process through participate in mentored research. Students may work under the direct supervision of a faculty member as research assistants, co-investigators, data collectors, lab assistants, and presenters. Undergraduates may not serve as principle investigators or research study coordinators.

Student-initiated studies involving human subjects must be submitted under faculty supervision and the supervising faculty member must indicate his/her acceptance of the responsibilities of a Principal Investigator by signing as the "Faculty Advisor or Faculty Mentor."

5. Human Subjects

Human subjects also have responsibilities. They should be expected to make every effort to comprehend the information presented to them so that they can make a good faith, informed decision regarding their prospective participation. In addition, potential participants should be willing to comply with the protocol requirements (unless they decide to discontinue participation) and inform the investigator of any problems.

CONFLICTS OF INTEREST	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	3.0
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

Institutional Review Board Member and Investigator Conflict of Interest that could affect the welfare and rights of participants must be eliminated or a management plan must be implemented so that the rights and welfare of participants are not affected by the interest.

1. Definitions

1.1 Conflicts of Interest

1.1 Investigator conflict of interest is any situation in which financial or personal interests may compromise or appear to compromise an investigator's professional judgment in conducting or reporting research.

1.2 IRB member conflict of interest is any financial interest or scholarly or social commitment or relationship that would impair the ability of the reviewer to make fair and impartial judgments about an application.

1.2 Immediate Family

IRB member or investigator's spouse or domestic partner, minor children, and anyone who resides with the IRB member or investigator or who is the IRB members' or investigators' dependent for tax purposes.

1.3 Significant Financial Interest

Anything of monetary value, including but not limited to salary or other payment for service, equity interests, or intellectual property rights.

2. The Disclosure Process

2.1 IRB Member

The Federal human subjects regulations and the Federal Policy (Common Rule) prohibit IRB members, chairs, or IRB staff who have a conflicting interest from participating in the IRB's initial or continuing review of research. Nor shall an IRB member participate in the discussion on an

application at a meeting of the IRB or vote on an application if he/she has a conflict of interest.

If an IRB member is assigned to review a research proposal with which he/she has a conflict of interest, the member should alert the IRB Administrator/Manager, Office of Human Subjects Research for proposal reassignment and/or document in the official IRB minutes that the IRB member was not present in the room during both discussion and voting.

2.2 Investigator Conflict

Investigators are required to disclose conflicts of interest as part of the application for initial review and approval. If an investigator conflict arises after IRB approval the investigator should promptly notify the IRB Administrator/Manager, Office of Human Subjects Research, submit the change as an amendment to the approved study protocol and include a revised consent form including a statement addressing any potential conflict of interest.

3. Management of Conflicts

Any conflicts of interest must be brought before the convened Board. As such, the IRB Administrator/Manager, Office of Human Subjects Research will place the item on the upcoming IRB agenda for discussion by the IRB.

The IRB will evaluate whether the conflict will affect the rights and welfare of the participants. If the IRB determines that the conflict of interest is such that it affects the rights and welfare of the participants, the conflict must be eliminated or a management plan must be implemented.

The Chair of the IRB notifies the Senior Vice President for Academic Affairs of the IRB determination. If the IRB approves the study, the Office of Academic Affairs is responsible for enforcing the management plan.

IRB SELECTION, MEMBERSHIP, STRUCTURE & SERVICE	Effective Date	**02/01/2007**
	Revisions Date	**06/09**
	IRB Policy Number	**4.0**
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

Dillard University currently has a single 7-voting-member IRB to review research from its faculty, students, employees, and other agents. In accordance with 45 CFR 46.107, the IRB is comprised of an ethnically and gender diverse faculty from each academic division at Dillard University as well as a community representative not affiliated with the University. The IRB faculty will also have sufficient expertise to review the broad variety of research in which Dillard University commonly becomes involved, will be knowledgeable about all relevant regulatory requirements, and will remain impartial and objective in its reviews.

1. Selection of IRB Members

IRB members are nominated by Board members and by a majority vote are presented to the Vice President of Academic Affairs for a formal invitation to serve.

The IRB must be sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds (including sensitivity to issues such as community attitudes), to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB must include one member whose primary concerns are in scientific areas, and at least one member whose primary concerns are non-scientific. In addition, a representative from that type of community, including minorities shall be considered in the IRB membership.

Only in extraordinary circumstances shall such a nomination be dismissed by the Senior Vice President for Academic Affairs. In such circumstances, the IRB Chair will be provided in writing concerning the reasons for the decision. The Chair will present the information to the IRB members during the next convened board meeting. A copy of the nomination dismissal documentation shall become a part of the permanent IRB records.

2. Appointment of IRB Members

With the exception of the chair, nominations of potential members of the IRB are formally presented to the Vice President for Academic Affairs for formal appointment by the IRB Administrator/Manager, Office of Human Subjects Research. Members serve a three- year term and are eligible for unlimited reappointment.

3. Appointment of Alternate Membership

The Committee for Organized Research and Sponsored Programs also identify and formally nominate alternate members to replace regular IRB members who are, on occasion, unable to attend convened meetings of the IRB, for appointment by the Vice President for Academic Affairs. Terms of the appointment, length of service, and duties are exactly as for regular IRB members.

4. Appointment of Non-Voting (Ex-officio) Members

The Vice President for Academic Affairs may appoint certain "non-voting" members to the IRB (e.g., IRB staff) who may present at IRB meetings to answer questions or pose issues for discussion, but who may not vote and whose presence does not count towards the quorum.

In an effort to facilitate a smooth transition between chairpersons, the current chairperson will serve in an ex-officio consultative capacity for an additional one (1) year at the conclusion of their length of service.

5. Consultants

The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB. Consultants may assist the IRB on either a regular or an as-needed basis.

6. Length of Service (General Membership)

Members appointed by the Vice President for Academic Affairs serve three- year terms and are eligible for unlimited reappointment. Members vote to approve, require modifications in, disapprove, suspend, terminate, or defer research protocols. Members are expected to (a) attend IRB meetings on a regular basis, (b) serve as primary reviewers for research within their areas of expertise, (c) serve as general reviewers on all research discussed at convened meetings, and (d) conduct expedited reviews on behalf of the IRB when so designated by the IRB Chairperson.

IRB members should be committed to the safeguarding of the rights and welfare of human subjects. Members who do not adequately fulfill their responsibilities as judged by the IRB Chair, the IRB Administrator/Manager, Office of Human Subjects Research and/or the Vice President for Academic Affairs may be removed from IRB membership by the Vice President for Academic Affairs.

7. Authorities and Responsibilities of IRB Members and Alternate Members

7.1 IRB members and alternate members are appointed to serve the Dillard University. Members and alternate members must put their duty to protect the rights and welfare of human subjects above their own interest or that of their academic department.

7.2 IRB members are responsible for attending, for their full duration, all convened IRB meetings in a timely manner. If an IRB member cannot attend a meeting or a part of a meeting, he/she should notify the IRB Administrator/Manager, Office of Human Subjects Research well in advance of the meeting to facilitate the preparation and attendance of an appropriate alternate IRB member.

7.3 All IRB members and alternate members should understand and apply the ethical principles of the Belmont Report and all federal, state and local regulations related to the protection of human research participants. Members and alternates should commit time and effort to receive training in these requirements. All members and alternate members shall be given copies of pertinent documents to review and understand including federal regulations and the Dillard University Written Policies and Procedures for the Protection of Human Subjects in Research. Attendance at Dillard University seminars pertaining to human subject protections is encouraged. These seminars are intended to provide background and new information. In addition, IRB members and alternates are encouraged to attend relevant local and national meetings and may be provided support to do so.

7.4 IRB members (and alternate members when appropriate) are expected to serve as primary reviewers for assigned studies and to participate as general reviewers on all studies discussed at convened meetings. IRB members (and alternate members when appropriate) shall vote to approve, set conditions for approval, defer review to expedited reviewer or convened IRB or disapprove studies submitted to the IRB following discussion of these studies. IRB members (and alternate members when appropriate) may discuss and vote on other matters pursuant to Dillard University Policies and Procedures.

7.5 IRB members may be appointed as IRB-designees by the IRB Chair. IRB-designees are expected to conduct exempt and expedited reviews.

8. Compensation of IRB Members (except Chair)

Compensation may be provided to IRB members who are employees of Dillard University. Such compensation may be provided if the IRB duties constitute a significant fraction of the member's time and if compensation for that time is not otherwise provided from institutional and/or department or other resources. The Vice President for Academic Affairs shall manage compensation standards for such services.

9. Liability Coverage

When acting in accordance with federal, state, and local regulations and the Dillard University IRB Written Policies and Procedures, IRB member actions are covered by the University's self-insurance policy, which protects individuals from liability when performing within the course and scope of their IRB responsibilities and in accord with faculty and staff serving on all University Boards or Committees. Unaffiliated members of the IRB are also covered by this policy when performing within the course and scope of their IRB service.

IRB CHAIR & VICE CHAIR	Effective Date	02/01/2007
	Revisions Date	06/09
	IRB Policy Number	4.1
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

1. Appointment of IRB Chair and Vice-Chair

1.1 Selected from the IRB membership, based on the recommendations and a majority vote of the IRB members, the Vice President for Academic Affairs formally appoints the IRB Chairperson.

1.2 In consultation with the IRB Chair, the Vice President for Academic Affairs shall appoint the IRB Vice-Chair.

2. Length of Service and Responsibilities (Chairperson)

The Chairperson serves a three-year term and is limited to serve no more than two consecutive terms (i.e., 6 years). In an effort to facilitate a smooth transition between chairpersons, the immediate past Chair will serve in an ex-officio consultative capacity for an additional one (1) year at the conclusion of his/her length of service.

3. Authorities and Responsibilities of IRB Chair and Vice-Chair

Responsibilities of the IRB Chair include but are not limited to those defined in the following three sections. In the absence of the IRB Chair, the Vice-Chair shall assume the responsibilities of the IRB Chair.

3.1 Ongoing IRB Chair Responsibilities:

a. Review and approve, when appropriate, expedited submissions in accordance with regulatory requirements.
b. Determine exempt submissions in accordance with regulatory requirements.
c. Review (or defer to the primary reviewer or other IRB-designee to review) all adverse event reports and unexpected problems affecting the safety of subjects and, as necessary, determine if one or more of the following is necessary:
    i. Immediate action to address the safety of subjects
    ii. Call an emergency meeting of the IRB

d. Appoint qualified IRB members as IRB-designees with authority for expedited reviews and other actions as defined in these Policies and Procedures.
e. Signature authority for all IRB correspondence.
f. Maintain a thorough understanding of federal regulations pertaining to human subject protections, the Dillard University IRB Written Policies and Procedures, and other applicable state, and local regulations. Assure that regulations and policies are applied in all IRB matters with a commitment to foster ethically and scientifically sound human subject research.
g. Respect the diverse backgrounds, perspectives and sources of expertise of all IRB members and foster such respect among the IRB members.
h. Uphold IRB judgments no matter how these are received or perceived by Principal Investigators.

3.2 IRB Chair Responsibilities Prior to Each Convened Meeting:

a. Review IRB meeting schedule and agenda composed by the IRB Administrator/Manager, Office of Human Subjects Research.
b. Ensure coverage by the Vice-Chair when not able to serve as Chairperson for the meeting and notify the IRB Administrator/Manager, Office of Human Subjects Research when not able to serve.
c. Assist the IRB reviewers and other IRB members with any concerns in preparing for the meeting, as necessary.
d. Recommended consults when appropriate to assist in IRB reviews.

3.3 IRB Chair Responsibilities During IRB Meetings:

Preside over IRB meetings and ensure that meetings are conducted in an efficient, orderly an fair manner with respect given to the opinions of all members. Robert's Rules of Order should be used as a guidebook for conducting the meeting.

a. Ensure a quorum for each study review and ensure that this quorum is properly documented.
b. Ensure that all regulatory-required elements of review are addressed during the meeting and that there is meaningful and substantive discussion of relevant matters and/or questions.
c. Ensure that assigned reviewers present a clear and concise review of study materials including consent documents and recruitment items and process
d. Ensure that all IRB-required changes to consent and other documents are documented
e. Ensure that the IRB discusses specific findings, as required by regulations, whenever these is the involvement of vulnerable populations, e.g. children, prisoners, pregnant women and fetuses
f. Accept appropriate motions from voting members of the IRB.

g. As necessary, ensure that the specific elements pertaining to the motion are clearly understood by the IRB and accurately recorded in the meeting minutes
h. Ensure that IRB decisions are made in accordance with federal, state and local regulations and with the Dillard University IRB Written Policies and Procedures
i. Ensure that minutes of IRB meetings and votes of the IRB members accurately reflect discussions and actions

4. Compensation for IRB Chair

The IRB chair receives 25% release time to carry-out the duties encumbent with office. The Vice President for Academic Affairs shall manage compensation standards for such services

ADMINISTRATIVE SUPPORT	Effective Date	**02/01/2007**
	Revisions Date	
	IRB Policy Number	**4.2**
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

DHHS regulations at 45 CFR 46.103(b2) require that Dillard University provide its IRB with sufficient meeting space and staff to support the IRBs' review and recordkeeping responsibilities.

1. **Resource Allocation**

   The Dillard University Vice President for Academic Affairs is ultimately responsible for protecting human subjects in research conducted at Dillard University. As such, the Vice President for Academic Affairs will allocate sufficient resources to support the IRBs' review and recordkeeping responsibilities.

2. **Reporting Lines and Supervision**

- The IRB Administrator/Manager, Office of Human Subjects Research is appointed by the Vice President for Academic Affairs. This position reports to the Vice President for Academic Affairs and represent the provost with internal and external audiences on human subjects research. The position works collaboratively with the IRB chairperson to assure that the business of the IRB is carried out efficiently, effectively, and within the regulatory statues.

3. **Administrator/Manager Duties & Responsibilities**

   The IRB Administrator/Manager of the Human Subjects Research Office is responsible for maintaining documentation that IRB activities and decisions fully satisfy all regulatory requirements. As such, the administrator must have a detailed, working knowledge of relevant regulatory requirements. The IRB Administrator/Manager, Office of Human Subjects Research is also responsible for the day-to-day operation of the IRB and the following IRB functions:

   a. Managing IRB/HSR Office and budget.
   b. Interpreting regulatory requirements for campus community
   c. Coordinating IRB member activities including reviews and training.
   a. Maintaining the official roster of IRB members.
   b. Scheduling IRB meetings and distributing pre-meeting materials.
   c. Ensuring IRB meetings are in compliance with regulatory requirements.

d. Ensuring IRB activities are documented and secure in compliance with Federal statute.
e. Serving as institutional liaison with OHRP, state, and local human subjects in research agencies.
f. Promptly reporting changes in IRB membership to OHRP.
g. Maintaining all IRB documentation and records in accordance with regulatory requirements.
h. Assisting new IRB members in completing orientation procedures and meeting required education standards.
i. Securely and properly archiving all IRB records.
j. Facilitating communication between investigators and the IRB.
k. Tracking the progress of each research protocol submitted to the IRB.
l. Serving as a resource to investigators on general regulatory information, and providing guidance about forms and submission procedures.
m. Developing and maintaining training and reference materials related to human subject protection requirements.
n. Maintaining and updating the IRB policies and procedures manual and IRB forms.
o. Advising and guiding principal investigators (PIs) on relevant IRB regulations, policies, procedures, guidelines, and deadlines. Consulting with researchers as needed on IRB requirements or human subjects protection issues.
p. Regularly communicate with campus community regarding IRB matters.
q. Assisting the Sr. Vice President and IRB members in identifying problems and initiating appropriate action to resolve them. Ensure compliance with IRB policy and procedures.
r. Drafting reports and correspondence to research investigators regarding the status of research, including conditions for initial or continuing approval of research and responses to reports of adverse events or unanticipated problems.
s. Preparing reports and correspondence directed to research officials, federal officials, and others on behalf of the institution.
t. Filing assurance documents with OHRP and state human protection agencies.

RECORD KEEPING	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	4.3
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

Federal regulations require that Dillard University implement written policies and procedures to govern the operations and direct the activities of the IRB. The Dillard University IRB policy and procedure document satisfies this requirement and delineates the process.

1. **Record Retention**

   IRB records will be retained by Dillard University for no less than five years after the completion of the research with which they are associated.

2. **Access to IRB Records**

   All IRB records will be kept secure in locked cabinets and or storage rooms in the Office of Human Subjects Research. Access is limited to the Vice President for Academic Affairs, Manager of the Human Subjects Review Office, IRB chair, and officials of Federal and State regulatory agencies, including OHRP. Principle investigators or their designee will be provided reasonable access to files related to their research. All other access is limited to legitimate need as collaboratively determined by the IRB Administrator/Manager, Office of Human Subjects Research, IRB chair, and Vice President for Academic Affairs.

3. **Correspondence & Records**

   The Manager of Human Subjects Office is responsible for maintaining accurate records of all correspondence to and from the IRB. The manager is also responsible for the organization of IRB records. Records will be filed according to the following categories:

   3.1 Written Operating Procedures
   3.2 IRB Membership Rosters
   3.3 Training Records
   3.4 Correspondence (non protocol-related)
   3.5 Research Application and Tracking Records
   3.6 Documentation of Exemptions and Exceptions
   3.7 Documentation of Expedited Reviews
   3.8 Documentation of Convened IRB Meetings
   3.9 Documentation of Review by another Institutions IRB
   3.10 Adverse Events Reports

4. Membership Rosters

4.1 Changes in IRB membership will be reported within 30 calendar days to the OHRP.

4.2 Most current IRB roster will be made available on the IRB webpage promptly after revision.

4.3 Rosters will become part of the permanent IRB records and stored indefinitely.

4.4 Rosters are provided upon request to sponsors, federal agencies, other institutions, etc.

4.5 Membership rosters will include the following information:

a. Name of IRB members.
b. Names of alternate members and the corresponding regular members for who each alternate may serve, if applicable.
c. Earned degrees and specialties of each member and alternate, if applicable, sufficient to describe each member's anticipated contribution to IRB deliberations.
d. The representative capacity of each member or alternate.
e. The beginning and end date of a member's term as indicated on the appointment letter from the Vice President for Research.

5. Education and Training Records

Dillard University will maintain accurate records listing the research investigators, research team members, IRB members, and staff that have fulfilled the training requirements for the protection of human subjects.

6. Research Application File

The IRB will maintain a separate file for each research application that it received for review will be maintained in the Human Subjects Research Office. Applications will be numbered sequentially by calendar year and exemption status in the order in which they are initially received (i.e. the first application for non-exempt research received in calendar year 2007 = DU-IRB 2007-01 NE, the second, DU-IRB 2007-02 NE, etc.). Each application will contain the following information:

a. The IRB Research Application;
b. Documentation of the type of IRB review;
c. The IRB-approved informed consent document;
d. Applications for Federal support, if applicable;
e. Advertising or recruiting materials, if applicable;
f. Applications for protocol amendments or modifications;
g. Continuing review progress reports and related information;

h. Reports of unanticipated problems involving risks to subjects or others;
i. All IRB correspondence related to the research;
j. Documentation of all IRB review and approval actions including initial and continuing convened (full) IRB review; and
k. Documentation of Project Completion and or Closeout

7. IRB Data File

The University will maintain a research-tracking data file in the Office of Academic Affairs by the IRB Administrator/Manager, Office of Human Subjects Research including but not limited to:

a. Title of Research.
b. Name of Principal Investigator.
c. Funding Source, if applicable.
d. Date of Initial Approval.
e. Date of Most Recent Continuing Approval.
f. End of Current Approval Period.
g. Type of Review.
h. Current Status (e.g., Under Review, Approved, Suspended).

MEETINGS, QUORUM & VOTING	Effective Date	02/01/2007
	Revisions Date	06/09
	IRB Policy Number	4.4
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

1. Meeting Frequency

1.1 Based on the needs of the research community, the IRB may hold at least one regularly scheduled meeting per month, at a time and place to be pre-determined and posted on the IRB web site. All members of the research community are welcome to attend and address specific concerns regarding their specific research protocol. Guests are asked to leave the meeting during all deliberations and votes.

1.2 Individual meetings may be cancelled by the Vice President for Academic Affairs following consultation with the IRB Chair due to:

a. Insufficient applications or other matters requiring convened board review
b. University holiday
c. Inability to secure a quorum for attendance
d. Other reasons (such as inclement weather) that make a scheduled meeting unnecessary or otherwise inappropriate

2. Quorum Requirements and Voting at IRB Meetings

2.1 Except when an exempt or expedited review procedure is used, the IRB shall review initial or continuing studies at convened meeting at which a quorum is present. A quorum for a convened IRB meeting is 50% of the voting primary membership (including alternate members who may replace voting members) plus one. A quorum must be maintained for each vote to occur. If a quorum is not maintained, the meeting shall end or be suspended and the study shall be tabled.

2.2 Institutional Review Board quorum requirements are based on the following standards:

a. A majority of the IRB members [or designated alternate(s)] must be present in order to conduct a convened meeting. In order for research to be approved, it must receive the approval of a majority of those members present at the meeting.
b. At least one non-scientist member must be present to conduct official IRB business.

c. Members may be present in person or audio (telephone) or audio-visual teleconference and noted as such in the meeting minutes. In addition, minutes will also indicate that the members received all pertinent information prior to the meeting and were able to actively and equally participate in all discussions.
d. IRB minutes will include documentation of the quorum and votes for each IRB action and determination by recording the votes as follows: Total number voting, Number voting for, Number voting against, and the number abstaining.
e. Members absenting themselves due to conflicting interests may not be counted toward quorum requirements (i.e. may not be counted among those voting or abstaining).
f. No individual who is not listed on the official IRB membership roster may vote with the IRB.
g. At least one member whose primary concerns are in nonscientific areas must be present to complete a quorum

3. At the discretion of the IRB Chair, voting may occur by written ballot, show of hands or verbally (if a member is participating through teleconferencing or videoconferencing). The official minutes shall define the number of votes to approve, disapprove, defer or table without identifying the IRB member who cast that vote. The official meeting minutes shall also define the number of votes cast as abstentions. In the event an IRB member elects to abstain, the minutes shall record the abstention.

CONFIDENTIALITY OF MEETINGS & GUEST ATTENDANCE	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	4.5
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

1. Proceedings of IRB meetings are considered confidential. IRB members, alternate members and ex officio members should not disclose information about studies including (but not limited to) contents of files, details of discussions and the attribution of comments to specific committee members.

2. Persons may be permitted to attend Dillard University IRB meetings as guests under the following conditions:
   - **2.1** Guest attendance is at the discretion of the IRB chair or IRB-designee
   - **2.2** Guests may be asked to leave at any time
   - **2.3** Guests may not be in attendance during the deliberations relative to a study in which they serve as PI, co-investigator or key personnel
   - **2.4** Guests shall sign in and may be asked to document the purpose of their visit

AGENDA & MINUTES	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	4.6
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

1. Agenda

Convened meetings of an IRB shall have an agenda, constructed by the IRB Administrator/Manager, Office of Human Subjects Research, which clearly shows the topics and items that the members will consider at the meeting. The agenda shall identify each study by title, IRB number and Principal Investigator name. Agendas will become part of the official meeting record to assist location of a specific item or action in the minutes of the meeting.

2. Minutes

2.1 Minutes of each IRB are recorded in writing. The IRB Chair will review, monthly, each set of minutes to evaluate the veracity of correct determinations and subsequent justifications. This is done in consultation with the IRB Administrator/Manager, Office of Human Subjects Research. Minutes are distributed monthly to all IRB members (chair, members, and alternates). The minutes are distributed to the members via a secure website and a vote for approval of those minutes taken at the next convened meeting. The IRB Chair documents approval of the minutes by signing the official copy of the document. Upon approval of the minutes, a copy of the minutes is provided to the Vice President for Academic Affairs for the purpose of informing with respect to all actions taken by the IRB.

2.2 Minutes include separate deliberations, actions, and votes for each protocol undergoing initial or continuing review by the convened IRB. The minutes will document the total number of members attending the meeting. In order to document the continued existence of a quorum, vote totals for each action will be recorded in the minutes by listing the number of members originally present, that were absent for this vote only, along with the breakdown of members voting for, against, and abstaining. In order for a protocol to be approved, it must receive the approval of a majority of members present at the meeting. The minutes include the documentation of any potential conflict of interest that an IRB member may have with a particular protocol and indicate that the IRB member was absent from the room for the discussion and vote. IRB minutes reflect decisions and justifications regarding human subjects research involving vulnerable populations. IRB minutes list all suspended and terminated

protocols that occurred during the previous month. ORS Program Coordinator(s) are

2.3 It is the responsibility of the IRB Administrator/Manager, Office of Human Subjects Research to ensure that official IRB meeting minutes, recording the reviews, deliberations and votes of the IRB are written and subsequently provided to the IRB for approval.

2.4 It is also the responsibility of the IRB Administrator/Manager, Office of Human Subjects Research to make any corrections to the minutes as defined by the IRB. IRB votes to approve, disapprove, defer or table studies or other matters shall be recorded. If an IRB member elects to abstain from a vote, the minutes shall record the abstention. Minutes shall not reflect how an individual member has voted on any particular motion but shall reflect only the outcomes of voting actions.

2.5 Required information to be documented within meeting minutes relative to IRB reviews and decision is defined in federal regulations [45 CFR 46.115(a)(2)]. This information shall include but is not limited to:

a. Attendance at the start of the meeting, the mode of attendance (in person, video conference, teleconference, etc.) and any changes in attendance or the mode of attendance that occur during the meeting
b. Documentation that all members received all pertinent materials prior to the meeting and were able to actively and equally participate in discussions
c. The presence of a quorum throughout the meeting including the presence of at least one member whose primary concern is in a non-scientific area, the presence of at least one member not affiliated with the university and the presence (if applicable) of consultants with the appropriate expertise to provide guidance/recommendations to the IRB upon request of the IRB
d. The review and approval of previous meeting minutes
e. That any IRB member with a real or potential conflict of interest relative to a study under consideration was not present during the deliberations or voting on the proposal (and that the quorum was maintained)
f. The determination of the level of risk in each reviewed study
g. The determination of whether or not the subject population will receive any direct benefit or if there is benefit to society as a whole
h. The deliberations (if application) on the justification for waiving any or all of the required elements of informed consent
i. The determination that informed consent documents were reviewed in accordance with applicable regulations and contains all of the required elements
j. Actions taken by the IRB
k. The vote on actions taken by the IRB including the number of members voting for, against and abstaining

l. The basis for requiring changes in or disapproving studies and documentation of resolution of these issues if/when resolution occurs
m. The length of time of an approval
n. A written summary of the discussion with emphasis upon the identification and deliberation related to controverted issues and the resolution of such issues
o. The deliberations relevant to the inclusion and safeguarding of vulnerable populations if entered as study subjects
p. Documentation of the four required findings (cf. 45 CFR 46.116) when approving a consent procedure that does not include or that alters some or all of the required elements of informed consent or when waiving the requirement to obtain an informed consent
q. Any educational/training information provided to the IRB during the convened meeting

REBUTTAL OF IRB DECISIONS	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	4.7
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

IRB approval is always necessary before a research project involving research participants may begin. An IRB decision to not approve a human research project, or require modifications as a condition for approval, cannot be overturned by any Dillard University official or Dillard University committee.

The IRB must provide the investigator with a written statement of the reasons for not approving proposed research and must give the investigator an opportunity to respond in person or in writing. The IRB must carefully and fairly evaluate the investigator's response in reaching a final determination.

If an investigator has concerns with respect to procedures or decisions of the IRB, the investigator may discuss his/her concerns with the Vice President of Academic Affairs (Provost-Signatory Official) with the understanding that the decision of the IRB cannot be reversed, nor can undue pressure be applied to the IRB to reverse a decision.

1. Process

Investigators must first put their concern(s) in writing to the Senior Vice President of Academic Affairs, who may use his or her sole discretion to determine the process for responding to an investigator's concern, including:

1.1 Notifying the IRB of the concern and requesting a response and relevant information from its records

1.2 Submitting the concern to mediation if the investigator agrees to participate

1.3 Appointing a fact-finder to review the matter and report back

1.4 Seeking assistance from consultants or Office of the Legal Affairs.

UNDUE INFLUENCE AND THE IRB	Effective Date	06/01/2009
	Revisions Date	
	IRB Policy Number	4.8
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

The IRB review processes and the implementation of standard operating policies and procedures governing the IRB, are to be conducted objectively and without undue influence over deliberations or processes. IRB members, IRB administrative staff, investigators, or research participants who believe that an attempt has been made to unduly influence the IRB, review processes, or application of policies and procedures may contact the Vice President of Academic Affairs or the IRB Administrator/Manager, Office of Human Subjects Research to report a concern. The Vice President of Academic Affairs or other delegated senior staff members will review reports. Outcome of the review will be documented, the complainant provided with a response, and a corrective action plan instituted if deemed necessary.

POLICIES GOVERNING THE IRB	Effective Date	06/01/2009
	Revisions Date	
	IRB Policy Number	4.9
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

Dillard University maintains written IRB policies and procedures reflecting current practices of the IRB in conducting reviews and approvals under its Assurance and also reflecting the supporting responsibilities of the OHR. These policies and procedures were written and implemented with three essential goals:

1. To ensure that the IRB and all institutional employees carry out their responsibilities pursuant to research involving human subjects in compliance with federal regulations and the high ethical standards of the University;
2. To provide a clear foundation, and a basis for consistency of, IRB review and actions;
3. To provide a structure for training of university faculty and staff, IRB members and HSRO staff

New IRB policies and procedures, or revisions to such policies and procedures, may be recommended by OHR staff, University faculty and staff, and IRB members or the convened IRB. Such recommendations should be addressed to the IRB Administrator/Manager, Office of Human Subjects Research for review and presentation to the IRB policy and procedure group. This group is composed of the Senior Vice President for Academic Affairs, the IRB Chair and the IRB Vice-Chair. By majority vote, IRB policy and procedure group shall approve or disapprove any or all sections of the policies and procedures and/or revisions. The dates of approval and/or revision shall be documented at the top of each section.

It is the responsibility of the IRB policy and procedure group to ensure that the IRB policies and procedures are reviewed periodically and to ensure that IRB members and OHR staff are informed of any changes. The Committee shall meet at least annually and shall undertake a review of IRB policies and procedures at least once during a 36 month period (Spring).

SUBMISSION OF DOCUMENTS (NEW & CONTINUING)	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	5.0
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

The IRB has the following written policies and procedures for conducting initial and continuing review and procedures for handling modifications to research studies.

1. Application Documents

Documents and necessary forms required for IRB review of new or continuing studies are provided by the IRB Administrator/Manager, Office of Human Subjects Research, on request, and are also available on the IRB website. Such documents and forms shall be submitted by the Principal Investigator to the IRB Administrator/Manager, Office of Human Subjects Research where it is assigned an IRB data file number.

The IRB Administrator/Manager, Office of Human Subjects Research or designee shall screen submitted documents and forms for completeness before it is routed to the IRB. If the application is found to be incomplete or otherwise not fully prepared for IRB review, it shall be returned to the Principal Investigator or a request shall be made for necessary changes or to provide additional information. The IRB Administrator/ Manager, Office of Human Subjects Research or an IRB member may contact the Principal Investigator to request clarification of study issues or revisions in document(s) prior to review by the IRB or during the review process.

2. Recommendations for Review Category

As part of the submission process for new or continuing studies, the Principal Investigator shall be asked to recommend whether the study, by its scope and protocol, falls into one of specific review categories defined in 45 CFR 46 and 21 CFR 56. These categories are: Exempt Review, Expedited Review, and Convened IRB Review.

2.1 It is the responsibility of the Principal Investigator to understand and request an appropriate review category for his/her application.

2.2 Those studies recommended under the exempt or expedited categories shall be forwarded to the IRB chair or chair-designee for review. Chair-designees must be members or alternate members of the IRB. The IRB chair or chair-designee shall make the final decision as to whether the study may be reviewed within the exempt or expedited category or whether the study should be referred to the convened IRB.

2.3 The IRB chair and chair-designees shall conduct reviews of studies that fit within the exempt or expedited categories on behalf of the IRB. The

applications of those studies that fit under the "Convened IRB Review" category shall be made available to all members of the IRB. IRB chairs/IRB-designees may determine that studies recommended for exempt or expedited review require convened IRB review. Conversely, the convened IRB may determine that studies recommended for "Convened IRB Review" require exempt or expedited review.

CRITERIA FOR IRB APPROVAL OF RESEARCH	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	5.1
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

The IRB chairs, IRB-designees and convened IRB shall conduct a systematic review of the study materials and shall consider the same principles and criteria in its deliberations of all new or continuing studies, no matter whether these fall into the exempt, expedited or convened IRB category, in accordance with 45 CFR 46. Among these criteria are:

1. **Levels of Risk**

   According to Federal regulations at 45 CFR 46.102(i), minimal risk is defined as "the probability and magnitude of harm or discomfort in the research are not greater in and of themselves than those encountered in daily life or during the performance of routine physical or psychological examinations or tests." Although a primary principle for investigators in designing research is to "minimize risks while maximizing benefits", the IRB is responsible for evaluating the proposed research for a determination of "greater than minimal risk" versus proposed research that is "no greater than minimal risk" (45 CFR 46.111).

2. **Risks Minimized**

   In order to approve research, the IRB must evaluate the soundness of both the research design and methodology and determine that the risks to subjects have been minimized. In addition, whenever appropriate, research should utilize procedures, diagnostics, and or interventions that are already being used. When the research designs present unacceptable or unnecessary risks without commensurate benefits, the research cannot ethically proceed (45 CFR 46.111).

3. **Investigator's Educational Requirements and Certification**

   The IRB must also consider researcher qualification, professional credentials, and licensing issues. In general, the research team must possess the professional and educational qualifications and resources to conduct the proposed research within the realms of federal regulatory edicts. In addition, the IRB should ensure that the PI and all key personnel in the study have met current educational requirements for the protection of human research subjects as mandated by the University.

4. Risk-Benefit Ratio

In order to approve research, the IRB must determine that the anticipated benefits from the research relatively outweigh the risks. The risk-benefit analysis should encompass an assessment of the relevant literature about the risks and benefits of the proposed research without the consideration for long-term application of the knowledge gained.

In assessing risks and benefits and the justifiability of research, the IRB shall follow the following five guidelines of the National Institutes of Health (http://ohsr.od.nih.gov/guidelines/Belmont.html):

a. Brutal or inhumane treatment of human subjects is never morally justified
b. Risks should be reduced to those necessary to achieve the research objective. It should be determined whether it is necessary to use human subjects at all and/or whether alternative procedures could reduce or eliminate risks
c. When research involves significant risk of serious impairment, the IRB should require written justification of the risk (looking usually to the likelihood of benefit to the subjects – or, in some rare cases, to the discernable voluntariness of the participation
d. When vulnerable populations are involved in research, the appropriateness of involving them should be demonstrated. Variables which should go into such judgments include the nature and degree of risk, the condition of the particular population involved, and the nature and level of the anticipated benefits
e. Relevant risks and benefits must be thoroughly defined in documents and procedures used in the informed consent process

5. Equitable Selection of Subjects

In order to approve research, the IRB must determine that the selection of subjects is equitable. In making this determination, the IRB should carefully exam (a) the research purpose, (b) the research setting, (c) the inclusion-exclusion criteria, (d) recruitment procedures, and (e) problems of research with vulnerable populations.

The IRB should also be attentive to the inclusion of minority groups as well as men, women, and children. In addition, the exclusion of any of these persons must be fully justified and based on sound scientific rationale.

6. Informed Consent Procedure

In order to approve research, the IRB must determine that legally effective informed consent and assent, when applicable, will be sought from each prospective participant and or their legal/authorized representative (see 45 CFR

46.116), unless informed consent is waived or altered according to Federal regulations and applicable law.

The following informed consent procedures apply to all research conducted at Dillard University or by Dillard University employees or agents:

a. Informed consent may only be sought under circumstances that provide the prospective participant, legal guardian, or legal representative with sufficient opportunity to consider whether or not to participate thereby minimizing the possibility for coercion or undue influence.
b. Informed consent information must be presented in language that is understandable to the participants, legal guardian, or legal representative.
c. No informed consent process may include any exculpatory language through which (i) the participant is made to waive, or appear to waive, any legal rights as research participants; or (ii) the investigator, sponsor, Dillard University, or Dillard University's employees or agents are released from liability for negligence, or appear to be so released.
d. Informed consent must be obtained prior to the initiation of any clinical screening procedures that are performed solely for the purposes of determining eligibility for research.

7. Privacy of Subjects and Confidentiality of Data

In order to approve research, the IRB must determine that, where appropriate, there are adequate provisions to protect the privacy of subjects and the confidentiality of data. Therefore, consideration will be given to the nature, probability, and magnitude of harm that would result from a disclosure of collected information outside the research. In addition, techniques for data management and storage should be evaluated for adequacy and effectiveness.

8. Payment to Research Subjects

The Dillard University designated IRB will review all proposed payments to research participants. Payments to research participants may not be of such an amount as to result in coercion or undue influence on the decision-making process for participation. In addition, Federal policy prohibits payment to prospective research participants when the research is an integral part of their medical care.

9. Student Participation as Research Subjects

Student participation as research subjects must be voluntary. Any participant must have the right to withdraw from an ongoing procedure at any time without prejudice, that is, with no penalty for withdrawal and no coercion to continue. Any student under the age of 18 must have parental consent in order to participate as a research subject.

If extra credit for research participation is offered, students must be provided with reasonable alternatives to research participation, which should be equal in extra credit value and approximately equivalent in both time and effort. This is necessary to avoid any possibility of indirect coercion. Students who begin research participation for extra credit but withdraw before it is completed, need not be given extra credit for the research participation. They should, however, be offered the opportunity for a reasonable alternative to research participation as described above.

SAMPLE SIZE	Effective Date	06/01/2009
	Revisions Date	
	IRB Policy Number	5.2
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

Principal Investigators must provide information regarding the number of participants to be enrolled in a research study. This number should be large enough to account for drop-outs, screen failures, or other complications that affect eligibility. *Once accrual for the study reaches the number approved by the IRB, enrollment must cease*. Enrollment of participants beyond the number of participants in the original, approved research plan is considered non-compliance.

The approved sample size is defined as the number of participants who sign the informed consent document, are enrolled using an oral consent process, or is "enrolled" with an IRB approved waiver of consent.

An increase to the number of participants approved in the original research plan requires an amendment to the IRB for review before enrolling the additional participants. The IRB has the authority to modify the sample size. Enrollment may not continue above the original sample size until the IRB approves the amendment, which may be eligible for an expedited review.

APPROVAL DURATION	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	5.3
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

Federal regulations ([45 CFR 46.109(e) require that continuing review of research be conducted by the IRB at intervals appropriate to the degree of risk and not less than once per year. Pursuant to regulations, the IRB shall define the duration of approval of each study with the requirement that all studies, no matter whether previously approved under the expedited or convened IRB review category, shall be subject to continuing review at intervals appropriate to the degree of risk and not less than once per year. Regulations make no provision for any grace period extending the conduct of the study beyond the expiration date of IRB approval.

1. Determination of Approval Duration

Among the factors that the IRB shall consider in determine whether a study requires continuing review by the IRB more frequently than annually are:

1.1 If the study involves experimental therapies or procedures in which a clear potential for significant adverse experiences has been identified at the time of review
1.2 The nature, probability and magnitude of anticipated risks to subjects
1.3 Likely medical or psychological condition of the proposed subjects
1.4 Qualifications of the PI and other members of the research team
1.5 Nature and frequency of adverse events observed in similar research
1.6 Vulnerability of the population being studied including familiarity with the language on consent forms and other documents
1.7 Other facts the IRB deems relevant

2. Review Expirations

2.1 Initial Review

The expiration date is calculated from the date of review by the convened IRB, Chair or designated reviewer and the date the protocol was approved or approved with stipulations. Protocols that have not undergone continuing review will expire at midnight on the expiration date. Research activities may not continue after midnight of the expiration date. A shorter interval would indicate a degree of risk greater than minimal and, if this is the case, the research does not qualify for expedited review.

1.2 Continuing Review Non-Exempt Research

Continuing review approval periods are one year from the day of formal re-approval, unless otherwise necessitated.

1.3 Exempt Research

Exempt protocols will be approved for a three-year period.

NOTIFICATION LETTERS	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	5.4
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

1. Determination Letters

The IRB Administrator/Manager, Office of Human Subjects Research shall notify Principal Investigators and institution leaders (when appropriate) in writing of IRB determinations relative to approval, disapproval, required modifications, suspensions, terminations and other information and matters for which such disclosure is required.

2. Elements of Determination Letters (except approval letters)

Determination letters shall reference the assigned IRB number of the study, Principal Investigator, project title, date of the IRB action, the IRB action itself, and other pertinent information.

3. Approval Letters

Letters documenting the approval of initial or continuing studies or study amendments, no matter whether approved by expedited review or by the convened IRB, shall specify conditions and terms of approval.

4. Elements of Approval Letter

Letters of approval of initial or continuing studies shall include at least the following information/instructions:

4.1 The Principal Investigator is responsible for compliance with all applicable federal regulations and Dillard University written policies and procedures.

1.4 It is necessary to retain signed consents by all subjects unless a waiver is granted.

1.5 Participants must sign a consent form that has been received IRB approval.

1.6 Any and all modifications (amendments) to the protocol and consent form must be submitted to and approved by the IRB before implementation.

1.7 Continuing and final reports are required.

EXEMPT STUDIES	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	6.0
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

In certain instances, social, behavioral, bio-social, and bio-behavioral research is exempt from the requirements of the Federal Regulations. In reviewing exemption requests, the IRB must elicit enough information from the investigator to ascertain whether the claimed exemption really applies. All exemptions claimed for research conducted at Dillard University or by employees or agents of Dillard University must be verified by the IRB.

Human subject research involving prisoners or pregnant women may never be exempt from IRB review. In addition, research involving minors may never be exempt under category 2 (research involving educational tests, survey procedures, interview procedures).

The exempt status applies only to the study as defined in the application that was reviewed by the IRB. Subsequent changes to previously exempted studies must be submitted to the IRB for review; and IRB approval is required prior to the implementation of any such changes. It is possible that the implementation of proposed changes to an exempt study may render that study no longer exempt. In this circumstance, the study must be re-submitted for IRB review.

Human subjects research may be exempt if all of the proposed research meets the criteria for one or more of the following six categories [45 CFR 46.101(b)(1) – (6)]. .

1. Social and Behavioral Research

Exemption 1: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exemption 2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:

a. When the subjects are adults, information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects and

b. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

c. When the subjects are children, research involving survey or interview procedures with children is NOT EXEMPT and

d. Observation of children is NOT EXEMPT if the investigator participates in the actions being observed.

Exemption 2 for research involving survey or interview procedures or observation of public behavior, does not apply to research with children (see 45 CFR Part 46, Subpart D), except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Exemption 3: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Exemption 4: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Research that meets the criteria for Exemption 4 is not considered "clinical research" as defined by NIH. Therefore the NIH policies for inclusion of women, minorities and children in clinical research do not apply to research projects covered by Exemption 4.

Exemption 5: Research and demonstration projects that are conducted by or subject to the approval of Department or Agency heads and that are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs (ii) procedures for obtaining benefits or services under those programs (iii) possible changes in or alternatives to those programs or procedures or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Exemption 6: Taste and food quality evaluation and consumer acceptance studies (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection

Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

EXPEDITED STUDIES	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	6.1
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

1. Initial Review

Approval of new or continuing studies may be made on an expedited basis by the IRB chair or designee. Criteria for approval by expedited review are the same as those of the convened IRB and the expedited review should be as meaningful and significant as that of the convened IRB.

A study may be qualify for expedited review and approval if it is considered that the study involves no more than minimal risk to human subjects and if it fits under one or more of the nine categories qualifying a study for expedited review in accordance with federal regulations 45 CFR 46.110 and the DHHS-FDA list of research eligible for expedited review http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm

If the study qualifies for expedited review, the IRB chair or designee may approve the study, seek additional information from the principal investigator, require modifications to the study to gain approval or defer the study to the convened IRB. If the IRB chair or designee determines that the study does not qualify for expedited review, the IRB chair designee shall refer the study to the convened IRB. The IRB Chair or designee conducting an expedited review may not disapprove a study but rather must forward the study for review by the convened IRB if he/she believes disapproval is warranted.

Expedited 1: Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Expedited 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Expedited 3: Prospective collection of biological specimens for research purposes by noninvasive means such as

Expedited 4: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Expedited 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Expedited 6: Collection of data from voice, video, digital, or image recordings made for research purposes.

Expedited 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Expedited 8: Continuing review of research previously approved by the convened IRB as follows:

a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

b. where no subjects have been enrolled and no additional risks have been identified; or

c. where the remaining research activities are limited to data analysis.

Expedited 9: Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

2. Expedited Review of Minor Changes in Previously Reviewed Research

Principal investigators must report to the University IRB any proposed changes in IRB-approved research, including proposed changes in the informed consent. No changes may be initiated without prior approval of the IRB, except where necessary to eliminate apparent immediate hazards to subjects.

The University IRB may expedite a proposed change to previously approved research if it represents a minor change to be implemented during the previously authorized approval period.

A minor change is one which, in the judgment of the IRB reviewer, makes no substantial alteration in either (a) the level of risks to subjects, (b) the research design and methodology, (c) the number of enrolled subjects, (d) qualifications of the research team, (e) facilities available to support safe conduct of the research, or (f) any other factor that would warrant review of the proposed changes by the convened IRB.

REVIEWS REQUIRING CONVENED IRB	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	6.2
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

The IRB Chair or IRB-designee shall recommend convened IRB review if a new or continuing study does not meet the criteria for exemption or for expedited review or if it is otherwise determined that the study requires review at a convened IRB meeting.

If a study is forwarded to the convened IRB for review, the IRB is responsible to make final decisions on the review category and may decide that the research may qualify for exemption or expedited review. If a study is recommended for convened IRB review, the IRB Administrator/Manager, Office of Human Subjects Research will assure that all relevant materials are routed to the IRB members with sufficient time, prior to the convened board meeting, to review and be prepared to participate in deliberations and voting.

The convened IRB may approve motions and thereby take any of the actions indicated below:

1. **APPROVED AS SUBMITTED**
   The study is approved as submitted, with no further action required. The Principal Investigator shall be notified in writing of the approval and its duration. The start date for the study shall be the date of this IRB approval, and the study may begin upon receipt of the letter of approval.

2. **APPROVED AS MODIFIED BY THE IRB**
   The study is approved with revisions, clarifications or other changes to the protocol or to the informed consent or other documents made by the IRB. The Principal Investigator shall be informed in writing of the changes made by the IRB and the duration of approval.

   2.1 The letter to the Principal Investigator shall state that the PI must conduct the study as modified by the IRB in accordance with the IRB approval.

   2.2 If the PI does not accept the changes made by the IRB, he/she may not initiate and the IRB approval is to be considered void. The study may not be started unless/until a new IRB approval is obtained and confirmed in writing to the PI.

3. **DEFERRED FOR SUBSEQUENT EXPEDITED REVIEW**
   The IRB has agreed to approve the study but with conditions that require revisions and/or clarifications that the IRB determined to be nonsubstantive and minor and not directly relevant to the IRB determinations required under 45 CFR 46.111. Such revisions or clarifications may be reviewed and approved by the IRB chair or designee on an expedited basis.

3.1 Required revisions or clarifications must be submitted within 30 calendar days following notification to the Principal Investigator unless the IRB requires a due date that is different

3.2 The Principal Investigator shall be notified in writing that the revisions and/or clarifications shall be reviewed on an expedited basis by the IRB Chair or designee. The IRB shall clearly specify the action(s) needed and who has the authority to review and approve the revised or requested materials on an expedited basis. The letter shall also define that the study has been deferred and has not received IRB approval and that the study must not be initiated until the IRB Chair or designee has approved it on behalf of the IRB.

4. **DEFERRED FOR SUBSEQUENT RE-REVIEW BY THE CONVENED IRB**
The IRB has agreed that the study needs revisions or clarifications from the Principal Investigator for subsequent review by the convened IRB. This motion shall pertain when the convened IRB has determined that the revisions or clarifications are substantive and directly relevant to the IRB determinations required under 45 CFR 46.111.

4.1 In this case, the Principal Investigator shall be informed in writing of the needed revisions and/or clarifications and the requirement that these revisions or clarifications be submitted within 30 calendar days unless otherwise specified by the IRB. The letter shall make clear that the study is not approved and the revisions and/or clarifications will be reviewed at a convened IRB meeting.

5. **TABLED**
The IRB is unable or unwilling to review and/or vote on a study or other matter. This may occur if the quorum is lost, pertinent documents are unavailable or the scope of IRB expertise is not considered sufficient for appropriate decision-making.

6. **DISAPPROVED**
The study is not approved by the IRB for reasons such as that the study requires major changes or that it is not likely to be feasible without a complete reassessment of the protocol by the Principal Investigator and/or sponsor.

6.1 The Principal Investigator shall be notified in writing of the disapproval. The letter shall include a description of the reasons why the IRB has taken this action and shall inform that the Principal Investigator has an opportunity to respond to the IRB in person or in writing.

INITIAL REVIEW EXEMPT	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	7.0
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

1. General Principles

The IRB Chair or the Chair's designee shall make the final determination whether an initial study qualifies for exempt status by virtue of the fact that it provides no more than minimal risk and that it falls within the criteria required to be exempted from federal regulations. This decision shall be made according to regulations included in 45 CFR 46.101(b)(1)-(6). The IRB may grant exempt status only if all research activities within the study involve procedures listed under 45 CFR 46.101(b). The IRB shall not grant exempt status to research involving prisoners, pregnant women, fetuses and human in vitro fertilization and to FDA-regulated research. Research involving minors will not be exempt under 45 CFR 46.101(b)(2).

The IRB Chair or designee may use their discretion as to whether a study should be exempt or requires IRB review even if the study fulfills the criteria for exemption according to the regulations.

2. Review Process

The Chair or designee shall conduct a substantive and meaningful review of all materials related to the assigned study, conduct informal queries of the Principal Investigator and/or other experts as necessary to provide a thorough review and present clear and concise requirements/recommendations for changes and/or questions in written form (by email or otherwise) for communication to the Principal Investigator. The Chair or designee may request minor revisions and/or clarifications before approval for exemption is granted. The chair or designee may request a second reviewer and/or may seek recommendations from an expert consultant(s) for issues which require expertise beyond, or in addition to, that available on the IRB.

3. Informed Consent

Approval of a study as exempt does not automatically include exemption from the informed consent or HIPPA authorization requirements. If exemptions from these requirements are requested by the Principal Investigator, these requests must be reviewed and decided upon by the IRB chair or designee. If informed consent is required, the documents should contain all required elements unless an exclusion is justified in writing by the Principal Investigator and approved by the IRB Chair or designee.

4. Notification of Exempt Status

If approved, the IRB Chair or designee shall document the exempt category, as defined in federal regulations, that apply to the study. This documentation shall be provided to the IRB Administrator/Manager, Office of Human Subjects Research who is responsible for record-keeping and for creating correspondence to the Principal Investigator.

The convened IRB shall be notified of exempt approvals in a timely manner. If the IRB Chair or designee does not approve a study as exempt, the chair or designee shall defer the study to expedited or convened IRB review by notifying the HSRO of this decision. The Principal Investigator shall be informed of this decision and its reasons. If the study is deferred for expedited review, the Principal Investigator may appeal this decision to the IRB chair. If the study is deferred for review by the convened IRB, the Principal Investigator may appeal this decision to the convened IRB.

5. Amendments-Modifications

All changes in exempt studies must be reported to the IRB for review and approval prior to implementation. The IRB and Principal Investigators shall understand that the criteria to exempt a study from federal regulations must remain applicable during the entire time that an exempt study remains active and that certain changes may disqualify the research from exempt status.

6. Continuing Review

Regulations do not require continuing review of exempt research. However, the IRB chair or designee may require such reviews at his/her discretion.

INITIAL REVIEW EXPEDITED	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	7.1
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

1. General Principles

The IRB Chair or the Chair's designee from among the IRB members shall determine whether a study involves no more than minimal risk and may be reviewed and approved within the "expedited category". This decision shall be made according to regulations included in 45 CFR 46.110, 45 CFR 46.111.

If the IRB Chair or designee disagrees with the applicability of expedited review for a given study, the Chair or designee may refer the study to the convened IRB by notifying the IRB Administrator/Manager, Office of Human Subjects Research of this decision. Even if the submission fulfills the criteria for expedited review according to the regulations, the Chair or designee may use his/her discretion as to whether the study should be expedited or referred for convened IRB review.

2. Process

In conducting an expedited review of an initial study, the IRB Chair or designee may exercise all of the authorities of the IRB with the exception of disapproval of the study.

The Chair or designee shall conduct a full, significant and meaningful review of all materials related to the assigned study, inquire of the Principal Investigator and/or other experts as deemed necessary and present clear and concise requirements/recommendations for changes and/or questions in written form (by email or otherwise) for communication to the Principal Investigator. The Chair or designee may request minor revisions and/or clarifications from the Principal Investigator before approval is granted. The chair or designee may request a second reviewer and/or may seek recommendations from an expert consultant(s) for issues which require expertise beyond, or in addition to, that available on the IRB.

3. Criteria for Approval

Approval by the IRB chair or IRB-designee of a study under the expedited review process requires:

3.1 Confirmation that the research poses no more than minimal risk

3.2 Identification of the specific permissible category of expedited review into which the study falls

3.3 Determination of the requirement for continuing review and additional requirements
3.4 Review of the informed consent process in accordance with regulations
3.5 Review of any recruitment procedures involving advertisements
3.6 Documentation of the above findings
3.7 Consideration of the principles and deliberation criteria including:
   i. Research relevance
   ii. Minimization of risks
   iii. Reasonable risk/benefit ratio
   iv. Equitable selection of subjects
   v. Appropriate informed consent process or waiver
   vi. Adequate safety monitoring and provisions for privacy and confidentiality
   vii. Protection of vulnerable subjects
   viii. Conflict of interest
   ix. Investigator's educational requirements and certification

If the chair or IRB-designee approves the study on an expedited basis, he/she shall determine the interval to a required continuing review. This interval shall not be greater than one year from the date of the initial IRB approval.

If expedited approval is granted by the IRB Chair or designee, he/she shall:

a) Document the expedited category(ies) that applies to the study
   [*NOTE – A children's category (under 45 CFR 46 Part D) must be identified if any minors under the age of 18 years are involved as research participants, and 45 CFR 46 SubPart B must be satisfied if the research involves pregnant women, fetuses, neonates of uncertain viability, placenta, dead fetus, or fetal material. New Studies involving 45 CFR 46 SubPart C (i.e. research involving prisoners) shall not be reviewed in an expedited manner.*]
b) Comment on the review of informed consent (unless a waiver of consent was approved)
c) Provide required findings if a waiver of consent (45 CFR 46.116(d) or alteration of consent (45 CFR 46.116(c)) or waiver of documentation of informed consent (45 CFR 46.117(c)(1 or 2) is requested/approved, 45 CFR 46(c) if the study includes a research subject who has become a prisoner

This documentation shall also include approval period dates (if less than annual continuing review is recommendation) and detail limitations to approval periods (such as limitations to enrollment numbers prior to reporting back for continuing review.

The IRB Chair or IRB-designee shall provide the documentation (above) to the HSRO which is responsible for record-keeping and for creating correspondence to the Principal Investigator. The HSRO shall ensure that notification of expedited review approval is made at the next convened IRB meeting.

If the IRB Chair or designee is not able to approve the study, the Principal Investigator shall be informed of the reasons and may request convened IRB review.

Throughout these studies, the requirements for informed consent (or its waiver or alteration) apply to all studies meeting criteria for approval on an expedited basis.

INITIAL REVIEW CONVENED	Effective Date	02/01/2007
	Revisions Date	06/10
	IRB Policy Number	7.2
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

Studies being reviewed by the convened IRB shall be assigned one primary reviewer. Primary reviewers shall be prepared to lead the discussion of the study, other materials related to the study and the risk/benefit ratio. Primary reviewers are encouraged to seek expertise/consultation as necessary, to conduct informal queries of the Principal Investigator and other experts in order to provide a thorough review. Primary reviewers shall present specific recommendations for IRB actions, including changes and/or questions for the Principal Investigator.

IRB members shall receive all appropriate study materials for their review at least two weeks prior to scheduled IRB meetings in order to be prepared to participate in deliberations and voting. After presentation by the primary reviewer and deliberations at IRB meetings, any IRB member may motion for an action. For a motion to pass, the majority of voting members present must vote affirmatively. The convened IRB may approve motions and thereby take any of the actions indicated below:

APPROVED AS SUBMITTED

This motion defines the study as approved as submitted, with no further action required. In this case, the OHR shall inform the Principal Investigator in writing of the approval and its duration. The start date for the study shall be the date of this IRB approval, and the study may begin upon receipt of the letter of approval.

APPROVED AS MODIFIED BY THE IRB

This motion defines the study as approved with revisions, clarifications or other changes to the protocol or to the informed consent or other documents made by the IRB. In this case, the OHR shall inform the Principal Investigator in writing of the changes made by the IRB and of the IRB approval of the study including those changes and also including the duration of approval.

The letter to the Principal Investigator from the OHR shall state that the Principal Investigator must conduct the study as modified by the IRB in accordance with the IRB approval.

If the Principal Investigator does not accept the changes made by the IRB, he/she may not initiate the study pursuant to the IRB approval and that IRB approval is to be considered void. The study may not be started unless/until a new IRB approval is obtained and confirmed in writing to the Principal Investigator by the OHR.

If the Principal Investigator does not accept the changes made by the IRB, he/she may withdraw the study, appeal to the IRB or make revisions to the study for reevaluation by the IRB.

DEFERRED FOR SUBSEQUENT EXPEDITED REVIEW BY THE IRB CHAIR OR DESIGNEE

This motion defines that the IRB has agreed to approve the study but with conditions that require revisions and/or clarifications that the IRB determined to be nonsubstantive and minor and not directly relevant to the IRB determinations required under 45 CFR 46.111. Such revisions or clarifications may be reviewed and approved by the IRB chair or designee on an expedited basis.

Required revisions or clarifications must be submitted to the OHR by the Principal Investigator within 30 calendar days following notification to the Principal Investigator by the OHR unless the IRB requires a due date that is different from that occurring 30 days following notification.

Pursuant to this motion, the OHR shall notify the Principal Investigator that the revisions and/or clarifications shall be reviewed on an expedited basis by the IRB Chair or designee. The IRB shall clearly specify the action(s) needed and who has the authority to review and approve the revised or requested materials on an expedited basis. A letter shall be forwarded to the Principal Investigator by the OHR indicating the specific required action(s) and the fact that the documents may be returned for review on an expedited basis and that another convened IRB review may not be required unless the study is deferred to the convened IRB by the IRB Chair or designee. The letter shall also define that the study has been deferred and has not received IRB approval and that the study must not be initiated until the IRB Chair or designee has approved it on behalf of the IRB.

If the study is subsequently approved by the IRB Chair or designee, the OHR shall inform the Principal Investigator of this approval and that the date of approval is the date that the fully-convened IRB deferred the study and set conditions for its expedited re-review rather than the date that the minor changes were approved on an expedited basis by the IRB Chair or IRB-designee. The study may begin upon receipt of this letter of approval.

If revisions and/or clarifications are submitted after the due date, the Chair/designee may seek an explanation from the Principal Investigator and/or:

a) Defer the study to the convened IRB for its review and approval/disapproval; **OR**
b) Defer the study to the IRB for withdrawal. If the IRB withdraws the study, the Principal Investigator may re-submit a new application for the study incorporating the revisions and/or clarifications from the prior IRB review; **OR**
c) Find the explanation and the revisions and/or clarifications acceptable and approve the study

DEFERRED FOR SUBSEQUENT RE-REVIEW BY THE CONVENED IRB

This motion defines the study as needing revisions or clarifications from the Principal Investigator for subsequent review by the convened IRB. This motion shall pertain when the convened IRB has determined that the revisions or clarifications are substantive and directly relevant to the IRB determinations required under 45 CFR 46.111. In this case, the Principal Investigator shall be informed by the OHR in writing of the needed revisions and/or clarifications and the requirement that these revisions or clarifications be submitted within 30 calendar days unless otherwise specified by the IRB. The letter shall make clear that the study is not approved and the revisions and/or clarifications will be reviewed at a convened IRB meeting.

If the study is subsequently approved by the convened IRB, the OHR shall inform the Principal Investigator of this approval and that the date of approval is the date that the fully-convened IRB gave final approval to the study. The study may begin upon receipt of this letter of approval.

If revisions and/or clarifications are submitted after the due date, the OHR shall seek an explanation from the Principal Investigator and the IRB may either conduct its review or it may withdraw the study. If the IRB withdraws the study, the Principal Investigator may re-submit a new application for the study incorporating the revisions and/or clarifications from the prior IRB review.

TABLED

This motion defines the situation if the IRB is unable or unwilling to review and/or vote on a study or other matter. This may occur if the quorum is lost, pertinent documents are unavailable or the scope of IRB expertise is not considered sufficient for appropriate decision-making. Although the Principal Investigator may be notified of this motion, no action by the Principal Investigator is required.

DISAPPROVED

This motion defines the study as not approved by the IRB for reasons such as that the study requires major changes or that it is not likely to be feasible without a complete reassessment of the protocol by the Principal Investigator and/or sponsor. In this case, the OHR shall inform the Principal Investigator in writing of the disapproval. The letter shall include a description of the reasons why the IRB has taken this action and shall inform that the Principal Investigator has an opportunity to respond to the IRB in person or in writing. If the Principal Investigator appeals the disapproval, it is the responsibility of the IRB to ensure that there is a fair hearing of the appeal.

MODIFICATIONS IN PREVIOUSLY APPROVED RESEARCH	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	7.3
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

Review and approval of proposed changes in approved research prior to initiation of any changes, with one exception. The exception is a change in research necessary to eliminate apparent immediate hazards to a research participant. In cases where changes were made to eliminate apparent immediate hazards, it is the responsibility of the Principal Investigator to inform the IRB promptly of the change and the IRB must determine if the modified research is consistent with ensuring participants' continued welfare.

Changes in research may encompass amendments, addenda, deletions, or revisions to either the protocol or consent document associated with a protocol. The Principal Investigator must submit information to allow the IRB to determine if the proposed change may be approved. For changes that are minor, an expedited review can be requested. A convened review process is necessary for all changes that are not minor. Changes or modifications reviewed through an expedited review process will be reported to the IRB members.

IRBs conducting review of changes in research are authorized to alter the approval period for the research based on degree of risk posed by the change in research or to retain the original approval period granted at initial review. IRBs have the authority to require revisions to consent documents and require notification to enrolled participants of approved changes in research that may affect the participants' decision to continue in the research.

INFORMED CONSENT	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	8.0
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

1. General Principles of Informed Consent

Informed consent is a fundamental and thoughtful process to ensure respect for human subjects and to ensure that their initial and continuing participation in studies is an informed, voluntary act. With few exceptions, investigators may not enroll human subjects in research unless they have obtained the legally effective, written, informed consent of the subject or the subject's legally authorized representative, prior to enrollment of the subject in the research.

Investigators are responsible for ensuring that the subjects, or their representatives, are given sufficient opportunity to consider whether or not to participate and must seek to avoid coercion or undue influence.

Occasionally, the institutional setting in which the consent is sought will pose the possibility of coercion or undue influence. Conducting research at institutions that provide services to subjects may be perceived as implying that continued service is dependent upon participation in the research. Students in the educational setting may be concerned that refusal to participate will affect their grades. These institutional pressures should be addressed in the research design. The protocol must adequately preserve the right to refuse participation.

The requirement to obtain informed consent should be seen as not only a legal obligation, but also as an ethical obligation. The research design must adequately address how informed consent will be obtained and what information will be given to prospective subjects. IRBs must look at the issues of coercion and undue influence in each proposal and insist on protocols where the circumstances of the consent process minimize the possibility of coercion and undue influence to participate.

2. Informed Consent & Non-English Speaking Participants

Dillard University is located in New Orleans, LA, a very culturally diverse city. Investigators are encouraged to recruit and include all segments of our community in research, including individuals whose primary language is not

English. Participants who do not speak English should be presented with a consent document written in a language understandable to them. Written consent documents should embody, in language understandable to the participant, all the elements necessary for legally effective informed consent. When research is being conducted in a language other than English, it is important that consent forms be translated accurately. Procedures for ensuring accurate translation should be described in the methods section of the proposal.

3. Informed Consent & Readibility

The JHM IRB recommends that the reading level of the informed consent document should be no higher than an 8th grade level. The IRB recognizes that some consent forms are of such a technical nature that it may not be possible to keep to an 8^{th} grade reading level.

4. Documentation

Appropriate documentation of the informed consent process is required unless a waiver or alteration of the consent has been approved by the IRB. The informed consent document should be signed and dated by the subject or his/her legally authorized representative and by the person obtaining consent and/or a witness who attests with his/her signature to the appropriateness of the consent process. The PI is responsible to ensure that the requirements of informed consent are fulfilled.

Full Consent

Written, signed consent should always be sought unless there are compelling reasons to seek an alteration or waiver of consent or waiver of documentation (e.g., signature)

ELEMENTS OF INFORMED CONSENT	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	8.1
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

The IRB shall recognize that the readability, cultural sensitivity and format of informed consent documents contribute to participant comprehension and satisfaction and decrease anxiety associated with the consent process. To assure these goals, eight required elements of informed consent have been defined by federal regulations [*45 CFR 46.116(c)* and *45 CFR 46.116(d)*]. The IRB shall examine informed consent documents for compliance with the required elements, seek clarifications from Investigators as appropriate and shall determine whether required elements of informed consent are adequately addressed (*Note: The informed consent requirements in this policy are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective).*

1. Required basic elements, unless waived by the IRB are:

1.1 A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental

1.2 A description of any reasonably foreseeable risks or discomforts to the subjects

1.3 A description of any benefits to the subjects or to others which may reasonably be expected from the research

1.4 A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subjects

1.5 A statement describing the extent, if any, to which confidentiality of records identify the subjects will be maintained

1.6 For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, and where further information may be obtained

1.7 An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subjects

1.8 A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subjects is otherwise entitled,

and the subjects may discontinue participation at any time without penalty or loss of benefits to which the subjects is otherwise entitled

2. **In addition to the eight required elements, federal regulations include additional elements of informed consent. When appropriate, one or more of these elements of information shall also be provided to each subject:**

2.1 If the risks of any research procedure are not well known, for example because of limited experience in humans: A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable;

2.2 If the research includes women of child bearing potential or pregnant women, and the effects of any research procedures on embryos and fetuses is not well known: A statement that the particular treatment or procedure may involve risks to the embryo or fetus, if the participant is or may become pregnant, which are currently unforeseeable.

2.3 If there are anticipated circumstances under which the participant's participation will be terminated by the investigator without regard to the participant's consent: Anticipated circumstances under which participation may be terminated by the investigator without the participant's consent.

2.4 If there are costs to the participant that may result from participation in the research: Additional costs associated with study participation.

2.5 If there are adverse consequences (e.g., physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research: Consequences of a participant's decision to withdraw from the research.

2.6 If there are adverse consequences (e.g., physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research: Procedures for an orderly termination of participation

2.7 If significant new findings during the course of the research that may relate to the participant's willingness to continue participation are possible: Statement that new findings developed during the course of the research that may relate to the participant's willingness to continue in the research study will be provided to the participant.

2.8 If the approximate number of participants involved in the study might be relevant to a decision to take part in the research: Approximate number of participants involved in the study

3. **Study Specific Additional Consent Information**

3.1 Psychological risk

The principles that apply to studies that involve psychological risk or mental stress are similar to those that involve physical risk. Participants should be informed of the risk and told that the University has no plan to provide treatment. They should be given the names and telephone numbers of agencies that may alleviate their mental concerns, such as a crisis hot line. If the principal investigator or the faculty sponsor of a

student investigator is qualified to treat mental health problems, that person may be listed as a resource.

3.2 Sensitive topics

Participants should be told that some of the questions are of a personal or sensitive nature and should be given examples of the topics or questions. They should also be told that they can skip a question if they do not wish to answer it. If questionnaires or interviews may generate reports of child physical or sexual abuse, the participant must be informed that the researcher is legally required to report this information to Child Protective Services. If the questionnaire or interview may generate reports that the participant plans to harm him or herself or others and the responses are not anonymous, the participant must be told that the investigator is ethically required to report that information the local police department.

3.3 Deception

Deception should be employed only when there are no viable alternative procedures. Where deception is a necessary part of an experiment, the IRB will generally require that a preliminary consent be obtained, in which the investigator informs the subject of the research. After the experiment, the subject should be informed of the deception and its purpose. We recognize that there are rare instances in which no consent can be obtained or debriefing done. Deception requires that a PI get formal approval of a waiver of informed consent, due to the initial consent being used.

3.4 Audio or video recording (participants must be told that):

3.4.1 The interviews or sessions will be audio or videotaped;

3.4.2 The cassettes will be coded so that no personally identifying information is visible on them;

3.4.3 The recordings will be kept in a secure place (e.g., a locked file cabinet in the investigator's office);

3.4.4 Recordings will be heard or viewed only for research purposes by the investigator and his or her associates; and

3.4.5 Recordings will be erased after they are transcribed or coded.

3.5 Studies that involve monetary or other compensation

The amount and type of the stipends or other compensations and the requirements to earn them must be clearly specified. This part of the consent form should be written as if it were a contract. If the study extends over a period of time, it is acceptable to reward a participant with a bonus if he or she completes all the interim components of the study.

3.6 Cover Letters

Cover letters, rather than consent forms, may be used for some categories of exempt minimal-risk research with adults such as survey or questionnaire research on non-sensitive topics. Cover letters are most frequently used for survey or questionnaire studies. The cover letter should state the purpose of the survey, the expected number of respondents, a description of the topic of the survey and the content of the questions on the survey, a statement about confidentiality or anonymity, and a statement about how the participant may obtain additional information about the study. The cover letter should also state that a decision not to participate will not affect, " ... Your current or future relationships with (names of relevant entities, such as Dillard University, standing in this class, grade in this class, status on this team, etc.)." The participant should be allowed to keep the cover letter. He or she need not sign it, because responding to the survey indicates a willingness to participate in the study. In the event that a cover letter is used, it must confirm to the authorization procedures required by HIPAA.

CONSENT-ASSENT FOR CHILDREN & MINORS	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	8.2
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

Whenever appropriate, Dillard University requires that adequate provisions are made for soliciting the assent of child subjects at least seven (7) years of age and older. Children ought to be apprised of the intended research activity even if the requirement for assent is waived by the IRB. This policy is based upon the Belmont Report, the principles in the Belmont Report which are established in federal regulations and the Report of the National Commission for the Protection of Human Subjects, which addresses research involving children.

1. Definitions

1.1 "Assent" is defined, for purposes of this policy, to mean a child's affirmative agreement to participate in research.

1.2 Child: Any individual who has not attained the legal age for consent to treatments or procedures involved in the proposed research under applicable laws of the jurisdiction in which the research will be conducted. In Louisiana, any person under the age of 18 who is not married, legally emancipated, or actively serving in the armed forces.

1.3 Guardian:
1.4 Parent:
1.5 Permission:
1.6 Ward:

2. Parental Permission

CFR Subpart D requires that adequate provisions be made for soliciting permission of parents or guardians of each child involved in a research study. All of the requirements concerning informed consent (policy****) apply to obtaining parental permission. The appropriate elements of consent must be included in a written informed consent document unless otherwise waived by the IRB.

If a person other than a parent(s) signs a permission form (informed consent), the PI should obtain, if possible, documentary evidence of guardianship or custody. If such documentation is not available, the investigator should call the Office of Legal Affairs for assistance.

3. Assent

CFR Subpart D requires that adequate provisions be made for soliciting the assent of all children involved in research, when the children are capable of providing assent. In determining whether children are capable of assenting, the ages, maturity and psychological state of the children should be taken into account (*Note: the mere failure of a child to object should not, absent affirmative agreement, be construed as assent).*

3.1 Children 7 – 11 years

Children in this age group should be fully informed about the research, using language appropriate to their age and maturity. Assent should be solicited in the presence of a parent or guardian. If a verbal assent was obtained, acknowledgement on the parental consent form should stipulate such. If assent is not waived by the IRB and is not solicited, the reason for not soliciting assent should be noted in the research record for the subject.

3.2 Children 11-17 years

Children in this age group should be fully informed about the research and documented assent should be obtained. The child may sign either his/her own assent form or may co-sign the parental consent form so long as the form is written in age appropriate language. If assent is not waived by the IRB and is not solicited, the reason for not soliciting assent should be noted in the research record for the subject.

IRB WAIVER CONSENT-ASSENT	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	8.3
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

1. Waiver of Documentation of Informed Consent

The IRB can waiver the requirement that the consent process include a signed consent form. Investigators desiring to not have a signed consent form must still provide participants with a consent document disclosing all the required elements necessary for informed consent. According to CFR 46.117 an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds:

1.1 The research presents no more than minimal risk; **and**

1.2 The research involves procedures that do not require written consent when performed outside of a research setting..... **Or,**

1.3 The principle risks are those associated with a breach of confidentiality concerning the subject's participation in the research; **and**

1.4 The consent document is the only record linking the subject with the research; **and**

1.5 Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern.

1.6 The study is not FDA regulated

2. Waiver or Alteration of Informed Consent

The IRB may waive the requirements for obtaining informed consent or approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, provided that **all** of the following five conditions are met:

2.1 the research involves no more than minimal risk to the subjects;

2.2 the waiver or alteration will not adversely affect the rights and welfare of the subjects;

2.3 the research could not practicably be carried out without the waiver or alteration; and

2.4 whenever appropriate, the subjects will be provided with additional pertinent information after participation. The criteria for a waiver or alteration of consent are explained in the guidance.

2.5 That the only record linking the subjects and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. In this instance, each subject will be

asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

IDENTIFYING VULNERABLE POPULATIONS	Effective Date	**02/01/2007**
	Revisions Date	
	IRB Policy Number	**9.0**
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

1. Identification of Vulnerable Populations

1.1 Federal regulations and ethical principals require that certain groups of human subjects shall be considered particularly vulnerable in a research setting. Those considered to be "vulnerable populations" are individuals who may have limited autonomy which precludes their full and free appreciation or participation in the consent process. Particularly vulnerable populations must receive, in addition to the general requirements for review of research by the IRB, further protections which are consistent with federal regulations and specific for: a) pregnant women, human fetuses and neonates involved in research (45 CFR 46 Subpart B), prisoners (45 CFR 46 Subpart C), and children (45 CFR 46 Subpart D).

1.2 Although federal regulations pertain specifically to the vulnerable populations defined above, other populations, though not considered vulnerable according to regulations, may still be particularly subject to coercion. These populations, which should be considered vulnerable and deserving of special consideration by investigators and the IRB, include but are not limited to those with dementia or other cognitive impairments, students and employees of the Principal Investigator and key personnel, the elderly, terminally ill patients, hospitalized patients, prospective transplant recipients, and patients who can receive certain treatment(s) only through research protocols. Both the Principal Investigator and the IRB should recognize such subjects as vulnerable and should provide special protections as necessary.

2. The IRB Review Process

In its review of studies involving vulnerable populations, the IRB should ensure the safeguarding of the subjects' rights, safety and welfare. To accomplish this, the IRB membership must include one or more members qualified to represent each involved group of vulnerable subjects with knowledge, expertise and sensitivity gained from working with these subjects or from personal experience. At least one member qualified to represent the involved

group of vulnerable subjects shall be present at the convened meeting when a study involving that group of vulnerable subjects is reviewed.

If the IRB believes that its expertise regarding a vulnerable population is insufficient to conduct an in-depth study review, the IRB may seek input from one or more internal or external consultants with appropriate scientific or scholarly expertise and knowledge of the vulnerable groups of subjects. The IRB has the authority to table its review until such consultant guidance/recommendation is received and presented.

RESEARCH INVOLVING CHILDREN	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	9.1
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

1. General Principles

The legal mandate of the IRB is to protect the rights and welfare of human subjects. This task becomes more difficult when considering children as research subjects. The Federal regulations provide for "Additional Protections for Children Involved as Subjects of Research." Subpart D of 45 CFR 46. "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted (45CFR46.402(a). In the state of Louisiana the legal age is 18 however some exceptions may apply.

The definition of "children" also takes into account the particular treatments or procedures involved in the proposed research; for example, in some places individuals who are sixteen years of age may legally consent to certain medical treatments, and so if the involvement of human subjects in a proposed research activity consists of these treatments, then they may be considered as adults for that purpose. If a proposed activity includes something for which the subject has not yet reached the legal age of consent, however, that person must be considered a child.

2. OHRP FAQ

HHS regulations at 45 CFR 46.402(a) define "children" as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." If research on a specific treatment involves solely treatments or procedures for which minors can give consent outside the research context (under applicable state and local laws, for example, research on sexually transmitted diseases or pregnancy), such individuals would not meet the definition of children as defined at 45 CFR 46.402(a). Thus, subpart D would not apply to the research and parental permission (or waiver thereof) is not a consideration for these minors. Under these circumstances, minors may provide their own informed consent.

3. IRB Review

3.1 When reviewing research involving children, there are three main issues that the IRB must consider: (1) risk-benefit, (2) parental permission, and (3) assent of the child.

3.2 Due to the vulnerable nature of the population the exemptions in 45 CFR 46.101(b) do not apply to certain types of research involving children and prisoners, Subparts C and D. Specifically, the exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, Subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed. Exemption from IRB review should be utilized conservatively when applied to research involving special classes of subjects who are not be defined by regulation as vulnerable.

4. Permitted Categories for Research Involving Children

Federal regulations classify permissible research involving children into four categories based on degree of risk and type of individual subjects. These categories are described in relation to " minimal risk ": Requests for approval of any research that exposes vulnerable populations to risks that do not meet one of the criteria below must be submitted to the United States Secretary of Health and Human Services for review and approval.

4.1 Research not involving greater than minimal risk **(45 CFR 46.404)**

4.2 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects **(45 CFR 46.405)**

4.3 Research that involves more than minimal risk and presents the prospect of no direct benefit to individual subjects, but generalizable knowledge (societal benefit) **(45 CFR 46.406)**

4.4 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children **(45 CFR 46.407)**

5. Parental Permission

Because children cannot legally provide consent for research on their own behalf, permission by at least one parent or legal guardian is required prior to enrollment of a minor in a research study.

5.1 Research involving no more than minimal risk requires permission from at least one parent (or guardian).

5.2 Research that involves more than minimal risk but presents the prospect of direct benefit to individual subjects requires permission from at least one parent (or guardian).

5.3 Research that involves more than minimal risk and presents the prospect of **no** direct benefit to individual subjects, but generalizable knowledge (societal benefit) requires permission from both parents .*

5.4 Research that presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children, does NOT provide direct benefit to the subject or societal (indirect) benefit requires permission from both parents .*

Note[1]: *If there are two parents available to give permission but they disagree about allowing their child to participate in the study, the child should not be enrolled unless that disagreement can be resolved.* This policy applies to all permissible categories of research involving children.

Note[2]: *The foster parent is usually not the legal guardian of a child in foster care. The social services department usually has legal authority for the child.*

**Unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. If these circumstances are present, the researcher should document this in the subject's research record.*

6. Assent

Assent is defined as a child's affirmative agreement to participate in research. The IRB must find that adequate provisions are made for soliciting the assent of children when, in the judgment of the IRB, the children are capable of providing assent. In determining whether children are capable of assenting, the IRB will take into account the ages, maturity, and psychological state of the children involved. When a child's assent is required, the child should be given an explanation of the proposed research procedures in a language that is appropriate to the child's age, experience, maturity and condition.

7. Discovery and Disclosure of Sensitive Information

In the course of research with children, especially adolescents, researchers may discover sensitive information about subjects that is not related to the study itself. For example, such information as sexual activity, STDs, use of illegal substances, and child abuse.

7.1 *Confidentiality* : Researchers need to consider how they will handle such situations should they arise. The permission and/or assent form should describe plans for disclosure—or non-disclosure—of such information to parents, legal authorities, and the subjects themselves. In some situations it may be appropriate to obtain a NIH Certificate of Confidentiality.

7.2 *Child Abuse Reporting* :

PREGNANT WOMEN, FETUSES & NEONATES	Effective Date	**02/01/2007**
	Revisions Date	
	IRB Policy Number	**9.2**
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

Research involving pregnant women, fetuses and human in vitro fertilization are subject to special federal regulations that guide IRB deliberations on such studies.

1. Research Involving Pregnant Women or Fetuses

The IRB may approve the enrollment of pregnant women or fetuses in research studies only if all of the following conditions are met:

1.1 Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

1.2 The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

1.3 Any risk is the least possible for achieving the objectives of the research;

1.4 If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;

1.5 If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

1.6 Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

1.7 For children as defined in §46.402(a) who are pregnant, assent and

permission are obtained in accord with the provisions of subpart D of this part;

1.8 No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

1.9 Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

1.10 Individuals engaged in the research will have no part in determining the viability of a neonate.

2. Research involving neonates

2.1 Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

2.1.1 Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

2.1.2 Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

2.1.3 Individuals engaged in the research will have no part in determining the viability of a neonate.

2.1.4 The requirements of paragraph (b) or (c) of this section have been met as applicable.

2.2 **Neonates of uncertain viability**. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met:

2.2.1 The IRB determines that the research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or

2.2.2 The IRB determines that the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and

2.2.3 The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized

representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

2.3 Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:

2.3.1 Vital functions of the neonate will not be artificially maintained;

2. 3.2 The research will not terminate the heartbeat or respiration of the neonate;

2.3.3 There will be no added risk to the neonate resulting from the research;

2.3.4 The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

2.3.5 The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of §46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).

2.4 Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part:

2.4.1 §46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

2.4.1.1 Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.

2.4.1.2 If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

2.4.2 §46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

2.4.2.1 The Secretary will conduct or fund research that the IRB does not believe meets the requirements of §46.204 or §46.205 only if:

The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the FEDERAL REGISTER, has determined either:

1. That the research in fact satisfies the conditions of §46.204, as applicable; or
2. The following:

    i. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;
    ii. The research will be conducted in accord with sound ethical principles; and
    iii. Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.

PRISONERS	Effective Date	02/01/2007
	Revisions Date	
	IRB Policy Number	9.3
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

DHHS regulations at 45 CFR Part 46, Subpart C delineate special protections for research involving prisoners, who as a result of their incarceration, may have a limited ability to make truly voluntary or uncoerced decisions about participation in research.

1. Definition

Prisoner is defined to include any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. (***Note**: If a previously enrolled research subject becomes a prisoner, the PI must notify the IRB immediately. The IRB should then promptly review the protocol in accordance with the requirements of 45CFR46 subpart C if the PI wishes to have the prisoner subject continue to participate in the research).*

2. Permitted Categories for Research Involving Prisoners

Biomedical or behavioral research may involve prisoners as subjects only if:

2.1 Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

2.2 Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

2.3 Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or

2.4 Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research.

3. Epidemiological Research Involving Prisoners

3.1 The Secretary of DHHS waived the applicability of 45 CFR 46.305(a)(l) and 46.306(a)(2) for certain research that involves epidemiologic studies that meet the following criteria:

3.1.1 In which the sole purposes are to describe the prevalence or incidence of a disease by identifying all cases, or to study potential risk factor associations for a disease, and

3.1.2 Where the institution responsible for the conduct of the research certifies to the Office for Human Research Protections, DHHS, acting on behalf of the Secretary, that the IRB approved the research and fulfilled its duties under 45 CFR 46.305(a)(2)-(7) and determined and documented that the research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and prisoners are not a particular focus of the research.

4. Criteria for IRB When Prisoners are Involved in Research

4.1 A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

4.2 At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

5. Additional Duties of the IRB Where Prisoners are Involved

5.1 In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

5.1.1 The research under review represents one of the categories of research permissible under §46.306(a)(2);

5.1.2 Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

5.1.3 The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

5.1.4 Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

5.1.5 The information is presented in language which is understandable to the subject population;

5.1.6 Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

5.1.7 Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

EMPLOYEES & STUDENTS AS RESEARCH PARTICIPANTS	Effective Date	**02/01/2007**
	Revisions Date	
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Employees & students of Dillard University may be considered vulnerable subjects, depending on the context of the specific research study proposed. This is because of the potential for perceived coercion due to the relationships to the institution and to the researchers (regardless of the researcher's intentions) especially if there is a power differential between the researcher and the prospective subjects. If the proposed subjects are part of a research team, there may also be inherent conflicts of interest in their participation.

Investigators should detail any extra precautions taken to safeguard the rights and welfare of subject populations. In the case of using employees or a student "subject pool," the IRB should ensure that consent for participation is sought only under circumstances, which minimize the possibility of coercion or undue influence, and that genuinely equivalent alternatives to participation are available.

1. **Considerations for Participation**
   Dillard University employees & students shall have rights to participate in human subject research. However, the IRB shall ensure that all of the following conditions are met in determining whether such individuals may participate as subjects:

   1.1 Participation in the research may not bestow upon the subject-employees or students any competitive academic or occupational advantage over other employees, students or trainees/fellows who do not volunteer to participate in the study.

   1.2 Investigators or others may not impose any academic or occupational penalty on those employees or students who do not volunteer.

   1.3 Employees or students participating in research may not be systematically treated differently from subjects in the study who are not employees, students or trainees/fellows

SUBJECT POOLS STUDENT CLASS PROJECTS	Effective Date	**06/01/10**
	Revisions Date	
	IRB Policy Number	**9.5**
	Approval: Vice President for Academic Affairs, IRB Chair, IRB Administrator/Manager, Office of Human Subjects Research	

1. Subject Pools

Subject pools are undergraduate students enrolled in particular departmental courses requiring participation in one or more research projects. The IRB provides guidance and oversight of departmental subject pools, and reviews all research requesting subject pool participation. All student participation in subject pool research must be completely voluntary. Departments provide students with incentives (usually extra credit) to participate in the subject pool. Reimbursement for participation must not jeopardize the subject confidentiality or anonymity. Any subject pools offering extra credit to participating students must provide alternative opportunities to earn extra credit to students declining to participate in research. Subject pools including subjects under 18 years-of age are required to obtain parental consent prior to their involvement in research unless those individuals are emancipated. It is up to the student to decide whether to participate in any study; instructors cannot mandate or require student participation.

ADDITIONAL CATEGORIES OF VULNERABLE SUBJECTS	Effective Date	**02/01/2007**
	Revisions Date	
	IRB Policy Number	**9.6**
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1. AIDS – HIV^{+} Subjects

Subjects involved in HIV-related research (HIV-infected persons and persons at risk of HIV-infection) are particularly vulnerable because of their disease status and because the disease disproportionately affects certain populations. In addition, the concerns related to confidentiality and privacy, since breaches of confidentiality could have severe adverse consequences. To this end, investigators should consider the following:

- Where identifiers are not required by the study design, they are not to be recorded.
- If identifiers are recorded, they should be separated, to the greatest extent possible, from data and securely stored, with linkage restored only if necessary to conduct the research.
- If subjects will be given a fair and clear explanation of how information about them will be handled, including whether and how the information will be recorded in their medical records.
- Whether the protocol will specifically set forth how to respond to attempts to force disclosure of subjects' medical records or requests by third parties who have authorizations for disclosure signed by subjects; and
- Whether the protocol will clearly state what information will be recorded, who is entitled to see records with identifiers, and whether any state laws require the reporting of HIV infection or the disclosure of other information.

2. Minority Populations

Federal regulations require the equitable selection of minorities as research subjects. The inclusion of minorities in research is important both to ensure that they receive an equal share of the benefits of the research and to ensure that they do not bear a disproportionate burden. Most research will affect all population groups. However, sometimes minorities are subject to a different risk. In addition, the exclusion or inappropriate representation of these groups, by design or inadvertence, would be unjust. Unless there is a sound scientific reason for exclusion of a minority population, the federal regulations require that research design include diverse populations.

3. Education or Economically Disadvantaged

The Department of Health and Human Services recognizes that certain populations may require additional protections because they are economically or educationally disadvantaged. The IRB will attempt to safeguard every subject's rights and welfare by making sure that any possible coercion or undue influence is eliminated