



## PROMOTING INTEGRITY IN RESEARCH AND REPORTING MISCONDUCT IN SCIENCE

Akron Children's employees and staff participate in research to contribute to the advancement of medical science. Dedication to objective inquiry and the uncompromised pursuit of truth are essential criteria of any scientific program.

We take our responsibilities seriously to provide an atmosphere of scientific inquiry and to ensure integrity in the performance of research. Our goal is to create and maintain an environment in which there is a pervasive attitude of high ethical standards and in which misconduct in research is not tolerated.

Under final rules published in the Federal Register, institutions that receive research-related grants must file certain required assurances with the Public Health Services (PHS) annually.

### Definitions

- **Research** is a systematic investigation, including testing and evaluation, designed to develop or contribute to generalized knowledge.
- **Human subject** is a living individual about whom an investigator conducting research obtains either [1] data through intervention or interaction with the individual or [2] identifiable private information by review of documents or records.
- **Risk** is the possibility of harm (physical, psychological or social) that may occur as a consequence of any activity that goes beyond the application of established and accepted methods needed to meet the patient's needs.
- **Benefit** is a valued or desired outcome or an advantage. Payment for participation is not a benefit.
- **Adverse events** are undesirable and unintended though not necessarily unexpected results arising during the course of a research protocol.
- **Misconduct.** Misconduct or Misconduct in Science is defined as fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.
- **Inquiry.** Information gathering and initial fact finding to determine whether an allegation or apparent instance of misconduct warrants an investigation.
- **Investigation.** The formal examination and evaluation of all relevant facts to determine if misconduct has occurred.

### Procedures

All allegations of scientific misconduct shall be presented in writing to the chief operating officer for initiation of immediate inquiry and investigation of the allegation. If the allegation involves a non-physician hospital employee, the inquiry shall be performed by the Human Resources department under the direction of the COO. If the allegation concerns a medical staff member, a departmental chair designated by the COO shall conduct the inquiry and report to the COO following the initial inquiry. A departmental chair and COO shall determine if a full investigation is warranted.

Each inquiry shall be investigated immediately and completed within 60 calendar days of its initiation unless circumstances warrant a longer period. A written report shall be prepared that states what evidence was reviewed,

summarizes relevant interviews and includes the conclusions of the inquiry. If the inquiry takes longer than 60 days to complete, the record of the inquiry shall include documentation as to the reasons for exceeding the 60-day period.

On the basis of the initial inquiry a determination shall be made as to the merits of the allegation. If an investigation is to be initiated, such decision shall be reported in writing to the director, Office of Scientific Integrity (OSI), a component of the Office of the Director of the National Institutes for Health, which oversees the implementation of PHS policies and procedures related to scientific misconduct, on or before the date the investigation begins.

The notification shall include the name(s) of the person(s) against whom the allegations have been made, the general nature of the allegation and the PHS application or grant number(s) involved. The OSI shall be notified by Akron Children's within 24 hours if it is ascertained at any stage of the inquiry or investigation that there is an immediate health hazard involved, there is an immediate need to protect federal funds or equipment, there is an immediate need to protect the interest of the person(s) making or who are the subject of the allegations or his/her co-investigators and associates, it is probable that the alleged incident will be reported publicly, or if there is reasonable indication of possible criminal violation.

Initial investigation and data gathering shall be coordinated by the COO and processed with the Multidisciplinary Clinical Review Committee (MCRC) as deemed appropriate. The individual(s) against whom the allegation(s) was/were made shall be given a copy of the inquiry report. If they comment on that report, their comments may be made part of the record. The documentation shall be sufficiently detailed to permit a later assessment of the reasons for determining that an investigation was or was not warranted. To the maximum extent possible the privacy of those who in good faith report apparent misconduct shall be protected. The affected individuals shall be afforded confidential treatment to the maximum extent possible, a prompt and thorough investigation, and an opportunity to comment on allegations and findings of the inquiry and/or the investigation.

Initiation of the investigation shall begin within 30 calendar days of the completion of inquiry should sufficient basis be provided for conducting such an investigation. An investigation shall ordinarily be completed within 120 days. This includes conducting the investigation, preparing the report of findings, making that report available for comment by the subjects(s) of the investigation, and submitting the report to the OSI. If they can be identified, the person(s) who raised the allegation should be provided with those portions of the report that address their role and opinions in the investigation.

The investigation shall include but not necessarily be limited to: the examination of all documentation of relevant research data and proposals, publication, correspondence and memoranda of telephone calls. Interviews shall be conducted of all individuals involved in making the allegation or against whom the allegation is made, as well as other individuals who might have information regarding key aspects of the allegations whenever possible; complete summaries of these interviews shall be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

All investigations are expected to be carried through to completion, and all significant issues shall be pursued diligently. If Akron Children's plans to terminate an inquiry or investigation for any reason without completing all relevant requirements hereunder, a report of such planned termination, including a description of the reasons for such termination, shall be made to OSI, which will then decide whether further investigation should be undertaken.

If it is determined that the investigation cannot be completed within 120 days, a written request for an extension shall be submitted to OSI together with an explanation for the delay that includes an interim report on the progress to date and an estimate for the date of completion of the report and other necessary steps.

Impartial experts shall be selected and called on as necessary to conduct appropriate inquiries and investigations.

Any real or apparent conflicts of interest on the part of those involved in the inquiry or investigation shall be identified. The role in the inquiry or investigation of the individual(s) with such a conflict shall be limited to providing information.

Documentation to substantiate the investigation's findings shall be prepared and maintained, and such is to be made available to the Director, OSI. Appropriate interim administrative actions to protect Federal funds and insure that the purposes of the Federal financial assistance are carried out shall be taken. OSI shall be kept apprised of any developments and facts during the investigation which may affect funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

The MCRC shall process and evaluate the relevant information and upon the conclusion of its deliberation, report its findings to Akron Children's president.

The proceedings of inquiries and investigations shall be documented and maintained in a secure manner for a minimum of 3 years following the completion of the inquiry or investigation, and shall, upon request, be provided to authorized personnel from the Department of Health and Human Services.

The Medical Staff Executive Committee and the Board of Trustees shall be advised that an investigation is in process.

Diligent efforts, as appropriate, shall be undertaken to restore the reputations of persons alleged to have engaged in misconduct when the allegations are not confirmed and also to protect the positions and reputations of those persons who in good faith, made the allegations.

Upon initiation of an investigation, expenditures related to Federal funds may be put on hold and the expenditures shall be evaluated to ensure that expenditures are within the purposes of the financial assistance as outlined.

The COO shall review all actions prior to their being taken to ensure to the maximum extent possible that the positions and reputations of those persons who in good faith made allegations of scientific misconduct and those against whom the allegations of misconduct are made are appropriately protected.

Akron Children's shall impose appropriate sanctions on the involved individuals where allegations of misconduct have been substantiated. These sanctions may include: removal from a particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, rank reduction or termination of employment. Medical staff practitioners against whom allegations are substantiated shall be afforded the Appellate Hearing Procedure as outlined in the Medical Staff Bylaws. Any adverse finding shall be documented in their credential file and reported as required by Federal and State laws.

At the conclusion of the investigation, in compliance with federal and state law, the OSI shall be informed of the investigation results and provided with a written report that thoroughly documents the investigation results and provided with a written report that thoroughly documents the investigative process and the findings. The final report submitted to the OSI shall describe the policies and procedures under which the investigation was conducted, how and from whom the information was obtained, the findings and the basis therefore, and the actual text or accurate summary of the views of any individual(s) found to have engaged in misconduct as well as a description of any sanctions taken by Akron Children's Hospital.

Upon the final determination that the allegations of misconduct are substantiated and following any appropriate appellate review process, consideration shall be given to notification of other appropriate concerned parties not previously notified.

Both the medical staff and the administration staff shall be informed of misconduct in science policies and related procedure and of the importance of compliance with them.