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

Title:	***Continuing Review Process***	Policy #:	**0330-1007**
		Replaced #:	ORMC IRB# 6000-303 MDACCO IRB# 1000-0001H
Page 1 of 4		Issued By:	Orlando Health Institutional Review Board (IRB)
Issue Date:	**7/19/95**	Approved By:	Philip Giordano, MD Institutional Official **SIGNATURE ON FILE**
Revision Dates:	1/1/01, 3/20/02, 11/12/07, 2/4/08, 6/24/10, 9/23/13, 8/11/14, 4/14/15, 10/13/16, 1/21/19, 12/11/19, 1/19/21, 9/14/22		

I. PURPOSE:

The IRB shall conduct continuing review of research taking place within its jurisdiction at intervals appropriate to the degree of risk to participants.

II. DEFINITIONS:

None.

III. POLICY:

Consistent with federal regulations, it is the policy of the IRB that human subject research activities (with the exception of 'exempt' protocols and certain ‘expedited’ protocols) under its jurisdiction be reviewed at least annually with the period appropriate to the degree of risk. This continuing review is additional to the review required for all changes, amendments and sponsor notifications. Serious adverse events and/or Protocol Deviations may be requested by the IRB during this time.

IV. PROCEDURE:

A. Required time frame for continuing review: Unless otherwise determined by the Orlando Health IRB, continuing review of all research approved by the Orlando Health IRB will be performed at least once a year, and may also be done at any other time at which it is deemed desirable. At a minimum, annual reviews must be performed before the 1 year anniversary date of the previous IRB review. Frequency of continuing review, which may happen quarterly, bi-annually, etc., shall be based on risk to subjects, the nature of the study, and the subject population, and shall be determined by the IRB. At any time, the IRB may request a continuing review (progress report). The Continuing Review Application shall be used to communicate study findings to date. The IRB may also approve, disapprove or request modifications to the continuing review application or informed consent.

B. Documents required at the time of Continuing Review:
   1. A completed Continuing Review Application
   2. A sample copy of the informed consent form must be submitted at the time of continuing review, if applicable. The submitted copy of the informed consent form will be used to verify that the most current consent form is being utilized. This is not required if the study is permanently closed to enrollment.
   3. A summary of internal serious adverse events (SAE) since last IRB review should be reported using the internal SAE log sheet when applicable.
   4. A summary of minor protocol deviations since last IRB review should be reported using the internal protocol deviation log sheet.

C. Review of Continuing Review at a convened IRB meeting:

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1. Continuing review takes place at a convened meeting of the IRB, unless it meets the criteria for expedited review under the federal regulations at 45 CFR 46.110 and, if applicable, 21 CFR 56.110 and the IRB has determined that continuing review is required.
2. If any questions or uncertainty regarding data presented to the IRB, the IRB may request verification from sources other than the investigators to clarify that no material changes in the research have occurred since previous IRB review. Any significant new findings, which may relate to the subject's willingness to continue participation should be reviewed and, as necessary, provided to the subject.
3. Continuing Review shall include: the number of subjects enrolled, experienced benefits and adverse reaction, withdrawals from the research (and reasons for withdrawal, if known), the research results obtained thus far, a current risk-benefit assessment based on study results, a summary of any complaints about the research from subjects (or others) enrolled at the local site since the last IRB review, and a summary of any recent literature, findings or other relevant new information since the IRB's last review, especially information about risks associated with the research.
4. For Continuing Review to be approved, a majority of IRB members present must approve it of which one must be a non-scientist per quorum requirements. **Refer to policy 0330-1013 for further guidance regarding quorum.**
5. Anytime there is a convened meeting no member may participate in the IRB's continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
6. The IRB meeting minutes must reflect meeting attendance, actions taken by the IRB, the votes taken on these actions, a summary of any discussion of controverted issues and their resolution, and confirmation that conflicted members did not participate in the IRB's continuing review of their studies.

D. Review of Continuing Review using Expedited Review procedures:
1. Where a project qualifies for expedited review, the review may be conducted by the IRB chairperson or their designee when required by the Orlando Health IRB. In most instances, the IRB will require an annual statement, via e-mail, that the 'expedited' study is still active (i.e., "annual check-in") at the discretion of the IRB chair. Otherwise, the procedure above, for continuing review, will be required.
2. Disapproval of a study at the time of continuing review cannot be performed using an expedited procedure and can only occur at a convened meeting.

E. Failure to submit a Continuing Review at the time of expiration:
1. If a Continuing Review Application is not approved prior to the expiration date indicated on the approval letter, than there will be a lapse in IRB approval. Notification of this action will be sent to the investigator and research personnel, and the sponsor, if applicable, via IRBNet. Suspension shall

preclude addition of new subjects to be enrolled in the study, but following enrolled subjects for safety reasons may be allowed if permitted/required by the IRB.

2. For more than minimal risk studies, if a continuing review of a lapsed protocol is not submitted after 30 calendar days of the IRB lapsed date, the IRB manager will bring the expired study to the next convened meeting as an agenda item so that the IRB can vote on the appropriate action. If a continuing review submission has not been received and approved by the IRB within 60 calendar days of the IRB lapsed date, the protocol will be administratively terminated per the action determined by the IRB. The individuals and agencies noted as listed above will be notified as well as the FDA or appropriate federal Department or Agency head (45 CFR 46.113 and 21 CFR 56.113). Please note: OHRP studies there is no need to report to OHRP/funding agencies when studies lapse. Of note, OHRP has opined that it does not consider such an expiration of IRB approval to be a suspension or termination of IRB approval. Therefore, such expirations of IRB approval do not need to be reported to OHRP as suspensions or terminations of IRB approval under the HHS regulations at 45 CFR 46.103(a) and 46.103(b)(5). However, if the IRB notes a pattern of non-compliance with the requirements for continuing review (e.g., an investigator repeatedly or deliberately neglects to submit materials for continuing review in a timely fashion or the IRB itself is frequently not meeting the continuing review dates), the IRB should determine whether such a pattern represents serious or continuing noncompliance that needs to be reported to appropriate institutional officials, the HHS agency that supported the research, and OHRP (45 CFR 46.103(b)(5). Subjects currently participating should be notified that the study has been terminated. If follow-up of subjects for safety reasons is permitted/required by the IRB, the subjects should be informed. Any adverse events/outcomes should also be reported to the IRB and the Sponsor. Termination will be required for the safety of the study subject, and a study termination report shall be submitted.

3. For minimal risk studies, if continuing review of a lapsed protocol is not submitted and approved by the IRB within 60 calendar days of the IRB lapsed date, IRB approval is no longer valid, and the IRB file will be administratively terminated.

F. Failure to provide an annual statement (“annual check-in”) to the IRB at the time of due date for studies which do not have an expiration date (i.e., require continuing review):

1. If an annual statement has not been received by the IRB Office, the study team has 60 calendar days to respond.

2. After 60 calendar days have passed, IRB approval for that study is no longer valid and the IRB file will be administratively terminated.

G. Reporting, in writing, findings and actions of the IRB to the Investigator and study team:

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1. The IRB Office will issue letters, which note the IRB action, to the Investigator, study team, and, if applicable, the Director of Graduate Medical Education/Academic Affairs for resident-driven studies via IRBNet.
2. The letters will be sent promptly after the conclusion of the Board meeting.

V. DOCUMENTATION:

A. Continuing Review Application
B. IRBNet Electronic Submission System

VI. REFERENCES:

a. Code of Federal Regulations – 45 CFR 46.108 and 21 CFR 56.108
b. Code of Federal Regulations – 45 CFR 46.109 and 21 CFR 56.109
c. Code of Federal Regulations – 21 CFR 56.113 and 45 CFR 46.113
d. IRBNet Forms and Templates Library

VII. ATTACHMENTS:

A. None