I. Policy Statement

This policy establishes Parkview Health System, Inc.’s (PH) conflict of interest program for research, which shall be implemented through the PH Institutional Review Board (PH IRB). It is PH’s objective to comply with all laws and regulations pertaining to conflicts of interests in research. This policy shall be interpreted and implemented in a manner that achieves compliance with those particular regulations listed in Section IV, References, of this policy as well as advances the following objectives.

A. In order to promote objectivity in research and to ensure, to the extent possible, that the design, conduct and reporting of human subjects research is to a reasonable extent free from bias, it is PH’s policy that all Investigators and PH IRB Members involved in human subject research conducted at PH must disclose their Significant Financial and Non-financial Interests so that PH can determine whether the Significant Financial and Non-financial Interests constitute Conflicts of Interest that need to be addressed.

B. PH will protect the confidentiality of information obtained from Investigators and IRB Members to the greatest extent possible. Information will be shared as necessary among those responsible to implement the conflict of interest review process, and disclosed to regulatory bodies and/or the public when and if required.

C. PH will promote and enforce compliance with this policy. If there is a conflict between this policy and any other PH IRB policy, the provisions of this policy shall prevail.

II. Definition of Terms

A. Conflict of Interest (COI) means any Financial or Non-financial Conflict of Interest.

B. Debt Interest means any notes, loans, bonds or other financial interest based on debt.

C. Equity Interest means any ownership interest, including, but not limited to, individual proprietorship, stock, stock options, warrants, partnership and limited partnership interests, and limited liability company membership. Equity interest includes indirect ownership interests, such as ownership or control of an entity that invests in other entities related to or potentially affected by the research. Equity interests shall also include interests in distributorships that market drugs, devices or other products related to the research. Equity Interests shall be determined through reference to public prices or other reasonable measures of fair market value.
D. Financial Conflict of Interest (FCOI) means a Significant Financial Interest that could directly and significantly affect the design, conduct, reporting or review of the research.

E. FCOI Report means an Institution's report of a FCOI that is sent to a Public Health Service agency or a unit of a Public Health Service agency funding research.

F. Financial Interest means anything of monetary value, whether or not the value is readily ascertainable.

G. Institution means PH and its affiliates.

H. Institutional Responsibilities means an Investigator's or IRB member's professional responsibilities on behalf of the Institution, including but not limited to activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as the PH IRB or Data and Safety Monitoring Boards.

I. Investigator means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research. Investigators may include research coordinators, collaborators, or consultants. Investigator also includes subrecipient investigators, who are those individuals or companies that PH contracts with to carry out study activities.

J. Manage means taking action to address a COI, which can include reducing or eliminating the COI to ensure to the extent possible that the design, conduct, and reporting of research will be free from bias.

K. Non-financial Conflict of Interest (NCOI) means a Significant Non-financial Interest that could directly and significantly affect the design, conduct, reporting or review of the research.

L. Public Health Service Funded Research means research that is funded by the Public Health Service of the U.S. Department of Health and Human Services, and any components of the Public Health Service to which the authority involved may be delegated, including the National Institutes of Health (NIH).

M. Remuneration means anything of value, including salary and any payment for services not otherwise identified as salary, including, but not limited to, consulting fees, honoraria, paid authorship. Remuneration also includes dividends, interests and any other income, other than capital gain, received with respect to a currently held equity or debt interest.
N. Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g. a published article, book, or book chapter) and product development (e.g. a diagnostic test, device, or drug).

O. Senior/Key Personnel means the project director or principal investigator and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the Public Health Service by the Institution.

P. Significant Financial Interest (SFI) means:

1. A Financial Interest consisting of one or more of the following interests of the Investigator or PH IRB member (including the interests of spouses and dependent children) that reasonably appears to be related to the Investigator's or IRB member's Institutional Responsibilities:

   a. With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000.

   b. With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator or PH IRB member (or spouse or dependent children) holds any equity interest.

   c. With regard to any entity, a SFI exists if the face value of any debt interest in the entity exceeds $5,000 as of the date of disclosure.

   d. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

2. Reimbursed or sponsored travel related to their Institutional Responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

3. SFI does not include the following types of financial interests:

   a. Salary, royalties, or other remuneration paid by the Institution to the Investigator or PH IRB member if the Investigator or PH IRB member is
currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights.

b. Any ownership interest in the Institution held by the Investigator or PH IRB member, if the Institution is a commercial or for-profit organization.

c. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator or PH IRB member does not directly control the investment decisions made in these vehicles.

d. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

e. Income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Q. Reimbursed Travel is travel for which the Investigator is paid back.

R. Significant Non-financial Interest (SNI) means any situation in which any non-financial personal consideration may compromise, or have the appearance of compromising, the judgment of individuals with respect to research.

S. Sponsored Travel is travel that is paid for on behalf of the Investigator, so that the exact monetary value may not be readily available.

T. Subrecipient or Subrecipient Investigators mean companies or individuals that PH contracts with to carry out study activities. A PH entity may itself be a Subrecipient.

III. Procedure

A. Training Requirements: PH will inform each Investigator and PH IRB member of this policy and any subsequent revisions and will require COI training, as set forth below:

1. Prior to engaging in any research study that requires disclosures

2. Immediately if:

   a. This policy is revised
| b. An Investigator or PH IRB member is new to PH or new to the PH IRB |
| c. An Investigator is not in compliance with the policy or management plan set forth due to a previous disclosure and review process |

3. If neither (a) nor (b) above are applicable, then no less frequently than every 3 years.

B. Disclosures:

1. Each Investigator and PH IRB member is required to complete the PH IRB Research Conflicts of Interest Disclosure Form (Disclosure) at least once a year on behalf of themselves, their spouse, and dependent children, related to their Institutional Responsibilities. The Disclosure must be completed in accordance with the timeframes specified by PH, regardless of whether or not an Investigator or PH IRB member has or is believed to have any SFIs or SNIs to disclose. In addition to this annual disclosure requirement, each Investigator must complete an updated Disclosure: (1) no later than at the time of a new study submission; (2) within thirty (30) days of discovering or acquiring a new SFI or SNI; and/or (3) no later than at the time of application if applying for Public Health Service funded research.

2. Each Investigator must also disclose the occurrence of any reimbursed or sponsored travel related to their Institutional Responsibilities. This disclosure does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with and Institution of higher education.

3. If Investigators fail to comply with this requirement, the policy will be enforced in accordance with Section III.K., in addition to any other actions which may be taken by PH in accordance with other policies.

C. Review:

1. The PH IRB chairperson, with the assistance of PH IRB staff, will solicit disclosures and perform primary review of disclosed SFIs and SNIs of Investigators (including their spouses and dependent children), which may include obtaining additional information regarding the disclosure and value of the SFI or SNI. Primary review will include determination of whether the SFI
or SNI could possibly be considered a COI. SFIs or SNIs can be considered COIs if they:

a. Relate to the research (meaning the SFI or SNI could be affected by the research or is with an entity whose financial interest could be affected by the research) and

b. Might reasonably affect the design, conduct, reporting or review of the research.

2. The PH IRB Chairperson shall determine whether the SFI or SNI could directly and significantly affect the design, conduct, reporting or review of the research, and therefore constitute a COI. He/she may consult with the PH IRB in the process of determining if the SFI or SNI should be considered a COI. If the PH IRB Chairperson determines there is a COI, a management plan is required. If the COI is an FCOI pertaining to Public Health Service funded research, the reports required by Section III.I. shall be made.

D. Determinations and Management of COIs

1. Prior to beginning research activity or expenditure of funds for a research project, whichever comes first, all Investigator disclosures of SFIs and SNIs will be reviewed by the PH IRB Chairperson and a determination as to whether or not a COI exists will be made as set forth above. Following such review, a management plan specifying conditions/actions to be taken to manage the COI will be put in place.

2. Examples of conditions that might be imposed to manage a COI include, but are not limited to:

a. Public disclosure of a COI when presenting or publishing the research

b. Disclosure of a COI to human subjects involved in the research

c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, reporting or review of the research against bias resulting from the COI

d. Modification of the research plan

e. Change of personnel and/or their responsibilities

f. Disqualification of personnel from participation in all or a portion of the research
g. Reduction or elimination of the COI (sale of an equity interest)

h. Severance of relationships that create COIs

E. New Disclosures

If new SFIs or SNIs are discovered or acquired or new Investigators are added to the project during the term of the research, the same process will be followed for disclosure, review, determination, and management.

F. Noncompliance

Within 60 days of identification of an SFI or SNI that was not disclosed timely by an Investigator, PH will complete a retrospective review of the SFI or SNI. If the SFI or SNI is determined to be a COI, PH will implement an interim management plan, which may include restricting expenditure of funds. In addition, within 120 days, PH will complete a retrospective review of the Investigator’s activities during the period of noncompliance and determine if there was bias in the design, conduct, or reporting of such research. The review will be documented and reported to the appropriate authorities per the terms set forth in this policy and applicable regulations. The PH IRB, Parkview Research Center and others as appropriate will be notified of this process and may impose additional conditions.

G. Subrecipients

PH will take reasonable steps to ensure that all Subrecipients and/or Subrecipient Investigators are held to the same requirements as Institutional Investigators. Written agreements with Subrecipients and/or Subrecipient Investigators will incorporate terms that establish their compliance with this policy and the applicable federal regulations. If the Subrecipients and/or Subrecipient Investigators cannot provide certification of this compliance, the agreement will state that Subrecipients and/or Subrecipient Investigators are subject to this COI policy related to their work with PH.

H. Monitoring

PH will provide oversight to monitor management plans as set forth by the PH IRB.

I. Reporting

All SFIs, SNIs, reimbursed travel and sponsor related travel must be disclosed as set forth in Section III.B. of this policy. COIs will be identified and managed as set forth in Sections III.C. and III.D. of this policy. Certain FCOIs and their management plans may be reportable as follows:
1. If and as required by the federal regulations listed in Section IV, References, of this policy, PH will send timely initial, annual, and revised FCOI reports, which include all required reporting elements for PH and its Subrecipients and/or Subrecipient Investigators, to the applicable regulatory agency, or, if PH is the Subrecipient, to the Recipient.

2. If and as required by the federal regulations listed in Section IV, References, of this policy, PH will send timely reports to the regulatory agency if an Investigator fails to comply with this policy or if a FCOI appears to have biased the design, conduct, reporting or review of publicly funded research, or, if PH is the Subrecipient, to the Recipient.

J. Maintenance of Records

All FCOI-related records will be maintained for at least 3 years from the date that the FCOI report is submitted to the federal agency or sponsor. If other applicable record retention policies require longer retention, those policies will apply.

K. Enforcement Mechanisms

1. PH may enforce this policy by exercising its right to impose employee sanctions or other administrative actions, including IRB conditions, to ensure Investigator compliance. Conditions may include, but are not limited to, suspension of enrollment, not accepting new studies from non-compliant Investigators, or declining requests for expenditures of funds.

2. An Investigator with a FCOI that was not disclosed therefore not properly managed or reported as required to a federal agency must disclose the FCOI in each public presentation of the results of the research and request an addendum to all previously published presentations.

L. Public Accessibility

As required by law, PH will post this policy on the PH IRB’s public website and, if so requested, make available information concerning identified FCOIs held by Public Health Service funded research Senior/Key Personnel and Subrecipient Senior/Key Personnel within 5 calendar days of a written request for this information. This information will remain available for 3 years from the date the information was last updated.

M. PH IRB

1. A SNI may arise out of a PH IRB member’s service in other capacities. Examples include, but are not limited to, the following categories with respect to a research protocol under review:
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Category: IRB Review Process

a. Principal Investigator  
b. Sub-Investigator  
c. Investigator receiving funding from the study, as listed in the study budget  
d. Clinical Research Coordinator or research staff  
e. A supervisory role over an Investigator participating in the study  
f. Project director  
g. Participating or having a spouse, domestic partner or children participate in a study under review.

2. A general statement will be printed on the meeting sign-in sheet at every PH IRB meeting reminding members of the conflict of interest policies and allowing any member to excuse himself from the deliberations of the committee. Their signature on the sign-in sheet will signify their agreement. No member of the PH IRB, Investigator or consultant will be allowed to participate in the initial or continuing review of any protocol in which the member, Investigator or consultant has a conflicting interest, financial or non-financial, other than to provide information to the PH IRB upon request and may be required to leave the room for the final deliberation and vote on that study.

3. PH IRB Meeting Minutes shall document the presence of any member, Investigator or consultant with an identified COI along with their departure from the room during final deliberations and voting.

IV. Reference

A. Regulations  
   42 CFR Part 50  
   45 CFR Part 94