ORLANDO HEALTH®

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Orlando, Florida 32806
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Type of Policy:	***PROTECTION OF HUMAN RESEARCH PARTICIPANTS***	Category:	**Orlando Health Institutional Review Board (IRB)**

Title:	***IRB Process for Receiving Complaints***	Policy #:	**0330-1009**
		Replaces #:	**MDACCO 1000-0001T**
Page:	1 of 3	Developed By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	**01/96**	Approved By:	Philip Giordano, MD Institutional Official
Revision Dates:	10/01, 10/03, 10/05, 12/07, 8/11/14, 1/16/17, 9/30/19, 11/15/22		SIGNATURE ON FILE

I. PURPOSE:

The purpose of this policy is to outline the steps the IRB will take when it receives a complaint or a concern from a research participant (or their family member) or any other involved party.

II. DEFINITIONS:

None.

III. POLICY:

It is the policy of Orlando Health IRB to include within the IRB-approved consent documents contact information for the Principal Investigator and the Orlando Health IRB Office should the subject (or other involved party) have questions related to the subject's rights and responsibilities and/or to report problems related to their participation in a research study. Complaints and concerns shall be investigated and shall result in an appropriate action relative to its level of seriousness. When addressing participant complaints, adequate and appropriate privacy and confidentiality protections must be in place throughout the process to ensure protection of the participant.

IV. PROCEDURE:

A. Reports of complaints or concerns may come to the IRB from various sources. For complaints or concerns from a research participant (or other involved party) received by the research team and/or the Corporate Office of Research Operations (CORO) office, the reporting requirements to the IRB Office are:
   1. The Other Submissions/Information Only IRB form shall be used for the submission.
   2. The submission shall be electronically signed by the Principal Investigator.

B. If the complaint or concern from a research participant (or other involved party) is received by IRB Office staff, the following procedures will be followed:
   1. The IRB Office will obtain and document the following appropriate information, if available:
      a. The person's name and contact information. However, if the person wishes to remain anonymous, the person will be advised that a thorough review may not be possible and, that without this information, follow-up with the person would not be possible.
      b. The Protocol Number and/or full study title, the name of the Investigator, and/or staff names.
      c. The person's relationship to the study (for example, past/present/potential research participant, family member, etc.).
      d. A detailed explanation of the complaint or concern.
      e. Who the person has contacted (such as the Investigator, research staff or anyone else when said contact was made) regarding the complaint or concern.
      f. A description from the person of a proposed resolution of the complaint, if the person has such a proposal.
   2. The IRB Office will communicate to the person that he/she will inquire into the circumstances associated with the complaint or concern and, if possible, that a response regarding the resolution of or a determination about the complaint or concern will be provided.

C. Regardless of the source, once the report of the complaint or concern is received by the IRB Office:

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1. The IRB Office will initiate the initial review of the complaint or concern by reviewing study documents and other relevant information. The IRB Manager should also contact, verbally or in writing, the Corporate Office of Research Operations, the study Investigator, and/or study staff to obtain information in association with the initial review.
2. After performing the initial review, the IRB Office will determine whether the complaint or concern can be handled administratively or whether the complaint or concern needs to be reviewed by the IRB Chair and at a convened meeting.
3. Types of IRB determinations:
   a. If the IRB Office or IRB Chair determined the complaint or concern does not pose any additional potential risk to subjects or others or cause a change in the risk/benefit ratio associated with participation in the study, then the response for such complaints or concerns may be done at the administrative level by the IRB Office. The report associated with the complaint or concern and response including, when appropriate, the corrective action plan to prevent future occurrence, will be made a part of the project file in IRBNet at the time of the next Continuing Review, as appropriate.
   b. If the complaint or concern is determined to involve potential risk to subjects or others, or possibly cause a change in the risk/benefit ratio associated with the study, the written report will be viewed as a possible unanticipated problem and it will be reviewed as outlined in *Reporting Serious Adverse Events* IRB Policy or the *Protocol Deviations/Violations/Non-Compliance* IRB Policy at a convened meeting.
   c. If the complaint or concern is determined to be an allegation of serious non-compliance, then the IRB will initiate the review as outlined in the *Protocol Deviations/Violations* IRB Policy and/or the *Study Closure, Termination, or Suspension of Research* IRB policy at a convened meeting.
4. Reporting, in writing, findings and actions of the IRB to the Investigator and study team:
   a. The IRB Office will issue determination letters, which note the IRB action, to the Investigator and study team via IRBNet.
   b. The letters will be sent promptly after the conclusion of the Board meeting.
5. The IRB Administration office shall maintain documentation for all formal complaints, decisions, and audits within IRBNet.

V. DOCUMENTATION:

None.

VI. REFERENCES:

A. Institutional Review Board Management and Function, Robert Amdur, M.D., and Elizabeth Bankert, MA, Jones and Bartlett Publishers, Copyright 2002, Chapter 7-4
B. IRB Policy #0330-1000: *Reporting Serious Adverse Events*
C. IRB Policy #0330-1001: *Protocol Deviations/Violations/Non-Compliance*
D. IRB Policy #0330-1019: *Study Closure, Termination, or Suspension of Research*

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VII. ATTACHMENTS:

None.