

## Process for Requesting Exemption to Maintenance Phase

How do you know if the research you would like to do is mission critical and therefore subject to exemption?

The exempted mission-critical functions are listed below:

1. Care and laboratory work related to the care of non-elective research subjects on NIH clinical protocols
2. Research directly on COVID-19
3. **Urgent Public Health Research, recommended by the CD/SD/IC Director and approved by a research subcommittee of the NIH COVID-19 Response Team\***
4. ***Significant*<sup>#</sup> research investments that could be lost if research is not continued, also recommended by CD/SD/IC Director and approved by a research subcommittee of the COVID-19 Response Team\***
5. Protection of life/property/resources (e.g., safety, security, animal care, property management)†

To request an exemption, please address the questions below:

1. The PI should determine what research is considered mission critical (see definition above). Projects that do not entail any activity on any NIH campus nor any direct human physical contact do not require approval by the Lab Maintenance Subcommittee.
2. For all potentially exempt research projects (including those within categories 3 and 4) the PI should then work with their SD to develop a Continuing Research Exemption Request (see form below)
3. Their SD with ICD approval will submit the request to the Lab Maintenance Subcommittee of the COVID-19 Response Committee for review at [NIH\\_COVID-19\\_LAB\\_MAINTENANCE@LIST.NIH.GOV](mailto:NIH_COVID-19_LAB_MAINTENANCE@LIST.NIH.GOV)
4. The subcommittee will review the request as quickly as possible and notify the ICD/SD of the result within 48 hours

## Criteria for Determining Criticality of Research/Approving Continuing Research

The Lab Maintenance Subcommittee will review all requests for exemptions to the minimal maintenance phase by considering the following criteria:

- Time-sensitivity, including duration of experiment(s) to be completed and urgency of completion of experiments; please indicate if there is a logical “stopping point” for the experiment (e.g. samples are collected, but then can be stored for future analysis without compromising the validity of the work)
- Complexity of experiments (e.g., how many people need to be in the lab at a given time to complete the experiment safely/effectively)
- Loss of resources (e.g., dollars, animals, time, etc.)
- Public health impact (distinguish between direct and immediate impact versus future/aspirational impact)

- Feasibility of experiments (e.g., given other labs/facilities will be operating at a reduced capacity/capability)
- Need for use of core facilities and other infrastructure (e.g. will the work put additional burden on other units at NIH, particularly the CC).

Requestors should take care to address each of the criteria in the submitted form, so that the subcommittee can effectively evaluate each request.

Please note that, for experiments that require multiple people in the lab at a given time, the PI must have approval from and work with their SD to ensure the safety of the individuals.

Projects that do not entail any activity on any NIH campus nor any direct human physical contact are exempt and do not require approval by the Lab Maintenance Subcommittee.

\*The review team will include: Steve Holland (chair), Michael Gottesman, Alfred Johnson, Hilary Marston, Tara Schwetz, Larry Tabak, and Carrie Wolinetz

#While each situation will be unique, as a rule of thumb, exceptions are likely to be investments that have taken years, as opposed to months, or involve truly unique resources that are not replaceable

†The intent is to stabilize research environments and protect significant investments – NOT begin new studies.

**Request for Continuing Research Exemption**

Date: IC: Requestor:

Lab/Branch:

Lab/Branch Chief: Scientific Director:

**Request Title:**

COVID-19 Related: Explain

Human Subject Related: Explain

Animal Care Related: Explain

Urgent Public Health Research: Explain

Significant Research Investments: Explain

Other (critical materials, time-sensitive, safety etc.): Explain

Delineation of Exempt Lab Member Roles, Days/Times in the Lab, and Duties: