

IRB Guidance for Investigators

Federal Stop-Work Directives

These guidelines are intended to assist investigators who may or have received a directive from a federal funding agency to stop, pause, terminate or otherwise prematurely end a human research study. Such orders can come in a variety of forms and are collectively referred to in this document as “stop-work” orders or directives.

What Should I Do If I Believe My Research Is at Risk for a Stop-Work Order?

- Evaluate whether your research can be modified to reduce the risk of a stop-work directive while maintaining its objectives
- Determine whether a sudden stop would put participants at risk (e.g., therapeutic studies)

If study participants would be AT RISK due to a sudden stop:

- Develop an Action Plan outlining steps that would be taken to safely wind down your research if necessary, considering factors such as:
 - The nature and severity of the risks to participants
 - Procedures that may be necessary for participants to safely stop (e.g., tapering meds, removing devices, labs and imaging, follow up assessments, referrals)
 - Alternative options for participants (e.g., arranging for therapeutic care outside of research)
 - Communication plans for:
 - Participants
 - Stakeholders (e.g., study personnel, collaborators, subcontractors)
 - Service providers (e.g., labs, imaging centers) and facilities where study activities take place (e.g., schools, clinics)
 - What will happen with study data and biospecimens (when applicable)
 - Participant compensation obligations
 - Work with your SPS Post Award Team to alert them of unavoidable costs due to participant safety

NOTE: For non-exempt research, Action Plans (other than the communication plans for stakeholders, service providers, and facilities) must be approved by the IRB prior to implementation. Action Plans should be submitted when a stop work directive is received. Alert your SPS Post Award Team if they are not already aware of the Stop Work order.

If study participants would NOT be at risk due to a sudden stop:

- Develop an Action Plan outlining steps that would be taken to safely wind down your research if necessary, considering factors such as:

- The current status of the research (e.g., open to enrollment, closed to enrollment but with active participants, follow up only, data analysis only)
- Managing scheduled visits or tests
- Communication plans for:
 - Participants
 - Stakeholders (e.g., study personnel, collaborators, subcontractors)
 - Service providers (e.g., labs, imaging centers) and facilities where study activities take place (e.g., schools, clinics)
- What will happen with study data and biospecimens (when applicable)
- Participant compensation obligations
- Work with your SPS Post Award Team to alert them of unavoidable costs obligations.

NOTE: For non-exempt research, Action Plans (other than the communication plans for stakeholders, service providers, and facilities) must be approved by the IRB prior to implementation. Action Plans should be submitted when a stop work directive is received.

- Contact the IRB office if you have questions or need assistance.

What Do I Do If I Receive a Funding Agency Directive to Stop or Pause Research?

- Notify Key Offices Immediately
 - Contact SPS (when not informed of the directive by SPS)
 - Contact your designated Post-Award Specialist:
 - [Storrs Post-Award](#)
 - [UCH Post-Award](#)
 - Contact the IRB (if the IRB of record is an external IRB, contact both the external IRB and the Storrs IRB office or UConn Health IRB office)
 - Storrs IRB Manager (karen.2.christianson@uconn.edu)
 - UConn Health IRB Manager (jblair@uchc.edu)
- Implement Your Communication Plans
 - Inform Stakeholders, Service Providers, and Facilities about the stop-work directive
 - Participant communication plans must be approved by the IRB for non-exempt research
- Mitigate Immediate Risks to Participants
 - If applicable, take any actions necessary to mitigate immediate risks to participants
 - Document and report those actions to the IRB
- Submit an amendment to the IRB with your Action Plan to safely wind down research activities (see prior section)