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Vice-President for Research and Economic Development

The Vice-President for Research and the Designated Official are responsible for the following:

Acting on behalf of the Committee to review and approve, require modifications in order to approve, or disapprove research activities reviewed by the Designated Official and the Institutional Official (Vice President for Research and Economic Development) and determine which activities require review by the convened IRB and which activities may be reviewed by the Designated Official and the Institutional Official.

5.1

Institutions are encouraged to develop additional activities which could be reviewed as minimal risk to the extent permitted by applicable federal regulations. Please refer to the USA Office for Human Research Protections guidance on this subject, but they should, but they should

5.1.1 Ongoing review of research activities
5.1.2 Ongoing review of changes to research activities that could affect the risk to subjects
5.1.3 Financial interests that could reasonably appear to be related to research (including those of family members and dependent children)
5.1.4 Serious or continuing noncompliance with the regulations or the requirements or determinations of the IRB

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5.2.4 Travel Costs

PHS-funded [illegible] PHS Financial Conflict of Interest Regulations [illegible] reasonable travel costs [illegible] paid for by a third-party entity [illegible] by the Federal government agency, a U.S. [illegible] research [illegible], a U.S. medical center, or a U.S. academic teaching hospital.

When a travel request [illegible] paid by a third party and the traveler is a PHS-funded [illegible] the Office of Research Compliance [illegible] Travel Request [illegible] *This description applies, as the Office of Research Compliance [illegible] the Travel Request* [illegible]. The Office [illegible] travel [illegible], including a determination [illegible] travel [illegible] PHS-funded research.

5.3 [illegible]

5.3.1 Identifying Who Needs Training

The [illegible] The Office of Sponsored Projects Administration [illegible] Financial Conflict of Interest [illegible] Public Health Service (PHS) agency [illegible] Non-PHS Conflict of Interest [illegible] agency. If so, [illegible] the PHS Conflict of Interest [illegible] (c)4 (o)6 148.6812.1 ..N-1 (2kMCID 15 >>MCID 0 ((c)4 (H)]TJ-0.003 Tc 0.007 Tw -4 8 2

5.3.2 How Do I Get Training?

The Collaborative Institutional Training Initiative (CITI) is a program that is available for free to research personnel. The Office of Research Compliance and Assurance has met PHS agencies and other applicable training agencies' standards for training requirements. Instructions for accessing the CITI training program are located on the

5.4 [illegible]

5.4.1 Identify Facial Contours

The Designated Official (Office of Research Compliance and Assurance) reviews contours submitted for research and consults with subject matter experts as necessary to determine whether facial contours are present. A physician will be consulted to determine whether facial contours pose a risk. This is done in order to ensure that research department and participants are protected in accordance with applicable regulations. A variety of factors will be considered in determining whether specific facial features create a contour that requires a PHS funded project.

The review will consider the nature of the research, the degree to which the contour is related to the research, the extent to which the subject could be affected by the research, and any management strategies that could mitigate, reduce, or eliminate the contour. Management strategies may include, but are not limited to

- Modification of the research plan
- Protocol design of facial contours
- Design of the subject participation
- Change of personnel involved
- Reduction of facial features (such as by covering, hiding)
- Appointment of independent monitor to take measures to protect the design, conduct and report of research against bias or appearance of bias
- Severance of relationship

Based on the physician review, the following may occur: 1) other actions are needed 2) actions are satisfactory 3) development of a management plan

If a management plan is required, the investigator will be advised on how to protect the image and how the facial contour will be reduced or eliminated. This is called the Image Management Plan

5.4.2 Management Plan

If is determined that a facility will be used for PHS-
research, Non -PHS cognizant agency or external facility (e.g., a management plan may be required to manage the facility and/or protection of human subjects. The following occurs:

Office of Research Compliance and Assurance (or designee) and/or Department Chair/Supervisor develops a management plan for each facility before awarded funds are expended.
Office of Research Compliance and Assurance management team members
Management team members review and discuss draft plan management plan
Management plans are approved by the Institutional Department Chair/Supervisor and Vice President for Research and Economic Development

The Institutional Official (IO) of the research that gives rise to Facility Certification, or the appointee of the IO, reviews and approves the plan.

5.4.3 Certification Management Team

The management team reviews and updates as prescribed in the management plan

Any changes to the Institutional Official (IO) may be required at the request of the Management Team. For example, if there are concerns regarding Institutional Animal Care and Use Committee (IACUC) findings at a facility, the IO may require

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5.6.1 The University shall, within 120 days of its determination of bias, complete a retrospective review of the Investigator's activities and the PHS-funded research to determine whether the design, conduct, or reporting of the PHS-funded research, or any part of it, was biased. Retrospective reviews will be conducted by the Office of Research Compliance and Assurance, in consultation with the Vice President for Research and Economic Development, to determine if the research or any part of it was biased, to decide a plan to address any bias

5.6.2 The University will document the retrospective review and its detailed findings to PHS, including at least the following key elements:

- project number;
- project title;
- Principal Investigator(s) and contact Principal Investigator(s) if there are multiple Principal Investigators on the project;
- name of the Investigator with the Significant Financial Interest;
- name of the Entity with which the Investigator has a Significant Financial Interest;
- period(s) of the retrospective review;
- detailed methodology used for the retrospective review (e.g., methodology for the review process, composition of the review panel, documents reviewed);
- findings of the review; and
- conclusions of the review

5.6.3 Based on the results of the retrospective review, USA will work with the Investigator with the Significant Financial Interest to promptly implement a management plan, develop and implement a mitigation plan, or impose other appropriate conditions/restrictions that will eliminate, mitigate, or manage the bias. If bias is found, USA will notify PHS promptly and submit a mitigation plan that will include:

- the key elements documented in the retrospective review;
- a description of the action(s) that will be taken to mitigate the bias in the research; and
- USA's timeline for implementing the action(s) taken to mitigate the effect of the bias

5.6.4 Thereafter, the Investigator with the Significant Financial Interest will submit an annual update as prescribed by PHS COI regulations

6.0 tion

The ele ble pa s for oversight and enforcement:

Pu by Oversight	Office for Research Integrity and Assurance
Pu by Enforcement	Vice President for Research and Economic Development

7.0 tion

Co ct of Interest and Co ct of Commitment Policy
Guidance for Determining if a Financial Conflict of Interest is Related to PHS-Funded Project
PHS Agencies and Non-PHS guidance that is inconsistent with PHS COI Regulations
PHS Solicitations and disclosures
Notification to Investigators/Staff of Financial Conflicts of Interest

2011 Public Health Service (PHS) Regulations Related to Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F)