

To: Clarkson NIH Researchers

From: Greg Slack, Director of Research and Technology Transfer

Subject: New NIH Conflict of Interest Regulations Effective August 24, 2012

Date: August 14th, 2012

New conflict of interest regulations go into effect for all institutions submitting proposals to and receiving funding from any U. S. Public Health Service (PHS) agency, **such as the National Institutes of Health (NIH)**, August 24th, 2012.

What does this mean for Clarkson?

PHS Investigators* at Clarkson University are obligated to disclose all Significant Financial Interests related to their Institutional Responsibilities. This disclosure ensures that you and the Institution are compliant with federal regulations designed to safeguard objectivity in research.

As required, the University has created a new policy, procedures, *PHS COI Disclosure Form*, and training. Please note the new requirements are stricter and separate from the current University COI disclosure process and are only being applied to PHS agencies, such as the NIH.

*"Investigator" is now defined as, "the Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants".

What do I need to know as a Clarkson Researcher?

Major changes affecting Investigators include:

- New definitions for Investigator and Significant Financial Interest and lowered thresholds
- Reporting of all financial interests related to an Investigator's Institutional Responsibilities for the preceding twelve months
- Updates required within 30 days of acquiring new financial interests
- · Reporting of travel, both reimbursed and paid by third party
- · Required training at least every four years

Expanded Institutional responsibilities include:

- · Review of all Significant Financial Interests
- Ensuring compliance of subrecipients
- Detailed reporting of Financial Conflicts of Interest to the PHS agency
- Retrospective bias review for unidentified or unmanaged conflicts of interest
- Public accessibility of Financial Conflicts of Interest

What do I need to do as a Clarkson Researcher?

- 1. Prior to submitting a proposal to NIH (or other PHS agency) on or after August 24, 2012 vou:
 - **Must** submit a *PHS COI Disclosure Form* to the DoR or if one is on file already, verify it is up-to date;

- Should complete the CITI Program web-based PHS COI training (required every four vears); and
- Should attend one of the scheduled information sessions or meet independently with the DoR (one time only).
- 2. Prior to engaging in NIH (or other PHS agency) research with a notice of award date or noncompeting continuation beginning on or after August 24, 2012 you **must**:
 - Have completed the CITI Program PHS COI training (required every four years);
 - Have attended one of the scheduled information sessions or met independently with the DoR (one time only);
 - Verify an up-to-date *PHS COI Disclosure Form* is on file with the DoR or complete a *PHS COI Disclosure Form*, if one has been previously submitted;
 - If required, complete a COI Management Plan for all identified Financial Conflicts of Interest.
- 3. You **must** update your *PHS COI Disclosure Form* within 30 days of discovering or acquiring a new Significant Financial Interest.
- 4. You must disclose all reimbursed for travel or travel paid on your behalf by an entity that engages in activities that could reasonably be perceived by non-experts as being related to your Institutional Responsibilities with 30 days of the end of the trip by updating your PHS COI Disclosure Form.
- 5. You **must** submit an updated *PHS COI Disclosure Form* on an annual basis, when requested.
- 6. You **must** require anyone working on the PHS funded award that meets the definition of an "Investigator" to complete a *PHS COI Disclosure Form*, training, and comply with Clarkson's *Conflict of Interest Policy and Procedures for PHS Funded Research*.

Where can I find the PHS COI Disclosure Form, CITI Program training, scheduled information sessions, new policy and procedures, and additional information?

The new *PHS COI Disclosure Form,* instructions for accessing the CITI Program for COI training, and Clarkson's *Conflict of Interest Policy and Procedures for PHS Funded Research,* along with additional information, can be found on the DoR webpage at http://www.clarkson.edu/dor/compliance/COI.html.

The DoR also has scheduled the following information sessions to discuss the specifics of Clarkson's *Conflict of Interest Policy and Procedures for PHS Funded Research*, ask questions, and receive assistance filling out the new *PHS COI Disclosure Form*. Additional sessions or one-on-one meetings are available upon request.

Thursday, August 16th 10:30am – 11:30pm TAC 107

Wednesday, August 22nd 1:30pm – 2:30pm TAC 107

Tuesday, August 30th 2:00pm – 3:00pm TAC 107

Who can answer my questions?

If you have any questions or require further assistance, please do not hesitate to contact Kimberly Klatt, Research Compliance Officer, kklatt@clarkson.edu, ext. 4441 or Greg Slack, Director of Research and Technology Transfer, gslack@clarkson.edu, ext. 6475.