COLUMBIA UNIVERSITY
HUMAN RESEARCH PROTECTION OFFICE
INSTITUTIONAL REVIEW BOARDS

GUIDANCE ON CHANGES IN PRINCIPAL INVESTIGATOR

SCOPE OF GUIDANCE:
This policy applies to all changes in Principal Investigator (PI), e.g., whether 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; revised October 2, 2023

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 new PI is from a department other than the one currently listed in the General Information page, the *Originating Department Code in the "General Information" page/tab should also be updated to list the new PI's department as the Originating Department.
3. 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;
4. If 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;
5. If the current PI will have a new role, the Personnel page updated to reflect such role;
6. Revised study documents to update the PI name and contact information;
7. A plan for notifying currently enrolled subjects* of the change in PI e.g., email, hard copy letter, Information Sheet or Consent Form Addendum. The documents to be used for such notification must also be provided. The plan should include clear indication as to whether documentation of receipt or acknowledgement of the notification is expected, and follow up procedures if such is expected but not received. The type and status of the study will impact whether documentation or acknowledgement is necessary, e.g., requirements may be different for an interventional clinical trial with active study visits vs the same study in data analysis phase; similarly, requirements may differ for a one-time online survey study vs a study that proposed return of genetic results.

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*Currently enrolled subjects are defined as subjects who have not completed the study, and therefore will include subjects who are in active treatment (if relevant) and those in long term follow up because there is still interaction with the study team.

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