FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY and TRAINING

1. **1.Policy**
   - **1.1. Statement of need and purpose**
     - 1.1.1. The primary goal of this policy is to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health System grants, cooperative agreements and contracts will be free from bias resulting from Investigator financial conflicts of interest.
   - **1.2. Federal Regulation**
     - 1.2.1. The policy and procedures outlined are intended to meet the most recent requirements published by the federal government regarding revised Financial Conflict of Interest (FCOI) Regulation, Promoting Objectivity in Research on August 25, 2011 (42 CFR Part 50 Subpart F and 45 CFR Part 94).
   - **1.3. Significant Financial Interests**
     - 1.3.1. Any investigator responsible for the design, conduct, or reporting of research activities funded or proposed for funding at Dayton Clinical Oncology Program by external sources must reveal all current Significant Financial Interests (SFI) that would reasonably appear to be affected by the research.
     - 1.3.2. Significant financial interest is defined as:
       - 1.3.2.1. Any current financial interest of the investigator and his/her immediate family that could reasonably appear to be affected by the activities proposed for funding; or
       - 1.3.2.2. Any interest held by the investigator and his/her immediate family in a business entity (company, corporation, or other enterprise) whose financial interests might reasonably appear to be affected by such activities.
     - 1.3.3. Specifically, significant financial interests might include, but are not limited to, any of the following:
       - 1.3.3.1. Anything of significant monetary value, including salary or other payments for services such as consulting fees or honoraria:
       - 1.3.3.2. Direct equity interests such as stock, stock options, or ownership interests;
       - 1.3.3.3. Intellectual property rights owned by the investigator such as patents, copyrights, and royalties from such rights.
     - 1.3.4. Significant financial interests do not include:
       - 1.3.4.1. Financial interests in business enterprises or entities that, when aggregated for the investigator and his/her immediate family, meet both of the following tests:
       - 1.3.4.2. The financial interest does not exceed $5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and
       - 1.3.4.3. The financial interest does not represent more than a five percent ownership interest in any single entity;
       - 1.3.4.4. Salary, royalties, or other remuneration from Dayton Clinical Oncology Program;
       - 1.3.4.5. Salary, royalties, or other payments that, when aggregated for the investigator and his/her immediate family, are not expected to exceed $5,000 during the next 12-month period;
       - 1.3.4.6. Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
       - 1.3.4.7. Income from service on advisory committees or review panels for public or non-profit entities.

1.3.5. An investigator may choose to disclose any other financial or related interest that might present an actual, potential, or perceived conflict of interest. Disclosure can be a key factor in protecting an individual's reputation and career from potentially harmful allegations of misconduct.

1.4. Disclosure of Significant Financial Interest

1.4.1. All individuals responsible for the design, conduct, or reporting of research by any grant or sponsored trial agreement, are required to file a Financial Interest Disclosure Form (FIDF).

1.4.2. Investigators must submit a FIDF on an annual basis.

1.4.3. Whenever a new transaction or activity is proposed that might involve a potential conflict of interest or whenever there is a change in interests that might pose a conflict of interest or whenever there is change in a previously reported potential conflict of interest.

1.4.4. Whenever the institution revises this FCOI policy that affects requirements of investigators.

2. Training

2.1.1. As per new regulations (42 CFR 604(b)), all individuals responsible for the design, conduct, or reporting of research by any grant or sponsored trial agreement, are required to undergo initial FCOI training and are required to be trained at least every 4 years. Training can be done at http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm

3. Investigator Responsibilities

3.1.1. The Investigator is responsible for completing FCOI Training prior to engaging in research related to any PHS-funded grant, at least every 4 years and immediately if: Dayton Clinical Oncology Program revises its FCOI policy that affects the requirements of Investigators, an Investigator is new to an Institution or if an Investigator is not in compliance with the policy or management plan.

3.1.2. The Investigator will complete a Financial Interest Disclosure Form (FIDF) at least annually and immediately if the following conditions are present: if Dayton Clinical Oncology Program revises its FCOI policy so that it affects the requirements of the investigators, if an investigator is new to Dayton Clinical Oncology Program or if an Investigator is not in compliance with the policy or management plan.

3.1.3. The Investigator must disclose a significant financial interest (SFI) (and those of the Investigator's spouse and dependent children) related to the Investigator's responsibilities that meets or exceeds the regulatory definition of SFI. The SFI must be disclosed no later than at the time of application for PHS-funded research, at least annually during the period of the award and within 30 days of discovering or acquiring a new SFI.

4. Disclosure Review, Management Plans

4.1. Disclosure Review

4.1.1. Dayton Clinical Oncology Program President & CEO, Principal Investigator, and Associate Principal Investigator will provide timely review of completed Financial Interest Disclosure Forms (FIDF) and will notify interested parties upon completion of such review. The review will determine whether an Investigator's FIDF contains a significant financial interest, and if so whether the SFI is a financial conflict of interest related to ongoing clinical trials

4.1.2. If the Disclosure being reviewed is that of the Dayton Clinical Oncology Program President & CEO, Principal Investigator, or Associate Principal Investigator, the Dayton Clinical Oncology Program Board of Directors will complete the review process.

4.1.3. Dayton Clinical Oncology Program will send initial, annual and revised FCOI reports, including all reporting elements required by the regulation, to the NIH as required by the most recent regulation. This process will include the following time points: prior to the

expenditure of funds; within 60 days of identification for an Investigator who is newly participating in the project; within 60 days for new, or newly identified FCOIs for existing Investigators; at least annually (at the same time Dayton Clinical Oncology Program is required to submit the annual progress report) to provide the status of the FCOI and any changes to the management plan, if applicable; until the completion of the project and following a retrospective review to update a previously submitted report, if appropriate.

4.2. Management Plans for reported Conflict of Interest

4.2.1. Upon reviewing an individual Financial Interest Disclosure Form with possible conflict the Dayton Clinical Oncology Program President & CEO, Principal Investigator, and Associate Principal Investigator, after discussion with the individual, will decide whether a management plan is needed.

4.2.2. Should management of a potential or actual significant financial conflict of interest be required, the Investigator and Dayton Clinical Oncology Program President & CEO, Principal Investigator, and Associate Principal Investigator will draft a "Management Plan." These written plans will manage, reduce, or eliminate the significant financial interest(s). Such plans will be designed to meet applicable legal requirements, facilitate the local resolution or management of any conflict, minimize administrative burden, and protect the confidentiality of disclosed information.

4.2.3. Management plans may include a single element or several elements such as:

4.2.3.1. public disclosure of significant financial interests (e.g., when presenting or publishing the research; to staff members working on the project; to Institution's Institutional Review Board(s);

4.2.3.2. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;

4.2.3.3. Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;

4.2.3.4. divestiture of significant financial interests; and/or other arrangements that manage, reduce, or eliminate a potential financial conflict of interest.

4.2.4. The Dayton Clinical Oncology Program Board of Directors will be responsible for developing a Management Plan for any significant financial conflicts involving the Dayton Clinical Oncology Program President & CEO, Principal Investigator, or Associate Principal Investigator.

5. Compliance

5.1.1. As part of the Financial Disclosure Statement, each Investigator must certify that if it is determined that a significant financial conflict exists, the investigator will adhere to all conditions or restrictions imposed upon the project and will cooperate fully with the individual(s) assigned to monitor compliance.

5.1.2. Dayton Clinical Oncology Program will complete and document retrospective reviews within 120 days of the determination of noncompliance for SFIs not disclosed or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulation.

5.1.3. Dayton Clinical Oncology Program will notify NIH promptly and take corrective action if an Investigator fails to comply with Dayton Clinical Oncology Program's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research.

5.1.4. Dayton Clinical Oncology Program will post this FCOI policy and any identified significant financial conflicts on the public webpage at http://daytonncorp.org/ The website will be updated annually and within 60 days of identifying any new FCOIs.

6. Enforcement

6.1.1. Failure to properly disclose significant financial interests or to adhere to conditions or restrictions imposed by the Management Plan will be considered a deviation from accepted standards of conducting research at Dayton Clinical Oncology Program.

6.1.2. The Dayton Clinical Oncology Program President & CEO, Principal Investigator, and Associate Principal Investigator will investigate alleged violations of this policy. Breaches of policy include failure to file the necessary disclosure statements; knowingly filing incomplete, erroneous or misleading disclosure forms, or failure to comply with procedures prescribed by the Management Plan. If the Dayton Clinical Oncology Program President & CEO, Principal Investigator, and Associate Principal Investigator determine that the policy has been violated, they may impose sanctions including, but not limited to, notification of sponsor and termination of award; formal admonition; a letter to the investigator's personnel file, or suspension of enrollment privileges. This will be reported to NIH through eRA Commons.

7. Records

7.1.1. The President & CEO will maintain records of all disclosures and associated activities securely and confidentially. All records will be maintained for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 74.53(b) and 92.42 (b) for different situations.

7.1.2. Records will not be routinely provided to sponsors unless such is an agency requirement and the agency submits a written request. Disclosure statements and associated information will not be released without notification to the investigator.