Rochester Epidemiology Project: Approval and Training for Researchers

Noted below is the required process to become a research collaborator eligible to utilize the resources of the Rochester Epidemiology Project (REP)

Rev: April 25, 2013

A researcher from outside of Mayo Clinic must first go through the following steps:

- Submit study protocol to the REP Executive Committee for review and approval.
- Obtain a REP sponsor who will be internally responsible for the research.
- Once approved by the REP Executive Committee and by the sponsor, the outside researcher must apply for a "research collaborator" appointment at the Mayo Clinic. This rigorous process applies to all research collaborators at Mayo Clinic, and is not exclusive to the REP.
  - Qualifications to apply for a research collaborator appointment include:
    - PhD, MD, or equivalent doctoral degree in a field deemed relevant
    - In some instances, a bachelors or master's degree may also be adequate
      - The application for an appointment requires:
        - 3 letters of recommendation from scientific colleagues
        - curriculum vitae (a record of training, experience, and publications)
      - The completed application packet is submitted to the Mayo Clinic Research Personnel Subcommittee for approval. This is the same committee that evaluates all of the appointments and promotions of Mayo Clinic researchers.
      - If approved, the research collaborator must pass a "background check."
      - Average time to approval is 3-6 months
- Each research collaborator is subject to annual review and approval by the REP sponsor and the Mayo Clinic Research Personnel Subcommittee.
- Once officially identified as a Mayo Clinic Research Collaborator, the following steps must be completed.

All researchers must go through the following process after obtaining a Mayo appointment:

- Write a study protocol and submit protocol to scientific colleagues for review (unless already done above).
- Submit protocol to both the Mayo Clinic and Olmsted Medical Center Institutional Review Boards (IRB).
- The researcher is required to complete Human Subjects Protection training and HIPAA (privacy) training. This involves taking online courses and passing an exam.

- If approved, the researcher will receive special training on how to use the REP browser (computer software to enter the REP data), and will be educated about practices for medical record review and proper data security procedures.
- Prior to gaining access to the REP Browser, the researcher is required to sign a form declaring that he or she will strictly observe confidentiality of all patient information. The signed form indicates the researcher's acknowledgement of data security procedures, including the loss of his/her job, if the procedures are not followed.
- At this point, the researcher is able to gain access only to those medical records that are part of their approved study. For example, they may access only the records of people with headache. This protection is implemented by requiring the researcher to enter 2 specific IRB approvals to access the REP browser.
- Researchers collect information from the patient's record, and may also be required to drive to individual clinics to collect additional information from records located on-site.
- The researcher will put all of the information in their own secure study database. Most of the time, this is done by direct online data entering. However, some studies involve writing data on paper forms and later entering the data into a computer file. All study files are protected by the Mayo Clinic computer firewall protection system.
- No medical records can be copied or stored anywhere outside of the REP database. The REP database is separate from the routine Mayo Clinic and Olmsted Medical Center medical records.
- When the data are inside the computer firewall, the data are linked to identifiers, because the researchers may need to go back to the original records for more information. This cannot be done if the data have been fully de-identified. However, if the data need to be shared with investigators outside of the computer firewall, then all identifiers are removed, and the data are completely anonymized as per federal data privacy rules.
- After the analyses are completed, the results are published in scientific journals. However, none of the data published can be linked back to a particular person.