

PRINCIPAL INVESTIGATORS TAKING A LEAVE OF ABSENCE, SABBATICAL, OR MOVING TO ANOTHER INSTITUTION

Principal Investigators (PIs) are responsible for timely closure of studies or transfer of PI responsibilities in the event of their absence for medical or family leave, sabbatical, or move to another institution.

In the event of a temporary absence, for example a 6 week medical leave where a complete return to duties is expected, it is acceptable to indicate that a co-investigator will take over PI responsibilities in the interim, without a formal change of PI. In the event of a leave of absence for 3 months or longer (for example, a year long sabbatical in another country or to take another full time position elsewhere "on leave"), a qualified on-site PI must be formally appointed by amendment to your project. The new PI must be willing to assume all PI responsibilities, a division chairperson must sign off on this transfer of responsibility, and a formal amendment must be submitted to the IRB offices. Conflicts of interest issues and conflicts of commitment should be considered. You should contact Grants and Contracts, because NIH mandates an interim or new PI for absences of 3 months or longer as well. Please also consult with your agreement associate in the Partners Clinical Research Office if your study is funded by industry. The PCRO agreement associate will determine if an amendment to the agreement or formal notification in writing is needed.

When a PI is leaving the institution, s/he is required to arrange timely transfer of responsibilities to the new institution, or, if relevant, within the institution. This is of special importance in clinical research studies which include medical treatment interventions. It is rarely possible to transfer subjects on a specific protocol to the same active protocol at a new institution. If this is not feasible, a new PI should be named to complete the study at our hospitals. Investigators should work with division and departmental chairs to ensure a careful transfer of responsibilities and care of subjects. Alternatively, it may occasionally be necessary to stop subjects' participation and transition them to new clinical care providers. These activities should be undertaken putting the interests of subjects/patients first. These activities should be completed BEFORE you leave the institution.

It is possible to allow departing staff and fellows access to data to complete publications as outlined formally at this site:

http://healthcare.partners.org/phsirb/Guidance/Policies_Procedures/Policy_Partners_Investigators_Leaving_Institution.1.09.pdf

PIs should contact the IRB offices directly for advice related to specific protocols in situations where they may be absent from the institution. We are happy to speak with you personally and advise you. Investigators should work with their divisions, departments, and grants management on the appropriate transfer of research records and funds.

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