

POLICY AND PROCEDURE MANUAL

Pennington Biomedical	POLICY NO. 302.00	Origin Date: 11/16/2012
Impacts:	ALL PERSONNEL ENGAGED IN HUMAN RESEARCH	Last Revised: 11/16/2012
Subject:	Human Research Protections Program Policy	Effective: 05/14/2013
Source:	Human Research Protections Program	Version No. 2

1.1 Scope

This Institution's Human Research Protection Program (HRPP) is a comprehensive system to ensure the protection of the rights and welfare of subjects in human research. The Human Research Protection Program is based on all individuals in this Institution along with key individuals and committees fulfilling their roles and responsibilities described in this plan. Throughout this document "Institution" refers to Pennington Biomedical Research Center.

1.2 Purpose

This Institution is committed to protecting the rights and welfare of subjects in human research. The purpose of this plan is to describe this Institution's plan to comply with ethical and legal requirements for the conduct and oversight of human research.

1.3 Definitions

1.3.1 Agent

An individual who is an employee is considered an agent of this Institution for purposes of engagement in human research when that individual is in any official capacity as an employee of this Institution. An individual who is not an employee is considered an agent of this Institution for purposes of engagement in human research when that individual has been **specifically authorized** to conduct human research on behalf of this Institution.

1.3.2 Clinical Trial

A biomedical or behavioral research study of human subjects designed to answer specific questions about therapeutic interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new therapeutic interventions are safe and effective. NIH PHS 398

1.3.3 Principal Investigator, Co-Investigator or Investigator

Principal Investigator ("PI"), Co-Investigator or "Investigator" is an individual who conducts research or under whose immediate direction research is conducted; or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. NIH PHS 398
Investigator means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. FDA 21 CFR 50.3.25(d)

For the purposes of this Institution Principal Investigators must be a member of the regular faculty, adjunct faculty, or a member of the faculty of one of the institutions affiliated with the Pennington Biomedical Research Center. Professionals in training (graduate students, post-doctoral researchers, interns, and residents) are permitted to be Principal Investigators as long as permitted by their home

institution policies. In order to serve as a Principal Investigator, any person who is not a member of the regular faculty must have at least one regular faculty member as a Co-Investigator on the project.

1.3.4 Engaged in Human Research

This Institution is engaged in human research when its employees or agents are interacting or intervening with human subjects for the purpose of conducting research. This Institution follows OHRP guidance on “Engagement of Institutions in Research” to apply this definition.

The Institution defines all research according the DHHS definition, unless the clinical trial is subject to FDA oversight.

1.3.5 Human Research

Any activity that either:

- Is “research” as defined by DHHS and involves “human subjects” as defined by DHHS (“DHHS Human Research”); or DHHS 45 CFR 46.102
- Is “research” as defined by FDA and involves “human subjects” as defined by FDA (“FDA Human Research”). FDA 21 CFR 56.102.22(c); 21 CFR 50.3.25 (c)

1.3.6 Human Subject as Defined by DHHS

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) information that is both private information and identifiable information. For the purpose of this definition:

1.3.6.1 Definitions of Human Subject as Defined by DHHS

- **Intervention** means 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.
- **Interaction** means communication or interpersonal contact between investigator and subject.
- **Private Information** means 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 Information** means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

DHHS 45 CFR §46.102(f) (1&2)

1.3.7 Human Subject as Defined by FDA

An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects. FDA 21 CFR 56.23(e)

1.3.8 Research as Defined by DHHS

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. The institution defines all research according the DHHS definition, unless the clinical trial is subject to FDA oversight. 45 CFR 46.102(d)

Generalizable Knowledge means information from which one may infer a general conclusion: knowledge brought into general use or that can be applied to a wider or different range of circumstances. For example, publication and presentation are typical methods used to disseminate

research findings, thereby contributing to generalizable knowledge. However, not all information that is published or presented represents generalizable knowledge. Generalizable knowledge is also interpreted to include data intended for general use, regardless of its eventual distribution or acceptance.

For additional guidance on when activities meet the definition of human research see Table 1 at the end of this document.

1.3.9 Research as Defined by FDA

Research means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505 (i) or 520 (g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. (21 CFR 50.3(c), 21 CFR 56.102(c))

1.4 Mission

The mission of this Institution's human research protection program plan is to protect the rights and welfare of subjects involved in human research that is overseen by this Institution. All human subject research is subject to the human research protection program plans policies and procedures.

The HRPP includes mechanisms to:

- Establish a formal process to monitor, evaluate and continually improve the protection of human research participants;
- Dedicate resources sufficient to do so;
- Exercise oversight of research protection;
- Educate IRB members, IRB support staff, investigators and research staff about their ethical responsibility to protect research participants;
- When appropriate, intervene in research and respond directly to concerns of research participants;
- Educate research participants and the community.

1.4.1 Ethical Requirements

In the oversight of all human research, this Institution (including its investigators, research staff, students involved with the conduct of human research, the Institution's Institutional Review Boards (IRBs), IRB members and chair, IRB staff, the Institutional official, and employees) follows the ethical principles outlined in the April 18, 1979 report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," also known as "The Belmont Report", which includes:

- Respect for Persons
- Beneficence
- Justice

1.4.2 Legal Requirements

All human research must undergo review by the Institution's IRB. Activities that do not meet the definition of human research (e.g., most classroom activities, quality improvement activities, program evaluation, and surveillance activities that do not meet the definition of human research) do not

require review and approval by the Institution IRB and do not need to be submitted to the Institution IRB unless there is a question regarding whether the activity is human research.

When this Institution is engaged in DHHS human research that is conducted, funded, or otherwise subject to regulations by a federal department or agency who is a signatory of the Common Rule, the Institution commits to apply the regulations of that agency relevant to the protection of human subjects.

When this Institution is engaged in FDA human research, this Institution commits to apply the FDA regulations relevant to the protection of human subjects.

Any questions about whether an activity meets the regulatory definitions of human research should be referred to the IRB Office who will provide a determination.

When there is a perceived conflict between state, local, federal or institution law, such situations will be referred to the Director of Legal and Regulatory Compliance.

1.4.3 Other Requirements

- This Institution commits to apply its ethical standards to all human research regardless of funding.
- For clinical trials, this Institution commits to apply the “International Council on Harmonisation – Good Clinical Practice E6.” International Research studies must adhere to recognized ethics codes such as: the Common Rule and the Declaration of Helsinki. (World Medical Association Declaration of Helsinki, A1,2)
- This Institution prohibits payments to professionals in exchange for referrals of potential subjects (“finder’s fees”) and payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments.”) FDA Guidance “Payment to Research Subjects”
- When Human Research is conducted or funded by the Department of Defense (DOD), this Institution commits to apply the Department of Defense (DOD) Directive 3216.02, which includes the requirement to apply 45 CFR §46 Subparts B, C, and D¹. This Institution will comply with the terms of the DFARS clause or comparable language used in the agreement with the Department of Defense (DOD) component supporting the research involving human subjects. See HRPP Policy 15.0 for Research Funded by the Department of Defense.
- When Human Research is conducted or funded by the Department of Education (ED), this Institution commits to applying 34 CFR §97 Subpart D (equivalent to 45 CFR §46 Subpart D), 34 CFR §98.3, 34 CFR §98.4, 34 CFR §356.3, and 34 CFR §99. See HRPP Policy 16.0 for Research Funded by the Department of Education

1.4.3.1 Research in Other Countries

- All policies and procedures that are applied to Human Research conducted domestically are applied to Human Research conducted in other countries.
 - For research conducted in other countries the PI must provide the IRB the following:
 - necessary information on local law and cultural context.

¹ Quick applicability table for DHHS Subparts:

	DHHS	DOD	ED
Subpart B	X	X	
Subpart C	X	X	
Subpart D	X	X	X

- qualifications of the researchers and research staff for conducting research in that country
- The PI must ensure the following:
 - initial review, continuing review, and review of modification
 - post-approval monitoring
 - handling of complaints, non-compliance and unanticipated problems involving risk to subjects or others.
 - consent process and document and other language issues
 - coordination and communication with local IRBs when appropriate.
- The IRB will ensure appropriate expertise and knowledge of the country(ies) either through IRB members or consultants.

1.4.4 Sponsored Human Research

For both sponsored and non-sponsored human research this Institution abides by its ethical principles, regulatory requirements and its policies and procedures.

1.4.5 Scope of Human Research Protection Program

The categories of human research overseen by the IRB include:

- Research conducted or funded by the Department of Defense (DOD). For additional requirements of research conducted by the Department of Defense, see Guidance G-003: Additional Requirements Conducted by the Department of Defense
- Federally funded research
- Research involving fetuses.
- FDA-regulated research.
- Research involving drugs that require an Investigational New Drug (IND).
- Research involving devices that require an Investigational Device Exemption (IDE) issued by FDA.
- Research involving pregnant women as subjects.
- Research involving non-viable neonates.
- Research involving neonates of uncertain viability.
- Research involving children as subjects.
- International research
- Research conducted or funded by the Department of Education (ED)
- Research involving children, pregnant women, fetuses, or neonates that is not otherwise approvable without approval of an agency secretary or director.
- Investigator held IND or IDE.
- Research involving devices that require an abbreviated IDE.
- Investigator held abbreviated IDE.

The categories of human research not overseen include:

- Research conducted or funded by the Veteran Administration (VA)
- Research conducted or funded by the Department of Justice (DOJ)
- Research conducted or funded by the Department of Energy (DOE)
- Research conducted, funded, or subject to oversight by the Environmental Protection Agency (EPA)
- Research involving *in vitro* fertilization.
- Research that plans to or is likely to involve prisoners as subjects.
- Research involving a waiver of consent for planned emergency research.

- Emergency use of a test article in a life threatening situation.
- Activities involving humanitarian use devices.
- Research using the short form of consent documentation.

1.4.6 Human Research Protection Program Policies and Procedures

Pennington Biomedical Research Center Policies and procedures are made available for all Pennington Biomedical investigators and research staff at the following web site: <http://pbrc.edu/HRPP>.

Pennington Biomedical uses the HRPP website to communicate policies and procedures, guidance to investigators and staff, required forms and contact information for the HRPP office.

1.5 Human Research Protection Program Components

The components comprising the HRPP and their responsibilities, ethical obligations, and authorities for carrying out the mission of the program are described below.

1.5.1 Institutional Official

The Executive Director of Pennington Biomedical Research Center is designated as the Institutional Official.

The Institutional Official has the authority to take the following actions or to delegate these authorities to a designee:

- Create the Human Research Protection Program budget.
- Allocate resources within the Human Research Protection Program budget.
- Appoint and remove IRB members and IRB chairs.
- Employ and remove research review staff.
- Determine what IRBs the Institution will rely upon.
- Approve and rescind authorization agreements for IRBs.
- Place limitations or conditions on an investigator's or research staff's privilege to conduct human research.
- Create policies and procedures related to the Human Research Protection Program that are binding on the Institution.
- Suspend or terminate research approved by one of the Institution's IRBs.
- Disapprove research approved by one of the Institution's IRBs.

Research that has been reviewed and approved by the IRB may be subject to further review and suspension and disapproval by the Institutional Officials consistent with Pennington Biomedical Research Center policy (see section 3.11.1 – Suspension or Termination). However, such Institutional Officials may not approve research that has not been approved by the IRB. Pennington Biomedical Research Center Institutional Officials may strengthen requirements and/or conditions or add other modifications to secure approval or approval by another committee.

The Institutional Official has the responsibility to:

- Oversee the review and conduct of human research under the jurisdiction of the Human Research Protection Program.
- Periodically review this plan to assess whether it is providing the desired results and recommend amendments as needed.
- Establish policies and procedures designed to increase the likelihood that human research will be conducted in accordance with ethical and legal requirement.

- Institute regular, effective, educational and training programs for all individuals involved with the Human Research Protection Program.
- Ensure that the research review process is independent and free of coercion or undue influence, and ensure that officials of the Institution cannot approve research that has not been approved by the IRB.
- Implement a process to receive and act on complaints and allegations regarding the Human Research Protection Program.
- Implement an auditing program to monitor compliance and improve compliance in identified problem areas.
- Investigate and remediate identified systemic problem areas, and where necessary removal of individuals from involvement in the Human Research Protection Program.
- Ensure that the Human Research Protection Program has sufficient resources, including that the IRB has appropriate resources to address the volume and types of human research to be reviewed, so that reviews are accomplished in a thorough and timely manner.
- Review and sign federal assurances (FWA) and addenda.
- Fulfill educational requirements mandated by OHRP.
- Grant the IRB the authority to act independently to bind the entire organization, including but not limited to the Institutional Official with regards to human subjects protections.

1.5.2 All members of the Institution

All individuals within the Institution have the responsibility to:

- Be aware of the definition of human research.
- Consult the IRB when there is uncertainty about whether an activity is human research.
- Not conduct human research or allow human research to be conducted without review and approval by the IRB.
- Report allegations of undue influence regarding the oversight of the Human Research Protection Program or concerns about the Human Research Protection Program to the Institutional Official.
- Report allegations or finding of non-compliance with the requirements of the Human Research Protection Program to the IRB.
- Not commence until the research has received all approvals required by the organization.
- Complete required training and education as mandated by Institutional Policy 106.00.

1.5.3 IRBs

The IRB designated by the Institutional Official to be the IRB relied upon by the Human Research Protection Program and the scope of review of this IRB is listed in the IRB roster available from the IRB Office.

Competing business interests can influence the review process when individuals responsible for business development serve on the IRB are involved in the day to day operations of the IRB.

Therefore, no individual responsible for raising funds or garnering support for research should serve as an IRB member or be involved in the day to day operations of the IRB.

The IRB functions independently of, but in coordination with, other institutional regulatory entities. The IRB, however, makes its independent determination whether to approve or disapprove a protocol based upon whether or not human subjects are adequately protected. The IRB has review jurisdiction over all research involving human subjects, conducted, supported or otherwise subject to regulation by any federal department or agency that has adopted the human subject regulations. The IRB verifies the research involving human participants does not commence until the research has received all approvals required by the organization.

This Institution may rely upon IRBs of another Institution provided one of the following is true:

- The IRBs are part of an AAHRPP accredited Institution.
- This Institution's investigator is a collaborator on Human Research that is primarily conducted at another Institution and the investigator's role does not include interaction or intervention with subjects.
- The Institution is engaged in the Human Research solely because it is receiving federal funds. (Employees and agents of the institution do not interact or intervene with subjects, gather or possess private identifiable information about subjects, nor obtain the consent of subjects.)

Reliance on an external IRB requires an Institutional Agreement for IRB review (IAIR) and a local review for compliance with local policies of the Institution.

The IRBs relied upon by this Institution have the authority to:

- Approve, require modifications to secure approval, and disapprove all human research overseen and conducted by the Institution. All human research must be approved by the IRB designated by the Institutional Official. Officials of this Institution may not approve human research that has not been approved by one of the Institution's IRBs.
- Suspend or terminate approval of human research not being conducted in accordance with an IRBs' requirements or that has been associated with unexpected serious harm to subjects.
- Observe, or have a third party observe, the consent process and the conduct of the human research.
- Determine whether an activity is human research as described in HRPP Policy 3.0. 45 CFR 46.102(d)
- Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan, if any, allow the human research to be approved. PBRC Policy 401.00

IRB member and IRB staff have the responsibility to follow Human Research Protection Program policies and procedures that apply to IRB members and staff.

1.5.4 Investigators and Research Staff

Investigators and research staff have the responsibility to:

- Follow the Human Research Protection Program policies and procedures that apply to IRB members and staff.
- Comply with all determinations and additional requirements of the IRB, the IRB chair, and the Institutional Official.
- Oversee the review and conduct of Human Research in their department or laboratory.
- Forward complaints and allegations regarding the Human Research Protection Program to the Institutional Official.
- Ensure that each Human Research study conducted in their department or laboratory has adequate resources.

1.5.5 Director of Legal and Regulatory Compliance

The Director of Legal and Regulatory Compliance has the responsibility to:

- Provide advice upon request to the Institutional Official, IRB, and other individuals involved with the Human Research Protection Program.

- Determine who meets the definition of “legally authorized representative” and “children” when human research is conducted in jurisdictions not covered by policies and procedures in accordance with applicable law.
- Resolve conflicts among applicable laws.

1.5.6 Sponsored Projects Office

The Sponsored Projects Office has the responsibility to review contracts and funding agreements for compliance with Human Research Protection Program policies and procedures.

1.6 Education and Training

All new employees are made aware of this plan as part of initial orientation. The IRB is to conduct refresher training on current employees as needed to maintain awareness of this policy.

IRB members, IRB staff, and others involved in the review of human research must complete CITI training in accordance with PBRC policy 106. The IRB is notified electronically when CITI training is completed and notified by the Director of Legal and Regulatory Compliance of any investigator and research staff out of compliance with the policy.

1.7 Resources for the HRPP

Resources for the HRPP components are provided through the annual budget review processes in the administrative units in which the components reside.

The need for study-specific resources is evaluated at the local level. Investigators and sponsoring units are responsible to ensure that sufficient resources are allocated to all projects, whether sponsored or investigator-initiated. These include staffing and personnel (in terms of availability, number, expertise and experience); psychological, social and medical services (including counseling or social support services that may be required because of participation in a study); psychological, social, or medical monitoring, ancillary care, equipment needed to protect participants, and resources for participant communication. Study-specific resources are verified electronically as defined by Policy 301.00 Clinical Study Budget, Resource Facilitation and Initiation.

The need for incremental or off-cycle resources may emerge as a result of special or unusual demands on the offices, either as reported by the offices or by quality assurance/review activities, or by Executive Director deliberations.

1.8 Questions and Additional Information for the IRB

The IRB Office wants your questions, information, and feedback.

Contact and location information for the IRB Office is:

Michelle Brignac

Human Research Protections Program Manager

Pennington Biomedical Research Center

6400 Perkins Road

Baton Rouge, LA 70808

Email: michelle.brignac@pbrc.edu

(225) 763-2693

1.9 Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported to the IRB Chair, IRB Office, Institutional Official or Director of Legal and Regulatory Compliance. The IRB has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed. The Institutional Official has the responsibility to investigate all other reports and take corrective actions as needed.

Employees who report in good faith possible compliance issues should not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the Institutional Official or designee.

To make such reports, contact:
Steven Heymsfield, M.D.
Executive Director
Pennington Biomedical Research Center
6400 Perkins Road
Baton Rouge, LA 70808
Email: steven.heymsfield@pbrc.edu
(225) 763-2513

1.9 Monitoring and Auditing

In order to monitor and ensure compliance, internal or external auditors who have expertise in federal and state statutes, regulations and Institutional requirements will conduct periodic audits. Audits will focus on areas of concern that have been identified by any entity, i.e., federal, state or Institutional. Random audits may also be conducted. See HRPP policy 13.0 – Quality Improvement in the HRPP Program

1.10 Disciplinary Actions

The Institutional Official may place limitations or conditions on an investigator's or research staff's privilege to conduct human research whenever in the opinion of the Institutional Official such actions are required to maintain the Human Research Protection Program.

1.11 Approval and Revisions to the Plan

This Human Research Protection Program Policy is to be approved by the Policy Committee of Pennington Biomedical Research Center. This policy is intended to be flexible and readily adaptable to changes in regulatory requirements. The Institutional Official has the responsibility to review this plan to assess whether it is providing the desired results. At the request of the Institutional Official the Executive Policy Committee has the authority to amend this plan as deemed necessary.

Table 1.

Below is a list of activities that may or may not constitute research involving human subjects. The table is intended to provide examples and is not a definitive determination of whether a specific activity requires IRB review or exemption. For study-specific determinations, contact the IRB office at irb@pbrc.edu

Activity	Research that may Involve Human Subjects?
Scholarly or Scientific	
Intent to Publish – Activities that obtain data about individuals, systematically performed with the intent to generalize findings and to publish or present the results (regardless of eventual publication or presentation)	Yes
Pilot Studies – Development of research, including activities involving individuals that are performed to refine a data collection or study methodology	Yes
Viewing Identifiable Private Information - Identification of potential participants for a study or use of living individuals' data for research purposes, whether or not the data will be recorded in an identifiable manner	Yes
Coded Data – Study or use of data that cannot be readily associated with the living individual about whom the information relates	No; however, there are some instances where you will need IRB approval. Contact the IRB office.
Deceased Individuals – Study of or use of data relating to individuals no longer living, when data do not also apply to living relatives	No, but there may be HIPAA requirements. Contact the IRB office.
Quality Improvement – Activities involving individuals intended solely for internal use, performed to improve services or develop new services or programs, (e.g., satisfaction surveys) without plans for presentation or publication; audits (internal or external) performed as a part of organizational operations	Yes
Data Banking – Collection and storage of private information, if the data may be used in the future for research purposes, whether or not the data will be recorded in an identifiable manner	Yes

Social Science, Behavioral, Educational	
Survey, Interview, Observation – Collection of individuals’ data using surveys, interviews, or observation with the intent to generalize findings	Yes
Audio- or Videotaping – Taping individuals for study in situations not normally expected to be recorded or when individuals can be identified from recordings	Yes
Internet Survey Research – Online collection of individuals’ data with the intent to generalize findings	Yes
Medical or Biomedical	
Practice of Medicine – Standard diagnostic or therapeutic procedures performed for treatment purposes to benefit an individual, with or without associated research activities	No
Additional Procedures – Standard diagnostic or therapeutic procedures that would not otherwise be performed if not for the research (e.g., additional x-rays or blood draws)	Yes
Changes in Procedures – Alterations in patient care (including randomization between standard acceptable treatments) with the intent to generalize the results	Yes
Clinical Investigation – Use of drugs or devices, except approved products used in the practice of medicine, including use of a human specimen with FDA-regulated devices	Yes
Retrospective Record Review – Review of existing personally identifiable records, including collection of historical controls for FDA-regulated studies, whether or not the data will be recorded in an identifiable manner	Yes
Remnant Specimens – Collection or study of specimens generated from routine clinical procedures that would otherwise have been discarded	Yes
Specimen Banking – Collection and storage of human fluids or tissue regardless of whether individual identifiers are retained	Yes

** This table was copied from Ohio State University HRPP policy with permission from their Office of Responsible Research Practices

Policy Committee Secretary's Attestation

Date of Policy Committee Meeting: 5/14/2013

Policy #: 302.00, Human Research Protections Program Policy

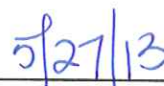
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Anne Duke, Policy Committee Secretary



Date

Approval by the Executive Director



Steven B. Heymsfield, MD
Executive Director



Date