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HRP's Commitment to the Research Community

HRP stands with our clients and the broader research community as we navigate the evolving political and economic landscape, including sudden grant funding cuts. We are just a few weeks into this journey, and we expect that as some actions are put on hold while litigated, other actions will be quickly taken to achieve the aims of reducing federal research funding and eliminating funding for certain research altogether.

Today we are providing sample IRB guidelines for investigators with research at risk for stop or pause work orders in the hope that this will be helpful as institutions develop their own instructions and guidelines. Please feel free to distribute to your colleagues. We hope to provide additional guidance and tools over the coming weeks. If you have suggestions for other helpful resources, please let us know.

3/19/2025 – Updated to include reference to SACHRP recommendations, Data Management & Sharing and other responsibilities, ClinicalTrials.gov reminder, and other minor changes.

5/14/2025 – Updated to include considerations for when research activities will continue after the receipt of a funding termination notice and about research that has been covered under an automatic Certificates of Confidentiality.

Sample 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, or otherwise prematurely end a human research study.

1. What Should I Do If 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
- Explore alternative funding options, including any options for bridge funding to support the safe wind down of research activities or for continuing the research
    - *[If available insert links to resources]*
- Identify studies where a sudden stop would put participants at risk (e.g., therapeutic studies)
    - Develop an action plan outlining steps that would be taken to safely wind down your research if necessary, considering factors such as:

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- The nature and severity of the risks to participants
- Whether it is in the best interests of participants to continue some or all research procedures, if possible
- 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., making arrangements for therapeutic care outside of research)
- Participant compensation obligations
- 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)

- Develop action plans for studies where stopping would not put participants at risk, 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
    - Participant compensation obligations
    - 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)
- *[Include a link to any resources to help investigators plan]*

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

- Contact *[Insert name of grants office]*
    - *[Insert contact information]*
- Contact the IRB (if the IRB of record is an external IRB, contact both the external IRB and the *[Insert name of local IRB office]*
    - *[Insert contact information]*

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- Implement your communication plans for Stakeholders, Service Providers, and Facilities.
    - Participant communication plans need to be approved by the IRB for non-exempt research
- When applicable, take any actions necessary to mitigate immediate risks to participants and then 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) or to continue it without the terminated federal funding
- Clarify ongoing Data Management and Sharing and other grant responsibilities with your program officer
- If applicable, update the study's ClinicalTrials.gov record to reflect the change in funding and status of the research

3. What should I do if I receive a directive to modify the research to avoid termination?

- Work with your Program Officer to make the necessary changes and then submit the changes as an amendment to the IRB of record if the changes impact any IRB forms or IRB-approved materials (e.g., changes to a demographic survey, changes to inclusion/exclusion criteria).

4. What should I do if I receive a termination notice but plan to hold off on winding down study activities?

If the termination will be appealed, if funds will be requested from the agency to support the safe and orderly closeout of the research, or if bridge or alternative funding is being sought from other sources:

- Review your approved research plan and study materials to determine whether any immediate changes are needed.
- Develop a Preliminary Action Plan providing information about the status of the research and describing the steps you will be taking in the interim, for example:
    - Information about your plan to appeal or seek funding, including any information that you have about the timeline for the appeal or funding and how costs will be managed in the interim.
    - Description of study status (e.g., open to accrual, closed to new enrollments, etc.)

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- Description of participant status (i.e., how many participants are currently enrolled and in what stages of the study are the participants)
- Whether, in your judgment, it is in the best interests of active participants to continue with certain study activities, which study activities should continue for this reason, and the risks of not continuing with those activities
- Any actions you have already taken to mitigate risks to participants (research regulations allow investigators to take actions necessary to mitigate apparent immediate risks to participants as long as those actions are promptly reported to the IRB)
- Any proposed communication plan with participants about what is occurring
- When the [Insert Institution name] IRB is the IRB of record for collaborating sites/investigators, the plans for each of these sites.
- Any other information that you think is important for the IRB to be aware of.

- Submit the Preliminary Action Plan along with the following materials to the [Insert Institution name] IRB as an *[Insert submission form/type]*. If the study is overseen by an external IRB, contact the external IRB for instructions.
  - Any revisions that are proposed to the IRB-approved research plan and study materials
  - A copy of the termination notice
  - Copies of any scripts, emails, or other planned communications with participants

5. What should I do if I plan to continue the research without the federal funding support?

- Review your approved research plan to determine whether any changes are needed. Areas that may need attention include:
  - Any written materials that refer to the funding source (e.g., application form, protocol, consent materials, recruitment materials)
  - Data Sharing and Management Plan
  - Provisions to protect the confidentiality of participant information and who has access to review or audit research records
    - See Certificates of Confidentiality section below for additional considerations

- Subject Injury Language, particularly if a new sponsor has been identified
- Provisions for participant compensation

6. What about Certificates of Confidentiality?

Certificates of Confidentiality (CoCs) may be either **automatic**—granted by virtue of funding from agencies such as the NIH, CDC, FDA, BARDA, or HRSA—or **discretionary**, meaning they are voluntarily requested and approved by the NIH or certain other federal agencies.

An **automatic CoC** expires when funding from the granting federal agency ends. While protections provided by a CoC continue in perpetuity for information already collected or used, **they do not extend to any new information collected** from or about already enrolled participants or from **new participants** enrolled after funding ends.

To maintain CoC protections for new data collection or for newly enrolled participants after the expiration of an automatic CoC, investigators must apply for and receive approval for a **discretionary CoC**.

- As of the time of this guidance, the NIH application system for discretionary CoCs is unavailable, with an expected update promised by July 2025. However, the FDA continues to accept applications for discretionary CoCs for studies that fall within the scope of its policy: FDA CoC Guidance.

Investigators with automatic CoCs who lose funding and intend to continue enrollment with new participants must submit an amendment to the IRB to update their consent materials (when consent is being obtained). This includes consent information in alternative formats such as emails, letters, information sheets, and scripts. Investigators may also need to revise other parts of their research plan that reference the CoC and take steps to strengthen their data security plan.

Investigators with automatic CoCs who plan to continue data collection with existing participants must submit an amendment to the IRB with a plan to inform those participants about the loss of the CoC and explain its implications, provided that consent was obtained, and participant contact information was collected. Investigators may also need to revise other parts of their research plan that reference the CoC and take steps to strengthen their data security plan.

Please consult with the IRB office *[Insert contact information]* if you have questions about the specific requirements for your study. If your study is under the oversight of an external IRB, please consult with the external IRB office or POC.