National Cancer Institute (NCI)
Experimental Therapeutics Clinical Trials Network (ETCTN) Guidance

ETCTN and NCI Central Institutional Review Board (CIRB) Rostering

Contents

Introduction

All research personnel participating in ETCTN trials must be rostered with the ETCTN to access Cancer Therapy Evaluation Program (CTEP) and Cancer Trials Support Unit (CTSU) applications. This includes but is not limited to the CTSU members' website for access to protocol documents and communications, Oncology Patient Enrollment Network (OPEN) for participant enrollment, Interactive Web Response System (IWRS) for slot reservations and cohort management, and Medidata Rave for data management.

At DF/HCC, all ETCTN studies use the NCI CIRB. All research personnel responsible for preparing and submitting documents to the NCI CIRB must also be rostered with the NCI CIRB in order to access the IRBManager system.

Procedure (Rostering with the ETCTN and NCI CIRB at DFCI and BWH)

1) Email Sharon Atkinson (Sharon_Atkinson@dfci.harvard.edu) and Shelby Watterworth (Shelbya_Watterworth@dfci.harvard.edu) with the following information:
   a) Name
   b) CTEP Person ID (All users must have a CTEP person ID and active CTEP Identity and Access Management (IAM) account. Refer to the DF/HCC NCI and CTEP Registration Guide for details.)
   c) Role: Investigator, Regulatory, CRC, Research Nurse, or Statistician.
2) Sharon or Shelby will contact the registered user when the rostering process is complete. The user will have access to the CTEP and CTSU systems and NCI CIRB IRBManager (when appropriate) using their CTEP IAM credentials.
3) Expect 24-48 hour turn-around.

Procedure (Rostering with the ETCTN and NCI CIRB at MGH)

1) Email Patrick Mostyn (pmostyn@partners.org) with the following information:
   a) Name and Institution Role (Investigator, Pharmacist, CRA, Research Nurse, etc.)
   b) CTEP Person ID (All users must have a CTEP person ID and active CTEP Identity and Access Management (IAM) account. Refer to the DF/HCC NCI CTEP IAM Registration Guide for details.)
   c) Documentation of CITI Human Subjects Protection (HSP) and/or Good Clinical Practice (GCP) training completion
   d) Systems Access:
      i) Will you require Rave access? (Specify if Data Entry or View Only)
      ii) Will you require OPEN access for patient enrollment?
2) Expect 24-48 hour turn-around.

Procedure (Rostering with the ETCTN and NCI CIRB at BIDMC)

1) Contact Jai Penner-Hahn (jpennerh@bidmc.harvard.edu)

Links

Rosters and Roles for ETCTN Participants (Institution Rosters and Person Rosters) Information Sheet: https://ctep.cancer.gov/initiativesPrograms/etctn_information_checklists.htm