

Addition or Deletion of an Investigator in an Ongoing Project:

There may be situations requiring addition or deletion of certain investigators in an ongoing research project. These shall be controlled and permitted under strict conditions. It is also important to ensure the change is appropriate and based on a need genuine for the conduct of the project. Under no circumstances, a new investigator can be added as investigator after the completion of the project.

Completion of a research project is defined as completion of all experiments, pre-defined data collection or compilation and data analysis.

Eligibility:

She/he shall be a staff of the institution preferably an academic staff related to the department /division of research proposal.

For addition of a new investigator to existing research project

1. The addition is essential for- experiment/data collection/compilation, analysis
2. For replacement of an investigator
3. Student or staff genuinely involved in the research project conceptualization, but missed out initially while submitting the proposal to IRB

Process:

The reason for the addition should be clearly mentioned in the communication to IRB by the PI. If PI is a student, Co-PI if a faculty shall submit the request in the prescribed format and the following shall be submitted

1. Consent of the investigator to be added
2. Consent of the HOD of the department to which the new investigator belong
3. Consent of other investigators
4. Conflict of interest declaration form to be signed by the new investigator

Annexure 1

It shall be presented in the SRC and IEC for approval. The approval shall be informed to the PI and the name of the new investigator shall be added to the project by the IRB office. The communication shall be sent to the new investigator too. Communication shall be as email and hard copy (Annexure -2)

If an external person is to be added, there shall be an initial permission from the administration with reasons submitted. The reason for the suggestion should be spelled out and the person shall be from an institution with which a research MoU exists. If it's a multicentric study (more than one centre in addition to MCC), the permission of all centres involved shall be obtained and the addition shall be informed to IRB. The concerned person shall provide a letter

Removal of an investigator:

Under following conditions an investigator shall be removed from the project

1. Resignation from the institution
2. PI confirms the noncompliance to the research proposals/protocols
3. Non-cooperative
4. Inability to deliver the required contributions to the project
5. Request from the investigator to be removed
6. Disciplinary action due to research related or professional misconduct

An appropriate replacement shall be suggested by head of concerned department.

REQUEST FOR ADDITION OR REMOVAL OF AN INVESTIGATOR

Title of the project:

IRB Number

Date of approval

Principal investigator/ Co-PI:

Name of new Investigator:

Designation:

Department/Division:

The reason for addition:

1. The addition is essential for- experiment/data collection/compilation, analysis
2. For replacement of an investigator
3. Genuinely involved in the research project conceptualization, but missed out while submitting the proposal to IRB

Assigned role in the project:

The reason for removal of the investigator:

1. Resignation from the institution
2. PI confirms the noncompliance to the research proposals/protocols
3. Non-cooperative
4. Inability to deliver the required contributions to the project
5. Request from the investigator to be removed
6. Disciplinary action due to research related or professional misconduct

Consent of the new investigator:

I herewith consent to be included me as a Co PI/ Co-investigator in the project titled.....
with IEC-IRB number.....dated.....

Signature:

Name:

APPROVAL OF HEAD OF DEPARTMENT

The matter has been discussed in the department and the suggestion is accepted

Signature of HOD:

Name:

Seal:

Consent of the investigators in the project:

Name	Status in project	Consent- Yes /No	Signature

OFFICE OF INSTITUTIONAL REVIEW BOARD:

Approval of Scientific committee:

Date of approval:

Approval of IEC :

Date of approval:

Annexure-2

Dear,

The request for adding Mr./Ms./Dr..... as PI/ Co-PI/ Co-I for the project titled

..... IEC No..... approved on.....is duly evaluated and approved/rejected by Scientific committee on..... and Institutional Ethics Committee..... on..... The new investigators name is added to the project.....

Member secretary IRB/IEC

Copy to:

- 1.IRB Office
2. New investigator