

## NIH sIRB POLICY IN THE CONTEXT OF THE INTRAMURAL RESEARCH PROGRAM

### New Process for Requesting Exceptions to the NIH Single IRB Requirements

On October 8, 2020 the Office for Human Research Protections (OHRP) issued [an exception to the single IRB \(sIRB\) review requirements for cooperative research conducted during the COVID 19 pandemic](#) – these are studies initiated on or after January 21st, 2019 that involve more than one institution engaged in human subjects research. The rationale for this exception is that in some instances, seeking sIRB approval may not be the most practical or appropriate review mechanism.

The exception applies to cooperative research:

1. that is ongoing or initially reviewed by the IRB during the Coronavirus Disease 2019 (COVID-19) public health emergency, as declared by the Secretary of Health and Human Services at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>;
2. where reliance on a single IRB would not be practical; and
3. for which the HHS division supporting or conducting the research approves of the use of this exception.

Refer to the [OHRP announcement](#) for greater detail and specific examples of the applicability of this exception.

To harmonize with the OHRP exception, NIH issued a notice ([NOT-OD-21-006](#)), providing information on how NIH is implementing the exception for research conducted or supported by NIH.

Requests by intramural researchers to utilize the exception must include a justification as to why the study meets the exception criteria defined by OHRP. The NIH Principal Investigator will provide the following information to Ms. Shirley Rojas at [shirley.rojas@nih.gov](mailto:shirley.rojas@nih.gov) and the NIH Office of IRB Operations (IRBO) at [IRB@od.nih.gov](mailto:IRB@od.nih.gov):

1. Study title
2. Study number if already submitted to the NIH Intramural IRB
3. PI name
4. Funding source for all other Participating Sites
5. Nature of the sIRB exception request and justification

The NIH Office of the Director (OD) will review all exception requests and will notify the IRBO of the determination. Note that NIH anticipates that the use of this exception will be rare.