

HRB Policy for change of Principal Investigator

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Purpose

This policy is intended to document the process required for a leading Host Institution to request a change of Principal Investigator or co-Principal Investigator on HRB awards.

As per HRB's General Terms and Conditions, the Host Institution must notify the HRB if there is any change in the status of Principal Investigator (PI) who hold active HRB awards or co-Principal Investigators (co-PI) named on awards. Any change to a PI or co-PI must be approved by the HRB in advance of assuming responsibility for overseeing research and/or research personnel supported by the HRB.

Procedure

Requests for approval to change Principal Investigator (PI) on either a single PI or co-PI HRB award must be sent to the relevant Programme Manager in the HRB for their consideration/approval, typically **no later than three months before any change** is due to take effect.

The written request should be signed by the authorised award contract signatory in the lead Host Institution (typically the Vice President for Research (or equivalent)) and any key parties to the original application should be included in copy, as appropriate (e.g., co-applicants, senior representative from hospital management where the award spans the academic and hospital system, other institutional partners on a collaborative national training programme).

The HRB **will not** process any variation requests which are submitted after the end date of the grant. In such cases, all HRB funding remaining unspent at the end date of the grant must be returned to the HRB

The (lead) Host institution's submission should, at a minimum, contain the following information:

- The background for the request, providing an explanation as to why the existing PI/co-PI is stepping down or why their status is changing
- Confirmation of when the change is proposed to take effect and the plans (and timelines) for an interim and/or permanent replacement, as appropriate
- A description of the impact that their departure will have on the operations or research
 activities of the award, as well as any steps being undertaken to manage or mitigate this
 risk. This should include, but not be limited to, a consideration of any regulatory and/or
 indemnity matters arising for the project from the change, if relevant
- A description of any (temporary or enduring) changes to scope, deliverables and budget resulting from the change in PI or co-PI
- A description of any proposals to ensure continuity in the supervision and training of staff or PhD trainees associated with an award
- The CV of the proposed replacement, to show that they meet the eligibility criteria of the original funding opportunity (as outlined in the original call Guidance Notes)
- A description of the role and responsibilities of the proposed replacement, if different from the incumbent, and details of any resultant changes to roles and responsibilities of co-applicants and partners
- Assurances that the proposed new PI or co-PI has the necessary responsibility and authority for research activities at the Host Institution and authorisation to commit institutional funds and resources
- A statement from the proposed replacement that they are prepared to act as PI or co-PI
 on the award, and will assume the responsibilities for the award that are attached to
 that role
- Assurances that other key parties to the award are aware of and are supportive of the request being made (e.g., co-PIs, sponsors, co-applicant steering groups)
- Any additional pertinent information

Approval

The HRB may approve this change without peer review of the new leadership team and Leadership Plan. The HRB reserves the right to seek independent peer review of the new leadership team and Leadership Plan.

If this process is initiated close to the proposed change and/or if the deliberations are protracted, the HRB may mitigate interim risks by pausing an award, pending completion of the review approval process.

If HRB denies a request, it will give its justifications for the rejection. The lead Host Institution for the award may be able to revise their proposal based on HRB feedback, and in the exceptional circumstance where a solution cannot be found that is acceptable to the HRB, the award may be terminated.