



A Path Towards Thriving

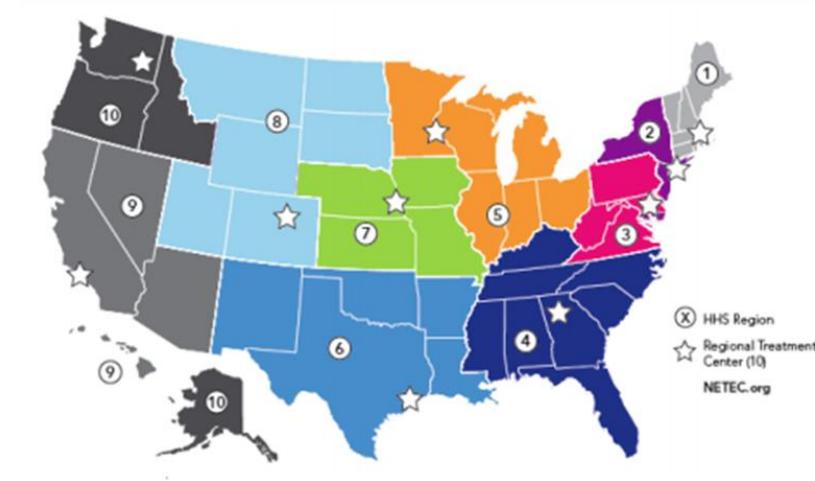


eConsents and REDCap

ITHS | Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Regional Ebola and Other Special Pathogens Treatment Centers (RESPCT)

1. Massachusetts General Hospital
2. NYC Health & Hospitals Bellevue
3. Johns Hopkins
4. Emory University Hospital
5. University of Minnesota Medical Center
6. University of Texas Medical Galveston
7. University of Nebraska Medical Center
8. Denver Health
9. Cedar-Sinai
10. Providence Sacred Heart Medical Center & Children's Hospital



April 2018 – Spokane Participates in Federal Ebola Exercise



ITHS

Institute of **Translational** Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

COVID related Challenges & Solutions

Anticipated challenges

- Face-to-face discussion is limited
- People are very ill
- Language barriers
- Family quarantined
- What goes in the room stays in the room
 - How long does virus survive on paper?
 - Is it enough of a transmission risk?

Plans

- Use traditional paper consent form
- Investigator dons & conducts discussion and gets signature
- Photograph consent form through the unit's video equipment, making sure signatures, version & IRB stamp clearly captured
- Leave the original consent form in the room
- Mail a copy to the participant's home

New Opportunities

- More inclusive
 - reach people who can't easily travel
 - facilitate non-English presentations
- Better comprehension features: links to FAQ, chat bot
- Automate processes: providing a copy and filing



Key Components of Consent Process

1. Enough information, time and opportunity to decide
2. Processes to facilitate comprehension
3. Required elements presented in the preferred language
4. Competency of participant to make a decision is assessed
5. Decision is voluntary
6. Process is well documented

Components of Electronic Consent

1. Easy to navigate forward, backward, stop and return
2. Include all elements of consent and HIPAA authorization
3. Provides a copy: electronic and paper option at no cost
4. Easily retrievable for monitors and auditors - links need to work for the duration of the study record retention period
5. Documents a valid signature- appropriate controls

Where Can I Find More Information?

- Your organizational policies
- Your IRB policies
- *FDA Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency* www.fda.gov
- Office of Human Research Protections | *Research Guidance on Coronavirus* www.HHS.gov



Policies Are Not All the Same

Here are some IRB examples:

- Remote consent approved only during the public emergency
- Allowed only for minimal risk trials /Remote consent for screening only in more than minimal risk trial
- Specifics about the consent form being provided prior to discussion
- Differences in witness requirements
- Contact via a secure mail system
- Teleconference platform must be HIPAA compliant
- Make sure Alexa is deactivated in the home



REDCap: Research Electronic Data Capture

- Licensed from Vanderbilt University
- Secure, HIPAA and Part 11 Compliant
- Customizable
- Self Service training modules
- Resources at ITHS:
- RedCap Training Series, RedCap support

REDCap – My Projects List

Create a new project for your consent

Home My Projects **+ New Project** Help & FAQ Training Videos Send-It

Logged in as **susan.hood** Profile Log out

Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. [Read more](#) To review which users still have access to your projects, visit the [User Access Dashboard](#).

My Projects Organize Collapse All Filter projects by title

Project Title	Records	Fields	Instruments	Type	Status
Food survey for the general clinic population	7	22	1 survey	■	🔧
Test consent	6	35	2 surveys	■	🔧
Study Authorized Users	1	15	1 form	■	🔧
Training Log	6	10	1 survey	■	🔧
Research Consent for Participants Who Speak Limited to No English	<input type="checkbox"/>	0	8	1 survey	■ <input checked="" type="checkbox"/>

REDCap 11.3.4 - © 2022 Vanderbilt University

REDCap – Create New Project

+ Create a new REDCap Project

You may begin the creation of a new REDCap project on your own by completing the form below and clicking the Create Project button at the bottom.

Project title:

Project's purpose: How will it be used?

Name of P.I. (if applicable):
First name MI Last name

Email of P.I. (if applicable)

Name of P.I. as cited in publications (if applicable): (e.g., Harris PA)

IRB number (if applicable):

Please specify:

- Basic or bench research
- Clinical research study or trial
- Translational research 1 (applying discoveries to the development of trials and studies in humans)
- Translational research 2 (enhancing adoption of research findings and best practices into the community)
- Behavioral or psychosocial research study
- Epidemiology
- Repository (developing a data or specimen repository for future use by investigators)
- Other

Project notes (optional): Description of the project's use or purpose (displayed on the My Projects page)

Project creation option:

- Empty project (blank slate)
- Upload a REDCap project XML file (CDISC ODM format) [?](#)
- Use a template (choose one below)

Opening Page of New Project

REDCap Production

Logged in as **susan.hood** | Log out

My Projects

Project Home and Design

- Project Home · Project Setup
- Designer** · Dictionary · Codebook
- Project status: **Development**

Data Collection

- Record Status Dashboard
- View data collection status of all records
- Add / Edit Records**
- Create new records or edit/view existing ones
- Show data collection instruments

Applications

- Project Dashboards
- Alerts & Notifications
- Calendar
- Data Exports, Reports, and Stats
- Data Import Tool
- Data Comparison Tool
- Logging
- Field Comment Log
- File Repository

Clinical Research Study eConsent

PID 5059

Project Home | **Project Setup** | Other Functionality | Project Revision History

Project status: **Development** Completed steps 0 of 7

Main project settings

Not started

Enable Use surveys in this project? [VIDEO: How to create and manage a survey](#)

Enable Use longitudinal data collection with defined events? [?](#)

I'm done!

Click here to change the settings you entered when you created the project

Design your data collection instruments

Not started

Add or edit fields on your data collection instruments. This may be done by either using the Online Designer (online method) or by uploading a Data Dictionary (offline method). Quick links: [Download PDF of all instruments](#) OR [Download the current Data Dictionary](#)

I'm done! Go to or Explore the [REDCap Instrument Library](#)

Have you checked the [Check For Identifiers](#) page to ensure all identifier fields have been tagged?

Learn how to use [Smart Variables](#) [Piping](#) [Action Tags](#) [Field Embedding](#) [Special Functions](#)

Begin to design your project

Project Online Designer Page

REDCap Production

Logged in as **susan.hood** | Log out

My Projects

Project Home and Design

- Project Home · Project Setup
- Designer · Dictionary · Codebook
- Project status: **Development**

Data Collection

- Survey Distribution Tools
 - Get a public survey link or build a participant list for inviting respondents
- Record Status Dashboard
 - View data collection status of all records
- Add / Edit Records
 - Create new records or edit/view existing ones

Show data collection instruments

Applications

- Project Dashboards
- Alerts & Notifications
- Calendar
- Data Exports, Reports, and Stats
- Data Import Tool
- Comparison Tool

Clinical Research Study eConsent PID 5059

Project Home | Project Setup | **Online Designer** | Data Dictionary | Codebook

Create snapshot of instruments | VIDEO: How to use this page
Last snapshot: never ?

The Online Designer will allow you to make project modifications to fields and data collection instruments very easily using only your web browser. NOTE: While in development status, all field changes will take effect immediately in real time.

Data Collection Instruments

Add new instrument:

- Create a new instrument from scratch
- Import a new instrument from the official REDCap Instrument Library ?
- Upload instrument ZIP file from another project/user or external libraries ?

Survey options:

- Survey Queue
- Survey Login
- Survey Notifications

Automated Survey Invitation options

- Upload or download Auto Invitation
- Re-evaluate Auto Invitations

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
Form 1	1		Enable	Choose action Rename Copy Delete	

Open Form

The Online Designer will allow you to make project modifications to fields and data collection instruments very easily using only your web browser. NOTE: While in development status, all field changes will take effect immediately in real time.

Data Collection Instruments

Add new instrument:

- [Create](#) a new instrument from scratch
- [Import](#) a new instrument from an existing instrument
- [Upload](#) instrument ZIP file

[Instrument Library](#) [Personal libraries](#)

Instrument name	Fields	View PDF	Instrument actions
eConsent	1		Choose action

Click on the form name to create or modify your form



Add a Field

Project Home Project Setup Online Designer Data Dictionary Codebook

Create snapshot of instruments VIDEO: How to use this page
Last snapshot: never ?

Ready to add fields

You may now begin adding fields to your data collection instrument below using the Online Designer. Alternatively, you may build your fields in the Data Dictionary (offline method) by clicking its tab above.

This module will allow you to create new data collection instruments/surveys or edit existing ones. Changes may be made by either using the **Online Designer** or **Upload Data Dictionary** (see tabs above), in which you may use either method or both. The Online Designer may help you get some initial fields/forms built quickly or to make quick edits, but using the Data Dictionary file may be more helpful if you will be adding a large number of fields for this project.

This page allows you to build and customize your data collection instruments one field at a time. You may add new fields or edit existing ones. New fields may be added by clicking the **Add Field** buttons. You can begin editing an existing field by clicking on the **Edit** icon. If you decide that you do not want to keep a field, you can simply delete it by clicking on the **Delete** icon. To reorder the fields, simply **drag and drop** a field to a different position within the form below. NOTE: While in development status, all field changes will take effect immediately in real time.

[Return to list of instruments](#)

Current instrument: **eConsent** [Preview instrument](#)

Variable: record_id

Record ID

NOTE: The field above is the record ID field and thus cannot be deleted or moved. It can only be edited.

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

Click on add field to start adding consent



Select the Field Type

Add New Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#).

Field Type: ---- Select a Type of Field ----

Add New Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#).

Field Type: ---- Select a Type of Field ----

- Select a Type of Field ----
- Text Box (Short Text, Number, Date/Time, ...)
- Notes Box (Paragraph Text)
- Calculated Field
- Multiple Choice - Drop-down List (Single Answer)
- Multiple Choice - Radio Buttons (Single Answer)
- Checkboxes (Multiple Answers)
- Yes - No
- True - False
- Signature (draw signature with mouse or finger)
- File Upload (for users to upload files)
- Slider / Visual Analog Scale
- Descriptive Text (with optional Image/Video/Audio/File Attachment)**
- Begin New Section (with optional text)



THIS

Enter the First Section of Consent

Add New Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#).

Field Type: Descriptive Text (with optional Image/Video/Audio/File Attachment) ▾

Field Label Use the Rich Text Editor [?](#)

TITLE OF STUDY: A Prospective, Observational Study Evaluating Persistence on Treatment, Safety, Tolerability, and Effectiveness of Diroximel Fumarate in the Real-World Setting (EXPERIENCE-US Study)

STUDY NUMBER: US-VUM-11760
PRINCIPAL INVESTIGATOR: Jessica Craddock, MD
24-HOUR EMERGENCY PHONE NUMBER: (509) 252-1700

Action Tags / Field Annotation (optional)

Learn about [@ Action Tags](#) or [using Field Annotation](#)

Variable Name (utilizes [sm](#) logic, calcs, and exports)
Title Enable auto naming of variable based upon its Field Label?
ONLY letters, numbers, and underscores

How to use [Smart Variables](#) [Piping](#) [Field Embedding](#)

Optional file attachment, image, audio, or video:

Embed an external video (provide video URL) [?](#)

e.g. <https://youtube.com/watch?v=E1cCuWMupz0>,
<https://vimeo.com/62730281>, <http://example.com/movie.mp4>

Display format of video: Inline Inside popup

- or -

Attach an image, file, or embedded audio

[Upload file](#)

Save **Cancel**

Designer Page with First Field

REDCap Production
- Create new records or edit/view existing ones

Show data collection instruments

Applications

- Project Dashboards
- Alerts & Notifications
- Calendar
- Data Exports, Reports, and Stats
- Data Import Tool
- Data Comparison Tool
- Logging
- Field Comment Log
- File Repository
- User Rights and DAGs
- Data Quality
- REDCap Mobile App
- External Modules

External Modules

- Data Dictionary Revisions
- Tableau Connector Instructions

Help & Information

- Help & FAQ
- Video Tutorials
- Suggest a New Feature
- Contact REDCap administrator

Current instrument: eConsent Preview instrument

Field 1: Variable: record_id
Record ID

NOTE: The field above is the record ID field and thus cannot be deleted or moved. It can only be edited.

Click on pencil to edit field

Add Field Add Matrix of Fields Import from Field Bank

Field 2: Variable: title
TITLE OF STUDY: A Prospective, Observational Study Evaluating Persistence on Treatment, Safety, Tolerability, and Effectiveness of Diroximel Fumarate in the Real-World Setting (EXPERIENCE-US Study)

STUDY NUMBER: US-VUM-11760
PRINCIPAL INVESTIGATOR: Jessica Craddock, MD
24-HOUR EMERGENCY PHONE NUMBER: (509) 252-1700

Add Field Add Matrix of Fields Import from Field Bank

Text: If you decide that you do not want to keep a field, you can simply delete it by clicking on the **Delete** icon. To reorder the fields, simply **drag and drop** a field to a different position within the form below. NOTE: While in development status, all field changes will take effect immediately in real time.

Return to list of instruments

Naming Variables: Study_Form_section

REDCap Production

External Modules

- Data Dictionary Revisions
- Tableau Connector Instructions

Help & Information

- Help & FAQ
- Video Tutorials
- Suggest a New Feature

Contact REDCap administrator

    Variable: use_consent_header

TITLE OF STUDY: A Prospective, Observational Study Evaluating Persistence on Treatment, Safety, Tolerability, and Effectiveness of Diroximel Fumarate in the Real-World Setting (EXPERIENCE-US Study)

STUDY NUMBER: US-VUM-11760

PRINCIPAL INVESTIGATOR: Jessica Craddock, MD

24-HOUR EMERGENCY PHONE NUMBER: (509) 252-1700

Add Field

Add Matrix of Fields

Import from Field Bank

    Variable: use_consent_intro

INTRODUCTION

You are being asked to volunteer to take part in this research study because you have multiple sclerosis (MS).

Before deciding whether you want to participate in this research study or not, it is important that you read and understand the following explanation of the study procedures. This consent describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative procedures, if any, that are available to you and your right to withdraw from the study at any time. No promises can be made about how you will be affected if you consent to be in the study.

This consent may contain words you do not understand. You should ask the study doctor or research staff to explain any words or information you do not clearly understand. Please review this informed consent carefully and, if possible, discuss with your family or friends before agreeing to participate.

For your safety it is important that you be completely honest with your study doctor about your health history in order to provide a complete and accurate understanding of your health condition.

Add Field

Add Matrix of Fields

Import from Field Bank

    Variable: use_consent_why



Continue Building Form

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

    Variable: use_consent_why

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to better understand how well the medication diroximel fumarate (VUMERITY®) is working for people who have multiple sclerosis (MS).

This study is funded by Biogen MA INC., who will be referred to as the 'Sponsor' in this form.

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

    Variable: use_consent_howmany

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

A total of about 200 participants will take part in this study in the United States. Locally about 36 will participate.

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

    Variable: use_consent_what

WHAT IS INVOLVED IN THE STUDY?

The study will not change how often you visit your doctor, or the clinical care that you are currently receiving, and no additional visits will be required. If you currently meet with your doctor using telemedicine (phone call, video call, etc), these visits will still be an option for you if you participate in this study (based on your doctor's decision).

The goal of the study is to observe your clinical care. After you have consented to take part in the study, we will collect past and/or current medical information that your doctor recorded in your medical records.

The personal information that will be collected from your doctor's files includes baseline characteristics (such as age, gender,



Field Types

Yes-No →

Variable: use_consent_consent1

PARTICIPANT CONSENT

I have read, or have had read to me, the information describing the study, and it is written in a language that I understand. All my questions have been answered to my satisfaction. I am signing this form voluntarily, indicating my willingness to be in this study. I understand that I am not giving up any of my legal rights by signing this form and I will receive a copy of this signed consent form.

Add Field Add Matrix of Fields Import from Field Bank

Signature →

Variable: consent_yn

Would you like to participate in the Research Study?

* must provide value

Yes
 No

reset

Add Field Add Matrix of Fields Import from Field Bank

Text Box →

Variable: use_consent_signature Branching logic: [consent_yn] = '1'

**Please click on "add signature" and sign here:
(You can use your finger on a tablet or your mouse on a computer)**

* must provide value

[Add signature](#)

Add Field Add Matrix of Fields Import from Field Bank

Date →

Variable: participant_firstname

Please type your first name

* must provide value

Add Field Add Matrix of Fields Import from Field Bank

Variable: participant_lastname

Please type your last name

* must provide value

Add Field Add Matrix of Fields Import from Field Bank

Variable: use_consent_date Branching logic: [consent_yn] = '1'

Please choose today's date

* must provide value

Today M-D-Y
Mon-day-year

Field Types: Yes-No



Edit Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#)

Field Type: Yes - No

Question Number (optional)
Displayed only on the survey page

Field Label Use the Rich Text Editor ?
Would you like to participate in the Research Study?

Choices (not modifiable)
1, Yes
0, No

Action Tags / Field Annotation (optional)

Learn about [@ Action Tags](#) or [using Field Annotation](#)

Variable Name (utilized in logic, calcs, and exports)
 Enable auto naming of variable based upon its Field Label?
ONLY letters, numbers, and underscores

How to use: [Smart Variables](#) [Piping](#) [Field Embedding](#)

Required?* No Yes
* Prompt if field is blank

Identifier? No Yes
Does the field contain identifying information (e.g., name, SSN, address)?

Custom Alignment Left / Vertical (LV)
Align the position of the field on the page

Field Note (optional)
Small reminder text displayed underneath field

Field Type: Signature

Edit Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#).

Field Type: Signature (draw signature with mouse or finger)

Question Number (optional)
Displayed only on the survey page

Field Label Use the Rich Text Editor [?](#)

Please click on "add signature" and sign here:
(You can use your finger on a tablet or your mouse on a computer)

Action Tags / Field Annotation (optional)

Learn about [@ Action Tags](#) or [using Field Annotation](#)

Variable Name (utilized in logic, calcs, and exports)
 Enable auto naming of variable based upon its Field Label?
ONLY letters, numbers, and underscores

How to use [Smart Variables](#) [Piping](#) [Field Embedding](#)

Required?* No Yes
* Prompt if field is blank

Identifier? No Yes
Does the field contain identifying information (e.g., name, SSN, address)?

Custom Alignment
Align the position of the field on the page

Field Note (optional)
Small reminder text displayed underneath field



Field Type: Text Box

Edit Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#).

Field Type: Text Box (Short Text, Number, Date/Time, ...)

Question Number (optional)
Displayed only on the survey page

Field Label Use the Rich Text Editor [?](#)

Please type your first name

Action Tags / Field Annotation (optional)

Learn about [@ Action Tags](#) or [using Field Annotation](#)

Variable Name (utilized in logic, calcs, and exports)
participant_firstname Enable auto naming of variable based upon its Field Label?
ONLY letters, numbers, and underscores

How to use [Smart Variables](#) [Piping](#) [Field Embedding](#)

Validation? (optional) ---- None ----
- or -
-- select ontology service --

Required?* No Yes
* Prompt if field is blank

Identifier? No Yes
Does the field contain identifying information (e.g., name, SSN, address)?

Custom Alignment Right / Vertical (RV)
Align the position of the field on the page

Field Note (optional)
Small reminder text displayed underneath field

Field Type: Text Box to Capture Date

Edit Field [X] [?]

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#).

Field Type: Text Box (Short Text, Number, Date/Time, ...)

Question Number (optional)
Displayed only on the survey page

Field Label Use the Rich Text Editor [?]
Please choose today's date

Action Tags / Field Annotation (optional)

Learn about [@ Action Tags](#) or [using Field Annotation](#)

Variable Name (utilized in logic, calcs, and exports)
use_consent_date Enable auto naming of variable based upon its Field Label?
ONLY letters, numbers, and underscores

How to use: Smart Variables Piping Field Embedding

Validation? (optional) Date (M-D-Y)
Minimum:
Maximum:
- or -
-- select ontology service --

Required?* No Yes
* Prompt if field is blank

Identifier? No Yes
Does the field contain identifying information (e.g., name, SSN, address)?

Custom Alignment Right / Vertical (RV)
Align the position of the field on the page

Field Note (optional) Mon-day-year
Small reminder text displayed underneath field

Add Field Add Matrix of Fields Import from Field Bank

Variable: use_consent_date Branching logic: [consent_yn] = '1'

Please choose today's date 31 Today M-D-Y
* must provide value
Mon-day-year

Field Type: Multiple Choice

      Variable: use_greenphire_yn Branching logic: [consent_yn] = '1'

I have read, or have read to me, the information above regarding the option of receiving a Greenphire ClinCard for my study disbursements.

* must provide value

I would like to receive a Greenphire ClinCard.

I do not wish to receive a Greenphire ClinCard, and would like the study coordinator to request that a check be mailed to me.

reset

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

     Variable: use_consent_cellphone Branching logic: [consent_yn] = '1' and [use_greenphire_yn] = '1'

Account balances can be checked by calling Greenphire Customer Support. As part of setting up your card, Greenphire can send you messages about new funds or account balances by email or text. Text message fees may apply; the fees are not paid for by the study. If you decide at a later date that you want to stop these messages, you can opt-out.

If you would like to be set up with notifications from Greenphire, please provide your preferred email and/or Cell Number below. You are not required to provide this information if you do not wish to.

Cell Phone

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

     Variable: use_consent_email Branching logic: [consent_yn] = '1' and [use_greenphire_yn] = '1'

Email



Branching Logic

We only want this section to show up if the patient wants to participate in the study



Variable: use_consent_consent1

PARTICIPANT CONSENT

I have read, or have had read to me, the information describing the study, and it is written in a language that I understand. All my questions have been answered to my satisfaction. I am signing this form voluntarily, indicating my willingness to be in this study. I understand that I am not giving up any of my legal rights by signing this form and I will receive a copy of this signed consent form.

Add Field Add Matrix of Fields Import from Field Bank

Variable: consent_yn

Would you like to participate in the Research Study?

* must provide value

Yes

No

reset

Add Field Add Matrix of Fields Import from Field Bank

Variable: use_consent_signature Branching logic: [consent_yn] = '1'

**Please click on "add signature" and sign here:
(You can use your finger on a tablet or your mouse on a computer)**

* must provide value

[Add signature](#)

Add Field Add Matrix of Fields Import from Field Bank

Variable: participant_firstname

Please type your first name

* must provide value

Add Field Add Matrix of Fields Import from Field Bank

Variable: participant_lastname

Please type your last name

* must provide value

Add Field Add Matrix of Fields Import from Field Bank

Variable: use_consent_date Branching logic: [consent_yn] = '1'

Please choose today's date

* must provide value

Mon-day-year Today M-D-Y

Branching Logic

Add/Edit Branching Logic

Test logic with a record: -- select record -- [Clear logic](#)

— OR —

Drag-N-Drop Logic Builder

Displaying field choices for the following data collection instrument:
Form 1

Field choices from other fields
(drag a choice below to box on right)

- record_id = (define criteria)
- use_greenphire_yn = I would like to receive a Greenphire ClinCard. (1)
- use_greenphire_yn = I do not wish to receive a Greenphire ClinCard, ... (2)
- use_consent_cellphone = (define criteria)
- use_consent_email = (define criteria)
- use_consent_yn = Yes (1)
- use_consent_yn = No (0)

Show the field ONLY if...

- ALL below are true
- ANY below are true

use_consent_yn = Yes (1) ✖

[Clear logic](#)

Save Cancel

Enable Consent Form as Survey

[Project Home](#) [Project Setup](#) [Online Designer](#) [Data Dictionary](#) [Codebook](#)

 Create snapshot of instruments

 [VIDEO: How to use this page](#)

Last snapshot: never 

The Online Designer will allow you to make project modifications to fields and data collection instruments very easily using only your web browser. NOTE: While in development status, all field changes will take effect immediately in real time.

Data Collection Instruments

Add new instrument:

-  [Create](#) a new instrument from scratch
-  [Import](#) a new instrument from the official [REDCap Instrument Library](#) 
-  [Upload](#) instrument ZIP file from another project/user or [external libraries](#) 

Survey options:

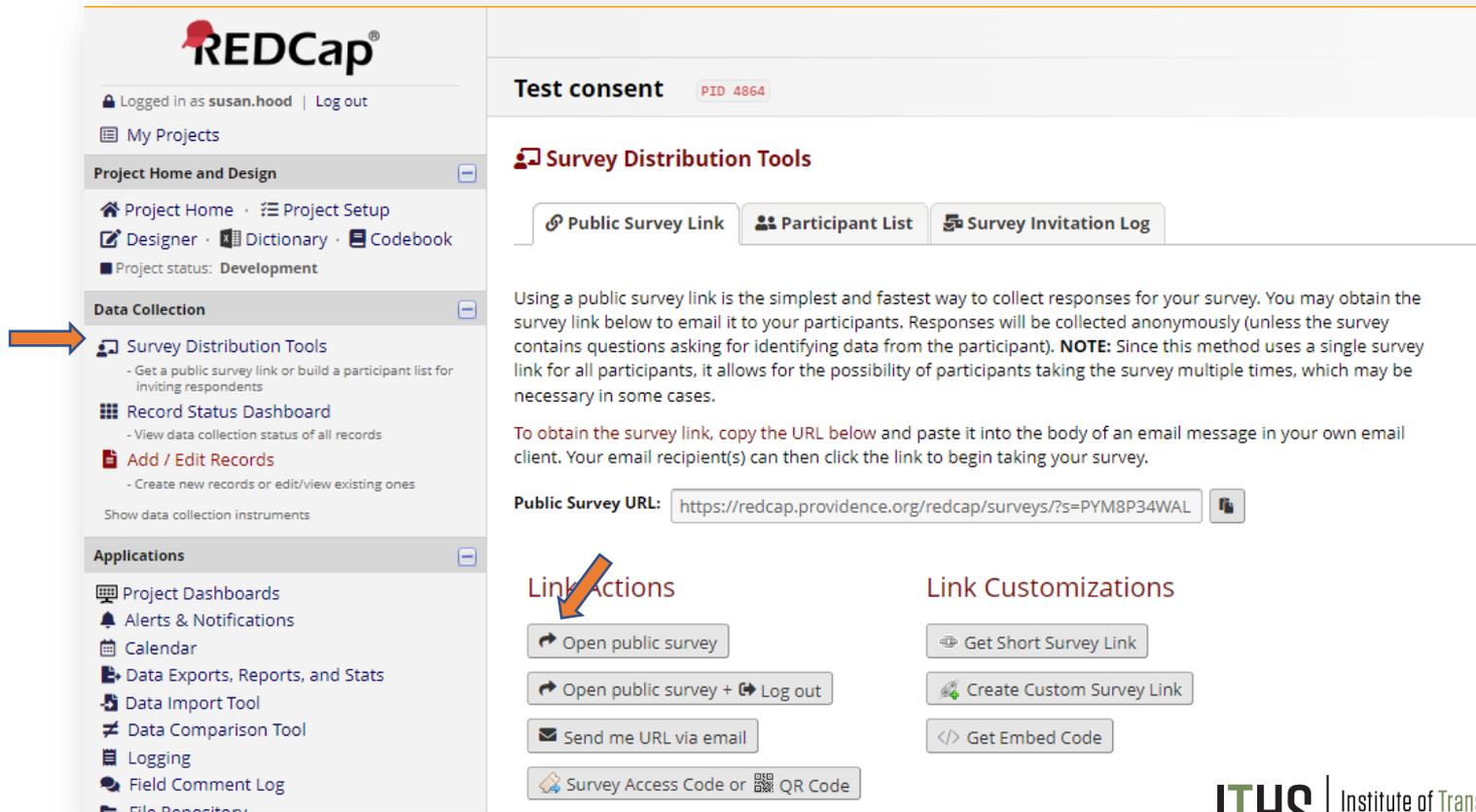
-  [Survey Queue](#)
-  [Survey Login](#)
-  [Survey Notifications](#)

Automated Survey Invitation options:

-  [Upload or download Auto Invitations](#) 
-  [Re-evaluate Auto Invitations](#)

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
eConsent	2		Enable	Choose action 	

Open a Public Survey



REDCap
Logged in as **susan.hood** | Log out
My Projects

Project Home and Design

- Project Home · Project Setup
- Designer · Dictionary · Codebook
- Project status: **Development**

Data Collection

- Survey Distribution Tools**
- Get a public survey link or build a participant list for inviting respondents
- Record Status Dashboard
- View data collection status of all records
- Add / Edit Records
- Create new records or edit/view existing ones

Show data collection instruments

Applications

- Project Dashboards
- Alerts & Notifications
- Calendar
- Data Exports, Reports, and Stats
- Data Import Tool
- Data Comparison Tool
- Logging
- Field Comment Log
- File Repository

Test consent PID 4864

Survey Distribution Tools

- Public Survey Link
- Participant List
- Survey Invitation Log

Using a public survey link is the simplest and fastest way to collect responses for your survey. You may obtain the survey link below to email it to your participants. Responses will be collected anonymously (unless the survey contains questions asking for identifying data from the participant). **NOTE:** Since this method uses a single survey link for all participants, it allows for the possibility of participants taking the survey multiple times, which may be necessary in some cases.

To obtain the survey link, copy the URL below and paste it into the body of an email message in your own email client. Your email recipient(s) can then click the link to begin taking your survey.

Public Survey URL:

Link Actions

- Open public survey
- Open public survey + Log out
- Send me URL via email
- Survey Access Code or QR Code

Link Customizations

- Get Short Survey Link
- Create Custom Survey Link
- Get Embed Code

Participant view of eConsent



Resize font:



Research Study Consent Form

Please read the following consent and decide if you would like to participate in this study.

Thank you!

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF STUDY: A Prospective, Observational Study Evaluating Persistence on Treatment, Safety, Tolerability, and Effectiveness of Diroximel Fumarate in the Real-World Setting (EXPERIENCE-US Study)

STUDY NUMBER: US-VUM-11760

PRINCIPAL INVESTIGATOR: Jessica Craddock, MD

24-HOUR EMERGENCY PHONE NUMBER: (509) 252-1700

INTRODUCTION

You are being asked to volunteer to take part in this research study because you have multiple sclerosis (MS).

Before deciding whether you want to participate in this research study or not, it is important that you read and understand the following explanation of the study procedures. This consent describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative procedures, if any, that are available to you and your right to withdraw from the study at any time. No





Participant view of eConsent

Would you like to participate in the study?
** must provide value*

Yes
 No

reset

Signature of participant [Add signature](#)

Please type your full name

Please choose today's date  Today M-D-Y
Mon-day-year

Signature of person obtaining consent [Add signature](#)

Typed name of person obtaining consent

Please choose date  Today M-D-Y

Submit





Participant view of eConsent

- It is necessary for your safety.
- You do not follow instructions.
- You do not meet the conditions of the study.
- The study is closed for any reason.

PARTICIPANT CONSENT

I have read, or have had read to me, the information describing the study, and it is written in a language that I understand. All my questions have been answered to my satisfaction. I am signing this form voluntarily, indicating my willingness to be in this study. I understand that I am not giving up any of my legal rights by signing this form and I will receive a copy of this signed consent form.

Would you like to participate in the study?

* must provide value

- Yes
- No

reset

Thank you for considering the Experience Research Study

Submit



THIS

Move Project Into Production

REDCap Production

REDCap®

Logged in as susan.hood | Log out

My Projects

Project Home and Design

- Project Home
- Project Setup
- Designer
- Dictionary
- Codebook

Project status: Development

Data Collection

- Record Status Dashboard
- Add / Edit Records

Applications

- Project Dashboards
- Alerts & Notifications
- Calendar
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- Data Comparison Tool
- Logging
- Field Comment Log
- File Repository

Clinical Research Study eConsent

PID 5059

Project Home | **Project Setup** | Other Functionality | Project Revision History

Project status: Development Completed steps 0 of 7

Main project settings

Not started

Enable Use surveys in this project? [?](#) [VIDEO: How to create and manage a survey](#)

Enable Use longitudinal data collection with defined events? [?](#)

I'm done!

Modify project title, purpose, etc.

Design your data collection instruments

Not started

Add or edit fields on your data collection instruments. This may be done by either using the Online Designer (online method) or by uploading a Data Dictionary (offline method). Quick links: [Download PDF of all instruments](#) OR [Download the current Data Dictionary](#)

I'm done!

Go to or Explore the

Have you checked the [Check For Identifiers](#) page to ensure all identifier fields have been tagged?

Learn how to use

Move Project Into Production

REDCap Production

- Logging
- Field Comment Log
- File Repository
- User Rights and DAGs
- Data Quality
- REDCap Mobile App
- External Modules

Reports [Organize](#) [Edit](#)

1) Consented Patients

External Modules

- Data Dictionary Revisions
- Tableau Connector Instructions

Help & Information

- Help & FAQ
- Video Tutorials
- Suggest a New Feature

[Contact REDCap administrator](#)



Enable optional modules and customizations

Optional

Repeatable instruments ?

Auto-numbering for records ?

Scheduling module (longitudinal only) ?

Randomization module ?

Designate an email field for communications (including survey invitations and alerts) ?

Set up project bookmarks (optional)

Optional

You may create custom bookmarks to webpages that exist inside or outside of REDCap. These bookmarks will be seen as links on the left-hand project menu and can be accessed at any time by users who are given privileges to do so. Every project bookmark has custom settings that allow one to control its appearance and behavior.

Go to

User Rights and Permissions

Optional

You may grant other users access to this project or edit the user privileges of current users on this project by navigating to the User Rights page. Additionally, if you wish to limit user access to certain records/responses for this project, you may want to use Data Access Groups, in which only users within a given Data Access Group can access records created by users within that group.

Go to or

Test your project thoroughly

Not started

It is important to test the essential components of your project before moving it into production. Try creating a few test records and entering some data for each to ensure that your data collection instruments look and behave how you expect, especially branching logic and calculations. Then review your test data by creating reports and exporting your data to view in Excel or a statistical analysis package. If you have surveys, complete the surveys as if you were a participant by using the Public Survey Link or Participant List by sending a survey invitation to yourself. If other project modules will be used regularly, test them out a bit too. The best way to test your project is to use it as if you were entering real production data, and it is always helpful to have colleagues (especially team members) take a look at your project to get a fresh set of eyes looking at it.

Move your project to production status

Not started

Move the project to production status so that real data may be collected. Once in production, you will not be able to edit the project fields in real time anymore. However, you can make edits in Draft Mode, which will be auto-approved or else might need to be approved by a REDCap administrator before taking effect.

Go to

Signing the eConsent Form in Person



Cap
Log out

Project Setup
Primary Codebook
ment

Tools
build a participant list for

inviting respondents

Record Status Dashboard
- View data collection status of all records

Add / Edit Records
- Create new records or edit/view existing ones

Show data collection instruments

Applications

- Project Dashboards
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Test consent PID 4864

Survey Distribution Tools

Public Survey Link Participant List Survey Invitation Log

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To obtain the survey link, copy the URL below and paste it into the body of an email message in your own email client. Your email recipient(s) can then click the link to begin taking your survey.

Public Survey URL: <https://redcap.providence.org/redcap/surveys/?s=PYM8P34WAL>

Link Actions

- Open public survey
- Open public survey + Log out
- Send me URL via email
- Survey Access Code or QR Code

Link Customizations

- Get Short Survey Link
- Create Custom Survey Link
- Get Embed Code





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Public Survey URL: 

Link Actions

- Open public survey
- Open public survey + Log out
- Send me URL via email
- Survey Access Code or QR Code

Link Customizations

- Get Short Survey Link
- Create Custom Survey Link
- Get Embed Code

Signing Consent Remotely-Sending Email or Text

Research Study Consent Form - Message (HTML)

File Message Insert Options Format Text Review Help Acrobat Tell me

Clipboard Paste Basic Text Names Include Tags Dictate Sensitivity Immersive Reader View Templates

To: Hood, Susan C

Cc:

Subject: Research Study Consent Form

The link below will take you to the consent form for the Clinical Research Study. Please review the form prior to our call on Thursday. Please do not sign the consent form until after you have spoken with me.

<https://redcap.providence.org/redcap/surveys/?s=PYM8P34WAL>

Susan Hood, PhD, CCRC
 Clinical Research Coordinator
 Providence Medical Research Center
 105 W 8th Avenue
 Suite 250E
 Spokane, WA 99204
 O 509-474-4224
 F 509-474-4325
susan.hood@providence.org

 Providence



Signing Consent Remotely Staff Signs Separately

Project Home Project Setup Online Designer Data Dictionary Codebook

Create snapshot of instruments VIDEO: How to use this page
Last snapshot: never ?

The Online Designer will allow you to make project modifications to fields and data collection instruments very easily using only your web browser. NOTE: While in development status, all field changes will take effect immediately in real time.

Data Collection Instruments

Add new instrument:
[+ Create](#) a new instrument from scratch
[↓ Import](#) a new instrument from the official [REDCap Instrument Library](#) ?
[↑ Upload](#) instrument ZIP file from another project/user or [external libraries](#) ?

Survey options:
[Survey Queue](#) [Survey Login](#)
[Survey Notifications](#)

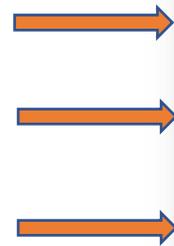
Automated Survey Invitation options:
[Upload or download Auto Invitations](#) ^
[Re-evaluate Auto Invitations](#)

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
Research Study Consent Form	28			Choose action ▾	Survey settings + Automated Invitations
Staff Obtaining Consent-Signature	8			Choose action ▾	Survey settings + Automated Invitations



Signing Consent Remotely Staff Signs Separately

Piping is used here to bring information in from the consent form the participant filled out.



Current instrument: **Staff Obtaining Consent-Signature** Preview instrument

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

Variable: use_participant_id
Participant ID

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

Variable: participant_first
Participant first name:

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

Variable: use_participant_last
Participant last name:

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

Variable: consent_record
Did patient consent to research study

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

Variable: sig_person_consenting *Branching logic: [consent_yn] = '1'*
Signature of person obtaining consent
** must provide value*
[Add signature](#)

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

Variable: firstname_obtaining *Branching logic: [consent_yn] = '1'*
Please enter your first name
** must provide value*

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

Variable: lastname_obtaining *Branching logic: [consent_yn] = '1'*
Please enter your last name
** must provide value*

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)

Variable: date_person_consenting *Branching logic: [consent_yn] = '1'*
Please enter the date M-D-Y

[Add Field](#) [Add Matrix of Fields](#) [Import from Field Bank](#)



Staff Signs Separately

Staff can access the form to sign through the Record Status Dashboard



REDCap Production

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My Projects

Project Home and Design

- Project Home · Project Setup
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- Project status: Development

Data Collection

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Research Study Consent Form PID 4864

Research Study Consent Forms

Dashboard displayed: Research Study Consent Forms Modify

Displaying record Page 1 of 1: "1" through "6" of 6 records

+ Add new record

Displaying: Instrument status only | [Lock status only](#) | [All status types](#)

Record ID	Research Study Consent Form	Staff Obtaining Consent-Signature
1	✓	✓
2	✓	✓
3	✓	○
4	✓	○
5	✓	✓
6	✓	✓



Staff Signs Separately



Research Study Consent Form PID 4864

Actions: [Modify instrument](#) [Download PDF of instrument\(s\)](#) [VIDEO: Basic data entry](#)

Staff Obtaining Consent-Signature Invitation status: [Survey options](#)

[Editing existing Record ID 7](#)

Record ID 7

Participant ID

Participant first name: Penelope
Participant last name: Participant
Did patient consent to research study: [Yes](#)

Signature of person obtaining consent [Add signature](#)

Please enter your first name

Please enter your last name

Please enter the date Today M-D-Y

Form Status

Complete?

[Save & Exit Form](#)
[Save & Mark Survey as Complete](#)
[-- Cancel --](#)
[Delete data for THIS FORM only](#)

NOTE: To delete the entire record (all forms/events), see the



Download PDF of Consent



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Research Study Consent Form

PID 4864

Research Study Consent Forms

Dashboard displayed: Research Study Consent Forms

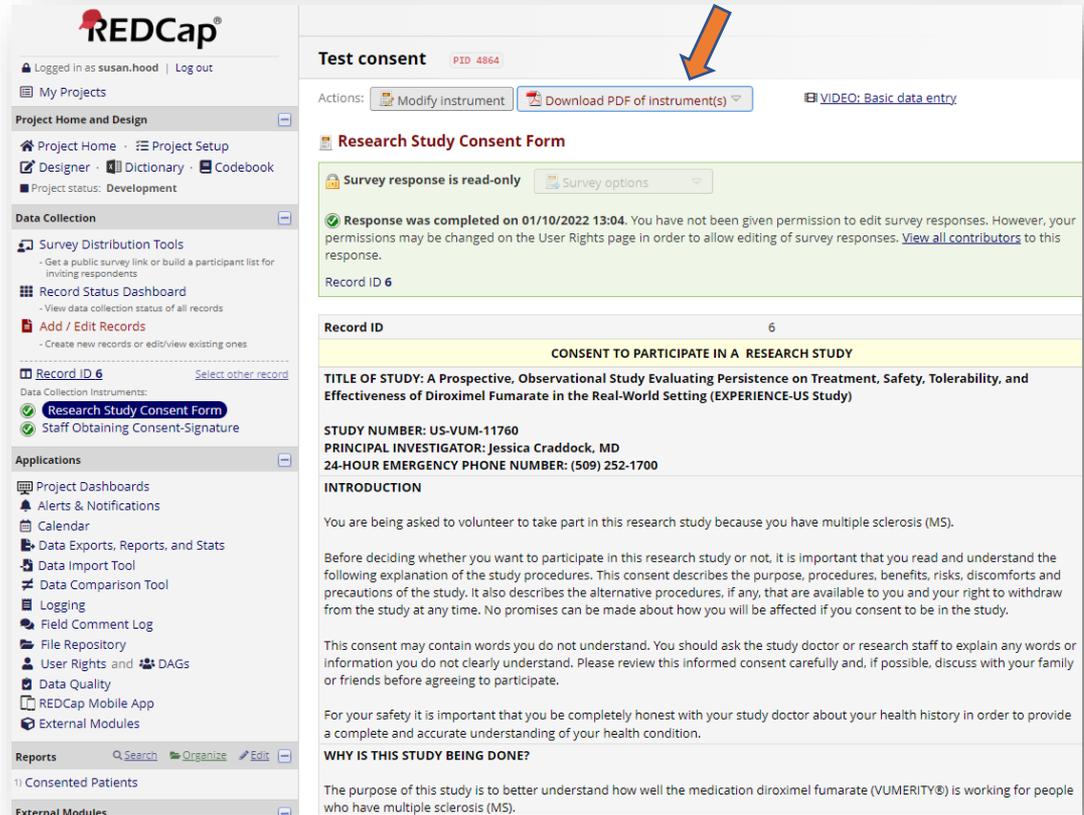
Displaying record Page 1 of 1: "1" through "6" of 6 records

Displaying: Instrument status only | [Lock status only](#) | [All status types](#)

Record ID	Research Study Consent Form	Staff Obtaining Consent-Signature
1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
3	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
4	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
6	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>



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My Projects
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Project Home · Project Setup
Designer · Dictionary · Codebook
Project status: Development
Data Collection
Survey Distribution Tools
Record Status Dashboard
Add / Edit Records
Record ID 6
Data Collection Instruments:
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Staff Obtaining Consent-Signature
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Data Import Tool
Data Comparison Tool
Logging
Field Comment Log
File Repository
User Rights and DAGs
Data Quality
REDCap Mobile App
External Modules
Reports
Consented Patients
External Modules

Test consent PID 4864
Actions: Modify Instrument Download PDF of Instrument(s) VIDEO: Basic data entry
Research Study Consent Form
Survey response is read-only Survey options
Response was completed on 01/10/2022 13:04. You have not been given permission to edit survey responses. However, your permissions may be changed on the User Rights page in order to allow editing of survey responses. [View all contributors](#) to this response.
Record ID 6
Record ID 6
CONSENT TO PARTICIPATE IN A RESEARCH STUDY
TITLE OF STUDY: A Prospective, Observational Study Evaluating Persistence on Treatment, Safety, Tolerability, and Effectiveness of Diroximel Fumarate in the Real-World Setting (EXPERIENCE-US Study)
STUDY NUMBER: US-VUM-11760
PRINCIPAL INVESTIGATOR: Jessica Craddock, MD
24-HOUR EMERGENCY PHONE NUMBER: (509) 252-1700
INTRODUCTION
You are being asked to volunteer to take part in this research study because you have multiple sclerosis (MS).
Before deciding whether you want to participate in this research study or not, it is important that you read and understand the following explanation of the study procedures. This consent describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative procedures, if any, that are available to you and your right to withdraw from the study at any time. No promises can be made about how you will be affected if you consent to be in the study.
This consent may contain words you do not understand. You should ask the study doctor or research staff to explain any words or information you do not clearly understand. Please review this informed consent carefully and, if possible, discuss with your family or friends before agreeing to participate.
For your safety it is important that you be completely honest with your study doctor about your health history in order to provide a complete and accurate understanding of your health condition.
WHY IS THIS STUDY BEING DONE?
The purpose of this study is to better understand how well the medication diroximel fumarate (VUMERITY®) is working for people who have multiple sclerosis (MS).





RECOVER Research Study Website

Home Study Partners About Eligibility What is PASC? Study Goals Screening Form [Get Started](#)

Welcome to the PNW Consortium

RECOVER Study

[GET STARTED >](#)





Help us better understand the **long-term effects** of COVID.

If you or someone in your family has had COVID, or are feeling the long term effects of COVID, you might be able to help us understand more about it and treat it. Even if you have not had COVID, you might be able to help.

[GET STARTED >](#)






RECOVER Research Study Screening Form

RECOVER Study Pre-Enrollment Screening

Thanks for your interest in joining RECOVER

The purpose of this study is to better understand the long-term effects of COVID-19, and who is at greatest risk of having long-term effects. Over several years, we will do this by studying people with and without a history of COVID-19.

Please enter your contact information and answer the questions below

A study coordinator will contact you to determine your eligibility and help you enroll if you qualify.

You must be at least 18 years of age to join the study. Are you 18 or older?

[reset](#)

Your first name

Your last name

Your email address

Your phone number

Does the phone number you provided receive text messages? [reset](#)

What is your preferred method of contact? [reset](#)

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[reset](#)

Your first name

Your last name

Your email address

Your phone number

Does the phone number you provided receive text messages? [reset](#)

What is your preferred method of contact? [reset](#)





RECOVER Research Study Consent Form

Resize font:



An Initiative Funded by the National Institutes of Health

Join the Study

Partner with us to support research on the long-term effects of COVID

Title of Study:

NIH RECOVER: A Multi-Site Observational Study of Post-Acute Sequelae of SARS-CoV-2 Infection in Adults

Site Study Leaders





REDCap Training Resources

- ITHS Online Training Courses

<https://www.iths.org/investigators/services/bmi/redcap/curriculum/>

- REDCap Training Videos (within the app) or online

<https://projectredcap.org/resources/videos/>



Questions?

