

ESETT

REGULATORY DOCUMENTS, READINESS AND SITE START UP

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ESETT Site Managers



On the website (www.ESETT.org) you'll find....

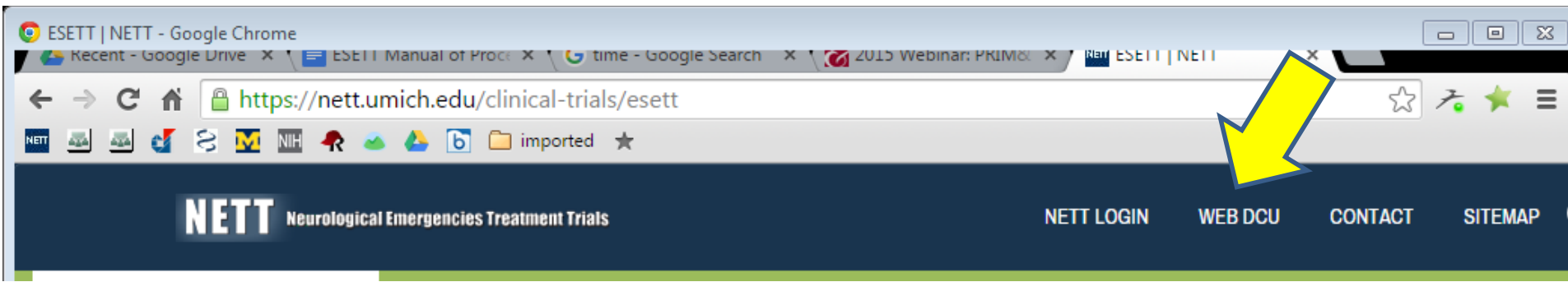
- UM Friends account info
- Protocol
- Other Study Team Items
 - MoP
 - Readiness checklist
 - Training materials
 - Etc.
- Website questions?
Joy Black at joypink@umich.edu

The screenshot shows the ESETT website interface. A yellow arrow points to the 'NETT LOGIN' link in the top right navigation bar. Another yellow arrow points to the 'NETT RESOURCES' section in the bottom right footer, which includes links for 'New to NETT?', 'Standard Operating Procedures', 'Grant Applications', 'NETT Map', 'Graphics', 'Presentations', and 'Virtual Conference Rooms'. A third yellow arrow points to the 'PATIENT COMMUNITY' section in the bottom left footer, which includes links for 'Community', 'Patient Advocacy', and 'Trial Summaries'. The main content area displays the ESETT logo and a brief description of the trial, with a link to the 'Synopsis'.

WebDCU – The ESETT Regulatory Database

<https://webdcu.musc.edu/NETT>

- Central repository for all regulatory documents.
 - Site Documents
 - People Documents
- Allows tracking, audits, and central monitoring
- Automated emails for expiring and missing documents
- Always use PDF and good PDF hygiene



Regulatory Parameters Document

- Your essential regulatory cookbook
- Outlines requirements for
 - Site Documents (applies to a site/spoke)
 - People Documents (applies to an individual)

Site Documents

- FWA
- CLIA
- IRB Submission for EFIC (and Approval)
- IRB Submission for Enrollment (and Approval)
- IRB Approved Informed Consent, Assent Forms
- FDA Form 1572
- Attestation of Study Team Training
- Electronic Delegation of Authority (eDOA) Log

FDA Form 1572

- Should reflect roles and responsibilities on eDOA.
- Includes those:
 - Responsible for the trial
 - Obtaining informed consent
 - Responsible for determining/reporting AE/SAE
- NETT Hub PI generally on their Spoke's 1572.
- Multiple sites can be listed on the same 1572

People Documents

- Requirements defined by eDOA
- All: CV, HSP, HIPAA, Protocol Training
- As needed: Medical License, ESETT Data Training, Regulatory Database Training, Sample Handling and Shipping Certification.
- Pharmacist: Pharmacy Data Training, CV, and License.

Readiness Call

- Readiness Call is the Site Initiation teleconference
- Guided by the Readiness Checklist
- Who
- Scheduling
- What to expect

Readiness Checklist

- Confirm regulatory and logistical readiness
- Lists who will be attending the call
- Must be completed and submitted by Email at least 2 business days prior to the call

Who is required on the call?

Site

- Site Study PI
- Site Primary Coordinator
- Site Pharmacist
- (NETT Hub PI and Project Manager)
- Other team members are welcome to attend!

Coordinating Center

- ESETT PI
- Project Manager
- Site Manager
- Data Manager

Scheduling your Readiness Call

- Schedule the call with your ESETT Site Manager
- Anticipate. Schedule a tentative call early
- Everything submitted at least 2 business days ahead
 - **All** documents uploaded
 - Email completed readiness checklist
- Call confirmed only when all required docs are approved

Structure of the Readiness Call

- Confirm all regulatory documents
- Confirm Study Drug Shipping address
- Confirm Use Next Box receipt
- Discuss site logistics and training
- Walk through an enrollment
- Questions, answers, and advice
- Duration expected to be about 1 hour

Ongoing Site Management

- It is the responsibility of each Hub/Site to maintain regulatory compliance
- Site documents and people documents must be kept current and accurate
- Study team personnel whose regulatory compliance lapses cannot participate in trial related activities

Things that get people in trouble

- Annual Scheduled Continuing Renewals
 - Application and Approval
- Changes to Team Members
 - eDOA, IRB approval, and 1572

Who is my Site Manager?

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A.I. DuPont Hospital for Children
Brown University
Emory University
Henry Ford Health System
Medical College of Wisconsin
Medical College of Wisconsin(PECARN)
Oregon Health and Science University
SUNY Downstate Medical Center
University of California at San Francisco
University of California, Davis
University of California, Los Angeles
University of Maryland
University of Michigan
University of Texas Southwestern
University of Texas, Houston
Virginia Commonwealth University
Wayne State University
Wayne State University (PECARN)

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Cincinnati Children's Hospital
Nationwide Children's Hospital
University of Pittsburgh
University of Utah
Washington University
Children's National Med. Ctr.
Massachusetts General Hospital
New York Presbyterian Hospital
Stanford University
Temple University
The Ohio State University
University of Arizona
University of Cincinnati
University of Kentucky
University of Minnesota
University of Pennsylvania
University of Pittsburgh
University of Virginia





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Questions?