

Institutional Handbook of Operating Procedures Policy 11.01.08	
Section: Research Policies	Responsible Vice President: Include the <i>title</i> of the vice president responsible for overseeing development, implementation, and revision of the policy.
Subject: General Research Procedures	Responsible Entity: Research Services

I. Title

Foreign Influence in Research

II. Policy

The University of Texas Medical Branch (UTMB) has provided a framework for its research faculty and staff to disclose all relationships and safeguard research from infringement and inappropriate influence by foreign entities, governments, or individuals.

III. Background

The United States Government has raised concerns regarding theft, hacking and covert efforts to compromise innovation. In 2019, The National Institutes of Health (NIH) identified at least 100 instances of Foreign Influence on extramural research after investigating scientists at over 65 grantee institutions. Individuals and institutions failed to report foreign ties, funding sources, and conflicts of interest.

UTMB values academic collaboration both domestically and abroad. Foreign Influence in research is an issue related to the orchestrated actions of foreign governments and their agents and is not about profiling any ethnicity or the activities of our employees. The intention of this policy is not to prevent or limit foreign collaborations, but to raise awareness of concerns that foreign influence presents and to mitigate risk by reiterating the requirements for researcher disclosure and transparency.

IV. Procedures

Institutional Disclosure Requirements

UTMB faculty and staff must disclose conflicts of interests per several existing policies including IHOP – 06.05.01 <u>Research Conflicts of Interest;</u> – 06.05.03 <u>Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities;</u> IHOP 06.05.04 <u>Institutional Conflicts of Interest;</u> and IHOP - 06.05.05 – <u>Gifts, Vendor and Industry Interactions, and other Activities</u>.

NIH Disclosure Requirements

On July 10, 2019, the NIH released <u>NIH Notice (NOT-OD-19-114): Reminders of NIH Policies on</u> <u>Other Support and on Policies related to Financial Conflicts of Interest and Foreign</u> <u>Components.</u> Faculty funded by or submitting to NIH must read this notice and FAQs to determine whether additional disclosures should be made to be compliant with NIH policies. Below is a summary of the current policy:

NIH applicants and recipients must disclose all resources or "Other Support" made available to a researcher regardless of its monetary value and regardless of whether the support is based at the current grantee institution. Per NOT-OD-19-114, applicants must:

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- 1. List all positions and scientific appointments both domestic and foreign held by senior/key personnel that are relevant to an application including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary).
- 2. Report all resources and Other Support for all individuals designated in an application as senior/key personnel including for the program director/principal investigator (PD/PI) and for other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation. Information must be provided about all current support for ongoing projects, irrespective of whether such support is provided through the applicant organization, through another domestic or foreign organization, or is provided directly to an individual that supports the senior/key personnel's research efforts.
- 3. Report all current projects and activities that involve senior/key personnel, even if the support received is only in-kind (e.g. office/laboratory space, equipment, supplies, employees). All research resources including, but not limited to, foreign financial support, research or laboratory personnel, lab space, scientific materials, selection to a foreign "talents" or similar-type program, or other foreign or domestic support must be reported.
- 4. Provide the total award amount for the entire award period covered (including facilities and administrative costs), as well as the number of person-months (or partial person-months) per year to be devoted to the project by the senior/key personnel involved.
- 5. All pending support at the time of application submission and prior to award must be reported using "Just-in-Time Procedures" by providing all information indicated above. Applicants are responsible for promptly notifying NIH of any substantive changes to previously submitted Just-in-Time information up to the time of award, including Other Support changes that must be assessed for budgetary or scientific overlap. Further, if Other Support, as described as above, is obtained after the initial NIH award period, from any source either through the institution or directly to senior/key personnel, the details must be disclosed in the annual research performance progress report (RPPR). Post-award, recipients must address any substantive changes by submitting a prior approval request to NIH in accordance with the NIHGPS section on "Administrative Requirements—Changes in Project and Budget—NIH Standard Terms of Award."

In addition, NIH grant recipients must identify and disclose whether there are any foreign components in its research projects. Foreign components include:

- 1. Performance of work by a researcher or recipient in a foreign location, whether or not NIH grant funds are expended; and/or
- 2. Performance of work by a researcher in a foreign location employed or paid for by a foreign organization, whether-or-not NIH grant funds are expended.

V. Enforcement and Compliance Disclosure is a Condition of Employment or Relationship to Institution

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- 1. UTMB Employees and Students: Timely, complete, and accurate disclosure of activities and financial interests consistent with this and other policies is a condition of employment and/or enrollment at UTMB, and a Covered Individual who does not comply with this policy, including but not limited to, failure to file or knowingly filing an incomplete, erroneous or misleading disclosure statement, and/or failure to comply with other policy requirements, is subject to discipline, up to and including termination of employment for employees or suspension or expulsion in the case of a student. Additional sanctions may include termination of the activity that is a conflict of interest, and/or divestiture of significant financial interests. In the case of a violation of criminal or civil law, violators may be subject to civil or criminal penalties.
- 2. Non-UTMB Employees: For a Covered Individual who is not an employee of UTMB, including contractors or consultants, compliance with this policy is a condition of participating with the institution in the capacity that qualifies the person as a Covered Individual. UTMB may require the Covered Individual to execute a document certifying that the individual knows that compliance with this policy is a condition of participation. Failure to comply with this policy including, but not limited to, failure to file or knowingly filing an incomplete, erroneous or misleading disclosure statement, and/or failure to comply with other policy requirements, is subject to discipline, up to and including termination of employment relationship, termination of the activity that is a conflict of interest, and/or divestiture of significant financial interests. In the case of a violation of criminal or civil law, violators may be subject to civil or criminal penalties.

Federal Enforcement

- 1. Federal regulations, 42 CFR Part 50, Subpart F, and 45 CFR Part 94, require the institution to notify the Public Health Service (PHS) of instances in which the failure of a Covered Individual to comply with this policy or a management plan appears to have biased the design, conduct, or reporting of PHS-funded research. The PHS awarding component may take enforcement action or require the institution to take action appropriate to maintaining objectivity in the research. The institution must make information available to the U.S. Department of Health and Human Services (HHS) or the PHS awarding component as required by federal regulation.
- 2. If the HHS determines clinical research funded by PHS to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by a Covered Individual with a research conflict of interest (RCOI) that was not managed or reported by the institution as required by federal regulation, the institution will require the Covered Individual involved to disclose the RCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

State Laws and Regulations, and Institutional and UT System Policies

This policy supplements, and Covered Individuals are required to adhere to, federal and state laws and regulations as well as other UTMB policies, including but not limited to the Rules and Regulations of the University of Texas System Board of Regents, University of Texas System Business Procedure Memoranda, and the UTMB Institutional Handbook of Operating Procedures (IHOP) and UTMB's Standard of Conduct Guide.

VI. Definitions

Conflicts of Interest: A significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

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Covered Individual: An Individual who is required to complete a financial disclosure conflicts of interest form. UTMB requires the following to submit a financial conflicts of interest disclosure form: (1) all faculty engaged in organized research activities; (2) members of institutional research review related committees; (3) staff members who negotiate or execute research agreements on behalf of UTMB; and (4) any Individual who, regardless of title or position, is responsible for the design, conduct, or reporting of research, including a principal investigator, co-investigator, faculty agent, research tech, research nurse, staff, fellow, or administrator who participates in research.

Foreign Influence: Inappropriate or inadvertent sharing by a foreign entity of confidential and/or proprietary information, intellectual property, or data of grant applications, unpublished research, or technologies.

Foreign Location: Any location outside of the United States.

Other Support: *All* resources made available to a researcher in support of and/or related to *all* of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant. This includes resource and/or financial support from all foreign and domestic entities, whether Federal, non-Federal, commercial or institutional, including but not limited to, grants, cooperative agreements, contracts, institutional awards, financial support for laboratory personnel, and/or provision of high-value materials that are not freely available (e.g., biologics, chemical, model systems, technology, etc.).

VII. Related UTMB Policies and Procedures

UT Regents' Rules and Regulations UT System Rule 180 UT System Rule 175

VIII. Additional References

<u>IHOP – 06.05.01 – Research Conflicts of Interest</u> <u>IHOP – 06.05.03 – Individual Conflicts of Interest, Conflicts of Commitment, and Outside Activities</u> <u>IHOP – 06.05.04 – Institutional Conflicts of Interest</u> <u>IHOP – 06.05.05 – Gifts, Vendor and Industry Interactions, and Other Activities</u>

IX. Dates Approved or Amended

Originated: 09/11/2023	
Reviewed with Changes	Reviewed without Changes

X. Contact Information

Research Administration (409) 266-9400