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CONTACTS, COMPLAINTS, ALLEGATIONS OF NON-COMPLIANCE AND CONFIRMED NON-COMPLIANCE IN CLINICAL RESEARCH	**116**	**1 of 9**

Prepared By	Prior Issue Date	Issue Date
Research Administration	**6/5/13**	**6/26/15**

PURPOSE

The purpose of this policy is to differentiate between:

- Contacts
- Complaints
- Allegations of non-compliance
- Confirmed non-compliance, and
- Allegations of research misconduct.

The processes for handling complaints, allegations of non-compliance, and instances of confirmed non-compliance in clinical research conducted at Beaumont Health are described. Research misconduct processes are not discussed in this policy (refer to Research Administration Policy 100, *Inquiries and Investigations of Alleged Research Misconduct).*

INTRODUCTION

Beaumont and the Research Institute (RI) are committed to protecting the safety and welfare of human research participants, maintaining the scientific integrity of research conducted at our facilities, upholding the highest standards of ethical and professional conduct, and complying with application of Federal, State and local laws and regulations pertaining to human participants research. For this reason, research participants are provided (in the informed consent document), with the phone number of the Institutional Review Board (IRB) and an assurance the IRB will address questions regarding their rights as a research participant, problems, concerns, complaints, requests for information or input they wish to provide. Additionally, the RI urges all individuals to report concerns, complaints and allegations of non-compliance, and provides processes for investigating, classifying, and instituting corrective actions. Contacts, complaints and allegations from any individual, including patients, research participants, RI employees, hospital employees, key research personnel, and IRB members are taken seriously and are investigated.

RESPONSIBILITY

It is the responsibility of all employees, medical staff members, key research personnel and IRB members to report clinical research complaints and allegations of non-compliance, in accordance with the Corporate and RI Compliance Plans. Other individuals, such as patients and research participants are urged to report.

It is the responsibility of any individual contacted to identify the appropriate party to handle the contact, complaint or allegation, as described below.

DEFINITIONS

Contact

For purposes of this policy, any communication coming from a participant, potential participant, member of the public or other interested individual with questions, problems, concerns, requests for information or input they wish to provide about research being conducted at Beaumont other than obvious complaints or allegations of non-compliance.

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Complaint	Dissatisfaction or uncertainty voiced by an individual about some aspect of research conduct. Complaints do not involve non-compliance or research misconduct. Examples of complaints include: • A participant expresses dissatisfaction with the repeated late arrival of key research personnel for study visits, or • An employee, concerned about the appropriateness of a study protocol, seeks clarification from the IRB Chairperson.
Complainant	An individual making a complaint, allegation of non-compliance, or allegation of research misconduct.
Allegation of Non-Compliance	An assertion by an individual that Federal, State, local laws/regulations pertaining to human participants research, RI policies/requirements or IRB determinations were not or are not being followed. All allegations of non-compliance must be investigated and must be supported by evidence before being considered confirmed.
Confirmed Non-Compliance	Allegation of non-compliance determined to be true, upon investigation.
Non-Compliance	Failure to comply with Federal, State and local laws/regulations pertaining to human participant research, RI policies and procedures, or IRB determinations. Non-compliance may include but is not limited to: • Failure to obtain IRB approval for research involving human participants. • Inadequate or non-existent procedures for informed consent and authorization. • Failure to follow RI and IRB policies and procedures. • Failure to follow determinations of the IRB to insure the safety of research participants. • Failure to follow the IRB-approved protocol. • Failure to gain prospective IRB approval of changes to the research. • Failure to report unanticipated problems or protocol deviations to the IRB, per IRB reporting criteria. • Failure to provide required reports to the IRB, such as the Progress Report or Final Report, per IRB policy. • Failure to comply with a Conflict of Interest Management Plan.
Level 1 Non-Compliance	Incidents meeting the definitions of **serious** non-compliance or **continued** non-compliance are considered **Level 1 Non-Compliance.** When the non-compliance is related to human participant protection, the determination of Level 1 Non-Compliance is made by the IRB. **Serious Non-Compliance** Failure to comply with Federal, State or local laws and/or regulations pertaining to human participants research, RI policies and procedures, or determinations of the IRB, when that failure increases risk of harm to participants or animals, adversely effects the rights and welfare of participants or animals, jeopardizes the integrity of the research or results

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in the misuse of federal funds. Serious non-compliance may include but is not limited to one (1) or more of the following:

- Harm to research participants.
- Exposure of research participants to a greater than anticipated risk of substantive harm.
- Compromised participant privacy and/or breach of confidentiality.
- Damage to the scientific validity of the data collected.
- Willful and knowing non-compliance.
- A violation of ethical principles.
- Attempts to inappropriately influence the IRB.

Continued Non-Compliance
A pattern of repeated non-compliance which, if unaddressed, could result in harm to participants or compromise the integrity of the research being conducted. The instances of non-compliance may or may not be similar or serious, and may include failure to follow direction from the Institutional Official (IO), the IRB, Research Administration or management to correct an instance of non-compliance.

Level 2 Non-Compliance

Non-compliance which does not meet the definition of Level 1 Non-Compliance.

Research Misconduct

Fabrication, falsification, plagiarism, or other practices which seriously deviate from those commonly accepted in the scientific community for proposing, conducting, or reviewing research or in reporting research results. It does not include honest error or honest differences in interpretation or judgments of data.

This policy does not address research misconduct in depth. Refer to Research Administration Policy 100, *Inquiries and Investigations of Alleged Research Misconduct.*

Respondent

Person who is the subject of a complaint or allegation and who is asked to respond.

POLICY

Contacts

Most communication from participants or others interested in the conduct of research at Beaumont involve routine questions, concerns, problems, requests for information or feedback/input they wish to provide. Common contacts might involve (but are not limited to) issues such as:

- Opportunities to participate in clinical research
- Rescheduling a visit
- Clarifying a medication schedule
- Confirmation the participant is responsible for payment of a bill for a research related procedure
- Understanding how a researcher gained access to their medical information

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- Requesting financial assistance
- Reports of adverse events following a research related procedure.

Research participants are encouraged to discuss issues involving their care with their physician or the principal investigator. However it is the Clinical Research Manager's (CRM) responsibility to coordinate responses to contacts involving research within their departments. The CRM will be able to resolve most contacts. There are also times when issues are more complex or individuals prefer to contact someone not directly affiliated with the research. When the CRM is unable to address the issue and/or the individual wishes to communicate with someone outside of the immediate research department, calls should be referred as follows:

- All contacts directly involving the protection of human participants must be referred to the IRB – (248) 551-0662.
- For billing issues – contact the Research Billing Coordinator in Research Administration – (248) 551-0650.
- For contacts involving the conduct or actions of a research investigator or staff member, contact the Administrative Director of the Research Institute - (248) 551-0650. The Administrative Director will communicate with the IRB when the contact involves human participant research.
- For contacts involving general questions or concerns, including those not related to research, contact the Director of Research Regulatory and Billing – (248) 551-0650, who will resolve the contact or refer it to the appropriate hospital department.

The individual contacted is responsible for following the contact through to resolution, including reporting activities and/or resolution to the individual who made the initial contact, the investigator, CRM or IRB. In the event a contact is subsequently identified as a complaint or an allegation of non-compliance, it will be handled as described below.

Making a Complaint or Allegation

All individuals are urged to voice complaints and/or report potential non-compliance. The Corporate and RI Compliance Plans describe avenues for Beaumont personnel to report instances of potential non-compliance. Beaumont mandatory education requirements include both Corporate and Research compliance training, and advise individuals to make reports to any of the following:

- Their supervisor
- The Vice President of Research/Institutional Official
- The RI Administrative Director
- The RI Compliance Coordinator
- The IRB Chairperson
- The Corporate Compliance Office
- Legal Affairs
- Beaumont Corporate Compliance Line.

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	Complaints or allegations may be submitted in any form (e.g., phone, written, e-mail), and may be anonymous. Research participants are provided investigator and IRB Chairperson contact information at the time of study enrollment, whenever informed consent is required.
Resolving Complaints	For purposes of this policy, complaints do not involve non-compliance or research misconduct. Routine complaints which can be resolved by the individual(s) receiving the report do not need to be reported to the RI Compliance Coordinator (RCC), although these individuals are invited to review events with the RCC. Complaints not resolved by the individual(s) receiving the report or those of a more serious nature must be reported to the RCC, and if they involve human participants research, the IRB. Legal Affairs will be notified when complaints extend beyond routine research operations or billing. The IRB Chairperson and designees will investigate complaints involving human research protections and review the results at the next fully convened IRB meeting. The outcome of the IRB review will be provided to the RCC. The decision of the IRB may not be overturned by the RCC, Administrative Director or Institutional Official however they may require additional administrative action to be taken. The RCC will work with the clinical research manager, principal investigator, complainant, and others towards resolution of administrative issues. If the RCC is able to resolve the complaint, the resolution is reviewed with the Administrative Director. If deemed appropriate and substantive, the complaint and resolution will be documented and reviewed at the next RI Compliance Committee (RICC) meeting. If the RCC is unable to resolve the complaint, the Administrative Director will assemble a team of at least three (3) individuals, which may include the RI Directors, IRB Chairperson, IRB Manager, Legal Affairs and others, to achieve resolution. The complainant and respondent are debriefed by the Administrative Director, as appropriate.
Investigating Allegations of Non-Compliance	Allegations of research non-compliance must be reported to the RCC. The RCC performs a preliminary evaluation to determine the credibility and likelihood of truth of the allegation. If the RCC determines the allegation lacks credibility or is untrue, he/she reviews it with the RI Administrative Director, then documents and presents findings at the next RICC meeting. The RCC communicates the resolution to interested parties, such as the IRB, principal investigator, or other key research personnel, and then closes the file. The complainant and respondent are debriefed as appropriate. However, if the RCC determines the allegation may be credible, she/he launches an investigation and notifies the Corporate Compliance Officer and the attorney from Legal Affairs assigned to the Research Institute.

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The RCC leads the investigation, and will interview those involved (e.g., complainant, respondent, and/or principal investigator) in an effort to gather the facts. The Administrative Director will assemble an investigative team consisting of a minimum of three (3) individuals, which may include the RI Directors, IRB Chairperson, IRB Manager, Legal Affairs and others. The investigative team may consult with the RICC and/or the Corporate Compliance Officer during the investigation. A report of the investigation, including any findings, will be provided to the Vice President (VP) of Research, the Institutional Official, the IRB Chairperson, the Administrative Director of the RI, and the Medical and Hospital Administrators for the Respondent(s).

The IRB will be notified of any investigations which, if confirmed, could result in serious harm to research participants. Otherwise, investigations will be conducted in a confidential manner until such time as the non-compliance has been confirmed.

Classifying the Confirmed Non-Compliance

If the investigative team determines the allegation of non-compliance is true, it becomes an episode of **Confirmed Non-Compliance.** The team then classifies the event as:

- Level 1 Non-Compliance, or
- Level 2 Non-Compliance.

Level 1 Non-Compliance

Determination to Suspend or Terminate the Research

If the investigative team determines the incident constitutes Level 1 Non-Compliance, appropriate disciplinary action will be taken, up to and including suspension or termination of the individual involved or the research being conducted. If the non-compliance involves human participant research, the IRB Chairperson will be notified and must promptly determine if the research should be suspended or terminated, in part or entirely, to avoid potential continued risk to participants and whether to notify current participants if the non-compliance could affect their willingness to continue participation, while an Action Plan is developed and implemented. For enrolled participants, appropriate clinical care should be provided if suspension of research activities would place these individuals at increased risk of harm.

Review by the Convened IRB

If the Confirmed Non-Compliance has been classified as Level 1 Non-Compliance, it must be reviewed by a convened IRB within thirty (30) days of this determination. A primary reviewer, usually someone involved in the investigation and with significant knowledge of the events, is assigned. The primary reviewer will have access to the entire IRB file as well as the Complaints/Non-Compliance checklist used during the investigation. At a fully convened meeting of the IRB, the primary reviewer provides a verbal synopsis of the non-compliance, any immediate action taken by the Chairperson and recommendation for addressing the non-compliance. If the Chairperson took any immediate

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action, the IRB either concurs or requires modifications to the Chairperson's actions. The IRB may require additional actions by the principal investigator, and will determine whether enrolled participants must be notified of the events, if such information might relate to the participants' willingness to continue participating in the research. The IRB Chairperson will ensure the decision of the IRB is communicated to the RCC and principal investigator, as appropriate.

Actions by the VP of Research or the Institutional Official
When the investigative team determines the incident constitutes Level 1 Non-Compliance, the VP of Research or the IO may take actions separate from the actions of the IRB. The VP of Research or the IO may determine the research must be suspended or terminated when he/she perceives an unacceptable risk to the institution, and suspending or terminating the research would not cause increased risk to participants. Additionally, the VP of Research or the IO may provide the report to the Chief Medical Officer and the Corporate Compliance Officer for further disciplinary action when deemed appropriate. The VP of Research or the IO may not reverse a decision by the IRB to suspend or terminate the research.

The VP of Research or the IO will report incidents to external regulators overseeing or funding the research, such as the Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA) within thirty (30) days when incidents meet the reporting criteria set forth by those agencies are met. In addition, reporting to other federal agencies when the research is overseen by those agencies, and they require reporting separate from that to OHRP. Determinations of serious or continuing non-compliance of DoD-supported research must be promptly (no longer than within 30 days) reported to the DoD human research protection officer. Once an incident has been classified as Level 1 Non-Compliance, those events meeting reporting criteria will be reported to the overseeing external regulators promptly. If details, such as an Action Plan, are incomplete at the time of the initial report, a follow-up report will be submitted including the final Action Plan.

Action Plan
An Action Plan will be sent to the principal investigator from the VP of Research or the IO within thirty (30) days of receiving the report. The plan will be reviewed by the investigative team, and follow-up will be provided to assure it has been implemented. If the non-compliant activity continues for any reason, including lack of principal investigator response, the VP of Research or the IO may withhold or withdraw project approval.

When the Level 1 Non-Compliance involves human participant research, the administrative Action Plan will be provided to the IRB for review at

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	a fully convened meeting. The RCC will provide the IRB with reports concerning Action Plan compliance.
Level 2 Non-Compliance	If the investigative team classifies the incident as Level 2 Non-Compliance, the IRB will require the principal investigator to respond to all IRB related concerns contained in the report, in accordance with its policies. The principal investigator must provide a written Action Plan to the IRB Chairperson within thirty (30) days. If the non-compliance issue is not dealt with adequately, the IRB, the VP of Research or the IO may withhold or withdraw project approval.
Reports of Attempts to Influence An Oversight Committee	The research review process must be conducted independently and objectively and without influence from those outside of the oversight committee, such as the Animal Care Committee, Biosafety Committee, Conflict of Interest Review Committee, Institutional Review Board, or Radiation Safety Committee. Reports of inappropriate attempts to exert influence over the outcome of a review will be taken very seriously and will be addressed jointly by the IO, the Chairperson of the oversight committee and the appropriate corporate administrator (e.g., Chief Medical Officer, Chief Nursing officer, Hospital President). Inappropriate influence by the principal investigator may result in withholding or withdrawal of study approval.
Reporting to RICC	All instances of non-compliance (Level 1 and Level 2) will be documented and presented at the next RICC meeting by the RCC.
Possible Corrective Actions	Corrective actions may include but are not limited to: • Barring the investigator from involvement in clinical research at Beaumont. • Suspending the specific research under investigation or all studies involving the investigator or clinical research department. • Withdrawing IRB approval for all or some of the study's research activities, resulting in termination of the research. • Requiring modification of the research plan to minimize risk to participants. • Notifying enrolled participants, if such information might affect their willingness to continue taking part in the research, and perhaps requiring re-consenting of participants. • Providing additional information to participants who have completed study participation. • Increasing the level or focus of monitoring, such as monitoring the consent process or the data analysis. • Requiring modifications to the consent and authorization document. • Requiring increased frequency of continuing review submissions to the IRB. • Requiring part or all of the research data to be destroyed. • Advising journals and professional organizations that research was

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not conducted per the IRB-approved protocol.
- Requiring retraction of submitted manuscripts and/or abstracts and/or planned presentations.
- Reporting to the individual's manager, legal counsel, or external regulators.

Privacy

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 compliance 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 non-compliance, all reasonable and practical efforts will be made to protect and restore his/her reputation and position.

Cooperation with Legal Affairs

If at any time a member of the Office of Legal Affairs determines the allegation, investigation or outcome is likely to have legal implications, the attorney assigned will provide guidance to assure activities related to the complaint or allegation are done in accordance with regulations and in a manner which will best protect Beaumont's interests.

ASSOCIATED POLICIES AND DOCUMENTS

Corporate Compliance Plan
Policy 350 *Beaumont Hospitals Code of Business and Ethical Conduct*
Research Institute Compliance Plan
RI Policy 100 *Inquiries and Allegations of Research Misconduct*
RI Policy 102 *Research Administration Oversight*
IRB Policy 225 *Organization of the Human Investigation Committee*

☐ Original ☒ Revision or Review

Research Institute Compliance Committee Review Date: _____

Corporate Administration Approval: _____ Date: _____
VP of Research or Chief Medical Officer

Research Institute Board Approval: _____ Date: _____

Research Administration Approval: _____ Date: _____
Administrative Director