Adding External Study Personnel to KUMC Studies

Is the person involved in human subjects research activities? (interacts or intervenes with a living individual, or uses the individual’s identifiable data or specimens for research purposes)

- yes
  - Submit modification for approval of new site, not the individual.
    1. Ensure study protocol lists the external site
    2. Enter the external site in the Scope / External site screen
    3. Upload copy of external site IRB approval letter and consent form(s), if applicable, in the Supporting Documents screen
    4. IRB will confirm that the consent reflects KUMC involvement and KUMC receipt of data
    5. No individual affiliate accounts are needed for persons covered by their home IRB

- no
  - Not affiliated with an institution w/ an IRB*
    - Other IRB wants to rely on KUMC
      - Contact HRPP to initiate an Unaffiliated Individual Agreement
    - Other IRB wants to rely on KUMC
      - Contact HRPP to initiate an IRB Reliance Arrangement

Is the person covered by the IRB at his/her home institution FOR THIS STUDY?

- yes
  - Submit modification to
    1. add individual as a study team personnel AND
    2. add the external site to the study (if applicable)

- no
  - No action needed

Person will provide proof of CITI or NIH Human Subjects training. Must complete KUMC COI

PI’s Department account requestor submits request for affiliate account and eCompliance access for the person

*please note: volunteers not associated with an IRB will need to meet additional department requirements prior to starting research activities. These requirements can be found here: [http://www.kumc.edu/Documents/hr/Volunteer%20Policy81a.doc](http://www.kumc.edu/Documents/hr/Volunteer%20Policy81a.doc)

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