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Type of Policy:	***PROTECTION OF HUMAN RESEARCH PARTICIPANTS***	Category:	**Orlando Health Institutional Review Board (IRB)**
Title:	***Study Closure, Termination, or Suspension of Research***	Policy #:	**0330-1019**
		Replaces #:	**MDACCO 1000-0001T**
Page:	1 of 4	Developed By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	**6/22/10**	Approved By:	Philip Giordano, MD Institutional Official **SIGNATURE ON FILE**
Revision Dates:	8/11/14, 4/4/17, 1/21/19, 4/5/21,1/16/24		

I. PURPOSE:

To provide IRB members and staff, investigators, and other research personnel information when Orlando Health IRB-approved research may be closed (ending further IRB oversight of the research) by the Principal Investigator (PI), Sponsor (if applicable), or by the IRB.

II. DEFINITIONS:

When used in this policy these terms have the following meanings:

A. IRB-Initiated Suspension of Approval: IRB-initiated suspension of approval refers to a determination made by the Orlando Health IRB to temporarily withdraw IRB approval for some or all activities of a currently approved research study.

B. IRB-Initiated Termination of Approval: IRB-initiated termination of approval refers to a determination made by the Orlando Health IRB to permanently withdraw IRB approval for some or all activities of a currently approved research study.

C. Investigator-Initiated Suspension of study activities: Investigator-initiated suspension of study activities refers to a determination made by the Principal Investigator to temporarily suspend some or all activities of a currently approved research study.

D. Investigator-Initiated Termination of study activities: Investigator-initiated termination of study activities refers to a determination made by the Principal Investigator to permanently terminate some or all activities of a currently approved research study.

E. Sponsor-Initiated Suspension of study activities: Sponsor-initiated termination of study activities refers to a determination made by the sponsor to temporarily suspend some or all activities of a currently approved research study.

F. Sponsor-Initiated Termination of study activities: Sponsor-initiated termination of study activities refers to a determination made by the sponsor to permanently terminate some or all activities of a currently approved research study.

III. POLICY:

The Orlando Health IRB has the authority to terminate or suspend its approval of a research protocol that is not being conducted in accordance with the IRB's requirements or that is associated with serious harm to human research subjects.

IV. PROCEDURE:

A. IRB-initiated termination or suspension of a research protocol

1. IRB-initiated termination of a research protocol:

a) When the Orlando Health IRB finds that an approved research protocol is not being conducted in accordance with the IRB's requirements or is associated with serious harm to human research subjects, the IRB has the authority to terminate its approval of the research. Such termination of approval shall be reported promptly to the PI and shall include a written statement of the reasons for the IRB's actions.

i. The action related to serious non-compliance will be taken only after the convened Board determines that non-compliance is serious and continuing, and that the study should be terminated.

ii. The action related to serious harm to human research subjects will be taken as soon as the convened Board determines that such harm has occurred and that the study should be terminated.

b) Notice of the termination will be sent to the Principal Investigator, the Sponsor, the FDA, the OHRP, the Institutional Official, and the Corporate Office of Research Operations, as appropriate. If there are subjects still enrolled in the study who require continued follow up, the Orlando Health IRB will work with the study sponsor to determine the best way to continue the necessary treatment and/or follow up of these patients.

2. Official IRB-initiated suspension of a research protocol:
   a) The IRB Manager, in consultation with the IRB Chair, may request that enrollment in a study be temporarily put on hold. This action is appropriate in situations where there may be questions about study conduct and/or patient safety. The action (including any resolution) must be reported to the convened Board at the next meeting.
   b) In extreme cases, the IRB Chair may officially suspend the study prior to a convened Board meeting.
   c) Once enrollment is held, it can be lifted when the IRB Manager and the IRB Chair are satisfied that the questions have been resolved. If questions remain unresolved, the convened Board, or the IRB Chair, may take official action to suspend or terminate the research as described above.
   d) Notice of the official suspension will be sent to the PI, the Sponsor, the FDA, the OHRP, the Institutional Official, and the Corporate Office of Research Operations, as appropriate.

B. Investigator/Sponsor-initiated termination or suspension of an IRB-approved research protocol:
   1. If the termination or suspension is based on other reasons (e.g. administrative), the termination/suspension shall be reported to the IRB Office in a timely fashion of the termination/suspension notice.
   2. If the termination or suspension is based on a change in the risk-to-benefit ratio of study participation (e.g., serious adverse events, non-effectiveness of the research intervention), the termination or suspension shall be reported promptly (i.e., within 5 business days upon receipt of the termination/suspension notice from the PI or sponsor) to the IRB Office. IRB notification shall include:
      a) The reason for study termination or suspension (e.g., subject accrual complete and data analyzed, demonstrated absence of benefit based on interim data analysis, serious adverse event).
      b) The number of subjects currently enrolled in the study at the Orlando Health sites and their status (e.g., currently undergoing research intervention and monitoring; completed intervention-follow-up monitoring only; completed study).
      c) If applicable, a description of the procedures that will be used to notify subjects currently participating in the study of the study termination/suspension and the procedures that will be undertaken to ensure their orderly and safe withdrawal from the study and their follow-up care.
      d) A description of the procedures that will be used to notify subjects who previously participated in the study of the study termination/suspension, if felt to be important to their rights or welfare.
   3. For research protocols that were suspended due to serious adverse events, IRB approval is required to re-initiate the research study. The written request for study re-initiation shall address:
      a) The outcome of investigations on the causality of the serious adverse event(s)
      b) The frequency of occurrence of the serious adverse event at Orlando Health sites or external sites, if applicable
      c) Modifications to the protocol and/or consent form to address the serious adverse event.

4. Circumstances for termination of IRB oversight for research protocols:
   a) IRB oversight may end (following a request for closure) only under the following circumstances and conditions:

      The research must be permanently closed to enrollment with no further interaction/intervention with subjects (or access to a subject's personally identifiable information) for the purpose of research data collection.

      OR

      All data analysis involving the research sites, under IRB approval, is complete; this means that the database is locked. In addition, data and/or samples which are de-identified must remain de-identified.

      OR

      Data has been de-identified, with no codes or keys that would allow for the potential of identifying individuals in the future. NOTE: This typically applies to multi-center research where de-identified data is provided to the sponsor and the sponsor authorizes IRB closure at a close out site visit and will lock the database.

5. If the Principal Investigator leaves Orlando Health, Inc., the PI must either choose to transfer in PI or meet the above criteria to close the study.
6. Procedure for investigator-initiated termination of approval:
   a) The PI must complete the IRB Continuing Review Application and submit it to the IRB Office to request the study from further IRB oversight. If the termination is finalized by the IRB, please note the ongoing obligations:
      i. The IRB will retain all pertinent documents in accordance with federal regulations.
      ii. If the PI closes a study and then later finds that future correspondence or interaction with human subjects formerly in that protocol is necessary (for the purpose of research data collection), the PI must immediately inform the IRB of the situation. The PI may request that the IRB re-open the study by continuing review (if less than 11 months has passed) or must request a new initial review by the IRB.
   b) Once termination is finalized by the IRB, it is the continued responsibility of the research team to maintain the confidentiality of the data.
   c) The PI must contact the IRB office if stored research data will be used for future research purpose other than that originally proposed (e.g. if data will be maintained for potential future research).
   d) It is the responsibility of the PI to request study closure. It is the responsibility of the IRB to review the request and approve of (discontinue IRB oversight) or disapprove of (require continuing IRB oversight) the study closure.

C. Notifying and withdrawing human research subjects due to termination or suspension:
   1. Human subjects currently participating in a research study must be notified of its termination or suspension due to safety issues and/or other problems (e.g., unanticipated problems, failure to obtain continuing IRB approval, investigator non-compliance) and the reasons therefore. The IRB must approve the notification

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process prior to implementation except for emergency situations.

2. The rights and welfare of human research subjects should be considered when withdrawing them. If follow-up of the subjects for safety or effectiveness reasons is permitted or required by the IRB (e.g., under a research protocol that is suspended or closed to enrollment), the subjects should be informed (i.e., through the use of a consent form addendum). Any adverse events or other outcomes identified during follow-up should be reported to the IRB, the research study sponsor, the OHRP, and the FDA, if applicable.

V. DOCUMENTATION:

A. Continuing Review Application

VI. REFERENCES:

A. Code of Federal Regulations – 21 CFR 56.113 and 45 CFR 46.113
B. Code of Federal Regulations – 21 CFR 56.109(f); 45 CFR 46.109 (e)
C. Code of Federal Regulations – 21 CFR 56.110, 45 CFR 46.110

VII. ATTACHMENTS:

None.