**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.

**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
  + *[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:
    - The nature and severity of the risks to participants
    - Whether it is in the [best interests](https://www.hhs.gov/ohrp/sachrp-committee/recommendations/interpretation-of-best-interests-standard-for-retention-of-human-subjects-research/index.html) 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]*

1. **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]
* 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)
* Clarify ongoing Data Management and Sharing and other grant responsibilities with your program officer
* If applicable, [update](https://clinicaltrials.gov/submit-studies/prs-help/how-edit-record) the study’s ClinicalTrials.gov record to reflect the change in funding and status of the research