

# *My Experience with Navigating the OHSP Process*

## A Journey of Multi-site Approval

**Tyler Cavin, MPH**  
Clinical Trials Manager

SCHOOL OF MEDICINE & DENTISTRY

**Department of Medicine**

Division of Allergy, Immunology and Rheumatology

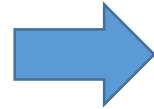
# Agenda

- 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

# *OHSP as the Reviewing IRB*

## **Step 1: Local Approval**

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



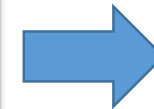
## **Step 2: Setting up the IREx platform**

- Adding all participating sites
- Sending each site communications and templates



## **Step 3: Working with each site to gain approval (longest step)**

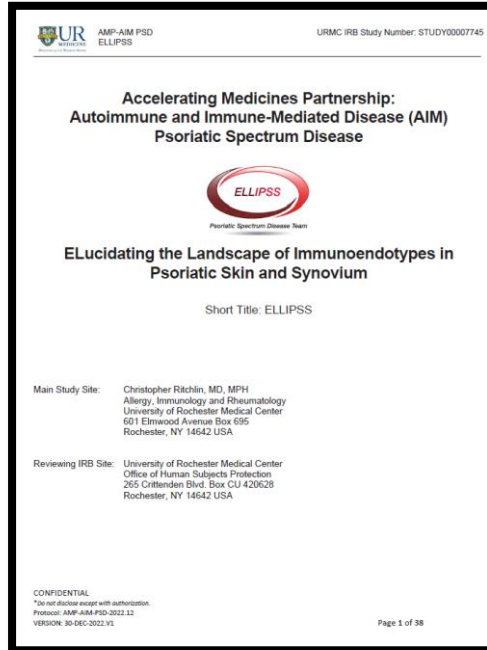
- Working with each site coordinator and IRB to make ICF edits
- Creating Reliance Agreements
- Reviewing for approval at Rochester



## **Step 4: Approval and Maintenance**


# Start - Up

## Protocol



URMC AMP-AM PSD ELLIPSS  
URMC IRB Study Number: STUDY00007745

**Accelerating Medicines Partnership:  
Autoimmune and Immune-Mediated Disease (AIM)  
Psoriatic Spectrum Disease**



**ELucidating the Landscape of Immunoendotypes in  
Psoriatic Skin and Synovium**

Short Title: ELLIPSS

Main Study Site: Christopher Elitchin, MD, MPH  
Allergy, Immunology and Rheumatology  
University of Rochester Medical Center  
601 Elmwood Avenue Box 636  
Rochester, NY 14642 USA

Reviewing IRB Site: University of Rochester Medical Center  
Office of Human Subjects Protection  
265 Crittenden Blvd. Box CU 420628  
Rochester, NY 14642 USA

CONFIDENTIAL  
\*Do not disclose except with authorization.  
Protocol: AMP-AM PSD-2022-12  
VERSION: 30-DEC-2022-V3  
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## ICF Templates

**INSERT DEPARTMENT LETTERHEAD ON PAGE 1**  
Note: Enrolling site to enter yellow highlighted information

**MAIN STUDY CONSENT FORM**

Study: Autoimmune and Immune-Mediated Disease (AIM) Psoriatic Spectrum Disease (PSD) - ELucidating the Landscape of Immunoendotypes in Psoriatic Skin and Synovium (ELLIPSS)

Site Investigator: **YOUR SITE INFO HERE**

This consent form describes a multi-site research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

**Key Information**


- Being in this research study is voluntary – it is your choice.
- You are being asked to take part in this study because you have been diagnosed with Psoriasis (PsO) or Psoriatic Arthritis (PsA).
- The purpose of this study is to better understand molecular pathways and joint destruction in patients with autoimmune diseases such as Psoriatic Arthritis (PsA).
- Your participation in this study may last for up to 4 years depending upon your disease course and treatment options and up to 8 separate research visits.
- Procedures will include blood draws, synovial and/or skin biopsies, ultrasounds, joint exams, physical exams, microbiome collection and surveys. Some of these procedures will be optional.
- If you are known to have an allergy to lidocaine or similar topical anesthetics, you will not be able to take part in this research study.
- There are risks from participating.
  - The most common risk is pain and/or bruising due to blood draw or synovial/skin biopsy.
  - One of the most serious risks is infection due to blood draw, synovial/skin biopsy or microbiome collection. See the "Risks of Participation" section in this consent form for more information. You should discuss these risks in detail with the study team.
- You will not benefit from being in this study.

**Introduction**  
This study is being conducted by **YOUR SITE INFO HERE** in conjunction with the Accelerating Medicines Partnership (AMP) Network.

STUDY00007745  
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## Rochester ICFs

SCHOOL OF MEDICINE & DENTISTRY  
Allergy, Immunology & Rheumatology



**MAIN STUDY CONSENT FORM**

Study: Autoimmune and Immune-Mediated Disease (AIM) Psoriatic Spectrum Disease (PSD) - ELucidating the Landscape of Immunoendotypes in Psoriatic Skin and Synovium (ELLIPSS)

Site Investigator: Dr. Christopher T. Ritchlin, MD MPH

This consent form describes a multi-site research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

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# IREx Creation

**UNIVERSITY OF ROCHESTER**

**2** Managing  
You are managing 2 studies

**0** Participant  
You are participating in 0 studies

**75** users  
There are 75 users at your site

[Home](#)

## Study Manager Dashboard

Search:

Study Title	Sites	Signed Agreements	Reliance	Local Consid.	Current Approvals	Expires
Accelerating Medicines Partnership: Autoimmune and Immune-Mediated Disease (AIM) - Psoriatic Spectrum Disease: ELucidating the Landscape of Immunoendotypes in Psoriatic Skin and Synovium <i>Project ID: 653</i>	9 / 9 Registered	SMART IRB 9	5	5	4 1/25/2023	12/12/2023
		IREx 9				
Accelerating Medicines Partnership: Autoimmune and Immune-Mediated Disease (AIM) - Rheumatoid Arthritis <i>Project ID: 657</i>	6 / 6 Registered	SMART IRB 6	4	3	2 1/3/2023	12/12/2023
		IREx 6				

Showing 1 to 2 of 2 entries

Previous **1** Next

# *Participating Sites*

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

## **Key Component!**

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

# *Study Maintenance*

- 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

## **Again!**

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

## *OHSP as a Relying Site*

- 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

