

## Suspension or Termination of Institutional Review Board (IRB) Approval of Research Procedure

### Scope

Applies to personnel of the Mayo Clinic Human Research Protection Program when suspending or terminating the IRB approval of Research.

### Purpose

To describe the steps taken when approval of research is suspended or terminated.

### Equipment/Supplies

N/A

### Procedure

Investigator	<ol style="list-style-type: none"><li>1. Cease research activities as specified in the IRB suspension notification until notified that the IRB has granted approval for resumption of the research activities, or in the case of termination, cease all research activities.</li><li>2. Notify subjects of the suspension or termination as directed by the IRB.</li><li>3. Report to the IRB any Adverse Event (AE) or Unanticipated Problems Involving Risk to Subjects or Others (UPIRTSO) that occur while the research activities are suspended.</li><li>4. Comply with all corrective action(s) as directed by the IRB.</li><li>5. Consider actions to protect the rights and welfare of study subjects; for example, arranging for medical care outside of the study or transferring subjects to another study.</li></ol>
IRB	<ol style="list-style-type: none"><li>1. Review any suspension or termination initiated by the sponsor or other outside entity.</li><li>2. Notify the investigator that research activities have been suspended or terminated and provide the rationale for their action.</li><li>3. Direct the investigator to undertake corrective action as appropriate. See IRB procedure, <a href="#">Review of Allegations of Noncompliance by an IRB Committee</a> for examples of possible corrective actions.</li><li>4. Direct the investigator to notify subjects of the suspension or termination as appropriate.</li></ol>

	<ol style="list-style-type: none"> <li>5. Review reports of UPIRTSO during the time in which research is suspended for cause.</li> <li>6. Report any Suspension for Cause or Termination for Cause to the Institutional Official and for federally funded research, also to regulatory agencies as appropriate. See IRB policy, <a href="#">Reporting to the Institutional Official and Regulatory Agencies</a>.</li> <li>7. Consider actions to protect the rights and welfare of study subjects; for example, arranging for medical care outside of the study or transferring subjects to another study.</li> </ol>
<p>IRB Medical Director, IRB Executive Committee, or convened IRB</p>	<ol style="list-style-type: none"> <li>1. The IRB Executive Committee or the IRB Medical Director, either individually or in conjunction with a convened IRB, makes a determination that approval of a research study must be suspended or terminated. <ol style="list-style-type: none"> <li>a. Decisions to suspend or terminate approval of research/research activities are documented in the electronic IRB (IRBe) system.</li> </ol> </li> <li>2. Informs the investigator that IRB approval of research is suspended or terminated.</li> </ol>
<p>Site Administrator</p>	<ol style="list-style-type: none"> <li>3. If the IRB Medical Director, Executive Committee, or convened IRB suspends or terminates IRB approval of research, the Site Administrator must be notified to initiate the research project's state change within the IRB electronic system. <ol style="list-style-type: none"> <li>a. Modify the "Current State" of the research project in the electronic system to 'Suspended' or 'Terminated' state.</li> <li>b. Notify the Office of Research Regulatory Support (ORRS)-Compliance of the suspension or termination. See IRB procedure, <a href="#">Issue Referral to Office Research Regulatory (ORRS) Compliance Team Procedure</a></li> <li>c. Generate a "Letter to PI" within IRBe notifying the investigator of the determination of the IRB.</li> </ol> </li> </ol>
<p>Office of Research Regulatory Support - Compliance (ORRS-C)</p>	<ol style="list-style-type: none"> <li>1. Upon receiving notification of the IRB determination to suspend or terminate research, ORRS-C will review and may initiate a Regulatory Review.</li> </ol>

## Troubleshooting

N/A

## Procedural Notes

N/A

## Related Documents

[Issue Referral to Office Research Regulatory \(ORRS\) Compliance Team Procedure](#)

[Reporting to the Institutional Official and Regulatory Agencies](#)

[Review of Allegations of Noncompliance by an IRB Committee](#)

[Suspension or Termination of Institutional Review Board \(IRB\) Approval of Research Policy](#)

## Definitions

**Suspension for Cause:** An action initiated by the IRB to stop temporarily some or all research procedures pending future action by the IRB or by the investigator or his/her designated personnel. Examples of a suspension for cause might include:

- Inappropriate involvement of human subjects in research
- Violation of the rights or welfare of human subjects or others
- Serious or continuing non-compliance with Federal regulations, IRB policies or institutional policies; or
- New information regarding increased risk to human subjects or others.

**Termination for Cause:** An action initiated by the IRB to stop permanently all research procedures

## References

N/A

## Owner

[Michelle K. Daiss](#) on behalf of the Office for Human Research Protection

## Contact

[Heidi M. Hanf](#)

## Revision History

Date	Synopsis of Change
11/09/2021	New procedure created by splitting instructions from policy (DOCMAN-0000047861). Updated Owner to Michelle Daiss.
10/11/2021	Approval for need to establish document: Institutional Review Board

# Content Information Stamp

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## Applicable Sites

**Arizona Sites:**  
Arizona

**Florida Sites:**  
Florida

**Rochester Sites:**  
Rochester, Kasson, Minneapolis, Northfield

**NW WI Region:**  
Barron, Bloomer, Eau Claire, Menomonie, Osseo, Chetek, Chippewa Falls, Glenwood City, Mondovi, Rice Lake

**SE MN Region:**  
Albert Lea, Austin, Cannon Falls, Faribault, Lake City, Owatonna, Red Wing, Adams, Ellsworth, Lake Mills, New Richland, Plainview, Wells, Zumbrota

**SW MN Region:**  
Fairmont, Mankato, New Prague, St. James, Waseca, Belle Plaine, Janesville, Le Sueur, Montgomery, St. Peter, Waterville

**SW WI Region:**  
La Crosse, Sparta, Arcadia, Caledonia, Holmen, Onalaska, Prairie du Chien, Tomah

## Reviewer(s):

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Michelle K. Daiss

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