I. Mission
The mission of the Disclosure Review Committee (DRC) is to protect the integrity of the University of New Hampshire’s (UNH) externally-funded research enterprise, and UNH employees who engage in externally-funded research, by identifying and resolving financial conflicts of interest in research (FCOIR). The DRC conducts its duties in a manner intended to promote, not hinder, research relationships.

II. Membership
A. The DRC will consist of a minimum of five (5) voting members, appointed by the Senior Vice Provost for Research (SVPR), at least three of whom will be faculty members representing the diverse colleges, schools, and programs of UNH. Members will serve three-year staggered terms.

B. One member of the DRC will act as Chair, or two members as co-Chairs (hereinafter, the Chair or co-Chairs will be referred to as “Chair”). The Chair should be an experienced member of the DRC who is familiar with DRC operations, pertinent FCOIR rules, regulations, and best practices, and ethical issues associated with FCOIR. The Chair may, from time to time, delegate certain duties to other members of the DRC in accord with DRC practices. The DRC Chair is responsible for:
   i. Convening and presiding at meetings,
   ii. When necessary, temporarily suspending research not in compliance with DRC guidelines, prior to review by the full DRC,
   iii. Informing the SVPR of serious or continuing noncompliance problems in research conducted with DRC oversight,
   iv. Advising researchers on requirements regarding FCOIR and related issues,
   v. Remaining informed of the latest changes in federal, state and local regulations and guidelines concerning FCOIR, and assisting DRC members in similar efforts,
   vi. Developing policies and procedures to implement applicable rules and regulations, and
   vii. Making recommendations to the SPVR for new member appointments,
   viii. Participating in developing, reviewing, and presenting educational opportunities for the UNH community on FCOIR.

III. Meetings
A. Meetings of the DRC shall be scheduled and held as needed. Any member of the DRC may call executive meetings for investigations and other special matters.
Only members (voting and non-voting) of the DRC and legal counsel shall be invited to attend executive DRC meetings. DRC meetings may be held in person or by teleconference. The DRC may also act by unanimous consent electronically, including via e-mail, without a scheduled meeting. Any such actions shall be entered into the minutes at the next scheduled DRC meeting.

B. The SVPR will serve as an ex-officio, non-voting member of the DRC.

C. The DRC is staffed by the Director of Research Integrity Services, the Compliance Officer in Research Integrity Services, and a representative from the UNH Office for Research Partnerships and Commercialization. A representative from the University System of New Hampshire (USNH) General Counsel’s Office (“legal counsel”) shall attend DRC meetings, and advise the DRC. These individuals are considered ex-officio, non-voting members of the DRC.

D. The DRC may invite individuals to attend meetings as situations warrant. Non-DRC members are not entitled to vote on DRC matters.

E. Each DRC voting member shall have one vote. Actions of the DRC require a majority of the votes cast at any meeting in which a quorum is present. The presence of a majority of DRC members shall constitute a quorum, and is necessary to conduct the DRC business.

F. All information disclosed at or in connection with a DRC meeting shall be kept confidential by all DRC members and meeting attendees, and used only for official DRC business.

G. All disclosure statements and related documents are considered sensitive information. As such, they will be treated as confidential and will not be disclosed outside the DRC without the investigator’s consent except in response to a request from the U.S. Department of Health and Human Services (for Public Health Service [PHS]-funded projects), or pursuant to a judicial order or lawfully issued subpoena. UNH will make reasonable efforts to notify the investigator of any judicial order or lawfully issued subpoena in advance of disclosure of this information unless the order is from a federal grand jury or is for law enforcement purposes and its terms prohibit UNH from disclosing its existence or contents.

H. Staff will keep minutes of all DRC meetings; minutes shall be approved at subsequent DRC meetings.

IV. Disclosure Review Procedures

A. OSVPR DRC staff screen Financial Disclosure Statements submitted by investigators to determine applicability and completeness (see Financial Conflict of Interest in Research Administrative Procedures). Financial disclosure statements that indicate significant financial interests in research as defined in
Section 3.9 of the UNH Policy on Financial Conflict of Interest in Research (FCOIR Policy) or in Section 3.17 of the UNH Policy on Financial Conflict of Interest in Research for PHS-Funded Projects (FCOIR PHS) are forwarded to the DRC for review.

B. OSVPR DRC staff may verify submitted documentation. Methods may include, but are not limited to: reviewing licensing agreements and/or patents; conducting Internet searches; contacting the outside company to confirm nature of the researcher's relationship; and/or reviewing consulting agreements, contracts, or other relevant agreements between the researcher and outside companies.

C. The DRC's primary responsibilities when reviewing financial disclosure statements and accompanying documentation are to determine whether:
   i. Interests disclosed qualify as significant financial interests as defined in Section 3.9 of the FCOIR Policy or Section 3.17 of the FCOIR PHS policy;
   ii. Significant financial interests of the investigator could reasonably be expected to affect the design, schedule, conduct, or reporting of the activities funded or proposed for funding for non-PHS-funded projects, or could directly and significantly affect the design, conduct, or reporting of PHS-funded research (see Appendix A for a Relatedness Checklist); and
   iii. The research may proceed, and if so, any conditions/restrictions to be placed on the research to ensure that any conflict is managed, reduced, or eliminated.

D. A perceived financial conflict of interest occurs when a third party might reasonably believe that an investigator's objectivity or actions may be affected by self-interest. While a perceived financial conflict of interest is, by definition, not an actual or potential conflict of interest, in appearance it can be as damaging as an actual or potential conflict of interest. In the event of perceived conflict of interest, investigators will be advised to submit a Financial Disclosure Statement to the SVPR.

E. The DRC may request additional clarifying information from the investigator; such information shall be treated as non-public to the extent allowed by law.

F. In reviewing disclosures and accompanying information, the DRC should use the following criteria to determine if an actual or potential significant financial conflict of interest in research exists:
   i. For sponsors other than PHS:
      a. The interest is financial in nature.
         1. Interests may include, but are not limited to the following:
            A. Anything of significant monetary value, including salary or other payments for services such as consulting fees or honoraria;
            B. Direct equity interests such as stock, stock options, or ownership interests; and
C. Intellectual property rights owned by the investigator such as patents, copyrights, and royalties from such rights.

2. Interests do not include:
   A. Salary, royalties, or other remuneration from UNH;
   B. Salary, royalties, or other payments that, when aggregated for the investigator and his/her immediate family, do not exceed $10,000 during the preceding 12 month period;
   C. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; and
   D. Income from service on advisory committees or review panels for public or non-profit entities.

b. The interest is significant. Significant financial interests include financial interests in business enterprises or entities that, when aggregated for the investigator and his/her immediate family, meet both of the following tests:
   1. The financial interest exceeds $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, or
   2. The financial interest represents more than a five percent ownership interest in any single entity.

c. The interest is held by the investigator or his/her immediate family, including an interest in a business entity (company, corporation, or other enterprise).

d. The interest could reasonably appear to be affected by the activities proposed for funding.

ii. For PHS-funded projects:
   a. The interest is financial in nature.
      1. Interests may include, but are not limited to the following:
         A. Anything of monetary value, whether or not the value is readily ascertainable, including salary or other payments for services such as consulting fees, honoraria, or paid authorship;
         B. Equity interests such as stock, stock options, or other ownership interests; and
         C. Intellectual property rights and interests owned by the investigator such as patents, copyrights, and royalties from such rights.
      2. Reimbursed or sponsored travel (i.e., travel that is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available) related to an investigator’s institutional responsibilities if the travel is reimbursed/sponsored by an entity that is not 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.

3. Interests do not include:
   A. Salary, royalties, or other remuneration from UNH if the investigator is currently employed or otherwise appointed by UNH.
   B. Intellectual property rights and interests assigned to UNH.
   C. Royalty income received from UNH.
   D. Publicly traded entities: the value of 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, for the investigator and his/her spouse/domestic partner, and dependent children, when aggregated, are less than $5,000;
   E. Non publicly traded entities: the value of remuneration received from the entity in the twelve months preceding the disclosure for the investigator and his/her spouse/domestic partner, and dependent children, when aggregated, is less than $5,000;
   F. 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;
   G. Income from service on advisory committees or review panels for 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;
   H. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles;
   I. Reimbursed or sponsored travel (i.e., travel that is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available) related to an investigator’s institutional responsibilities if travel is reimbursed/sponsored by an entity that is 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.

b. The interest is significant. Significant financial interests consist of the following interests of the investigator (and those of the investigator’s spouse/domestic partner, and dependent children) that reasonably appear to be related to the investigator’s institutional responsibilities:

1. Publicly traded entities: The value of 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, exceed $5,000;
2. Non publicly traded entities: The value of remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000; or
3. Non publicly traded entities: Any equity interest.
4. Reimbursed or sponsored travel (i.e., travel that is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available) related to an investigator’s institutional responsibilities if travel is reimbursed/sponsored by an entity that is 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.

c. The interest could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

G. The following are examples of research activities in which a financial conflict of interest would require management:

i. Externally-sponsored research projects in which any of the involved UNH investigators (or members of their immediate family) have employment or consulting arrangements with or significant financial interests in the sponsor, or with subcontractors, vendors, or collaborators.

ii. An investigator’s use of UNH resources to conduct research sponsored by an entity in which the investigator or his/her family member(s) has a significant financial interest.

iii. An investigator hiring UNH students in consulting or research activities for a company in which the investigator has financial interests. If a student’s thesis/dissertation research is supervised by the investigator, the conflict of interest situation may not be manageable.

iv. Equity (ownership) interest of the investigator (or members of the immediate family) in a sponsor of the investigator’s research.
H. For PHS-funded projects, the DRC shall determine whether an investigator’s significant financial interest is related to the PHS-funded research, and if so related, whether the significant financial interest represents a financial conflict of interest.

i. An investigator’s significant financial interest is related to the PHS-funded research when UNH reasonably determines that the significant financial interest:
   a. Could be affected by the PHS-funded research; or
   b. Is in an entity whose financial interest could be affected by the research.

The DRC may involve the investigator in the determination of whether a significant financial interest is related to the PHS-funded research.

A financial conflict of interest exists when UNH reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

I. In determining whether a significant financial interest represents a financial conflict of interest in PHS-funded projects, and/or when evaluating whether research should proceed notwithstanding a significant financial interest, the DRC may consider, at its discretion, the following:

i. Whether basic academic values are upheld, an open academic environment is maintained, the research is appropriate to UNH’s mission, and the research is of a fundamental or basic nature;

ii. The nature and amount of the disclosed interest, how closely the financial interest is related to the research, the control or influence such relationship or interest might have over the sponsor’s or financially-interested company’s decisions, and the extent to which the research results could be influenced by the financial interest;

iii. The number and nature of relationships the investigator has with an entity. Multiple roles may create a relationship with an entity that is stronger than the sum of the parts;

iv. Whether the research is essential to maintain the continuity of a research effort related to UNH’s rights in intellectual property covering a product or process to be used in the research;

v. The potential gains to the scientific and UNH communities in the immediate and long-term future in the event the research is successful;

vi. The role of the investigator in the research and the opportunity to bias the results;

vii. Any unique expertise of the investigator (e.g. inventorship, experience, special insights, knowledge, or laboratory resources) that may make his/her involvement essential, including the degree to which the safety or effectiveness of the research might be compromised without that individual;

viii. Restrictions, if any, on publications, presentations or other disseminations related to or referencing the research or the research results;
ix. Where applicable, whether the risks to human subjects are sufficiently low;
x. The steps proposed by the investigator for effective oversight and management of the financial interests;
xi. What role students, trainees, and junior faculty and staff will play and whether that role is appropriate and free from undue influence;

J. Under certain circumstances, DRC members may be disqualified from reviewing a disclosure statement. The standard for disqualification is a reasonable belief that a member may be unable to make a decision based solely on the evidence. Situations that would warrant disqualification include:
i. The member is directly involved in the disclosure under review;
ii. The member has a prior or existing relationship with the investigator that would interfere with the member's objectivity; or
iii. The member's objectivity or ability to serve reasonably appears to be adversely affected by the circumstances.

K. The DRC Chair may act on behalf of the full DRC provided that such acts are conditional pending ratification by the DRC at the next scheduled meeting. The DRC Chair may take such temporary action only in the event that a project will lapse or otherwise be materially compromised if a delay is required until the next scheduled DRC meeting.

V. Management Strategies
A. A conflict management plan (the “Plan”) template is available on-line to investigators. OSVPR staff, in conjunction with the DRC, shall keep the template up to date. The DRC will encourage investigators to use the Plan template when proposing management plans.

B. The DRC shall review the proposed conflict management plan (the “Plan”) and approve it, or add conditions or restrictions to ensure that any conflict is managed, reduced, or eliminated. The Plan shall describe the conditions under which the activity may proceed and the individuals, including the investigator, subject to the Plan. In its deliberations, the DRC shall consider the following management strategies for inclusion in the Plan, according to the nature of the research and the level of risk of influence on the objectivity of the research posed by the conflict:

i. Disclosure of significant financial interests: to individuals working on the research; to the sponsor; to the federal or state government as required by law; and in any substantive public communication related to or referencing the research or the research results (including publications, presentations and other disseminations, whether oral or written).
ii. Disclosure of significant financial interests to research subjects in IRB-approved informed consent documents.
iii. Appointment of reviewers with sufficient independence and expertise to evaluate the research and its progress, and/or to monitor the research data. The reviewers may be from within or outside the UNH. Two types of reviewers could be used in a Plan:
   a. Data monitors who are specific individuals assigned by the DRC to review the appropriateness of data collection methods; and
   b. Scientific reviewers who are external (to UNH) experts brought in to perform scientific audits of the research.
   Any information submitted by the investigator to the reviewers must also be submitted to the DRC.

iv. Periodic or annual reports to the DRC certifying compliance with the applicable Plan;
v. Disqualification or restriction of the conflicted investigator's participation in all or relevant portions of the research activity.
vi. Revision of study design to address potential bias from the financial interests (possibly subject to sponsor approval).
vii. Reduction, divestiture, or elimination of the significant financial interest(s).
viii. Severance of relationships creating the conflict.

The DRC may consult with the investigator's department chair or supervisor, and appropriate academic dean when determining the appropriate strategies to include in the Plan.

C. Unless otherwise stipulated in the Plan, the investigator's department chair or supervisor shall provide general oversight for implementation of the Plan, and is responsible for monitoring implementation of, and the investigator's compliance with, the Plan.

D. A Plan permitting an activity notwithstanding a significant financial interest should contain a description of the scope and frequency of any compliance audits required by the DRC.

E. The DRC shall use its best efforts to develop a standard approach to managing those types of interests for which a standard approach is reasonable and appropriate.

F. The DRC negotiates with the investigator the details of the Plan until they are acceptable to both parties.

G. In all cases, resolution of the conflict or establishment of an acceptable Plan must be achieved prior to commencement of the applicable sponsored project (including enrollment of research subjects) or the expenditure of any awarded funds.

H. Any changes in the Plan require prior approval by the DRC.
I. The UNH Sponsored Programs Administration (SPA) designee is responsible for communicating with sponsors regarding financial conflicts of interest, as required by the sponsor.

VI. **Training of Investigators**  
All investigators submitting management plans must complete UNH’s Web-based training on conflicts of interest and commitment (available at [https://rit.sr.unh.edu/training/rcr-training/conflict-of-interest.html](https://rit.sr.unh.edu/training/rcr-training/conflict-of-interest.html)) before project funds may be released for spending.

VII. **Appeals of Management Plans**  
The DRC's requirements as stipulated in a Plan may be appealed in writing by investigators to the UNH President. The President shall consult with the SVPR, the DRC and the investigator in making a determination. The President’s determinations are final, and shall be submitted in writing to the investigator and the DRC.

VIII. **Oversight of and Monitoring Compliance with a Plan**  
A. The SVPR shall provide copies of approved Plans to the investigator’s department chair or supervisor, and the appropriate assistant/associate dean. Unless otherwise stipulated in the Plan, the investigator’s department chair or supervisor shall provide general oversight for implementation of the Plan, and is responsible for monitoring implementation of, and the investigator’s compliance with, the Plan. Any suspicion that an investigator is not complying with an approved Plan must be promptly reported to the SVPR and/or the Provost.

B. Any reports related to administration of a Plan that are over 30 days late may prompt the SVPR to freeze project funds until the reports are submitted to the DRC for review.

C. At the end of the period for which the Plan is in effect, the investigator shall certify that he/she has complied with the Plan.

IX. **Investigation of Violations of FCOIR Policy**  
A. The DRC is responsible for investigating alleged violations of the FCOIR Policy. Breaches of the policy include, but are not limited to:
   i. Failing to file necessary disclosure statements
   ii. Knowingly filing incomplete, erroneous or misleading disclosure statements, or
   iii. Failing to comply with the Plan.

B. Anyone who suspects that an employee has violated the FCOIR policy must report the matter to the SVPR. DRC members may likewise report their own
concerns about an investigator's FCOIR policy violation. Allegations of FCOIR policy violations must be submitted in writing, and shall be treated as confidential. UNH encourages good faith reporting of concerns about financial conflict of interest in research.

C. The procedures delineated in UNH’s policy on Misconduct in Scholarly Activity (Misconduct Policy) may be used to guide investigation of allegations of violations of either FCOIR policies; investigations under the FCOIR policies, however, may be handled less formally than specified in the Misconduct Policy. For any alleged noncompliance with a Plan, the SVPR shall notify the investigator, his/her department chair or supervisor, and the appropriate dean and assistant/associate dean. Upon completion of an investigation, the DRC shall make recommendations for action to the UNH President.

D. If the President determines that the FCOIR Policy has been violated, he/she may impose sanctions including, but not limited to:
   i. Notification of sponsor and termination of award;
   ii. Formal admonition;
   iii. A letter to the investigator's personnel file;
   iv. Ineligibility to supervise graduate students;
   v. Suspension of the privilege to apply for external funding; or
   vi. Recommend termination of the investigator from UNH

E. The President will communicate the sanctions in writing to the investigator, his/her department chair or supervisor, the appropriate dean and assistant/associate dean, and the DRC. If an investigator's noncompliance with the FCOIR Policy may have biased the design, conduct or reporting of the research, the SVPR shall promptly notify the sponsor. Sponsors may impose additional restrictions, including suspension of funding.

X. Comparative Authority of the DRC and the IRB
The UNH Institutional Review Board for the Protection of Human Subjects in Research (IRB) shall not approve new projects that have been referred to, but not yet approved by, the DRC, nor approve monitoring procedures or other conditions that are less restrictive than those imposed by the DRC. No authorization granted by the DRC may supersede the authority of the IRB, and the IRB may modify the Plan to impose more stringent restrictions than those imposed by the DRC.

XI. Records
The DRC shall document its determinations. The OSVPR shall maintain records of all disclosures and associated DRC activities securely and confidentially. All records shall be maintained for three years following termination or completion of the project or resolution of any government action involving the records. For non-PHS-funded project, records shall not be routinely provided to sponsors unless such is an agency requirement, the agency submits a written request, or UNH is unable to
satisfactorily manage an actual or potential conflict of interest. For PHS-funded projects, UNH shall report according to Section 5 of the FCOIR PHS policy.

XII. **Review of Operating Guidelines**
The DRC shall review these Operating Guidelines at least once per academic year, and recommend changes as deemed necessary.

XIII. **Enforcement Responsibility**
The SVPR is responsible for enforcing the UNH FCOIR policies, and the DRC is responsible for investigating alleged violations of the UNH FCOIR policies.
Appendix A
Relatedness Checklist

Issues to consider when determining the relatedness of significant financial interests (SFI) to the research project, or the researcher’s institutional responsibilities:

A. Intellectual Property (IP) developed by the researcher is being used, tested, or further developed in the research.

B. IP owned by UNH and optioned/licensed to an entity in which the researcher has a SFI is being used, tested or further developed in the research.

C. Products/services are being provided by or purchased from a company in which the researcher has an SFI.

D. The researcher has an SFI in a company which manufactures or sells a concomitant or comparator drug, device, or procedure.

E. The researcher has an SFI in an entity to which research space will be leased or from which research space will be rented.

F. The entity in which the researcher has an SFI is a subrecipient under the proposed research.

G. The researcher will be involved in research under a subaward from an entity in which he/she has an SFI.

H. The researcher has an SFI in an entity that is part of a consortium or will otherwise participate in the research.

I. The researcher has an SFI in an entity whose products are related to the topic of the research, but research subjects will not receive treatment using the entity’s products.

J. The researcher is a founder of, holds a management or executive position with, serves on a Board of, is a consultant (with or without compensation), and/or has received travel income/reimbursement from an entity whose products or services will be used in, are the subjects of, and/or are closely aligned with the research (including comparator/competitor).

Adapted with permission from UCLA Relatedness Checklist, 9/13/13 Ver. 2.