1. PURPOSE

1.1 The purpose of this Policy is to describe the impact on and continuity parameters for clinical research that is funded by the National Institute of Allergy and Infectious Diseases (NIAID), Division of Microbiology and Infectious Diseases (DMID) in the event of a US Federal Government Shutdown.

2. SCOPE

2.1 This policy applies to all DMID-funded clinical studies or clinical trials and the involved DMID staff when a federal government shutdown is in effect.

2.1.1 Partial shutdowns may occur that only affect some federal departments and agencies, but not all. In the event of a partial federal government shutdown, this policy applies to when the shutdown impacts the US Department of Health and Human Services (HHS).

2.1.2 The US Office of Personnel Management (OPM) may close federal offices, delay arrival, or give early departure for weather or other reasons. This is not considered a federal government shutdown and is not covered by this policy.

3. DEFINITIONS

3.1 Federal Government Shutdown: A shutdown furlough (also called “shutdown”) occurs when there is a lapse in annual appropriations. Shutdown furloughs can occur at the beginning of a fiscal year if no funds have been appropriated for that year, or upon expiration of a continuing resolution if a new continuing resolution or appropriations law is not passed.

3.2 Excepted employees: In the context of shutdown furloughs, the term “excepted” is used broadly to refer to employees whose work is funded through annual appropriations but who are not furloughed because they are performing tasks that, by law, are allowed to continue during a lapse in appropriations.

- The term “excepted employees” is different from “exempt employees” (used in reference to the Fair Labor Standards Act) and “emergency (or essential) employees” (those employees who must report for work in emergency situations, e.g., severe weather conditions, etc.).

3.3 Furlough: Placement of an employee in a temporary non-duty, non-pay status because of lack of funds.

3.4 Recall: Notification of a furloughed employee to return to work and perform excepted activities.

For additional definitions, see DMID glossary.

4. RESPONSIBILITIES

4.1 The DMID Office of the Director (OD) is responsible for communicating shutdown notices to Division staff.

4.2 The DMID Associate Director for Clinical Research (ADCR) will ensure the appropriate coverage of responsibilities related to DMID-funded clinical studies and clinical trials within DMID when a federal government shutdown is in effect.

4.3 DMID staff are responsible for following all federal government shutdown procedures.

5. POLICY

5.1 As a lapse in federal funding does not immediately affect funded contracts or grants, it is anticipated that DMID-funded clinical research activities will continue at the time of a federal government shutdown.

5.1.1 It is anticipated that the NIH Office of the Director (OD) will provide guidance on work being performed under grants and cooperative agreements.

5.1.2 It is anticipated the NIAID Division of Extramural Activities (DEA) Office of Acquisitions will provide guidance on work being performed under contracts.

5.2 DMID will propose excepted employees to ensure that clinical studies and trials can be conducted with no increase in risk to participants or to the scientific or data integrity of the clinical research.

5.2.1 These activities fall into the HHS categories of exception:

- Staff performing activities authorized by necessary implication – support of funded activities.
- Safety of human life – activities other than direct medical services.

5.3 The following is the default plan for coverage during a shutdown.

IND/IDE Clinical Trials

Type of Trial	Grant	Cooperative Agreement	Contract
IND/IDE held by DMID	See 5.8	See 5.8	See 5.8
IND/IDE held by another entity	See 5.7	See 5.7	See 5.7

Non-IND/IDE Clinical Trials and Clinical Studies

Type of Trial/Study	Grant	Cooperative Agreement	Contract
Clinical Trial: High Resource	See 5.6	See 5.6	See 5.6
Clinical Trial: Low Resource	No Coverage See 5.5	No Coverage See 5.5	No Coverage See 5.5
Clinical Study (not a trial): Higher Risk Procedure	No Coverage See 5.4	No Coverage See 5.4	No Coverage See 5.4
Clinical Study (not a trial): Not High Risk	No Coverage See 5.4	No Coverage See 5.4	No Coverage See 5.4

5.4 For a clinical study (not a clinical trial) regardless of funding type, clinical research activities can continue during a government shutdown without any input from DMID staff.

5.5 For a low-resource non-IND clinical trial regardless of funding type, clinical research activities can continue during a government shutdown without any input from DMID staff.

5.6 For a high-resource non-IND clinical trial regardless of funding type, the grantee or contractor has the primary responsibilities for oversight of the trial during a government shutdown. DMID will ensure there is a person identified to answer general questions about study implementation and safety reporting.

5.7 For an IND (or equivalent) clinical trial where the IND holder is not DMID, regardless of funding type, the sponsor has the primary responsibilities for oversight of the trial during a government shutdown. DMID will ensure there is a person identified to answer general questions about study implementation and safety reporting, as well as support for progress towards trial implementation (i.e., clinical project manager and program officer roles).

5.8 For an IND (or equivalent) clinical trial where the IND holder is DMID, regardless of the type of funding:

5.8.1 DMID will ensure there are excepted/recalled DMID staff to cover the following roles (generally 3 people):

- A person knowledgeable about the trial as the contact for medical and study implementation questions.
- A person as the contact for all human subjects and safety related issues including serious adverse event reporting.
- A person as the regulatory contact for enquiries from the US FDA or other regulatory bodies including international regulatory agencies.

5.8.2 Based on the anticipated activity and complexity of the trials, DMID will decide if representation from the primary DMID team is needed or if cross coverage is sufficient.

5.8.3 Protocols still in development will be assessed as to the public health need to complete development during a shutdown.

5.8.4 For active trials, enrollment and operational calls are anticipated to continue. In general, new protocol and amendment finalization, sign-off, site training, or site activation will not occur during a shutdown (as these activities usually take engagement of the full team at DMID). Protocols that are anticipated to need these activities during a shutdown should be brought to the attention of the DMID Associate Director for Clinical Research (ADCR).

5.9 DMID staff should contact the DMID Associate Director for Clinical Research (ADCR) at least three days prior to an anticipated shutdown should any coverage different than the default coverage be needed.

5.10 At the time of a shutdown, for all clinical studies and trials:

5.10.1 It is anticipated that the NIH Office of the Director (OD) will provide guidance on work being performed under grants and cooperative agreements. In the absence of specific guidance, all work and activities being performed under currently active NIH grant awards (including cooperative agreements) may continue through the funded grant period. Grantees should consult the most recent NIH guidance when available.

5.10.2 It is anticipated the NIAID Division of Extramural Activities (DEA) Office of Acquisitions will provide guidance on work being performed under contracts. In the absence of specific guidance, all work and activities being performed under contract may continue as planned through the funded period of performance unless notified otherwise by the Contracting Officer (CO). Contractors should contact the NIAID DEA CO for any questions.

6. REFERENCES

6.1 DMID-GA-SOP-00001 Federal Government Shutdown Procedure

6.2 OPM Operating Status

6.3 OPM Policy, Data, Oversight-Guide to Processing Personnel Actions

6.4 OPM Guidance for Shutdown Furloughs

6.5 FY 2024 HHS Contingency Staffing Plan for Operations in the Absence of Enacted Annual Appropriations

6.6 NIH Office of Human Resources FAQ: Dismissal and Closures

7. APPENDICES

Not applicable

8. REVISION HISTORY

8.1 Revision 02, effective 18 Jan 2024, is the original enacted version of this policy.

8.2 Revision 03 updated the table in 5.3 for Section 508 Compliance.

9. ADDITIONAL INFORMATION

9.1 Document Lead: Associate Director for Clinical Research

9.2 Posting externally: Yes