

THE UNIVERSITY OF TEXAS

# MD Anderson Cancer Center

Making Cancer History®

## **IRB Policy on Human Subjects Research Termination, Termination of IRB Oversight and Activities that are not subject to IRB Oversight**

### **SCOPE**

These guidelines apply to Principal Investigators, Research Teams, IRB Staff, and designated IRB Chair or designee.

### **PURPOSE**

This policy provides guidance and information on the following:

- Termination of human subjects research;
- Termination of IRB oversight of human subjects research; and
- Human subjects research-related activities that may be carried out whether or not the research is under IRB oversight and whether or not the research has been terminated.

**Note:** termination of IRB oversight of human subjects research is not the same as suspension or termination of IRB approval of human subjects research.<sup>1</sup>

### **DEFINITIONS**

**Human Subjects Research:** Is any of the following:

- (a) Research that involves a living individual about whom an investigator conducting the research obtains (i) data through intervention or interaction with the individual, or (ii) identifiable private information;
- (b) Research that involves the use and/or disclosure of Protected Health Information;
- (c) Research in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

**Note:** *In vitro* research that involves human tissues that cannot be linked to a living individual is excluded from this definition of human subjects research.

**Human Subjects Research Protocol:** Means a written description of Human Subjects Research, including objective(s), design, and methods. It may also include relevant scientific background and statistical considerations.

<sup>1</sup> Suspension or termination of IRB approval of human subjects research is addressed in the IRB policy on IRB Committee Determination for Reviewing Research Non-Compliance, Suspending or Terminating IRB approval of Research and IRB reporting procedures to Institutional and External Officials.

**Institutional Review Board (IRB):** The board(s) formally designated by MD Anderson to assure the protection of the rights and welfare of human subjects, and to conduct initial and continuing review and approval of Human Subjects Research.

**Principal Investigator (PI):** The individual who is the leader of an investigative team and is responsible for the design, conduct, or reporting of Human Subjects Research.

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## PROCEDURE

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### I. Guiding principles

- A. Human Subjects Research may only be conducted in accordance with the applicable Human Subjects Research Protocol that has been reviewed and approved by an IRB.
- B. Termination of Human Subjects Research means cessation of all activities included in the applicable Human Subjects Research Protocol. Cessation of one research activity, *e.g.*, enrollment, does not constitute termination.
- C. Termination of IRB oversight of Human Subjects Research means cessation of IRB review, approval, and other actions with regard to such Human Subjects Research.
- D. IRB oversight of Human Subjects Research is no longer required and therefore may be terminated after the PI notifies and assures the IRB in writing that all research activities including enrollment, treatment and/or intervention, follow-up, and analysis of identifiable data have ceased. For example, when:
  1. The PI does not intend to continue or carry out the research described in the applicable Human Subjects Research Protocol; or
  2. The research as described in the applicable Human Subjects Research Protocol has been completed.

### II. Termination criteria

- A. Human Subjects Research may be terminated prior to completion of the research described in the Human Subjects Research Protocol under the following circumstances.
  1. At the request of the PI, Department Chair or Division Head, data safety monitoring board, the FDA, study sponsor, MD Anderson, or IRB; or
  2. Upon or in preparation for termination of the PI's employment at MD Anderson or association with MD Anderson if the PI responsibilities have not or will not, be transferred to another MD Anderson employee; or
  3. When the PI is not able to fulfil his/her duties, *e.g.* extended leave, death, and the PI responsibilities will not be transferred to another MD Anderson employee; or
  4. Upon loss or unavailability of funding.

**B. Human Subjects Research carried out at a single site may be terminated if all of the following conditions are met:**

1. The research is permanently closed to enrollment of new subjects;
2. All subjects have completed all research-related interventions;
3. Long-term follow-up of all study subjects has been completed;<sup>2</sup> and
4. All data analysis is complete.

**Note:** It is permissible to terminate IRB oversight if the final manuscript(s) or report(s) have not yet been prepared and preparation of such document(s) will not require further access or use of PHI of participants, *i.e.* it will only involve the use of data that meets HIPAA de-identification standards.

**C. Human Subjects Research where MD Anderson is one of multiple sites and is not the lead site, may be terminated if all of the following conditions are met:**

1. The research is permanently closed to enrollment of new subjects at MD Anderson and there are no plans to enroll new subjects;
2. All MD Anderson subjects have completed all research-related interventions;
3. Long-term follow-up of all MD Anderson subjects has been completed;<sup>3</sup> and
4. MD Anderson has no data analysis or other data management responsibility, *e.g.* all data queries have been addressed, and close-out visit has been completed, and MD Anderson data has been locked.

**D. Human Subjects Research that is conducted at multiple sites and MD Anderson is the lead site, may be terminated if all of the following conditions are met:**

1. The research is closed to enrollment of new subjects at all study sites and there are no plans to enroll new subjects;
2. All subjects at all sites have completed all research-related interventions;
3. Long-term follow-up of all subjects at all sites has been completed;<sup>4</sup> and
4. All data analysis or other data management responsibility for all sites is complete, *e.g.* all data queries have been addressed, and close-out visits have been completed, and the databases at all sites has been locked.

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<sup>2</sup> If a PI wishes to continue long-term follow-up while avoiding having Human Subjects Research as described in multiple individual Human Subjects Research Protocols under IRB oversight where long-term follow-up of subjects is the only remaining activity, PIs are encouraged to use the option of carrying out long-term follow-up as a separate Human Subjects Research activity described in a separate Human Subjects Research Protocol.

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

5. MD Anderson has received documentation from the applicable IRBs from each of the non-MD Anderson sites confirming that such Human Subjects Research at each such site has been terminated.

### III. Other

The following Human Subjects Research-related activities may be carried out whether or not the research is under IRB oversight and whether or not the research has been terminated.

- A. Invoicing the sponsor for Human Subjects Research-related items and services.
- B. Receipt of final payment from a Human Subjects Research sponsor
- C. Return or destruction of unused Human Subjects Research drug(s)
- D. Preparation of final research report provided such report preparation does not involve the use or disclosure of protected health information/individually identifiable information of subjects.
- E. Resolution of data queries from sponsor or corrections that are required as a result of an FDA or other regulatory body inspections after Human Subjects Research has been terminated and IRB oversight has also already been terminated.
- F. Data analysis required to respond to queries from journal editors, manuscript reviewers or readers, provided such analysis does not involve the use or disclosure of protected health information/individually identifiable information of subjects.

Note: Investigators are required to request un-termination of human subjects research if the data analysis required to be carried out to respond to queries and/comments from journal editors, manuscript reviewers or readers will involve use of or disclosure of protected health information/individually identifiable information.

### IV. Obtaining IRB approval to terminate Human Subjects Research

- A. The Human Subjects Research PI will submit a request to terminate such research to the IRB using prescribed termination request procedures via applicable institutional systems. The request to terminate a protocol will need to be done using the Request for Termination form. Requisite supporting documentation should be obtained from the research sponsor, granting agency, or external sites, as applicable.
- B. Human Subjects Research termination requests and supporting documentation will be reviewed by IRB staff to ensure receipt of all required information and documentation and provide such request and documentation to the IRB Chair or designee. IRB staff will confirm that appropriate sponsor documentation is attached to support the termination request and there are no outstanding compliance concerns.

- C. The IRB Chair or designee will review the Human Subjects Research termination request and supporting documentation and either approve the termination request or designate the request for full board review and determination.

#### **V. Termination of IRB oversight of Human Subjects Research**

- A. Following IRB Chair or designee or IRB approval of termination of Human Subjects Research in accordance with Section IV above, IRB oversight of such research will be terminated.
- B. The IRB staff will document the Human Subjects Research termination date as the date the IRB Chair or designee approved the request to terminate.
- C. The termination date will be entered in the electronic IRB system, and will be sent electronically to other systems that support the research process (e.g. TissueStation, EPIC, etc.)
- D. For Human Subjects Research under the oversight of a non-MD Anderson IRB, the PI will need to contact the external IRB to request termination. The non-MD Anderson IRB determination must be submitted to the Office of Protocol Research for processing in MD Anderson human subjects protections record systems.

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## **REFERENCES**

### **Applicable Regulations, guidance, and references**

1. 45 C.F.R. 46.101(b), 45 C.F.R. 46.103, 45 C.F.R. 46.109, 45 C.F.R. 46.108, 45 C.F.R. 46.110, 45 CFR 46.115(b),
2. 21 CFR 56.108, 21 C.F.R. 56.109, 21 C.F.R. 56.110
3. 42 C.F.R. 11.10 "Completion date" and "Protocol" definitions
4. FDA Guidance for IRBs, Clinical Investigators, and Sponsors. IRB Continuing Reviews after Clinical Investigation Approval. (February 2012).
5. Office for Human Research Protections FAQ – What are investigators' responsibilities once a study is completed? (Available at <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html> (last visited on April 24, 2017)).

### **Applicable IRB policies**

11.010 Initial IRB Review of Research – See Chapter 11

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## Policy Stewards

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Madhu Purewal, Sr Legal Officer & Director, Institutional Compliance  
 Wanda Quezada, Assoc Director, Human Research Regs, Protocol Research  
 Marion Olson, Manager, Human Research Regs, Protocol Research

Date	Action	Initials	Description
4/26/17	IRB3 Review	IRB3	Policy was reviewed by the IRB3, and suggested changes
7/26/17	Approved with contingencies	IRB3	IRB3 convened board reviewed and approved the revised policy with contingencies
9/7/17	Approval	JC	IRB3 Chair administratively approved the policy
9/18/17	Implementation	WQ	Revised title, and policy implemented

### Signature Manifest

**Document Number:** CLR-POLICY-0042

**Revision:** 01

**Title:** IRB Policy on Human Subjects Research Termination, Termination of IRB Oversight and Activities that are not subject to IRB Oversight

All dates and times are in Central Standard Time.

### Quick Approval

### Approve Now

Name/Signature	Title	Date	Meaning/Reason
Wanda Quezada (WQUEZADA)	ASSOC DIR, HUMAN RSCH REGS	18 Sep 2017, 05:21:02 PM	Approved