POLICY FOR THE RESPONSIBLE CONDUCT OF RESEARCH

Monitoring the Scientific Integrity of Research Projects

The procedure an investigator establishes to monitor the scientific integrity of a specific research project will depend on the unique aspects of the study. For research involving human subjects, federal regulations require that IRBs determine whether data and safety monitoring is necessary and, if so, whether the research protocol makes adequate provision for monitoring the data collected to ensure the safety.

Unanticipated problems involving risks to study participants or others or unexpected adverse events must be reported to the investigator's IRB following the IRB's guidelines. If changes are made to a study protocol, the study modification is submitted to the ONS Foundation for approval after review and approval by the investigator's IRB. If the study has changed significantly from the original funded proposal, the proposal will need to be reviewed by the appropriate ONS or ONS Foundation review team.

Guidance On Reporting Adverse Events To Institutional Review Boards For NIH-Supported Multicenter Clinical Trials. Retrieved December 4, 2008 from http://grants1.nih.gov/grants/guide/notice-files/not99-107.html

NIH Policy for Data and Safety Monitoring Release Date: June 10, 1998. Retrieved December 4, 2008 from http://grants.nih.gov/grants/guide/notice-files/not98-084.html

Office for Human Research Protections (2007). *Guidance on Reviewing Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events.* Department of Health and Human Services. Retrieved December 4, 2008 from http://hhs.gov/ohrp/policy/AdvEvntGuid.htm

Research Misconduct

The ONS or ONS Foundation grantee's Institution must certify that the institution has established policies and procedures for addressing allegations of research misconduct. Certification is indicated by the signature of the official signing for the application organization on the Title Page of the application. By signing the application, the official certifies that the organization has established administrative policies as required by 42 CFR 50, Subpart A ((http://www.ori.dhhs.gov), and will comply with those policies and the requirements of the regulations.

Office for Human Research Protections (2006). *Definition of Research Misconduct.* Department of Health and Human Services. Retrieved December 4, 2008 from http://www.ori.dhhs.gov/misconduct/definition_misconduct.shtml

Requirements for Institutional Policies and Procedures on Research Misconduct Under the New PHS Policies on Research Misconduct - 42 CFR Part 93 (2005) Retrieved December 4, 2008 from http://www.ori.dhhs.gov/policies/Requirements-Reg-6-05.shtml

Reporting Incidents of Scientific Misconduct to ONS and the ONS Foundation

Investigators are expected to follow the policies and procedures established by their local institution for dealing with issues of scientific misconduct. The principal investigator, research study team and institution have an affirmative duty to protect ONS or ONS Foundation funds from misuse by ensuring the integrity of all ONS or ONS Foundation supported work, and primary responsibility for responding to and reporting allegations of research misconduct.

All information pertaining to allegations, inquiries or investigations of research misconduct should be reported to ONS or the ONS Foundation promptly from the time such allegations are known to the investigator. The investigator is responsible for keeping the ONS Research Director and/or the ONS Foundation Executive Director informed of the status of the ongoing investigation. If a good faith allegation of misconduct is made to ONS or the ONS Foundation by a whistleblower, they will be protected from retaliation as described by the DHHS policy on whistleblowers (DHHS,1995). The grantee's institution will be notified of the allegation.

If a misconduct investigation has been initiated, the grantee must take any necessary steps, in addition to its normal and ongoing responsibilities under the grant, to protect the scientific integrity of the project, protect human subjects and animals, provide reports to ONS or the ONS Foundation, and ensure the proper expenditure of funds and continuation of the project during the investigation, if appropriate.

At the conclusion of the local investigation, the investigator must promptly submit the findings of the investigation to the ONS Research Director and/or the ONS Foundation Executive Director. If research misconduct is proven, the ONS or ONS Foundation grant is revoked and the grantee is ineligible for future ONS or ONS Foundation research funding. In situations where a specific research team member is confirmed of research misconduct rather than the entire team, only this person will be ineligible for future ONS or ONS Foundation research funding. Where research misconduct has affected data validity or reliability, the grantee and its employee/collaborator authors will submit a correction or retraction of the data if it has been published or submitted for publication. .

Department of Health and Human Services (2005). *Requirements for Institutional Policies and Procedures on Research Misconduct Under the New PHS Policies on Research Misconduct - 42 CFR Part 93.* Retrieved December 4, 2008 from http://www.ori.dhhs.gov/policies/Requirements-Reg-6-05.shtml

Department of Health and Human Services (2005). *Public Health Service Policies on Research Misconduct; Final Rule. 42 CFR Parts 50 and 93.* Retrieved December 4, 2008 from http://www.ori.hhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf

Department of Health and Human Services (1995). *ORI Guidelines for Institutions and Whistleblowers: Responding to Possible Retaliation Against Whistleblowers in Extramural Research*. Retrieved December 18, 2008 from http://www.ori.dhhs.gov/misconduct/Guidelines_Whistleblower.shtml

ONS/Foundation Approval: 3/95, 6/96
ONS Nursing Foundation/Society 5/99
ONS Nursing Foundation/Society 01/01
Revised 5/01, 12/07, 12/08

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