

AMERICAN COLLEGE OF RADIOLOGY CONFLICT OF FINANCIAL INTEREST IN RESEARCH POLICY

Chancellors, officers, committee or commission members, staff, volunteers, investigators and all others representing or acting on behalf of the American College of Radiology (ACR) should avoid conflicts of interest or the appearance of conflicts of interest. All decisions and actions considered or made by such individuals should be based solely on the best interests of the ACR and in accordance with applicable federal, state, and local laws and regulations. Personal considerations should not be a factor in any action or decision made on behalf of the ACR. The confidence that members of the profession and the public have depends on the integrity of those who represent the ACR.

Conflict of Financial Interest in Research

As a recipient of National Institutes of Health (NIH) grant funds, the American College of Radiology is subject to the NIH requirement for grantees and investigators to comply with the requirements of 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." In the handling of all such grant funds the ACR will take steps to ensure that the Principal Investigator (including spouse and dependent children) or any other persons responsible for the design, conduct and reporting of all research will not be biased by any conflicting "significant financial interest." This provision applies to all persons representing or acting on behalf of the ACR (including individuals engaged in RTOG, ACRIN or other specific ACR research activities).

What Constitutes a Conflict of Interest?

A "significant financial interest" is defined as anything of monetary value in excess of \$10,000 and derived from consulting fees, honoraria, other payments for service, equity interests (or in excess of 5% ownership) or intellectual property rights. In reaching the \$10,000 or 5% equity ownership threshold the aggregated amounts from an investigator and his/her immediate family are considered. 42 CFR Section 50.603 provides further information regarding what does and does not constitute a significant financial interest.

Disclosure

Disclosure of a significant financial interest is required when the investigator makes application to participate in the research supported by NIH funds. A form will be provided by the ACR to the investigator for this purpose. The form will be completed by the investigator and returned to the ACR. This disclosure requirement is considered an "on-going" obligation of the investigator, requiring submission of the appropriate documentation should his/her financial interests change during the course of the research. At a minimum, the investigator will be

required to complete and submit to the ACR a new conflict of interest form annually or a new assurance form from the institution.

All financial disclosure forms will be reviewed by the administrator of the research activity (i.e., ACRIN, RTOG) involved with guidance from ACR legal counsel. Any identified significant conflicting financial interests will be reviewed with the affected investigator and reported to NIH within 60 days of its discovery by the ACR (but not the nature of the interest or other details) and actions to manage, reduce or eliminate the conflict of interest will be taken by the administrator of the research activity involved with advice from legal counsel and included in the report to NIH. All financial disclosure forms and any actions taken by the ACR to resolve conflicting significant financial interests will be recorded and kept on file in accordance with Section 50.604(e) of the regulation.

Institutions through whom investigators provide services to the ACR shall provide ACR with a written assurance that the institution is compliant with the conflict of interest requirements of 42 CFR 50, Part F and all institutions must provide ACR with a copy of their most current conflict of interest policy. However, this does not relieve institutions from the responsibility of reporting to the ACR any identified significant financial conflicts of interest so that the ACR may comply with its reporting obligation to NIH.

Conflict of Interest Disclosure Forms

In addition to the above guidance, formal Conflict of Interest disclosure forms will be required from the following groups of individuals on an annual basis or at the commencement of a research activity:

- Group leadership (i.e., ACRIN, RTOG)
- Scientific and support committee chairs
- All clinical trial investigators
- Data and Safety Monitoring Committee members
- Research consultants
- Speakers at ACRIN, RTOG or other ACR research meetings

Management and Enforcement

Management and enforcement of this policy is the responsibility of the administrator of the research activity (i.e., ACRIN, RTOG) affected with involvement from the respective Clinical Chair and ACR Executive Director. In the case of reported significant financial conflicting interests such actions to manage, reduce or eliminate the conflict of interest may include, but are not limited to, public disclosure of the conflict of interest, restriction on the equity involved (such as placing a stock in escrow or in a trust during the period of time of the research), limiting the role of the investigator, divestiture of the financial interest or severance of the relationship that is the source of the conflict of interest.

Any significant conflict of financial interest not reported but discovered during the course of a research activity will be immediately investigated by the administrator of the research activity involved with assistance from ACR legal counsel. Reporting to NIH will be in accordance with the guidance described above. Depending upon the nature of the conflict of financial interest and the facts surrounding the failure of reporting in accordance with 42 CFR Part 50, Subpart F, corrective action to manage, reduce, or eliminate the conflict of interest will at a minimum include consideration of those actions described above. In addition, ACR may take more punitive action such as elimination of the investigator and/or the institution involved from further participation in ACR research activities.

Notice

All institutions and individuals providing or engaged in research activities for the ACR will be provided with a copy of this policy.