



Enabling Better Workflows through DFdiscover, Randomization, and eConsent Integration

24 July 2024

Questions

Use the Chat feature in Teams at any time to ask questions or share feedback.

Recording

You'll receive a link to the webinar recording via email after the event.

Resources

Check out previous webinars and more about DFnet at <https://dfnetresearch.com>

Speakers



Anthony Varacalli

Director of Sales, DFnet

United States



Laura Joldersma

Product Manager, DFnet

Canada



Alex Lemnar

CEO, Diamind Solutions Inc.

Canada



Better Data. Better Insight. Better Care

DFUG 2024

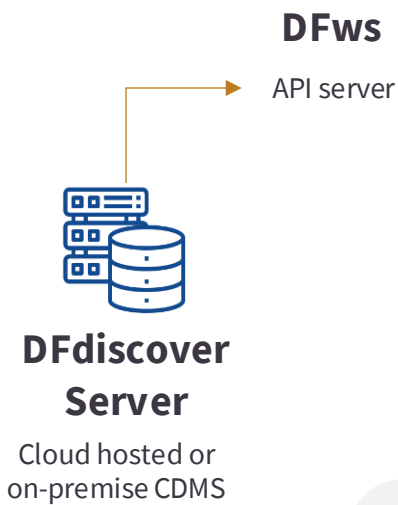
Drive Your Research Forward with AI

October 3-4th, 2024 | Boston, MA

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Early-Bird BOGO (Buy One, Get One Free): \$1,049 USD

Full-Price DFUG Ticket: \$1,049 USD



DFws
API server

Web and mobile apps

DFweb
Web app for browser-based EDC

DFcollect
Tablet app for online/offline EDC

DFsources
Mobile app for source document submission

Add-ons

DFengage
ePRO mobile app

Randomization
Integrated randomization module

DFconsent
Integrated electronic consent system

Desktop apps for power users

Desktop apps for paper studies

DFexplore
Data collection and management

DFsetup
Study setup and configuration

DFadmin
User, study, and server admin

DFATK
Acceptance Test Kit

DFsend
Submit scanned paper CRFs

DFbarcode
Create barcodes for paper CRFs

Client-side command-line programs: DFattach, DFaudittrace, DFbatch, DFexport, DFpass, DFpdfpkg, DFreport, DFuserPerms

Integrated eConsent and Randomization



- Reduce administrative burden of paper forms and manual data entry
- Obtain informed consent in person or remotely



- Lower sample sizes and adjust to enrollment reality with adaptive randomization
- Support flexible randomization methods

Powered by **DI▲MIND** and  **dfdiscover**



Electronic Consent

- Integrates seamlessly with DFdiscover EDC
- Reduces data transcription, paper, storage
- Suitable for in-person or remote consent
- Custom workflows meet study requirements
- Compliant electronic and/or digital signatures

The image displays three overlapping components of the electronic consent process:

- Consent Form (Providence):** A document titled "Consent to Contact You if Researchers Discover New Information After Your Participation Ends" and "Consent to Use of Data and Specimens for Future Research". It includes checkboxes for consent and non-consent, and fields for the participant's signature and date.
- Signature Certificate:** A green document certifying the electronic signature. It includes the participant's name, email, and a digital signature. It also contains a "Viewed" and "Signed" timestamp.
- Consent - Step 4 Confirmation:** A blue confirmation screen stating "Confirmation - Consent Has Been Provided!". It displays the Site ID (902), Subject ID, Consent Type (Patient), Consent Method (Electronic), Consent Options (Stay In Study), and Document Link (Patient Consent). It features "Randomize" and "Randomize later" buttons.

Powered by **DIAMIND** and **dfdiscover**

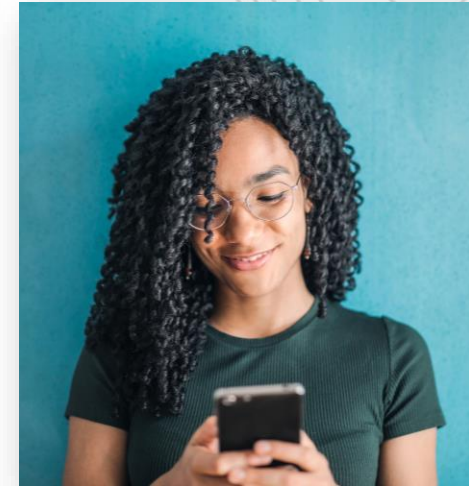


Consent Methods

Electronic: Use one device for all consent parties to review and complete the consent form (e.g., tablet, laptop)

Email: Send consent parties a link to the electronic consent form via email or text message

Paper: Upload a scanned copy of the consent form if completed on paper





Secure Electronic & Digital Signatures

- Ease of use for everyone involved in consent
- Signature certificate generated for each consent
- Digital certificate signing is also available


SIGNATURE OF STUDY PARTICIPANT:

* Name of Participant :

Test Participant

* Signature of Participant :

Draw Signature Type Signature



Clear

SIGNATURE OF THE WITNESS:

Name of Witness (if applicable) :

Laura Joldersma

Signature of Witness :

Draw Signature Type Signature

Laura Joldersma

Laura Joldersma

Signature Certificate

Type: Consent patient electronic

Reference number: 7ed400e17fa4b32d24ad40204a6246b97c29b0d666c49675fc58c7c5dd3a516d

Consent document hash (sha256):
fd62e10023787c4875ccbb71a59dee00988e23e34cd80ae665bacc88b17ab3

Signer	Timestamp	Signature
Test Participant Consent subject Email: laura@dfnetresearch.com	Viewed: 2024-06-06 16:45:03 UTC Signed: 2024-06-06 16:48:47 UTC	
Laura Joldersma Witness	Viewed: 2024-06-06 16:45:03 UTC Signed: 2024-06-06 16:50:46 UTC	<i>Laura Joldersma</i>
Dr. Tina Investigator Investigator	Viewed: 2024-06-06 16:45:03 UTC Signed: 2024-06-06 16:49:41 UTC	

Document completed by all parties on: 2024-06-06 16:50:46 UTC

Consent Version: 12

Date form consent: 2024-05-30 22:07 UTC

Page 1 of 2



eConsent Form Styles

Consent - Step 3a
Consent Process - Surrogate

Site ID: 901
Subject ID:

MAIN CONSENT TO PARTICIPATE IN RESEARCH

TITLE: A Multicentre, Prospective, Randomized, Parallel Group, Open-label Design to Determine the Efficacy and Safety of Endovascular Thrombectomy for ischemic stroke patients with symptomatic Acute Medium Vessel Intracranial Occlusions (ESCAPE-MeVO Trial)

PROTOCOL NO.: UNI-CL-5000 WCG IRB Protocol #20222522 STUDY2022000726

SPONSOR: Governors of the University of Calgary

FUNDER: Canadian Institutes of Health Research (CIHR), Medtronic

COORDINATING CENTRE: University of Calgary

INVESTIGATOR: George Lopez, MD, PhD
500 17th Ave, Suite 400 Seattle, WA 98122
United States

STUDY-RELATED
PHONE NUMBER(S): 206-320-2208
206-320-2800(24 hours)

INTRODUCTION

Server Date (UTC): 2024-06-11 16:51:57
Consent Type: Patient
Consent Method: Electronic

* CONSENT TO CONTACT YOU IF RESEARCHERS DISCOVER NEW INFORMATION AFTER YOUR PARTICIPATION ENDS:

- Yes I consent for the researchers to share findings with me.
- No I do not consent for the researchers to share findings with me.

* CONSENT TO USE OF DATA AND SPECIMENS FOR FUTURE RESEARCH:

- Yes I consent to the use of my research data and/or specimens for future research.
- No I do not consent to the use of my research data and/or specimens for future research.

* CONSENT TO CONTACT YOU FOR FUTURE RESEARCH/INFORMATION:

- Yes I consent to be contacted in the future.
- No I do not consent to be contacted in the future.

* CONSENT TO CONTACT YOUR FAMILY DOCTOR:

- Yes I consent for my family doctor to be informed of my participation.
- No I do not consent for my family doctor to be informed of my participation.


* Please check the appropriate box to indicate your decision:

- I wish to remain in the study.
- I wish to withdraw from the study.

SIGNATURE OF STUDY PARTICIPANT:

* Name of Participant:
Test Participant

* Signature of Participant:
Draw Signature Type Signature

 Clear

Sign PDF

UNIVERSITY OF CALGARY

**Declaration of Investigator and Independent Physician
for enrollment of a patient incapable to consent**

TITLE: A Multicentre, Prospective, Randomized, Parallel Group, Open-label Design to Determine the Efficacy and Safety of Endovascular Thrombectomy for ischemic stroke patients with symptomatic Acute Medium Vessel Intracranial Occlusions (ESCAPE-MeVO Trial)

PROTOCOL NUMBER: UNI-CL-5000

SPONSOR-INVESTIGATOR: Governors of the University of Calgary

FUNDER: Canadian Institutes of Health (CIHR), Medtronic

COORDINATING CENTRE: University of Calgary

SITE INVESTIGATOR: Dr. Andrew Demchuk (403) 944-8671

Printed name of patient: _____
Subject Study No: _____

Deferral of Consent - Inclusion Criteria - Must meet all Inclusion criteria by answering YES

Is the deferral of consent process being utilized? Yes—complete form No—Do not complete

1. In the opinion of the study physician who has performed a capacity assessment, the participant does not have the capacity to provide his/her own informed consent.	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
2. In the opinion of the independent physician, who has performed a capacity assessment, the participant does not have the capacity to provide his/her own informed consent.	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
3. A Legally Authorized Representative (LAR) (i.e. substitute decision maker) is not available at the time of proposed enrollment (time of baseline CT scan).	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
4. Available alternatives to study enrollment have been considered (including no enrollment), and enrollment in the present study is felt to be in the best interest of the participant after weighing the potential benefits and potential risks of study participation.	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
5. The investigator will continue to make reasonable efforts to locate a LAR for review of the informed consent from as soon as possible after randomization, and will reassess the participant's capacity to consent on an ongoing basis, as outlined in the protocol.	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes

Overall Eligibility Status

Subject meets all criteria for deferral of consent: Yes to ALL inclusion No Yes


Has this form been signed and dated (below) by both Investigator and Independent Physician No Yes

Name of Investigator (print) _____ Signature _____ Date _____ Time _____

Name of Independent Physician (print) _____ Signature _____ Date _____ Time _____

* Big new signature: Clear

Draw Type



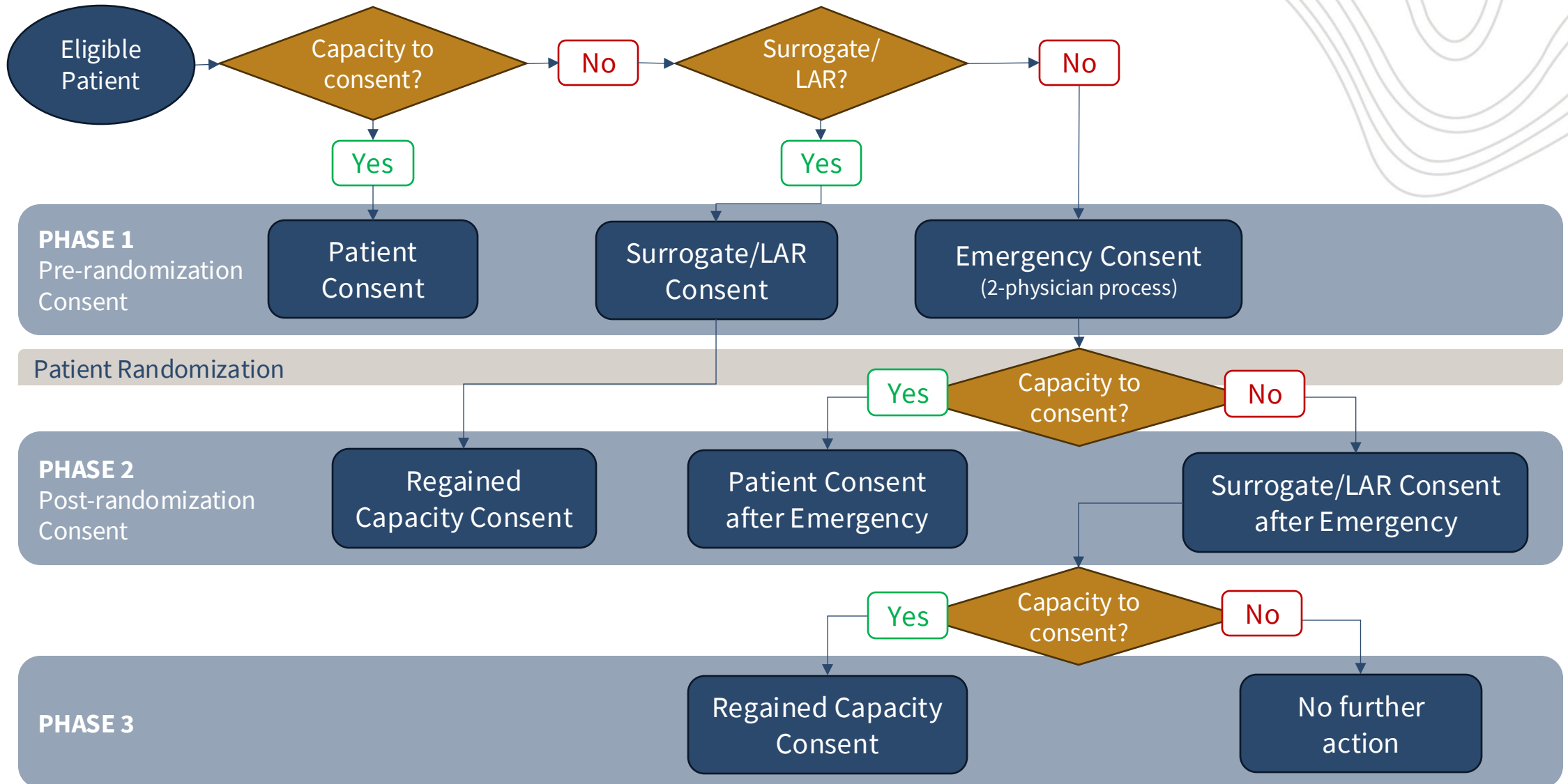
Next

HTML Style

PDF Style

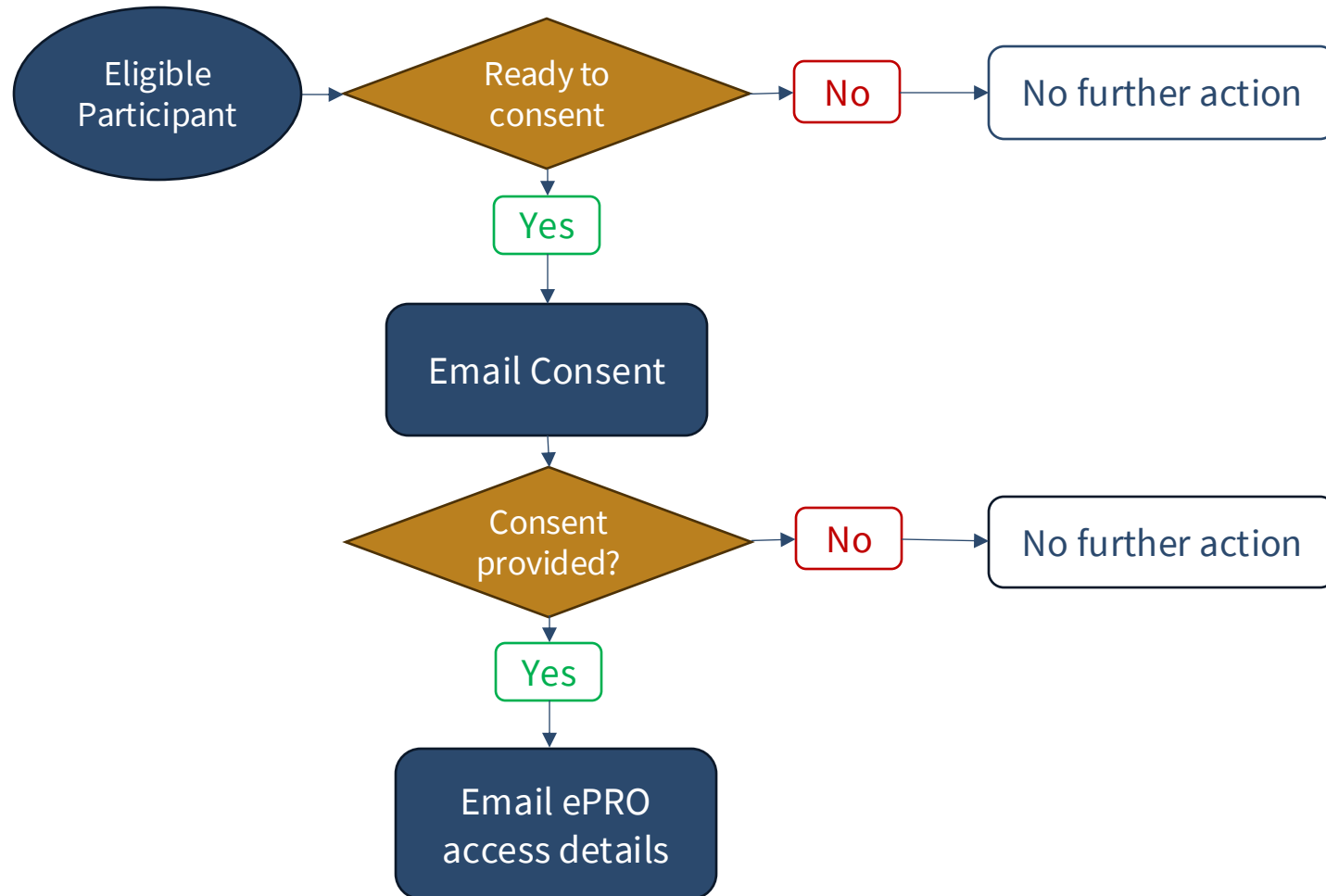
USE CASE 1

Consent Workflow for Acute Treatment Trials



USE CASE 2

Integrated Email Consent & ePRO Workflow

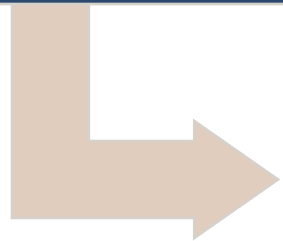




Obtaining eConsent

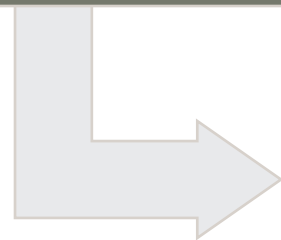
Identify consent type & method

- Who is giving consent? *Patient, Surrogate, Emergency*
- How is consent being obtained? *Electronic, Email, Paper*
- Who is obtaining consent? *Investigator, Other Role*



Consent parties review & sign

- Appropriate parties review and sign
- Type or draw electronic signatures
- Additional custom fields per consent requirements



Consent PDF & data shared

- Consent PDF and certificate stored in system
- Consent PDF shared with participant by email
- Consent data pushed to DFdiscover



eConsent DFdiscover Integration

399: eConsent Integration Save ⋮

▼ Main Screen

Subject ID

901009

This form is view only and auto-completed from the eConsent system.

Consent obtained

Yes No

Who provided consent	Date of Consent	Time of Consent	Outcome of Consent Process
<input checked="" type="radio"/> Patient <input type="radio"/> Surrogate <input type="radio"/> Emergency	06/JUN/2024	10:48	<input checked="" type="radio"/> Subject Consented <input type="radio"/> Subject Declined <input type="radio"/> Surrogate Consented <input type="radio"/> Surrogate Declined

Who obtained consent	Person obtaining consent	Investigator certifying consent
<input type="radio"/> Investigator <input checked="" type="radio"/> Other Role	Alice Study Nurse	Dr. Tina Investigator

- When consent is complete, data is pushed to DFdiscover with matching subject ID
- Fields pushed to EDC:
 - Consent date & time
 - Consent type & method
 - Person obtaining consent
 - Investigator certifying consent
 - Other data as needed

eConsent integration CRF in DFweb

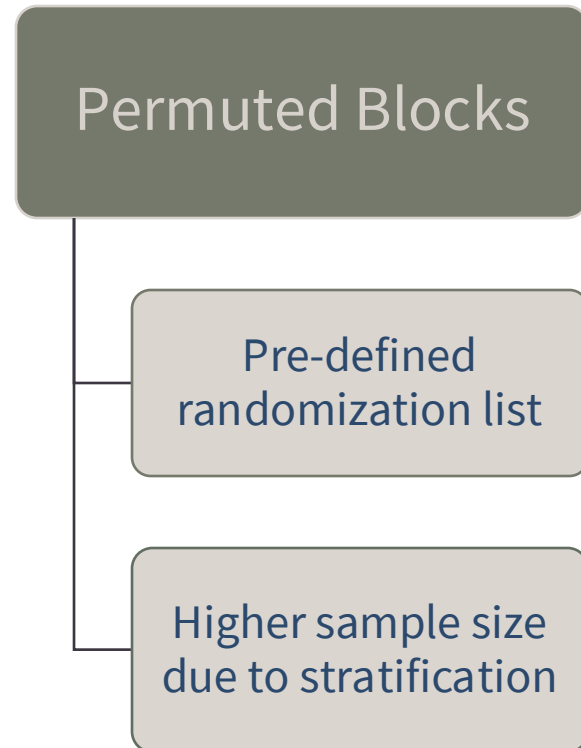
Integrated Randomization

- State of the art randomization algorithms
- Minimize sample size without losing statistical power
- Adapt to study enrollment challenges and realities
- Online and offline randomization options
- Integrates seamlessly with DFdiscover EDC
- Secure, compliant electronic systems

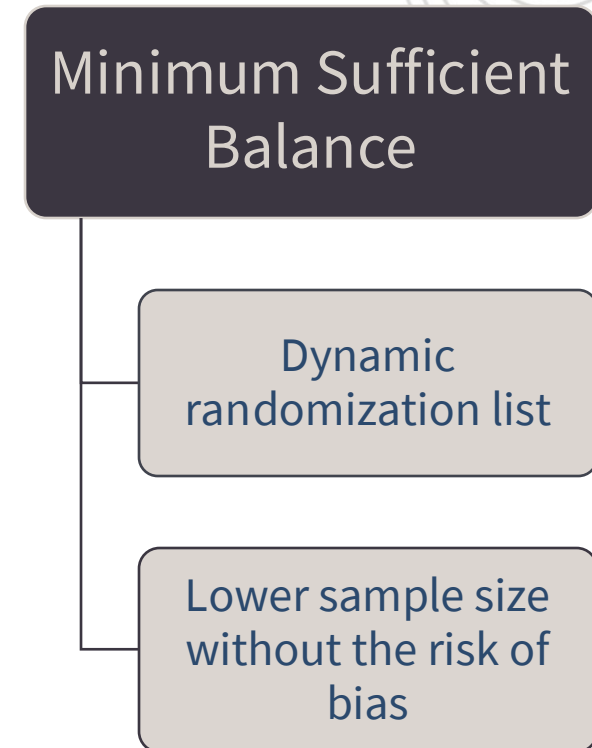
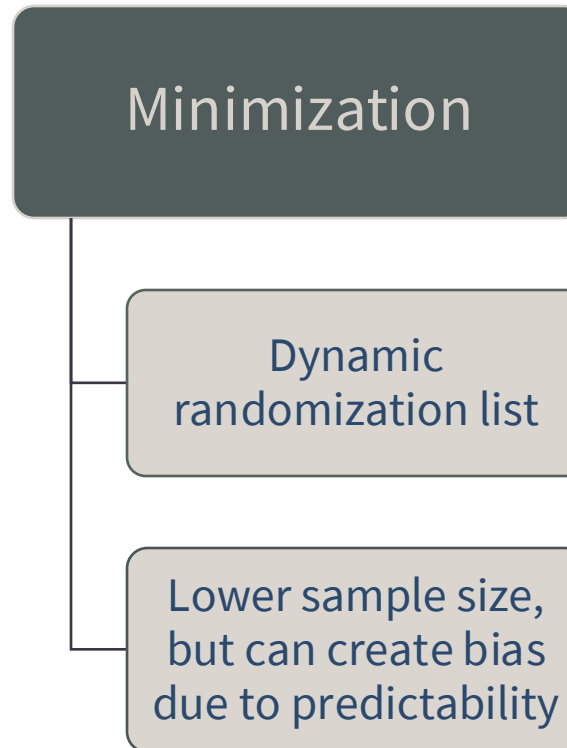
Powered by **DI▲MIND** and  **dfdiscover**

Randomization Algorithms

Static Algorithms



Adaptive Algorithms



Proven solution for faster enrollment

Adaptive Randomization algorithms can help reduce your study sample size by 20% or more

Example 1 (7 covariates, $p \leq 0.05$):

- Permuted blocks algorithm: 1,267 participants required
- Adaptive algorithm: 550 participants required

Example 2 (10 covariates, $p \leq 0.05$):

- Permuted blocks algorithm: 1,600 participants required
- Adaptive algorithm: 850 participants required



References:

Westland, J.C. (2010). Lower bounds on sample size in structural equation modeling. *Electronic Commerce Research and Applications*, 9(6), 476-487.

Soper, D.S. (2024). A-priori Sample Size Calculator for Structural Equation Models [Software]. Available from <https://www.danielsooper.com/statcalc>

Key Benefits of Adaptive Randomization

Can balance a very high number of variables

Supports continuous, categorical and mixed variables

Balances subjects at patient enrollment

Reduces overall number of subjects required

Improves the chances of detecting effects

Adapts to challenges like low enrolling sites, early termination

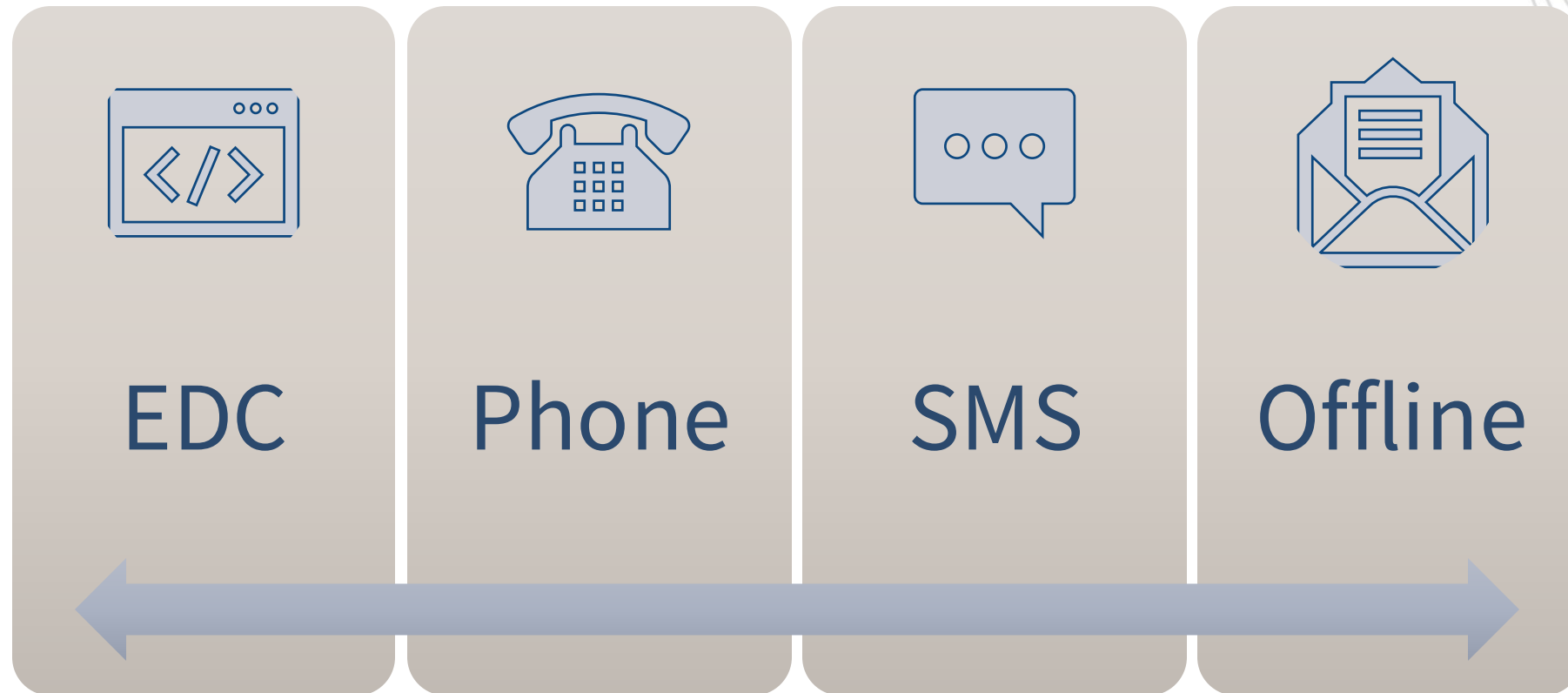
Reduces cost and time of executing trials

Additional Randomization Considerations

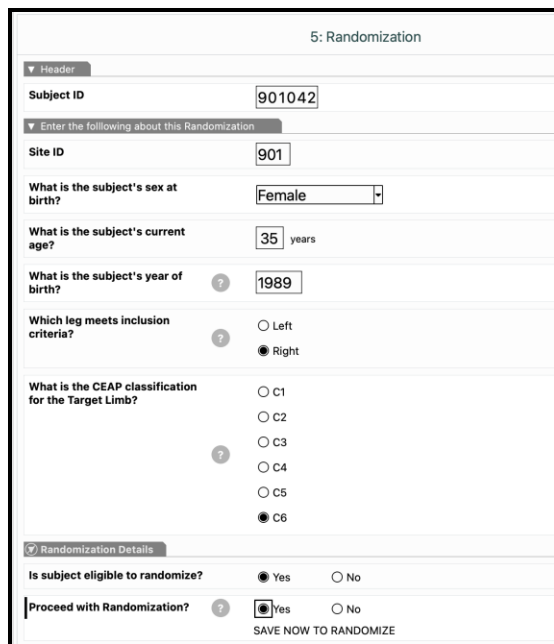
- Emergency Unblinding
 - On demand treatment unblinding for safety reasons
 - Request & approval by authorized personnel
- Randomization Error Handling
 - Address randomization errors, protocol violations, and re-randomizations



Randomization Mechanisms



EDC Randomization with DFdiscover



5: Randomization

▼ Header

Subject ID

▼ Enter the following about this Randomization

Site ID

What is the subject's sex at birth?

What is the subject's current age? years

What is the subject's year of birth?

Which leg meets inclusion criteria? Left Right

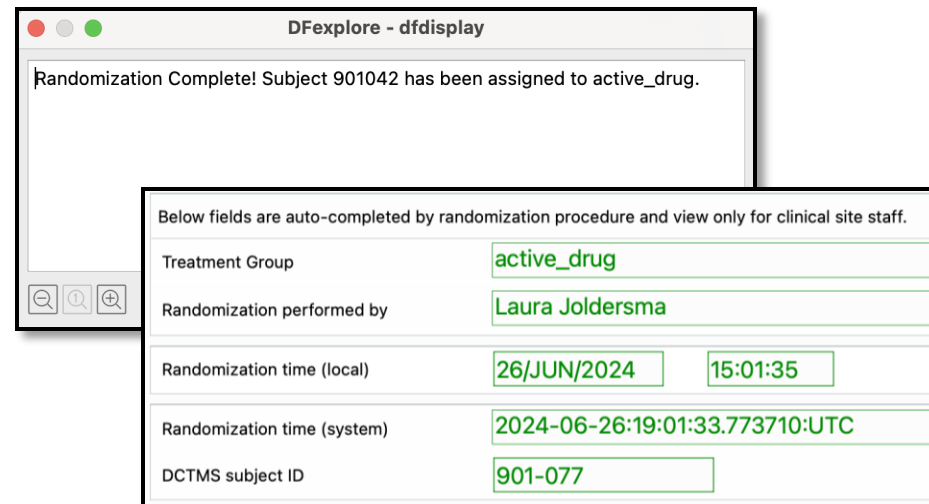
What is the CEAP classification for the Target Limb? C1 C2 C3 C4 C5 C6

▼ Randomization Details

Is subject eligible to randomize? Yes No

Proceed with Randomization? Yes No

SAVE NOW TO RANDOMIZE

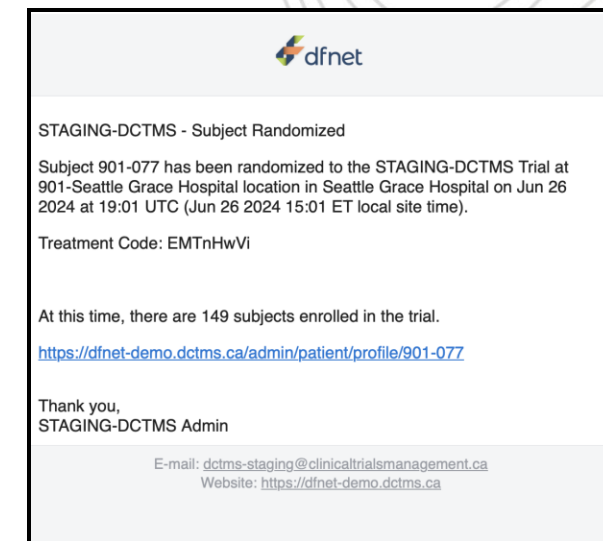


DFExplore - dfdisplay

Randomization Complete! Subject 901042 has been assigned to active_drug.

Below fields are auto-completed by randomization procedure and view only for clinical site staff.

Treatment Group	<input type="text" value="active_drug"/>
Randomization performed by	<input type="text" value="Laura Joldersma"/>
Randomization time (local)	<input type="text" value="26/JUN/2024"/> <input type="text" value="15:01:35"/>
Randomization time (system)	<input type="text" value="2024-06-26:19:01:33.773710:UTC"/>
DCTMS subject ID	<input type="text" value="901-077"/>



dfnet

STAGING-DCTMS - Subject Randomized

Subject 901-077 has been randomized to the STAGING-DCTMS Trial at 901-Seattle Grace Hospital location in Seattle Grace Hospital on Jun 26 2024 at 19:01 UTC (Jun 26 2024 15:01 ET local site time).

Treatment Code: EMTnHwVi

At this time, there are 149 subjects enrolled in the trial.

<https://dfnet-demo.dctms.ca/admin/patient/profile/901-077>

Thank you,
STAGING-DCTMS Admin

E-mail: dctms-staging@clinicaltrialsmanagement.ca
Website: <https://dfnet-demo.dctms.ca>

Provide eligibility & randomization variables on CRF

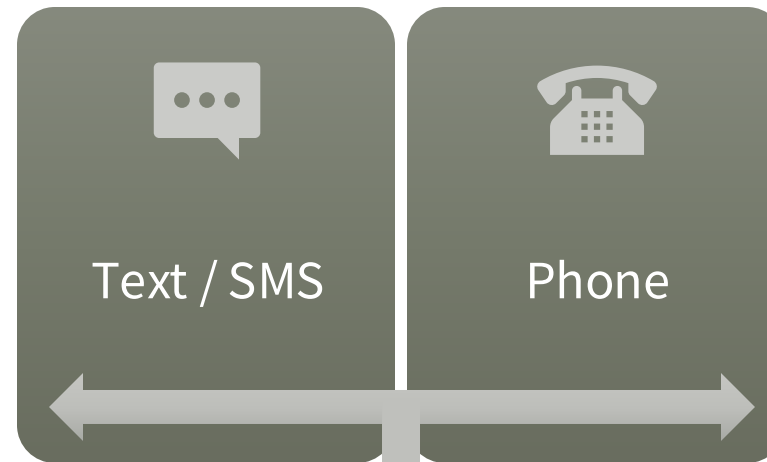
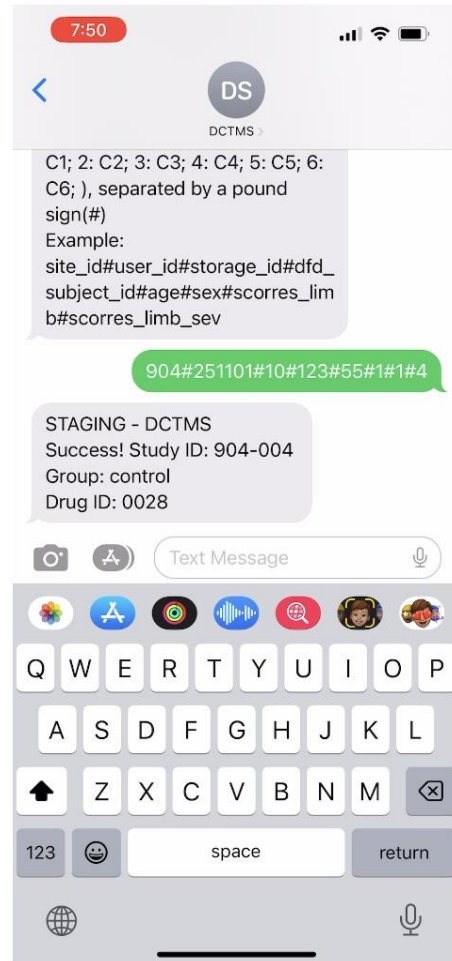


Randomization results displayed and details auto-filled in CRF



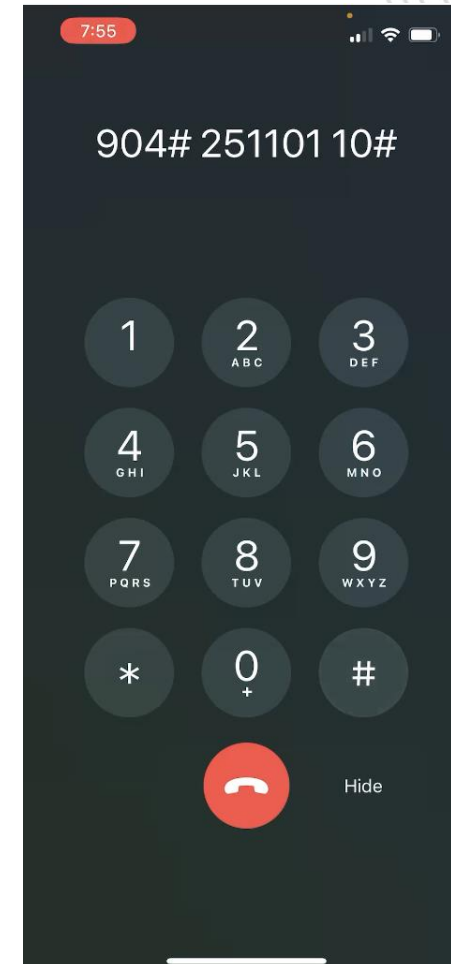
Randomization notifications sent via email to appropriate parties

Text & Phone Randomization



Randomization results auto-filled
in DFdiscover CRF

Randomization notifications sent
via email to appropriate parties



System Security & Compliance

High-availability solution, multiple parallel instances

Supports both cloud and on-prem deployments

Flexible geographic data location

Encryption at-rest and in-transit

Multi-factor authentication

Role-based access controls

Complete audit logging

21 CFR Part 11 compliant, enables FIPS 140-2/3



Electronic Consent & Randomization



https://dfnet-demo.dctms.ca/admin/login



DCTMS Trial Admin Portal

Authenticate

Forgot your User ID or password? [Click here](#)

Need a new password creation token? [Click here](#)

Need help? [Click here](#)



Remote Email Consent & ePRO



https://dfweb.dfdiscover.com/login



explore.dfdiscover.com




Username

Password

[Forgot Password?](#)

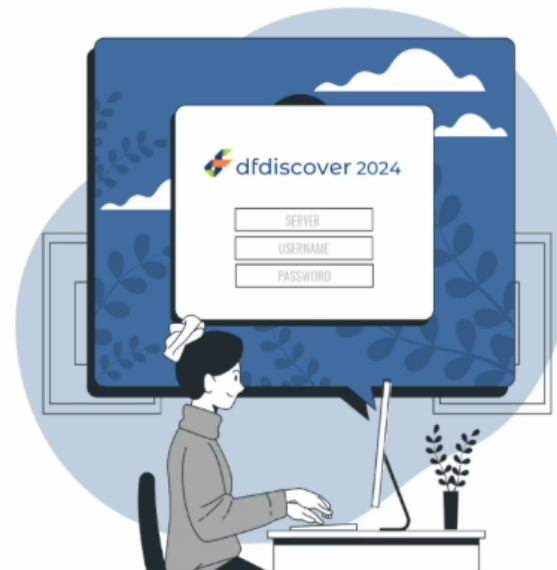
Login

OR

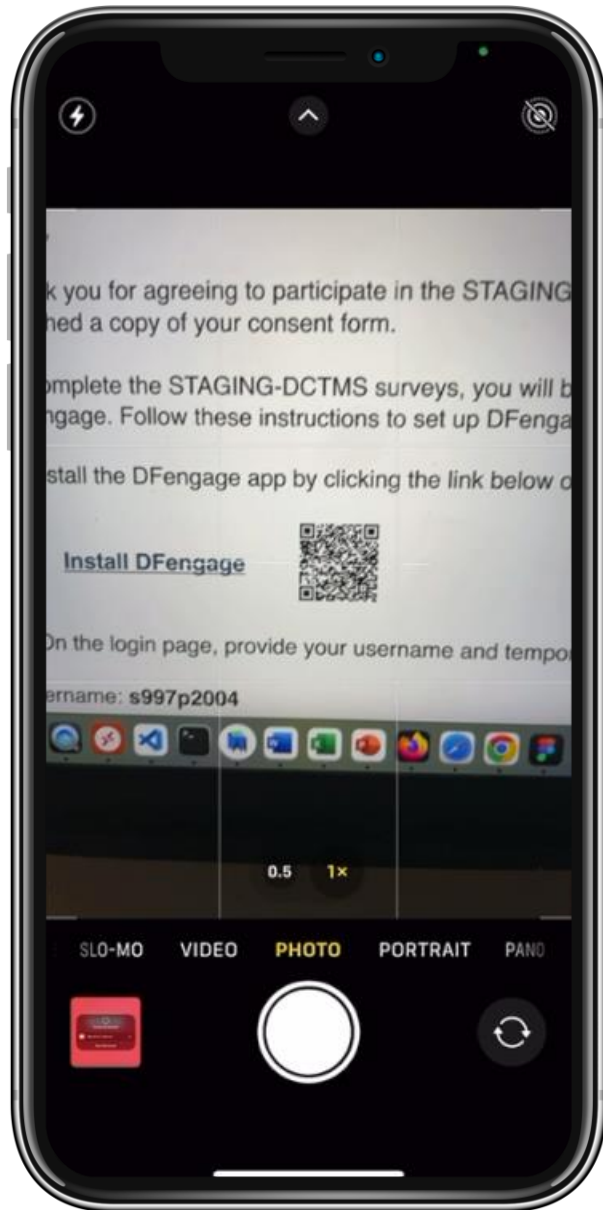
 Login with Microsoft

 Settings

 Privacy Policy



Welcome to explore.dfdiscover.com





eConsent Form Setup

- Create multiple consent versions as needed
 - Site-specific versions
 - Consent setting types
- **HTML:** Copy & paste text with formatting options
- **PDF:** Upload PDF form
- Define custom questions & signature fields

Consent Management

Admin Settings / Consent Management / Edit

Add Consent

Name:

Consent setting type: Consent workflow type: Template file type:

Applied to: Site ID:

Consent version: Consent form date: HH:mm

[Code](#) [Visual editor](#) [Preview](#)

Content:

Informed Consent Form

Project title
Exposure to pesticides among farm workers in Saskatchewan

Study Investigators
Principal Investigator: Dr. Jane Smith, Healthy Environments and Consumer Safety Branch, Health Canada. Phone: 613-555-1545. jane.smith@canada.ca
Co-investigator: Dr. Mike Jones, Healthy Environments and Consumer Safety Branch, Health Canada. Phone: 613-555-1212; michael.jones@canada.ca

Funding source
This study is funded by Health Canada using internal funds.

Invitation to participate
You are being invited to participate in a research study on exposure to pesticides among farm workers in Saskatchewan. Your participation is entirely your choice. If you decide not to participate, there will be no negative impacts on your relationship with the information provided in this form tells you about what is involved in the research, what you will be asked to do, and any potential risks. Please read this form carefully, take all the time you need, and ask any questions you may have.

Consent is an ongoing process. During the research study, we will tell you about any significant finding that could affect your work to participate in this study.

Preview gets updated AFTER SAVE

Consent setting type:

- Consent Patient Form
- Consent Patient Regained Capacity Form
- Consent Surrogate
- Consent Emergency
- Participant After Deferral
- Surrogate After Deferral
- Patient Regained Capacity After Deferral
- SITE

Drag Pdf

Validate and log
Scroll to element

Edit Field

Type: InputText

* Field Name:

Required

* Label:

Required

EDC & ePRO



- Powerful, flexible, user-friendly data capture with real-time access
- Ensure data quality and integrity both online and offline

eConsent



- Go digital with a secure and compliant eConsent system
- Improve patient experience, reduce paper and data entry burden

Randomization



- State of the art algorithms reduce sample size without reducing power
- Flexible, anytime access via web, text message, and phone

Q & A

SHORT SURVEY

Help Shape Future DFnet Webinars

Scan for survey or follow the link in the chat.



GETTING STARTED

Interested in eConsent or Randomization?

Contact us at info@dfnetresearch.com

UPCOMING EVENTS

[DFUG 2024] DFdiscover User Group Meeting

October 3-4, 2024 | Boston, MA

Early-Bird BOGO (Buy One, Get One Free) registration ends next Thursday, August 1st

Questions? Contact dfug@dfnetresearch.com



Thank you!