Administrative Policy and Procedure	
Subject: Financial Conflict of Interest in Research	Page: 1 of 8
Effective: December 11, 2012	Revised:
Approved On: 12/12/12 CEO	Approved on: 12/12/12 Director of Research

POLICY:

This Administrative Policy is applicable to human subject research activities at Asheville Gastroenterology Associates, PA (AGA) and its members, managed organizations, associated outpatient clinics and Investigators, research coordinators, research assistants, and its officials and administrators. The policy applies to all human subject research proposals including subgrantee/contractor/collaborating agreements submitted to any sponsor except Phase I support under the SBIR and Small Business Technology Transfer (STTR) programs funded by the U.S. Public Health Service (PHS).

PURPOSE:

The intent of this policy is to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements or contracts will be biased by any conflicting financial interest of an Investigator (45CFR50, Subpart F; 45CFR94.1)

Furthermore, the purpose of this policy is to protect the integrity of AGA. The U.S. Public Health Service, including the National Institutes of Health (NIH), and the Food and Drug Administration (FDA) have issued rules and regulations that require AGA to identify and manage, reduce, or eliminate financial conflicts of interests (FCOI) related to research activities.

Financial interests are not prohibited, and not all financial interests cause conflicts of interest or affect the rights and welfare of research subjects. However, the extent to which financial interests may affect the rights and welfare of human subjects in research is of concern.

Relevant PHS regulations are available at:
http://grants2.nih.gov/grants/compliance/42_CFR_50_Subpart_f.htm

Relevant FDA rules are available at http://www.FDA.gov/oc/guidance/financialdis.html

DEFINITIONS:

Covered Study
Any study of a drug, biological product, or device in humans in which AGA participates.

DHHS
The United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution
Any public or private entity or organization (excluding a Federal agency) (1) That submits a proposal for a research contract whether in response to a solicitation from the PHS or otherwise, or (2) That assumes the legal obligation to carry out the research required under the contract.

Investigator
The listed or identified Investigator, Co-Investigator, or Sub-Investigator who is directly involved in the treatment or evaluation of research subjects or who is responsible for the design, conduct, or reporting of the proposed research, or any staff who is responsible for obtaining informed consent of the subjects. The term also includes the spouse and each dependent child of the Investigator.

PHS
The Public Health Service, an operating division of the United States Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated.

PHS Awarding Component
An organizational unit of the PHS that funds research that is subject to this part.

Principal Investigator
The listed or identified individual who has the authority and responsibility for leading and directing the research project.

Proprietary Interest
Property or other financial interest in the tested product including, but not limited to, a patent, trademark, copyright, or licensing agreement.

Public Health Service Act or PHS Act
The statute codified at 42 U.S.C. 201 et seq.

Research
A systematic investigation 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 and product development.

SBIR
Small Business Innovation Research (SBIR) Program means the extramural research program for small business that is established by the awarding components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this part, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

Significant Financial Interest
A financial interest consisting of one or more of the following interests of the Investigator that appears to be related to the Investigator's Institutional responsibilities:

1. With regard to any publicly traded entity, a *significant financial interest* 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. For purposes of this definition, remuneration includes salary and any payment of services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
2. With regard to any non-publicly traded entity, a *significant financial interest* 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 holds any equity interest (e.g., stock, stock option, or other ownership interest); or
3. Intellectual property rights and interest (e.g., patents, copyrights), upon receipt of income related to such rights and interests that exceeds $5,000;
4. The occurrence of any reimbursed or sponsored travel (i.e., that which 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 their Institutional responsibilities, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources provided in regulation.
5. Exclusions:
    a. Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
    b. Intellectual property Rights assigned to the Institution and agreements to share in royalties related to such rights;
    c. Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;

d. 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;
e. Income from seminars, lectures, teaching engagements, service on advisory committees or review panels sponsored by a federal stat, or local government agency, and 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.

Sponsor of the covered clinical study

The party providing support for a particular study at the times it was carried out. Under applicable regulations (21 CFR, Parts 54, 312, 314, 320, 330, 601, 807, 812, 814, and 860), an applicant is required to submit to FDA, a list of clinical Investigators who conducted covered clinical studies and certify and/or disclose certain financial arrangements as follows:

1. Certification that no financial arrangements with an Investigator have been made where study outcome could affect compensation; that the Investigator has no proprietary interest in the tested product; that the Investigator does not have a significant equity interest in the sponsor of the covered study; and that the Investigator has not received significant payments of other sorts; and/or
2. Disclosure of specified financial arrangements and any steps taken to minimize the potential for bias.

PROCEDURE:

Investigator's Roles and Responsibilities:

1. Investigators who are planning to participate or are currently participating in research, must complete the required Financial Conflict of Interest (FCOI) training. Training will consist of a combination of learning modules in the CITI program and online training on topics that include (i) this revised Institutional policy; (ii) Investigator's disclosure responsibilities; and (iii) Federal Regulations.
    - Investigators must complete this training (i) immediately following the effective date of this revised Financial Conflict of Interest in Research Policy; (ii) immediately following gained employment at AGA; (iii) prior to engaging in research related to a PHS-funded grant; and/or (iii) in effort to establish compliance once non-compliance has been discovered. Training must occur at least every four years.
2. Investigators must complete a financial disclosure statement (i) no later than the time of application for research and before the proposed research activity through the applicable sponsor(s); (ii) at least annually during the ongoing research or the period of the award; and (iii) within thirty (30) days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new significant financial conflicts of interest.

    a. If the Investigator discloses a significant financial interest (by giving an affirmative answer to the questions listed under the Financial Conflict of Interest section, in any one of the IRB applications), notification to the sponsor must be disclosed and documented.

b. The Investigator(s) will be reminded of the policy on Financial Conflict of Interest in Research in each approval letter issued by an applicable IRB. It is the Principal Investigator's responsibility to ensure that any potential financial conflict of interest that exists in relation to the proposed research is reported as required by the applicable sponsor.
c. The Investigator(s) must update his/her financial disclosure statements annually upon the IRB renewal date or as new reportable financial interests occur.

AGA's Roles and Responsibilities:

3. The Research Director (or designated Sub-I or CEO) will review the disclosure statements for potential conflicts of interest.
    a. The Research Director will make a determination whether a potential Financial Conflict of Interest (FCOI) exists. A FCOI exists when the designated official(s) reasonably determines that a Significant Financial Interest, as defined above, could directly and significantly affect the design, conduct, or reporting of the research.
    b. The Research Director may confer with AGA's CEO and/or Board of Directors for additional guidance.
    c. The Research Director will issue a decision regarding the disclosure within a timely manner following receipt of the documentation.
    d. The Research Director will communicate the findings to the applicable sponsor/IRB and the Investigator.

4. The Research Director will develop and implement a management plan to ensure that the disclosed FCOI are managed, reduced, or eliminated.
    a. A Management Plan will be drafted for each identified FCOI and will include the following elements:
        1. Role and principal duties of the conflicted Investigator;
        2. Conditions;
        3. Safeguards to protect the objectivity in the Research;
        4. Confirmation of the Investigator's agreement to the plan;
        5. Monitoring of compliance to the Plan;
        6. Other information as needed.
    b. Examples of safeguards that might be imposed in the Management Plan include, but are not limited to:
        1. Public disclosure of significant financial interests;
        2. Monitoring of the research by independent reviewers;
        3. Modification of the research plan;
        4. Disqualification from participation in all or a portion of the research that could potentially be affected by significant financial interest;
        5. Divestiture of significant financial interests, or;
        6. Severance of relationships that create actual or potential conflicts.
    c. An IRB of the applicable sponsor may require that additional information be given to subjects in order to protect their rights and welfare (45CFR46.109(b), 21CFR56.109(b).

5. Asheville Gastroenterology Associates will maintain records of all financial disclosures and all actions taken with each conflicting interest.
    - All records will be maintained for at least three years from the date of submission of the final expenditures report of PHS funded research, the research termination, or where applicable, from other dates specified in 45CFR74.53(b) and 92.42(b) for different situations.

6. Reporting Requirements **(PHS Funded Research Only)**
    a. AGA will provide initial and ongoing FCOI reports directly to the NIH (i) prior to the expenditure of funds; (ii) within 60 days of identification of a new Investigator; (iii) within 50 days of a newly identified FCOI for existing Investigators (iv) at least annually, which may coincide with the Investigator's continuing review submittal to the IRB, to report on the status and any changes, and/or (v) following a retrospective review to update a previously submitted report as indicated in the Non-Compliance section of this policy.
    b. All reports will be submitted to the NIH through the eRA Commons FCOI Module.
    c. The FCOI report shall include the following elements:
        1. Grant number;
        2. Principal Investigator or contact PI;
        3. Name of the person with the FCOI;
        4. Name of the entity with which the Investigator has an FCOI.
        5. Nature of FCOI (e.g. equity, consulting fees, travel reimbursement, honoraria);
        6. Value of the financial interest or a statement that a value cannot be readily determined;
        7. A description of how the FCOI relates to the PHS funded research and the basis of the determination.
        8. AGA's key elements for managing the FCOI as set forth in the Management Plan.
    d. Subrecipient Requirements
        1. In cases where AGA is a subrecipient, subgrantee, or collaborator (e.g., subcontractor or consortium members), AGA will establish, via a written agreement with the Prime Awardee, stating that AGA will comply with AGA's own Financial Conflict of Interest policy and that of the collaborator.
        2. Upon request, AGA will supply the Prime Awardee with certification that AGA's Financial Conflict of Interest policy complies with Federal regulations.
        3. AGA will submit all FCOI reports directly to the Prime Awardee institution within a sufficient timeframe to ensure the Prime Awardee will meet their disclosure and/or reporting obligations to the PHS awarding component.
        4. The Prime Awardee Institution is responsible for monitoring compliance with the FCOI regulation, management plans, and for reporting all identified FCOIs to the PHS awarding component on behalf of AGA.

7. Public Accessibility of Financial Conflict of Interest in Research Policy
    - AGA's Institutional policy of FCOI will be publicly available through AGA's website: ashevillegastro.com.

8. Public Accessibility of FCOIs **(PHS Funded Research Only)**
    a. Prior to expenditure of PHS funds, AGA will ensure that information concerning FCOIs held by Investigators or Senior Key Personnel is publicly accessible by providing written response within five business days of a public request.
    b. The information will be updated with newly identified FCOIs and written requests will include such updated information.
    c. The information will remain available for three years from the date the information was most recently updated.
    d. Information that will be made publicly available will include the following:
        1. Investigator's name.
        2. Investigator's title and role in the research project;
        3. Name of the entity in which the FCOI is held;
        4. Nature of the FCOI;
        5. Approximate value or a statement the interest is one whose value cannot be readily determined through references to public prices or other reasonable measure of air market value.

9. Non-Compliance with Policy on Conflicts of Interest in Research
    a. All Investigators and other personnel to whom this Policy applies are expected to comply fully and promptly with all requirements.
    b. Non-compliance includes, but is not limited to (i) failure to disclose Significant Financial Interest in a timely manner; (ii) failure to disclose any Significant Financial Interest when one exists; and/or (iii) failure to manage Significant Financial Interest in a timely manner.
    c. Non-Compliance in PHS Funded Research
        1. Should an instance of Non-Compliance be identified in PHS funded research, the Board of Directors of the institution will complete a retrospective review of the Investigator's activities and the project to determine if bias in the study design, conduct, or reporting exists.
        2. The retrospective review will take place within 120 days of the determination of noncompliance. Documentation of the review will include:
            (a) Project number;
            (b) Project title;
            (c) Principal Investigator contact;
            (d) Name of the Investigator with the FCOI;
            (e) Name of the entity with which the Investigator has an FCOI;
            (f) Reason for the retrospective review;
            (g) Detailed methodology used for the retrospective review;
            (h) Findings and conclusions of the review.
        3. Based upon the findings of the retrospective review, the previously submitted FCOI report will be updated.

4. In cases where bias is discovered through the retrospective review as it relates to the conduct, design, and reporting of NIH-funded research, a Mitigation Report will be prepared and promptly submitted to the NIH, in accordance with the Federal Regulations.
5. The Mitigation Report will include the following elements:
    (a) Key elements documented in the retrospective review;
    (b) Description of the impact of the bias on the research project;
    (c) Plan of action to eliminate or mitigate the effect of the bias.

d. Possible sanctions for violation of this Policy, including furnishing false, misleading, or incomplete information, can range from administrative intervention, termination of the research, and/or disciplinary action.
e. The Corporate Compliance Officer and Executive Leadership will be responsible for reviewing all financial conflict of interest disclosures. Unresolved issues or concerns will be reported to the CEO and Board of Directors of AGA.
f. If a failure to comply with this Policy has biased the research, the Research Director will notify the Sponsor of the occurrence and the corrective action taken.
g. In the event non compliance is discovered by the Department of Health and Human Services or any other Federal Agency, AGA will require the Investigator to (i) disclose the Financial Conflict of Interest in each public presentation of the results of the research; and (ii) request an addendum to previously published presentations, as applicable.