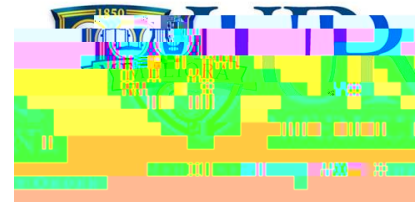
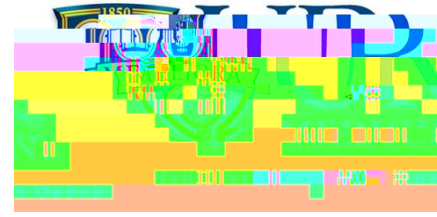


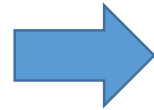
A Journey of ~~50~~ ∞ EIC Process



-
- Navigating OHSP acting as a the single reviewing IRB for a Multi-site Project
 - Start-up
 - Approval Process
 - Maintenance
 - Navigating OHSP as a Relying site
 - Site Approval
 - Maintenance
 - Using the IREx system portal

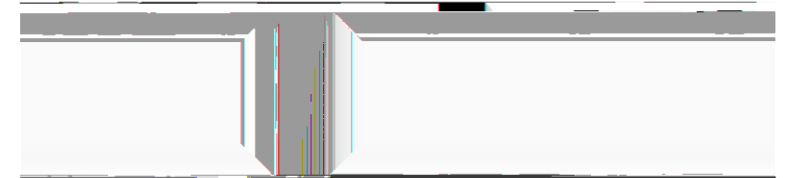
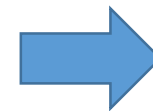


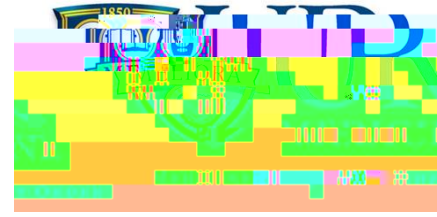
-
- Multi-site protocol
 - ICF templates
 - Local Rochester ICFs



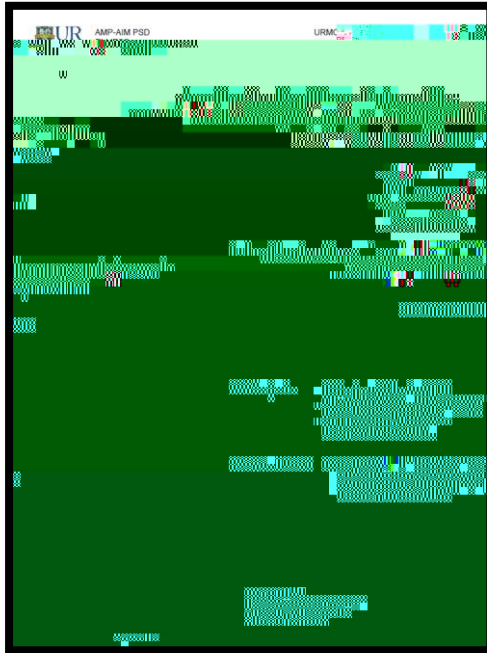
longest step

- Working with each site coordinator and IRB to make ICF edits
- Creating Reliance Agreements
- Reviewing for approval at Rochester

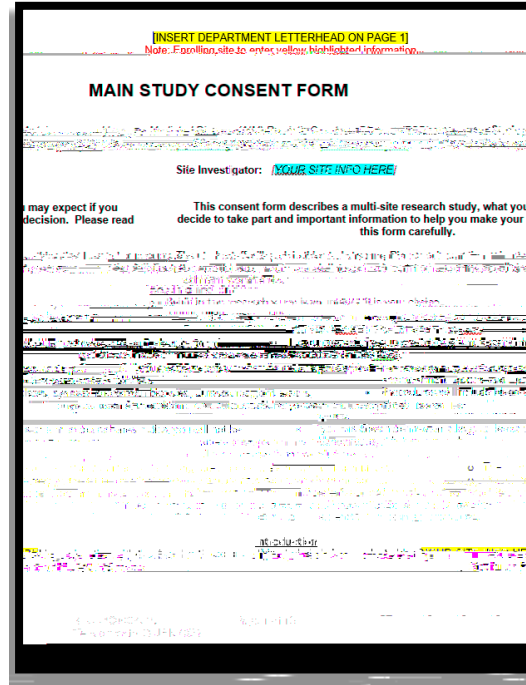




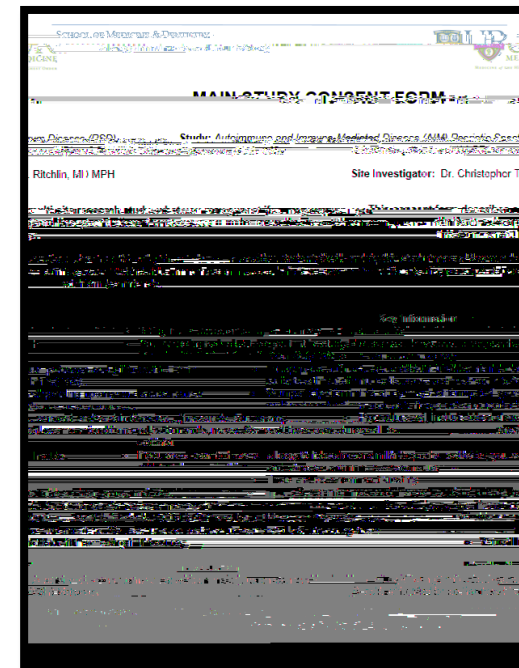
Protocol

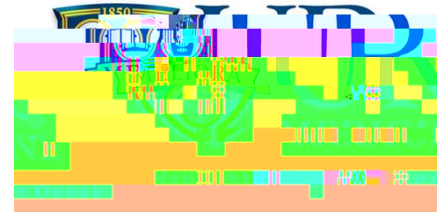


ICF Templates



Rochester ICFs





IBD Live

SEARCH

2 You are managing 2 studies

Q Search:

Signed Local Current 0 You are participating in 0

Accelerating Medicine

1/25/2023

There are 75 users at

Partnership: Autoimmune and Immune-Mediated Disease (AIM) - Psoriatic Spectrum Disease: Elucidating the Landscape

Home

Psoriatic Skin and Synovium
Project ID: 653

Accelerating Medicine

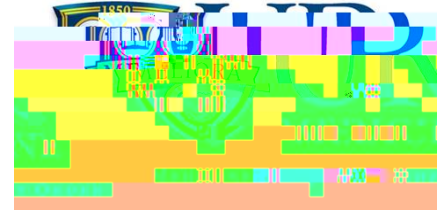
1/9/2023

IBFY 6

Partnership: Autoimmune and Immune-Mediated Disease (AIM) - Rheumatoid Arthritis
Project ID: 657

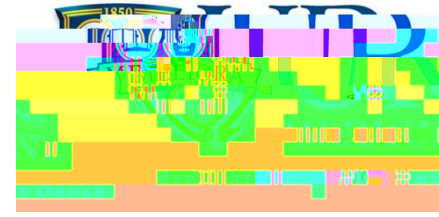
Showing 1 to 2 of 2 entries

Previous 1 Next



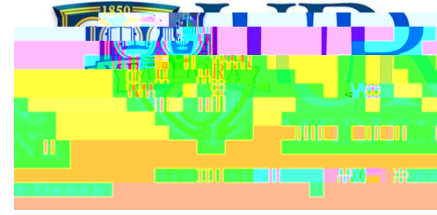
- Add each participating site
- Work with each site to edit ICF templates
- Exchange through IREx
- Rochester IRB approval

Working with your IRB specialist throughout this process is essential to avoid long delays in the approval process.



- After all sites have gained approvals it is non-stop maintenance
 - Every modification must go through Rochester and then approved at each applicable site
 - Continuing reviews
 - Data reporting and IRB reportable events

Working with your IRB specialist throughout this process is essential to avoid long delays.



-
- Life is much simpler when you are a participating site!
 - First step will be creating a CLICK IRB submission for the study.
 - Rochester will require a reliance agreement with the central site.
 - You will receive the protocol, ICF templates to edit for site-specific language, and any other study related documents from the central site.
 - Rochester will require all documents for review in CLICK before signing off in the IREx system.

Questions and Discussion

