

**COLUMBIA UNIVERSITY IRVING MEDICAL CENTER  
HUMAN RESEARCH PROTECTION OFFICE**

**POLICY ON RESUBMISSION OF PROTOCOLS AFTER 60/90 DAYS**

**SCOPE:**

This policy applies to Protocols submitted in Rascal for review by a Columbia University IRB (CU IRB) or the Administrative Review Committee (ARC), which is comprised of Human Research Protection Office (HRPO) staff and is responsible for making exempt and 'Not Human Subjects Research' (NHSR) determinations. It does not apply to Protocols for which CU is relying on an external IRB for review.

**EFFECTIVE DATE:** August 27, 2014; updated May 11, 2023

**BACKGROUND:**

A Protocol (Event type) is the electronic package consisting of the IRB application and related documents that is submitted in Rascal to obtain IRB approval or an exempt or NHSR determination for a new study.

During the review process, Protocols may be returned to investigators following administrative pre-review by HRPO staff, following regulatory review by an IRB member or a convened IRB, following review by an ancillary review committee such as the Institutional Biosafety Committee or the Human Use Subcommittee of the Joint Radiation Safety Committee, or at the request of the study team. Each Protocol is assigned to a committee, such as IRBs 1-5 or Exp for non-exempt human subjects research, or Admin for exempt and NHSR projects.

Resubmissions of Protocols after several months require additional considerations for the IRB administrative and regulatory reviews, including confirmation of adherence to potential new requirements, e.g., as a result of new or revised policies, laws, and regulations. A fresh look at the Protocol is required.

**POLICY**

A policy has been implemented whereby resubmissions of Protocols will only be accepted within:

- 60 calendar days of the return for Protocols assigned to the Admin Committee or IRB Exp
- 90 calendar days of the return for Protocols being reviewed by IRBs 1-5

New protocols for which the applicable interval has passed must be withdrawn in Rascal.

If the investigator wishes to pursue IRB approval to conduct the study, a new protocol must be submitted in Rascal. Before withdrawing the initial protocol from Rascal, it is recommended to use the "Copy Protocol" option available under the "Protocol Actions" menu.

## **PROCEDURES**

Before submitting the new Protocol:

1. In the General Information page:
  - a. Answer “yes” to the question “Was this protocol previously assigned a number by an IRB”.
  - b. Add your previously issued IRB protocol number (i.e., ABCD1234) to the “Previous protocol number” field (this field appears when you answer “yes” as instructed in item a above).
2. If you created the new Protocol by copying the previous Protocol, review all information that has been entered to be sure that it is complete, current and accurate.
3. Review the Researcher Tasks from the previous Protocol to be sure that each one has been addressed in the new Protocol. Provide correspondence or attach a file that describes how each item was addressed.