**COLUMBIA UNIVERSITY IRVING MEDICAL CENTER**

**HUMAN RESEARCH PROTECTION OFFICE**

**GUIDANCE on CHANGES IN PRINCIPAL INVESTIGATOR**

**SCOPE OF GUIDANCE:**

This policy applies to all changes in Principal Investigator (PI), e.g., if the previously approved PI (the “current PI”) is being removed from the Personnel list or will remain among Personnel but will have a different role.

**EFFECTIVE DATE:** June 1, 2022

**BACKGROUND:**

It is a regular occurrence for there to be a change in PI for an IRB-approved study. Written guidance is necessary to provide research personnel with the information that is needed when such a change is proposed, to avoid returns of the Rascal Event through which the change is proposed.

**GUIDANCE:**

When a change in PI is proposed, submission via Rascal of a Modification Event or a Renewal Event with the proposed change described in the modification summary is required. The Event must include, as applicable:

1. The Personnel page updated to reflect the proposed change(s);
2. If the current PI will be removed from the Personnel list, a written statement from them, e.g., a signed letter, or an email, transferring the overall responsibility of the study to the proposed PI, as an attachment;
3. In the event that the current PI will be removed from the Personnel list and is not available to provide the written statement, a signed letter or email from the applicable department Chair or other unit head, authorizing the change in PI;
4. If the current PI will have a new role, the Personnel page updated to reflect such role;
5. Revised study documents to update the PI name and contact information;
6. A plan for notifying currently enrolled subjects of the change in PI e.g., Information Sheet or Consent Form Addendum. The documents to be used for such notification must also be provided.