Office of Research Integrity

Assurance Program

1101 Wootton Parkway

Suite 240

Rockville, MD 20852

Phone: (240) 453-8400

Fax: (301) 594-0042

TO: Foreign Institutions

Each Institution that applies for research, research-training, or research related grants or cooperative agreements under the United States Public Health Service (USPHS) Act is required to maintain a misconduct in science assurance with this office.

A U.S. Federal regulation requires that each institution establish an administrative process for investigating and reporting instances of alleged or apparent misconduct, when such research involves USPHS funding. The Federal regulation, 42 CFR Parts 50 and 93, is available on the ORI web site at https://ori.hhs.gov.

Due to various laws and requirements of other countries, ORI has developed a congenial way for other countries to comply with this Federal requirement, without compromising their respective country’s procedures and laws.

The simplified method is outlined in the attached “Statement on Dealing with Allegations of Research Misconduct Under Public Health Service Research-related Activities for Foreign Institutions.” 1 If your institution wishes to meet the assurance requirement for receiving USPHS funding through this legally binding Statement, please submit a signed copy on your organization’s letterhead.

If you have any questions regarding this statement or your institution’s responsibilities in applying for or receiving PHS funding, please contact me at (240) 453-8400 or via e-mail at ORI\_Assurance@hhs.gov.

 Sincerely,

 Robin Parker

 Assurance Program Specialist

1The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies."

**Statement on Dealing with Allegations of Research Misconduct Under United States Public Health Service (USPHS) Research‑related Activities for Foreign Institutions.**

**[name of organization]** has incorporated into its policies and procedures the following approach for dealing with and reporting possible research misconduct when USPHS funds are involved.

1. **[name of organization]** will designate an official to receive allegations and develop procedures for use by research employees or others who wish to make an allegation of research misconduct involving USPHS funds. This designated official will notify the U.S. Office of Research Integrity (ORI) when an allegation of research misconduct involving USPHS funds is received. Phone: (240) 453-8800. Fax: (301) 594-0043. E-mail: askORI@osophs.dhhs.gov.

2. **[name of organization]** will then work with ORI or other appropriate offices of the U.S. Department of Health and Human Services (HHS) to develop and implement a process for responding to the research misconduct allegation that is consistent with U.S. Federal regulation, 42 CFR Parts 50 and 93.

3. **[name of organization]** will submit appropriate reports (in English) to ORI that describe the process followed in conducting the investigation, the evidence on which the conclusions of the investigation are based, and if a finding of research misconduct is made, the administrative actions that are taken against the respondent.

4. **[name of organization]** will inform research employees about the official who is designated to receive allegations and the procedures for the employee or other individuals to make an allegation of research misconduct involving USPHS supported research. This information will also be posted on the organization’s web site.

5. **[name of organization]** certifies that this statement will be a permanent amendment to the institution’s procedures for responding to allegations of research misconduct.

6. **[name of organization]** will submit the “Annual Report on Possible Research Misconduct” to ORI by April 30 of each year. The report is submitted electronically through the ORI web site at https://ori.hhs.gov.

Name of Organization\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Responsible Official's Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Responsible Official's Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Responsible Official's Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-Mail Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_