

# Reporting Requirements for UH Researchers

Internal and External Disclosure Requirements

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# What UH Researchers Need to Know

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- **Disclosures to the University (internal)**
  - Conflict of Interest disclosure
  - Conflict of Commitment disclosure
  - Intellectual Property and Inventions disclosure
- **Disclosures to Sponsors (external)**
  - Current & Pending Support
  - Foreign talent programs
  - Foreign components



# Disclosures to the University

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## UH Conflict of Interest Policies

- **UH Executive Policy 12.214:** Conflicts of Interest and Commitment
- **UH Administrative Policy 12.304:** Procedures for Disclosing and Addressing Conflicts of Interest Related with Extramurally Funded Activities
- **A5.504:** Procedures for disclosing and addressing conflicts of interest and commitment



# Disclosures to the University

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## Key Definitions from UH COI policies:

**Investigator** – Principal Investigator (PI), Project Director (PD) or any other senior/key person responsible for the design, conduct, or reporting of research

**Immediate Family** – Investigator’s spouse, domestic partner or dependent children

**Institutional Responsibilities** – Investigator’s professional responsibilities on behalf of UH, e.g., research, teaching, training, professional practice and memberships or service

**Conflict of Interest (COI)** – financial or other professional/personal interest which may influence or appear to influence an Investigator’s objectivity or judgement in fulfilling his or her institutional responsibilities

**Significant Financial Interest (SFI)** – anything of monetary value to an Investigator or Investigator’s immediate family member, that reasonably relates to an Investigator’s institutional responsibilities



# Disclosures to the University

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- **Significant Financial Interests (SFI)** include but are not limited to:
  - Remuneration (outside income) over \$5000 from any outside entity;
  - Equity interest (e.g. stocks) in a public entity over \$5000;
  - Equity interest of any value in a private entity;
  - Aggregated interests, both income and equity, over \$5000 per entity
  - Royalties or income from intellectual property (e.g. patents, copyrights, and trademarks) from an outside entity
  - Sponsored Travel: reimbursement or sponsorship for travel by an outside entity (applies only to PHS-funded investigators)

*“Entities”  
includes  
foreign  
organizations*



# Disclosures to the University

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## What must investigators disclose to UH?

Investigators must disclose any **Significant Financial Interest (SFI)** held in the last 12 months that reasonably appears to be related to their institutional responsibilities:

- prior to, or at the time of, proposal submission;
- within 30 days of acquiring SFI; and
- at least annually

## Are all SFI's considered a conflict of interest?

An SFI which may influence or **appear to influence** an Investigator's objectivity or judgement in fulfilling his or her institutional responsibilities is considered a conflict of interest



# Disclosures to the University

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## Disclosure Examples

- Income, reimbursement, or sponsorship of travel by a foreign (non-U.S.) government agency, foreign institution of higher education or foreign research entity
- Board positions, offices, appointments, or memberships held in any outside entity, whether compensated or not
- Industry collaborations, both officially and unofficially, with foreign or domestic entities
- Employment, assistantships or exchanges (e.g. Post-docs, visiting scholars) of any international citizens involved in your UH research or extramurally-funded activities
- Any of your private outside interests that could relate to your Institutional responsibilities (e.g. start-ups, or spin-offs)
- Compensation for outside (non-UH) consulting, service, other related work
- Equity or ownership in entities that could reasonably appear as related to UH work
- Employment of UH staff/students in an entity for which an SFI exists



# Disclosures to the University

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## Internal COI Disclosure to UH is not required for:

- Income, reimbursement, or sponsorship of travel by a government agency, **U.S.** institution of higher education or academic teaching hospital, medical center, or research institute affiliated with a **U.S.** higher education institution
- Salary, royalties, or intellectual property right payments from UH
- Income from investment vehicles, e.g., mutual funds and retirement accounts (no direct control over investment decisions)
- Remuneration unrelated to UH institutional responsibilities





# Disclosures to the University

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## Annual COI Disclosure

- UH and RCUH employees due **April 15** - “paper”/PDF form fillable disclosure from AP A5.504 attachment A page 22 – 29

***UPDATE: For the 2022 deadline, a Kualu Build form is being developed to replace the form fillable PDF. Link will be provided from ORC website.***

- Extramurally-funded Investigators and key personnel submit disclosure online via myGRANT rCOI module (rolling expiration every 12 months)

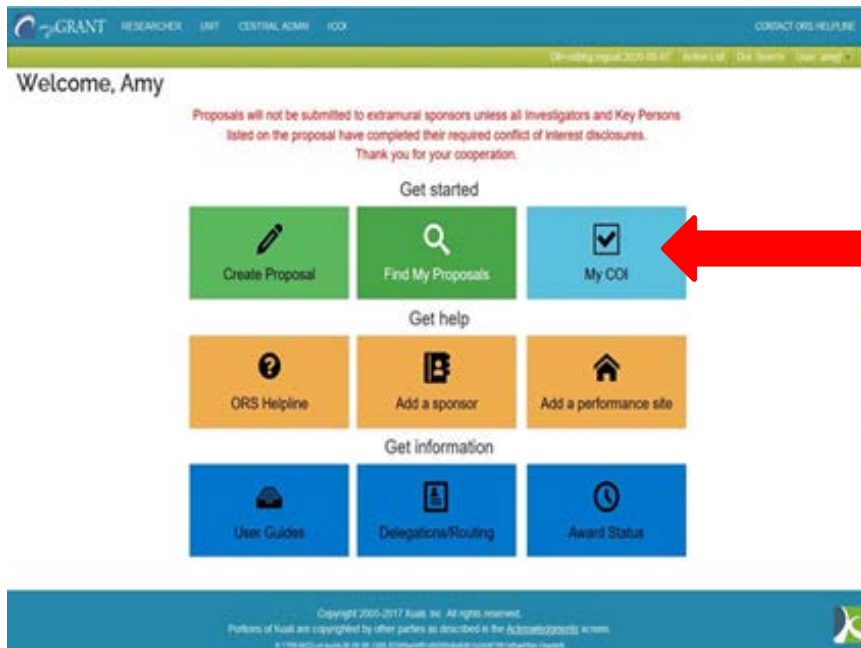
## Ongoing Submission

- New employees
- Changes to annual disclosure
- Proposal/Award – updates in myGRANT



# Disclosures to the University

The new rCOI system launched on September 21, 2020.



There are two ways to access rCOI:

- Click on the **My COI** box from the myGRANT homepage  
or
- Follow the link below  
<http://mygrant.ors.Hawaii.edu/rCOI>  
(myGRANT access not required)

A User Guide for using the new rCOI system can be found at  
<https://research.hawaii.edu/ors/conflicts-of-interest-coi-information/>



# Disclosures to the University

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## COI Training Requirement

\*PHS-funded Investigators must also complete COI training available through CITI at <https://www.citiprogram.org/?pageID=668>:

- At least every four years; *and*,
- Immediately, *if* :
  - UH revises its policy
  - Investigator is new to UH
  - UH finds an Investigator is not in compliance with COI policy or management plan.

### ***\*What is PHS?***

PHS is Public Health Service which includes the National Institutes of Health (NIH), the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA) and the Substance Abuse and Mental Health Services Administration (SAMHSA)



# Disclosures to the University

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## Conflicts of Commitment (COC)

Federal research agencies are focusing on strengthening disclosure requirements due to concerns over undue foreign influence (Jan 2021):

- 2021 JCORE Subcommittee on Research Security (National Science and Technology Council - Joint Committee on the Research Environment)
- NSM-33 Presidential Memorandum on US Government-Supported Research and Development National Security Policy
- National Defense Authorization Act for FY 2021

As a result, universities are evaluating their COC policies and procedures.



# Disclosures to the University

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## **Conflicts of Commitment (COC) *continued***

### **Definition of COC - based on 2021 JCORE and NSM-33**

“A situation in which an individual accepts or incurs conflicting obligations between or among multiple employers or other entities”

### **Current UH policies related to COC**

- Board of Regents Policy 9.207: Outside Employment
- AP 9.240 Record of Outside Employment



# Disclosures to the University

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## Conflicts of Commitment (COC) *continued*

### UH Board of Regents Policy 9.207: Outside Employment

“Members of the university faculty and staff are encouraged to promote the cultural and economic development of the state by utilizing their special abilities and skills in research, teaching, scholarly or artistic production, and consulting over and above the full requirements of the position to which they are appointed. Such additional supplementary activity **must in no way interfere** with the creditable performance of the **primary obligation to the university**. Outside employment must be of a professional nature, and it should contribute to the professional competence of the faculty member.” (III.B.1.)

# Disclosures to the University

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## Conflicts of Commitment (COC) *continued*

### AP 9.240 Record of Outside Employment

- Completion of Form 50
- Signed endorsement by Chair and approval by Dean/Director

Deadline for completion of Form 50:

*The form must be filed at least **one week prior to the beginning of each semester** (or fiscal year, if appropriate) in which outside employment is contemplated, or, when there has been a change in plan previously proposed and approved. The form may be **filed promptly at other times to accommodate situations where outside employment opportunity materializes on short notice.** (AP 9.240 3.b.)*



# Disclosures to the University

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## Intellectual Property and Inventions

- Promptly report all inventions to the Office of Innovation and Commercialization (OIC)
  - Submit online through *myInvention* portal at <https://www.hawaii.edu/research/disclosing-an-invention/>
- OIC will meet with you to discuss the invention and make a preliminary determination of licensing feasibility, novelty, potential applications, and possible markets





# Disclosures to Sponsors

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## **Current and Pending (Other Support)**

- Update and maintain your current and pending support documentation
- Include ALL sources of support, including
  - Foreign and domestic
  - Scholarships or fellowships
- Follow specific sponsor instructions
- When in doubt, report



# NIH Requirements

<https://grants.nih.gov/policy/protecting-innovation.htm>

The screenshot shows the NIH Grants & Funding website. The header includes the NIH logo and the text 'GRANTS & FUNDING NIH Central Resource for Grants and Funding Information'. A search bar is located in the top right corner. The main navigation menu includes 'HOME', 'ABOUT GRANTS', 'FUNDING', 'POLICY & COMPLIANCE' (which is highlighted), 'NEWS & EVENTS', and 'ABOUT OER'. Below the navigation, a breadcrumb trail reads 'Home > Policy & Compliance > Protecting U.S. Biomedical Intellectual Innovation'. On the left side, there is a 'POLICY & COMPLIANCE' section with a 'Policy Topics' list where 'Protecting U.S. Biomedical Intellectual Innovation' is selected. The main content area features the title 'Protecting U.S. Biomedical Intellectual Innovation' and a paragraph explaining that NIH and the biomedical research enterprise have a long history of international collaborations with rules of engagement that allow science to advance while also protecting intellectual capital and proprietary information. It states that these rules are designed to limit bias in the design, conduct, and reporting of NIH-supported research. The text continues: 'This page describes actions that NIH, institutions, and researchers can take to protect U.S. biomedical intellectual innovation. The principles described here align with those announced by the White House Office and Science and Technology Policy in June 2020.' Below this is an 'Overview' section with two paragraphs. The first paragraph states: 'NIH research is built on a set of bedrock principles of scientific excellence, unassailable integrity, and fair competition. NIH expects applicants for and recipients of NIH-supported research — both domestic and foreign — to abide by these principles.' The second paragraph states: 'It is critical for NIH-supported institutions and their researchers to be wholly transparent about financial support from and affiliations with international institutions. Such transparency ensures that NIH's funding decisions are fair and appropriate, and that U.S. institutions and the American public benefit from their investment in biomedical research.' The third paragraph states: 'The biomedical research workforce continues to be greatly enriched and strengthened by scientists working together from many parts of the world. The extraordinary contributions of foreign nationals to American science are indisputable. The overwhelming majority of researchers participating in NIH grants, both in the U.S. and in other countries, are honest contributors to the advancement of knowledge that benefits us all. The research community must find ways to build and continue these important and successful relationships with foreign scientists around the world while simultaneously protecting the Nation's biomedical innovations and intellectual property.' The final section is titled 'Inappropriate Foreign Influence'.



# NIH Requirements

## Examples of What to Disclose to NIH about Senior/Key Personnel on Applications and Awards:\*

Type of Activity	Report in Biosketch / Application	Report as Foreign Component in Application	Obtain Prior Approval and Report as Foreign Component in RPPR	Report as Other Support (JIT)	Report as Other Support (RPPR)	Review for potential FCOI
All positions and affiliations, including volunteer positions, relevant to the application	X					X If salary support
Relevant appointments at foreign institutions – even if labeled as “guest,” “adjunct,” “honorary,” with or without salary support	X					X If salary support
The number of person-months devoted to projects, even if there is no salary support or direct personal payments to the scientist				X	X If new	
Income, salary, consulting fees, and honoraria in support of an individual's research endeavors				X	X If new	X
Participation in a foreign talent or similar-type programs				X	X If new	X
Ongoing and completed research projects from the past three years that the applicant wishes to highlight	X					
All resources and other support, both domestic and foreign, for ongoing research projects, including those conducted at a different institution				X	X If new	X
In-kind contributions from domestic and foreign institutions or governments that support research activities				X	X If new	X
Performance of any significant part of an NIH project outside of the US, whether or not funds are expended		X	X If new			
Post-doc, student, or visiting scholar supported by a foreign government or institution				X	X If new	
Travel paid by a foreign institution or government over \$5,000 per year						X
Financial interests received from a foreign Institution of higher education or a foreign government						X

# NIH Requirements

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NIH NOT-OD-19-114 (July 10, 2019)

Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components

- Current and Pending (Other Support)
- Foreign Components
- Financial Conflicts of Interest



# NIH Requirements

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## Current and Pending (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.

### Examples of Other Support

- Salary or other support for a research project(s)
- Honorary, visiting or adjunct appointment at a foreign university
- Non-monetary resources or in-kind support, such as lab space, personnel (like a visiting post-doc), equipment or supplies (can include support from a foreign talent or similar program)

# NIH Requirements

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## Current and Pending

### When to report:

- Proposal submission
- At Just-In-Time before award is made
- When key personnel are added
- When there are changes in support from original Other Support submission
- Annual research performance progress report

### Who must report:

- PI on behalf of all senior and key personnel



# NIH Requirements

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## Foreign Component

- Significant scientific element or segment of a project conducted outside the U.S.
  - Whether or not NIH funds are expended
  - Addition of foreign component must receive PRIOR approval by NIH



# NIH Requirements

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## **Financial Conflict of Interest (FCOI)**

### 42 CFR Part 50, Subpart F, Objectivity in Research

- Requires the Institution (UH) to have a disclosure policy that researchers must comply with
- Includes disclosure of financial interests related to a foreign entity
- UH must provide FCOI reports to NIH





# NIH Requirements

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## NIH NOT-OD-21-073 Upcoming Changes to Biographical Sketch and Other Support Format Page for Due Dates on or after May 25, 2021

**Supporting Documentation:** For Other Support submissions that include foreign activities and resources, recipients are required to submit copies of contracts, grants or any other agreement specific to senior/key personnel foreign appointments and/or employment with a foreign institution as supporting documentation. If they are not in English, recipients must provide translated copies. This supporting documentation must be provided as part of the Other Support PDF following the Other Support Format page.

**Immediate notification of undisclosed Other Support:** When a recipient organization discovers that a PI or other Senior/Key personnel on an active NIH grant failed to disclose Other Support information outside of Just-in-Time or the RPPR, as applicable, the recipient must submit updated Other Support to the Grants Management Specialist named in the Notice of Award as soon as it becomes known.



# NSF Requirements

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- [Dear Colleague Letter](#) issued July 2019
- Proposed clarification of the proposal disclosure requirements and reporting requirements for both Current and Pending Support and Professional Appointments
- October 2020 – Use NSF-approved format for biographical sketches (including disclosure of all domestic and **foreign** appointments and Current and Pending Support information)



# NASA Requirements

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- Since 2011 NASA has had restrictions on using NASA funds to enter into agreements “to participate, collaborate, or coordinate bilaterally in any way with China or any Chinese-owned company, at the prime recipient level or at any subrecipient level, whether the bilateral involvement is funded or performed under a no-exchange of funds arrangement”
- See NASA [FAQs](#) for more information

# Department of Energy requirements

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## June 2019 DOE Directive

- Participation in foreign talent programs is prohibited for its employees and contractors

*Defined as “any foreign-state-sponsored attempt to acquire US scientific-funded research or technology through foreign government-run or funded recruitment programs that target scientists, engineers, academics, researchers, and entrepreneurs of all nationalities working or educated in the United States.”*



# Additional Resources

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<https://research.hawaii.edu/foreign-influence/>

Training for individuals and departments available upon request

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