Title: **Inquiries and Investigations of Alleged Research Misconduct**	*Applicable to: **Beaumont Health**	Effective Date: **01/12/2018** Last Periodic Review Date: **01/12/2018**
Policy Owner: **Administrative Director**	Document Type: **Policy**	Functional Area: **Research Administration, Research Institute**

***For This Document, Beaumont Health Includes**:
Beaumont Corporate Shared Services
Beaumont Hospital, Dearborn
Beaumont Hospital, Farmington Hills
Beaumont Hospital, Grosse Pointe
Beaumont Hospital, Royal Oak
Beaumont Hospital, Taylor
Beaumont Hospital, Trenton
Beaumont Hospital, Troy
Beaumont Hospital, Wayne
Beaumont Medical Group
Beaumont Pharmacy Solutions
Post Acute Care

I. PURPOSE AND OBJECTIVE:

The purpose of this policy is to outline the procedure for inquiry and investigation into alleged or suspected misconduct by investigators and other research personnel involved in research governed by the Beaumont Health Research Institute. This policy applies to all types of research including, but not limited to clinical, animal, bench, and outcomes. It applies to any federally funded research, although Beaumont reserves the right to apply the same practices to research funded by other means, including but not limited to commercial, philanthropic, and internal. Office of Research Integrity (ORI) guidelines will be explicitly followed, for federally funded research.

II. POLICY STATEMENT:

Beaumont Health and its Research Institute are committed to protecting the safety and welfare of participants involved in research, maintaining scientific integrity in basic and clinical research, and stimulating the development of useful knowledge. Principled collaboration between Beaumont representatives and all research sponsors is vital to preserve the public's trust.

III. DEFINITIONS:

A. **Research Misconduct:** Research misconduct is fabrication, falsification, plagiarism, in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or honest differences in interpretations or judgments of data.
B. **Fabrication:** Fabrication is making up data or results and recording or reporting them.
C. **Falsification:** Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the

research record (i.e., the record of data or results that embody the facts emerging from the research. This includes but is not limited to, information within research proposals, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and books).

D. **Plagiarism:** Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

E. **Requirements for Findings of Research Misconduct:** A finding of research misconduct requires all three of the below are present:
   1. There be a significant departure from accepted practices of the relevant research community;
   2. The misconduct be committed intentionally, knowingly, or recklessly;
   3. The allegation be proven by a preponderance of the evidence.

IV. POLICY PROCEDURE:

A. **Obligation to Report:** It is the responsibility of all employees, medical staff members and others to report potential research misconduct. Reports may be made to any of the following:
   1. Vice President of Research
   2. Director of Research Regulatory and Billing/Research Integrity Officer.

   The person who, in good faith, makes an allegation of research misconduct will be known as the Complainant. The Complainant's role subsequent to the initial report will be primarily as a witness.

B. **Burden of Proof:** Beaumont has the burden of proof, beyond a preponderance of the evidence (the facts show it more likely happened than not), for making a finding of misconduct. The Respondent(s) have the burden of proof, based on a preponderance of the evidence that honest error or difference in opinion occurred.

C. **Confidentiality:** The identity of the Complainant, the Respondent(s) and all research participants should remain confidential except on a need to know basis, consistent with thorough, competent, objective, and fair research misconduct proceedings. All reasonable and practical efforts will be made to protect the privacy, reputation and position of the Complainant, witnesses, or committee members throughout and following the proceedings. Additionally, should the Respondent(s) be found not to have engaged in research misconduct, all reasonable and practical efforts will be made to protect and restore his/her reputation and position.

D. **Assessing the Allegations of Misconduct:** Promptly after receiving a report of potential misconduct, Beaumont will assess the allegation to determine if: 1) it meets the definition of research misconduct as stated in 42 CFR Section 93.102, and 2) the allegation is sufficiently credible and specific to potential evidence of research misconduct.

E. **Inquiries into Alleged Misconduct:** If warranted after the assessment, an inquiry will be made consisting of information gathering and initial fact finding to determine whether an

allegation of misconduct warrants an investigation. The inquiry shall be conducted by the VP of Research and Administrative Director of the Research Institute (Directors), along with an ad hoc committee consisting minimally of three persons, selected by the Directors, each having necessary and appropriate expertise and each being free from real or apparent conflicts of interest regarding the subject of the inquiry.

At all times during the inquiry and investigation of potential misconduct, Beaumont will take appropriate actions to protect our patients, the public health, federal funds and equipment, the integrity of Beaumont Health, our research sponsors, including the Public Health Service (PHS), and the scientific research process.

A written draft report shall be prepared and include the name and position of the Respondent(s), a description of the allegations of research misconduct, the funding sponsor of the research, including specific PHS support involved (i.e., grant numbers, application numbers, contracts, etc.) if applicable, and the basis for recommending the alleged actions warrant an investigation (the evidence that was reviewed, summary of relevant interviews, and conclusion of the inquiry). The draft report must be provided to the Respondent(s) and an opportunity provided for the individual to comment on the report within fourteen (14) days. The draft inquiry report may, at the discretion of the Directors, be provided to the Complainant for comments. Any comments provided by the Respondent(s) or Complainant will be attached to the Final Inquiry Report.

Upon completion of the inquiry, the Directors along with the *ad hoc* committee shall determine if an investigation is required based upon evidence provided by the inquiry. The Final Inquiry Report shall be given to the Respondent(s) and the Chairperson of the Education, Innovation and Research Committee. If the research involves human participants or animals, a copy will be provided to the appropriate oversight committee (Institutional Review Board (IRB) or Animal Care Committee (ACC)). A copy of this policy for research misconduct must be included with the Final Inquiry Report.

The inquiry must be completed within sixty (60) days of its initiation unless circumstances clearly warrant a longer period. If the inquiry takes more than sixty (60) days to complete, the record of the inquiry shall include documentation of the reasons for exceeding the sixty (60) day period. All information gathered during an inquiry, and an investigation if required, shall be considered professional/peer review information and will be maintained confidentially to the maximum extent possible to protect both the Complainant(s) and Respondent(s).

F. **Research Records and Evidence:** Either before or at the time Beaumont notifies the Respondent(s) of the allegation or inquiry, Beaumont will take all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the misconduct proceeding. Beaumont will inventory the records and evidence and sequester them in a secure manner, except where scientific instruments are shared by a number of

users, as long as the instruments are included in the inventory listing. Throughout the inquiry and investigation, the Respondent(s) may have copies of, or supervised access to, the research records. As additional evidence or records are identified during the proceedings, Beaumont will take custody of those records and add them to the inventory of evidence. Beaumont may make copies of research records and evidence as deemed necessary. Copies of research records and evidence will be maintained for no less than seven (7) years after the completion of the proceedings by Beaumont or the department of Health and Human Services (HHS), whichever is later. The original research records and evidence will be maintained according to the appropriate legal requirements for the specific types of research records.

G. **Reporting to the Office of National Institutes of Health:** If an investigation is warranted, and if the subject of the investigation is a researcher involved in PHS supported research, applications for PHS supported research, or research specified in 42 CFR Section 93.102, a copy of the Final Inquiry Report, along with a statement of intention to begin an investigation, must be submitted to the Director of the Office of Research Integrity (ORI), National Institutes of Health within two (2) weeks. During the initial inquiry or investigation, the Director of the ORI must also be notified if:
   1. There is an immediate health hazard involved.
   2. There is an immediate need to protect federal funds or equipment.
   3. There is an immediate need to protect the interests of the person(s) making the allegations or the individual who is the subject of the allegation as well as his/her co-investigator(s) and associate(s), if any.
   4. It is probable the alleged incident will be reported publicly.
   5. There is reasonable indication of possible criminal violation; in this instance, ORI must be notified within twenty four (24) hours of obtaining the information.

H. **Investigation:** If warranted, based on the Final Inquiry Report, a formal examination and evaluation (investigation) of all relevant facts will be undertaken within thirty (30) days of the completion of the inquiry. The purpose of the investigation is to explore the allegations in detail, to examine the evidence in depth, and to determine whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human subjects or the general public, or if it affects research that forms the basis for public policy, clinical practice, or public health practice.

   The Respondent will be notified in writing of the determination an investigation is warranted. The notice must be made prior to the start of the investigation. In addition, the Respondent

will be notified of any new allegations which arise as a result of the inquiry or during the investigation.

The Directors will be responsible for notifying the Chairperson of the Education, Innovation and Research Committee of the need for an investigation. The investigation will be conducted by an ad hoc Investigation Committee appointed by the Research Institute Compliance Committee, chaired by a member of the Research Institute Compliance Committee and consist minimally of another member of the Research Institute Compliance Committee, two (2) members of the appropriate staff (e.g., biomedical, bioscientific, nursing, etc.), each having necessary and appropriate expertise and each being free from real or apparent conflicts of interest regarding the subject of the investigation, and a member of the Legal staff. At the discretion of the Chairperson of the Investigation Committee, other members may be added as needed to provide specific expertise.

An investigation should include examination of all documentation and interviews of involved individuals. All interviews will be recorded and transcribed. The transcription should be reviewed and corrected as necessary by each interviewee. All significant issues and leads discovered which are determined to be relevant to the investigation, including any evidence of additional misconduct, must be pursued prior to completion of the investigation. Diligent efforts will be made to ensure the investigation is thorough and sufficiently documented.

A draft report of findings should be prepared and a copy of the draft report given to the Respondent(s) for comment. Copies of, or supervised access to, records and evidence used during the investigation should also be provided to Respondent(s). The Respondent(s) should be allowed thirty (30) days to respond.

The investigation, including the review of the draft report and thirty (30) day comment period for the Respondent(s), should be completed within one hundred and twenty (120) days. For PHS supported research, if an extension is needed, a written request must be submitted to and granted by the ORI.

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

I. **Report of the Investigation:** At the conclusion of the investigation, a written Final Report should be generated which includes the following:
   1. **Allegations** - Describe the nature of the allegations of research misconduct.
   2. **PHS or other support** - Describe and document the type of support, including any grant numbers, grant applications, contracts, and publications listing such support.
   3. **Institutional charge** - Describe the specific allegations of research misconduct for consideration in the investigation.

4. **Policies and procedures** - If not already provided to ORI with the inquiry report, Beaumont policies and procedures under which the investigation was conducted will be included.
5. **Research records and evidence** - Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed.
6. **Statement of findings** - For each separate allegation of research misconduct identified during the investigation, provide a finding as to whether research misconduct did or did not occur.

If research misconduct is substantiated, a report will be forwarded to the Vice President of Research for appropriate disciplinary actions. If PHS supported research is involved, a copy of the Final Report will be sent to the ORI including an acknowledgement of misconduct identified during the investigation and a description of pending or completed disciplinary action taken. Beaumont is committed to full and continuing cooperation with the ORI during its review.

J. **Terminating Research Human Participants:** If research misconduct is substantiated and it involves human subjects, the Investigation Committee Chairperson will inform the IRB Chairperson. The IRB Chairperson will determine if:

1. The research is appropriate to continue considering the type of misconduct identified.
2. The continuation of the research poses risk to the participants beyond what was originally identified during the project review by the IRB.
3. Current participants must be notified, if such information might relate to their willingness to continue participating in the research.
4. There are appropriate personnel to oversee the continued research.
5. The research should be suspended or terminated, in part or in its entirety.

The IRB Chairperson will ensure IRB approval is withdrawn or limited and communicated to the PI, as appropriate. The Vice President of Research or the Institutional Official may suspend or terminate the research, if she/he perceives an unacceptable risk to the institution may result from the research misconduct, and suspending or terminating the research will not cause increased risk to participants.

K. **Animal Research:** If research misconduct is substantiated and it involves animals, the Investigation Committee Chairperson will inform the ACC Chairperson, who will determine whether the research should be suspended or terminated.

L. **Disciplinary Action:** If the Investigation Committee determines research misconduct has occurred, disciplinary action may be taken by the Vice President of Research. In cases where the Respondent(s) is employed outside of the Research Institute and/or has a contractual arrangement with the hospital, the Vice President or Institutional Official has sole authority

related to the individual(s) privileges to conduct research. Other disciplinary actions may be jointly determined by the Corporate Compliance Officer and Medical Administration. Regulatory and licensing authorities will be notified as deemed appropriate. Disciplinary action may include but is not limited to:

1. Barring the Respondent(s) from conducting or participating in research at Beaumont Health. When practical and appropriate, replacement personnel will be named.
2. Suspending research in which the Respondent(s) is currently participating.
3. Requiring modification of the research plan to minimize risk.
4. Withdrawing approval of funding or contracts.
5. Sanctions affecting the Respondent(s) employment status, up to and including termination of employment.
6. Informing the Respondent's school, if the misconduct involved their role as a student working on research.
7. Notifying journals of the research misconduct determination.

M. **Appeals Process:** Should the Respondent(s) wish to appeal during the investigation or once the Final Report has been issued, they may appeal to the Chairperson of the Education, Innovation and Research Committee. Respondents may launch an appeal within thirty (30) days of receiving the Final Report from the Investigation Committee Chairperson.

N. **Termination of the Investigation:** If a decision is made to terminate an inquiry or investigation for any reason without completing the inquiry or investigation, a report of the planned termination, including a description of the reasons for such termination, should be completed. If an investigation is terminated and PHS supported research is involved, a copy must be sent to the ORI.

O. **Retention of Documents:** All documentation related to an inquiry or investigation shall be maintained by the Research Institute for at least seven (7) years from the date of the completion of the investigation by Beaumont or PHS, whichever is later. If the investigation involved work supported by federal funds, upon request, documents must be provided to authorized personnel of the HHS.

P. **Inquiries:** All inquiries or questions regarding this policy can be directed to the Director of Research Regulatory and Billing or the Vice President of Research.

V. REFERENCES:

This policy was written with consideration of 45 CFR Parts 50 and 93, effective June 2005 and the Guidance on Managing Allegations of Scientific Misconduct, January 2000, Office of Research Integrity.

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VI. ASSOCIATED POLICIES:

RI Policy Research Administration Oversight
RI Policy Competitive Grant Proposal Development and Submission
RI Policy Conflict of Interest for an Individual Involved in Research
RI Policy Contacts, Complaints, Allegations of Non-Compliance and Confirmed Non-Compliance in Clinical Research
IRB Policy Compensation and Incentives Offered to Research Participants
IRB Policy Informed Consent and Authorization in Research
IRB Policy Vulnerable Populations: Children as Research Participants
IRB Policy Vulnerable Populations - Inclusion of Pregnant Women, Fetuses and Neonates in Research
IRB Policy Vulnerable Populations - Enrollment of the Cognitively Impaired
IRB Policy Use of Protected Health Information for Research
IRB Policy Research Record Retention and Destruction
RI Policy Clinical Trials Billing Cycle
RI Policy Time and Effort Reporting
RI Policy Intellectual Property Policy

VII. CORPORATE AUTHORITY:

Beaumont Health ("BH") as the corporate parent to William Beaumont Hospital, Botsford General Hospital, and Oakwood Healthcare Inc., ("Subsidiary Hospitals") establishes the standards for all policies related to the clinical, administrative and financial operations of the Subsidiary Hospitals. The Subsidiary Hospitals, which hold all health facility and agency licenses according to Michigan law, are the covered entities and the providers of health care services under the corporate direction of BH. The Subsidiary Hospitals' workforces are collectively designated as BH workforce throughout BH policies.