

## **MD Anderson IRB Policy on IRB Committee Determinations for Reviewing Research Non-Compliance, Suspending or Terminating Research and IRB reporting procedures to Institutional and External Officials**

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### **SCOPE**

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This policy applies to all human subjects research at (or conducted with) MD Anderson that falls under the regulatory oversight of the MD Anderson IRB System.

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### **PURPOSE**

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It is the policy of The University of Texas MD Anderson Cancer Center Institutional Review Board (MD Anderson IRB) to comply with the regulations governing human subject research to ensure that incidents relating to Noncompliance, Unanticipated Problems and/or Suspension or Termination of IRB approval are reported to appropriate Institutional and External Officials after appropriate review and determination.

The purpose of this policy is to protect human subjects' safety, welfare and rights by assuring that timely and appropriate determinations are made regarding suspending and/or terminating human subject research and to outline the IRB process for determining which incidences require prompt reporting to institutional Officials and applicable federal agencies.

This policy describes the IRB procedures for:

- 1) reviewing and making a determination of (i) unanticipated problems involving risks to research participants or others, (ii) serious or continuing non-compliance or (iii) termination or suspension of IRB approval of a study and
- 2) promptly reporting these Reportable Incidents and certain other information to, institutional officials and the department or agency head of the federal department or agency responsible for conducting, funding or overseeing the affected research

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## DEFINITIONS

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**Designated Government Department or Agency:** The federal department or agency to which Reportable Incidents must be reported under this policy and applicable federal regulations. If there is more than one Designated Government Department or Agency the reports will be made to all Designated Government Departments or Agencies.

- For research conducted, funded or overseen by the Department of Health and Human Services, the Office for Human Research Protections (OHRP) is a Designated Government Department or Agency.
- For research regulated by the Food and Drug Administration (FDA), the FDA is a Designated Government Department or Agency.
- For research conducted, funded or overseen by another federal department or agency that is a signatory to the Common rule, that department or agency is a Designated Government Department or Agency.
- For research conducted, funded or overseen by a component of Department of Defense (DOD), the component of DOD is the Designated Government Department or Agency.

For privacy related issues, reporting to the Office of Civil Rights may need to occur in conjunction with reporting to OHRP

**Institutional Official(s):** is the person authorized to act for the institution and assumes overall responsibility for compliance with the federal regulations for the protection of human research participants. This individual is the person who signs the Office for Human Research Protections Federalwide Assurance (FWA) of compliance. The FWA is a written agreement signed by Institutional Officials that demonstrates the institution's commitment to the principles of human subjects protection as outlined in the federal regulations.

**Non-compliance:** An intentional or unintentional action or activity relating to human subjects research by a person subject to the MD Anderson Human Research Protection Program (HRPP) that violates or otherwise fails to adhere to one or more of (i) the requirements or determinations of the IRB, (ii) the IRB or institutional research policies, or (iii) laws or Regulations governing the conduct of human subjects research including applicable FDA and DHHS regulations.

For purposes of this policy, non-compliance may be serious, continuing or minor. "Noncompliance" does not include protocol deviations that are beyond the immediate control of the Principal Investigator (PI) and their study staff (e.g. delays caused by weather or by the acts or omissions of third parties such as outside labs or scheduling changes not caused by the PI or his or her staff). However, this type of protocol deviation may constitute an unanticipated problem involving risks to research subjects or others reportable under the *IRB Policy on Reporting Protocol Deviations, Protocol Violations and Unanticipated Problems* (Human Subject Research Manual, Chapter 25).

**Reportable Incident:** An incident that is required under federal regulations to be reported to federal agencies that are responsible for the regulation of drugs and devices.

Reportable incidents include:

**Unanticipated Problems that Involve Risk to Research Participants or**

**Others:** Any incident, experience, or outcome that meets the following criteria:

- Unexpected (in terms of nature [specificity], severity, or frequency) given(a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Indicates that the research places research participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
- Indicates that there is serious or continuing noncompliance with the IRB-approved protocol

**Suspension of IRB Approval:** Study accrual is temporarily closed. This means that the treatment/intervention with previously enrolled research participants ceases, as determined by the IRB. However, the PI may request, in writing, that the IRB permit currently enrolled research participants to receive treatment and/or intervention based on their health needs. The PI must provide appropriate rationale, in writing, to the IRB.

**Termination of IRB approval:** Study accrual is permanently closed, treatment and intervention with previously enrolled research participants must cease, as determined by the IRB.

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## PROCEDURES

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This policy describes how the MD Anderson Cancer Center (MD Anderson) IRB Chair (or designee) or the IRB Committee makes determinations for suspending or terminating research and the IRB process for determining which incidences require prompt reporting to institutional Officials and applicable federal agencies.

The Vice President for Clinical Research Administration (VPCRA) (Institutional Official who has signed the FWA) or designee will be responsible for reporting, on his/her own, or at the request of any IRB each reportable incident as described in this policy to all government departments and agencies that are legally required to receive a report by thirty (30) days after a verified incident is reported to the IRB or 30 days after an IRB

has determined the validity of an alleged incident. The VPCRA or his designee may with the concurrence of an IRB Chair determine that more expeditious reporting to the appropriate government agency or department is warranted. Any determined unanticipated problem or event that is reportable to a government agency or department will also be reported to the Office of Institutional Compliance.

In rare instances a reportable incident may be determined without a fully convened IRB determination. This might happen if a verified incident is reported to the IRB and further review by the IRB will not add substantively to the determination that has been made. Reportable incidents as defined by this policy will also be reported to the Office of Institutional Compliance.

The VPCRA will provide a copy of each interim and final report to the IRB of record, the OPR Director, the PI, Office of Institutional Compliance and the Provost for Research.

## **I. Procedure for IRB Review and Determinations**

### **A. Reporting Requirements**

The IRB will accept information indicating or suggesting non-compliance from any source.

Principal Investigators, research staff and other agents or employees of MD Anderson are required to report in accordance with the IRB policies.

### **B. Type of Review**

Once a report is made it will be reviewed with the IRB Chair or designee of record for the specific study. The IRB Chair or designee may consult with other responsible parties, such as the VPCRA or others, as deemed appropriate.

The IRB Chair or designee will utilize one of the following methods of review based on the possible increase of risk to research participants, the welfare and safety of research participants; or, if data integrity of the study is affected due to continued noncompliance or an unanticipated problem which meets the criteria as defined above:

- 1. Regularly scheduled IRB meeting:** The IRB will review the event at a regularly scheduled meeting. The IRB staff will notify the PI that the incident will be reviewed at the next scheduled IRB meeting.
- 2. IRB Ad Hoc:** An IRB ad hoc is a meeting that takes place outside the regularly scheduled IRB meeting dates. If the review must take place immediately, an IRB ad hoc is scheduled. The IRB Chair or the VPCRA may call for an emergency meeting if there are urgent participant safety concerns.

The PI will be notified that an IRB ad hoc will be scheduled. If a decision is made to suspend accrual for a protocol, that decision will be reviewed and approved at the next convened IRB meeting.

3. Events that are potentially reportable and that could involve multiple protocols will routinely be referred to the Executive Session IRB with the concurrence of the IRB Chair of record for a specific study.

### **C. Actions and Decisions by Convened IRB**

The IRB Committee will be forwarded a copy of the Initial *IRB Noncompliance/Unanticipated Problem Report* and may take an action that may include, but is not limited to, one of the following:

- Require a response from the PI with a plan for corrective actions.
- Initiate audits of the active protocols involved.
- Require that research participants previously enrolled in the study be contacted and provided with additional information and/or re-consented.
- Require more frequent review of the study.
- Determine that the data collected cannot be used for publication.
- Report to the supervisor/department leadership.
- Report to the sponsor, administrative officials, and governmental agencies, e.g., FDA, OHRP.

Actions that involve suspension of research privileges or federal funding should be addressed by the VPCRA or the Chief Academic Officer.

### **D. Suspensions or Termination of IRB Approval**

If the convened committee determines the previously approved research is not being conducted in accordance with the IRB's requirements or that the research encountered new findings or new information that may have changed the risks/benefits assessment or if the incident represents serious and/or continuing non-compliance, the following actions may be taken: suspend or terminate IRB approval in accordance with 45 CFR 46.113 and 21 CFR 56.113. An IRB Chair or designee, or the VPCRA may immediately suspend the research if there is a clear concern regarding subject safety. Such actions must be reviewed by the next convened IRB.

### **E. Actions taken when Study Approval is Suspended:**

- Accrual of new research participants into the study will cease
- Currently enrolled research participants will be notified of the Suspension.

- All suspensions of subject accrual upon action of the VPCRA are Reportable Incidents and must also be presented at the next convened meeting of the IRB of record or to the Executive Session IRB.
- A study that has been temporarily closed to new participant entry can only be reopened following review by a convened meeting of the IRB of record or to the Executive Session IRB.

## **II. Procedure for Notification of Reportable incidents to the Institution and External Agencies/Government Departments**

### **A. Reporting Requirements Relating to Reportable Incidents**

The VPCRA or their designee will report each Reportable Incident to all appropriate Government Departments and Agencies by thirty (30) days after a verified incident is reported to the IRB or 30 days after an IRB has determined the validity of an alleged incident.

If, in the reasonable judgment of the VPCRA, or their designee, in consultation with the IRB Chair or a designee, a Reportable Incident involves a serious risk to research participants or to the integrity of the MD Anderson HRPP or, serious or continuing non-compliance, the VPCRA or designee will report the incident to all Designated Government Departments and Agencies as soon as reasonably possible after the original report of the incident is received. If the IRB has not completed its review of a Reportable Incident that the VPCRA, or designee, considers serious by the time the VPCRA, or designee, is ready to report. *The VPCRA, or designee, with the concurrence of the IRB Chair, may file an initial report with all Designated Government Departments and Agencies.* If an interim report is made, the draft interim report will be sent to the Office of Institutional Compliance for additional input. Once a final interim report is available, the VPCRA or designee will send the report to all Designated Government Departments and Agencies within a reasonable period.

The IRB may take immediate actions if the VPCRA does not address the non-compliance in a timely manner (i.e., that is within 30 days of a determination by the IRB that it is a reportable event).

The VPCRA, or designee, will send a copy of any interim or final report to the IRB, the Office of Human Subjects Protection (OHSP) Director, the PI, the PI's Department Chair and/or Division Head, the Chief Academic Officer, the Office of Institutional Compliance and other executive leadership as appropriate, concurrently with sending the report to all Designated Government Departments and Agencies. The VPCRA will distribute subsequent communications from the Designated Government Departments and Agencies to the IRB, the OHSP Director, the PI and the Office of Institutional Compliance, as appropriate.

## B. Information Included in Reports Relating to Reportable Incidents

Reports to all Designated Government Departments and Agencies under this policy will contain at least the information described in this section.

Initial reports will contain the information described to the extent it is available at the time of the report.

1. **Unanticipated Problems.** Reports of unanticipated problems involving risk to research participants or others should contain at least the following information:
  - Name of the Institution conducting the research.
  - FWA number
  - Title of the research project and grant proposal.
  - Name of the PI on the protocol.
  - Number of the research project assigned by the IRB and the number of any applicable Federal award(s) (grant, contract, cooperative agreement).
  - A detailed description of the problem.
  - Actions the institution is taking or plans to take to resolve the problem and to prevent future occurrences.
  
2. **Noncompliance.** Reports of serious or continuing noncompliance should contain at least the following information:
  - Name of the Institution conducting the research;
  - FWA number
  - Title of the research project and grant proposal;
  - Name of the PI on the protocol;
  - Number of the research project assigned by the IRB and the number of any applicable Federal award(s) (grant, contract, cooperative agreement);
  - A detailed description of the noncompliance;
  - Actions the institution is taking or plans to take to address the noncompliance.
  
3. **Study Suspension or Termination.** Reports of the suspension or termination of IRB approval of a study should contain at least the following information:
  - Name of the Institution conducting the research;
  - FWA number
  - Title of the research project and grant proposal;
  - Name of the PI on the protocol;
  - Number of the research project assigned by the IRB and the number of any applicable Federal award(s) (grant, contract, cooperative agreement);

- A detailed description of the reason for the termination or suspension; any actions the institution is taking or plans to take to address the suspension or termination.

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## REFERENCES

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45 CFR §46.103(b)(5)(ii)  
 45 CFR §46.113  
 45 CFR §46.116(b)(5)  
 38 CFR §46.103(b)(5)(i)  
 38 CFR §46.116(b)(5)  
 21 CFR §50.25(b)(5)  
 21 CFR §56.108(b)(l) and (3)  
 21 CFR §56.11 3  
 21 CFR §812.150(a)(l)

OHRP Guidance on Reporting and Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events, January 15, 2007

OHRP Compliance Activities: Common Findings and Guidance # 22, #71 (a)-(c) and (m)-(o), and #72

FDA Information Sheets: Continuing Review after Study Approval

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## SUPPORTING DOCUMENTS

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IRB Policy on Reporting Protocol Deviations, Protocol Violations and Unanticipated Problems, MD Anderson Human Subject Research Manual, Chapter 25

IRB Continuing Review of Research, Chapter 11

Date	Action	Initials	Description
05/23/2012	AWC	WQ/RF	Approved with minor modifications; must return to full board for review
07/25/2012	Approve	WQ/RF	Approved As Is
03/3/2019	Admin.	WQ	Administrative changes only