



Financial Conflict of Interest Policy

This policy applies to all employees, including all full-time, part-time, temporary, and contract employees, of Metis Health Analytics, LLC (METIS) who are planning to participate in, or are participating in, Public Health Service (“PHS”) funded research.

Preamble

Metis Health Analytics, LLC recognizes and aims to identify and manage any conflicts of interest (COI) that may be created by a financial interest of an individual related to its activities following the principles below:

1. Separation:

Individuals maintain separation between responsibilities to the company and those to other entities to which they might be affiliated (eg, Duke University).

2. Disclosure:

Individuals working with METIS should inform other collaborating individuals outside METIS about their involvement in the company. This includes all colleagues, students, trainees, fellows, lab members, and co-authors both within and outside of Duke University.

Individuals are required to provide disclosure as to the existence of equity/IP relationship in all publications, presentations, and informed consent documents, involving research related to METIS, its products, and/or IP.

In the relationship between Duke and METIS, individuals shall disclose any financial interest to the office negotiating on behalf of Duke (*e.g.*, OTC, ORS, ORC, Procurement).

Training Requirements

Per PHS regulations, METIS will require that each employee complete FCOI training:

1. Prior to engaging in research related to any PHS funded project;
2. At least every four years;
3. Immediately when any of the following circumstances apply: (A) METIS revises the Policy in a manner that affects the Investigator; (B) when an Investigator is new to METIS; or (C) when METIS finds an Investigator is not in compliance with the Policy or management plan.

FCOI training can be completed using NIH web-based training which can be accessed at: (<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>). Employees must save and print the FCOI Certificate as proof of completion.



Disclosure process

All employees must submit an annual disclosure form including all Significant Financial Interests (SFIs) for themselves and their immediate family.

SFI means a financial interest that reasonably appears to be related to the individual's institutional responsibilities, including, but not limited to:

1. Payments for services (e.g., consulting fees, lecture payments, paid authorship or honoraria), the value of which in the 12 month months preceding the disclosure and as of the date of disclosure is \$5,000 or more;
2. Equity interests (e.g., equity, stocks, stock options, or other ownership interests). For publicly traded entities, the equity interest must be \$5,000 or more, and for a privately held entity, there is no financial threshold;
3. Intellectual property rights and interests (e.g., patents, copyrights, and royalties from such rights).

The PHS project Principal Investigator (PI) is responsible to set an annual date and form for the FCOI disclosure. In addition to the annual disclosure, a new or updated disclosure must be completed in a timely manner whenever a new or potential SFI arises or when a significant change occurs concerning an existing disclosure. A disclosure must be made within thirty (30) days of discovery or acquiring a new SFI. Newly hired employees should make a disclosure as part of their new hire employment process.

Review process

The PHS project Principal Investigator is responsible to review and determine if a disclosed SFI represents a FCOI. Furthermore the PI will:

1. Take actions to manage a FCOI;
2. Monitor compliance with management plans according to the Management process section of this Policy;
3. Manage noncompliance with FCOI Policy;
4. Maintain records relating to all disclosures of SFIs and the related reviews.

Management Process

If a determination is made that a FCOI exists the PI shall seek input from the Employee and recommend to METIS board a suitable action plan (Management Plan) to eliminate or manage the FCOI consistent with the objectives of this Policy. Examples of actions that might be imposed to manage a FCOI are: public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research); modification of the research plan; change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research; reduction or elimination of the financial interest (e.g. sale of an equity interest).

In the event that there is no reasonable way to manage a FCOI then the Employee may be



prohibited from participating in the related Research until such a time as the FCOI is eliminated.

METIS board shall review the proposed Management Plan and can approve, modify and approve, or return to the PI for additional work. Final review and determination must be completed prior to the expenditure of any PHS funds for the research.

Reporting requirements to PHS awarding component

For PHS and other applicable-funded research projects, prior to the expenditure of funds, METIS will provide the sponsor a report of any FCOI determined to be related to the project and ensure that a management plan has been implemented in accordance with this Policy. During the period of the award, METIS will report to the PHS awarding component within 60 days any FCOI identified by a new Employee, or subsequent to the initial FCOI report by an existing Employee. When the grantee submits his/her annual progress report or at the time of extension, METIS will report the status of any FCOI and any changes in management plans to the PHS Awarding Component. At least annually (at the same time as when METIS is required to submit an annual progress report, multi-year progress report, if applicable or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project. The content and format of reports will be consistent with regulations.

Recordkeeping

METIS will maintain records of all financial disclosures and all actions taken by METIS with respect to each FCOI for at least three years from the date of submission of the final expenditures report to the PHS Awarding Component.

Noncompliance and Sanctions

The following items in the non-exclusive list are grounds for a finding of noncompliance and possible sanction against an Individual:

1. Not complying with the terms of the Policy;
2. Not submitting a truthful and timely disclosure form;
3. Failing to fulfill training requirements;
4. Failing to update a disclosure form when a new SFI is obtained;
5. Failing to cooperate with or otherwise respond to requests for additional information from the METIS board;
6. Failing to fulfill the terms and conditions of a conflict management plan

Where noncompliance is perceived, the PI will review the matter and communicate with the Employee. The following non-exclusive list of means by which noncompliance may be resolved:

1. Request that a disclosure form be completed, updated, amended, etc.;



2. Provide the Employee with another opportunity to respond to requests for information or collaboration;
3. Recommend a delay or cessation of disbursement of the Employee's funding;
4. Conduct a retroactive review in compliance with applicable regulations and report the matter to the funding agency, as appropriate.

METIS shall require sub-recipient compliance with pertinent FCOI requirements as mandated by PHS regulation.

In any case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment that has been designed, conducted, or reported by an Employee with an FCOI that was not managed or reported by METIS as required by the PHS regulation, METIS will require the Employee involved to disclose the FCOI in each public presentation of the results of the research and request an addendum to previously published presentations.

Public accessibility of FCOI policy and information

This Policy is accessible on the METIS website (www.metiscare.com). FCOI informational requests by the public should be made to METIS. METIS shall respond to requests for FCOI information within five (5) business days. In situations where METIS is working with a subrecipient, it is METIS's responsibility to make FCOI information publicly accessible.