



eConsent: A practical guide to developing and using eConsent

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Outline

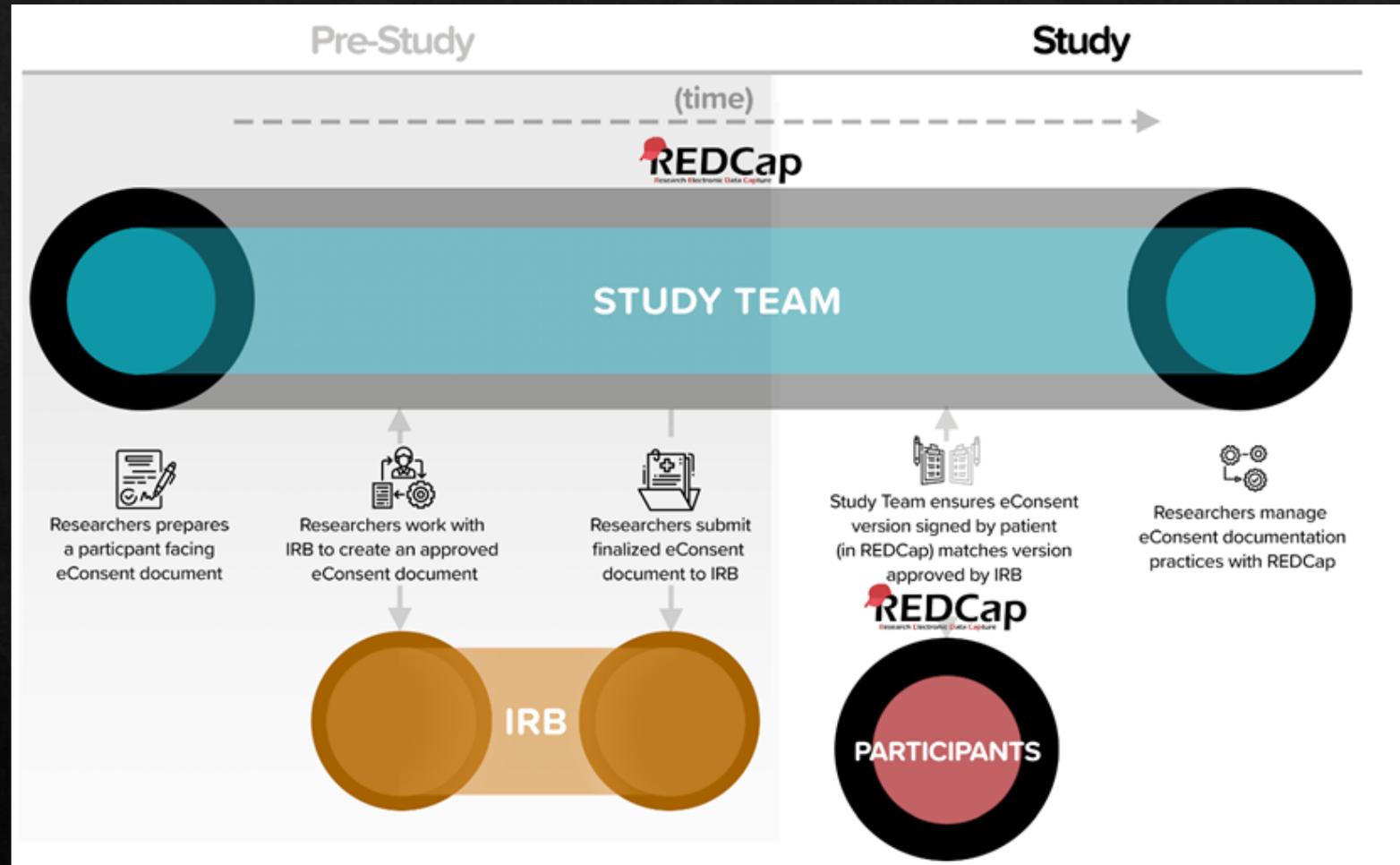
- ◇ eConsent overview
- ◇ Part-11 compliance
- ◇ Multi-center clinical trials
- ◇ Key features and External Modules
 - ◇ Videos
 - ◇ Hover and click
 - ◇ Avatar
 - ◇ Analytics
- ◇ Help me
- ◇ Building an eConsent (version control, setup, file repository)
- ◇ Additional Resources

Overview

- ◆ eConsent is a REDCap-based framework which seeks to provide a more personalized consent experience.
- ◆ Users may be guided through a web-based consent document that utilizes avatars, contextual glossary information supplements, videos, images, text reader functions, branching questions for comprehension, and other features.
- ◆ The goal of the framework is to facilitate communication of information to patients in a culturally relevant manner respective of health literacy level – “precision consenting”

Process

- ◆ The development and approval of an appropriate eConsent rely on input from the Study team, IRB, and participants.



Part-11 Compliance

What is it?

- ◇ 21 CFR Part 11 (or Part 11 herein) refers to the Code of Federal Regulations, established by the FDA to govern the criteria under which electronic records and signatures can be considered secure and trustworthy (i.e. equivalent in fidelity to paper records).
- ◇ Software cannot be 21 CFR Part 11 compliant alone – procedural controls are also required.
- ◇ VUMC has verified and documented its software and required procedural controls with the validation of the REDCap Informed Consent module. Validation of the Informed Consent Module at VUMC was conducted by JAF Consulting, Inc. (NJ).

Who needs it?

- ◆ Applies when doing drug or device studies or other FDA-regulated projects



Table of Contents

Signature Page	2
Revision History	2
1 Introduction	6
1.1 Purpose	6
1.2 Objective	6
1.3 Rationale.....	6
1.4 In-Scope	6
1.5 Out of Scope.....	7
2 Assumptions and Exclusions	7
2.1 Assumptions	7
2.2 Exclusions	7
3 Responsibilities.....	7
3.1 Management	7
3.2 System Owner	7
3.3 Quality Assurance Representative	8
3.4 Application Manager/IT Representative	8
3.5 Validation Representative	8
3.6 Validation Project Team.....	8
4 Project Plan.....	9
4.1 Organizational Impact	9
4.2 Training	9
5 Validation Overview.....	9
5.1 Validation Testing	9
5.2 Validation Deliverables.....	10
6 Validation Deliverables	10
6.1 Validation Plan.....	10
6.2 User Requirement Specification.....	10
eConsent functional processes to be considered for inclusion as requirements:	10
6.3 Functional Specification.....	11
6.3.1 Interfaces.....	11
6.3.2 System Diagram.....	11
6.3.3 Hardware and Software details	11



REDCap eConsent Module Validation Plan

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<https://redcap.link/econsent2020>

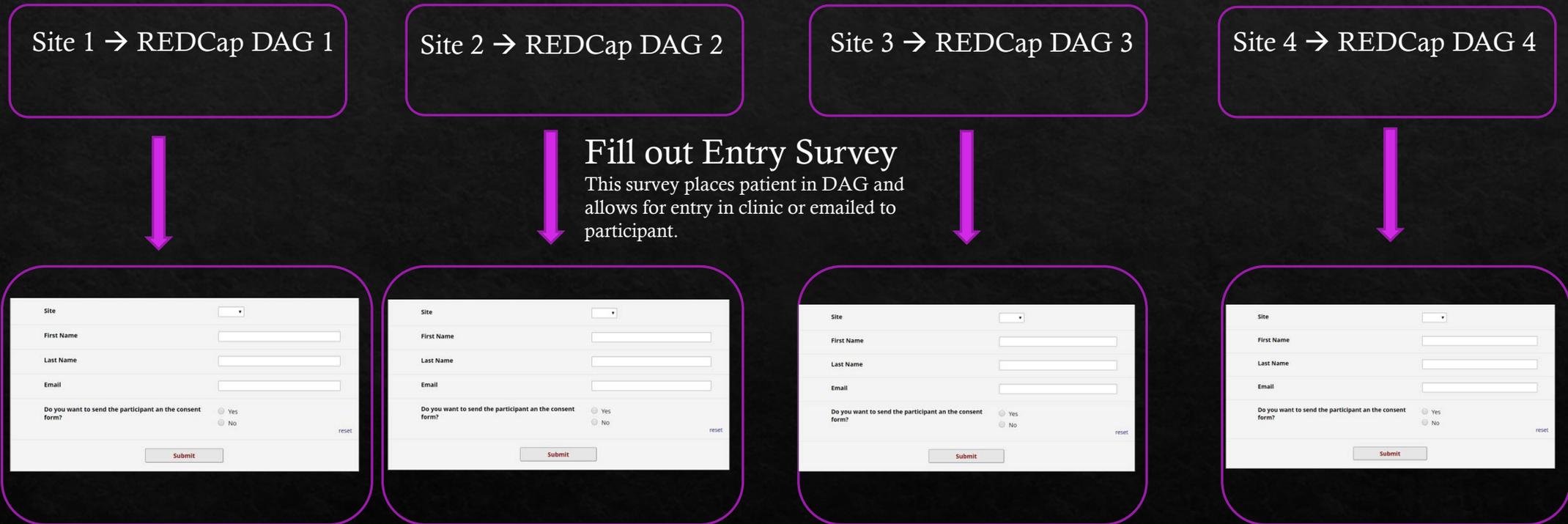
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- REDCap eConsent Operation SOP V01.docx

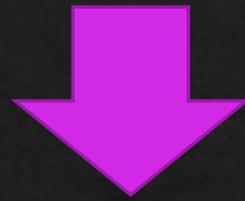
Multi-Center Clinical Trials

Single site (VUMC) might organize eConsent with implementation at VUMC for all sites



One REDCap Project Managed By Coordinating Center.





Four things are happening in the eConsent Intro (first instrument)

1. Auto DAG Module is assigning record to a DAG. This is done when the site drop down is entered and the form is submitted.
2. Name will pipe into eConsent framework.
3. Email address is captured.
4. If “Do you want to send the participant the consent form” = Yes, alerts and notification sends the participant an email with link unique like to their consent form.

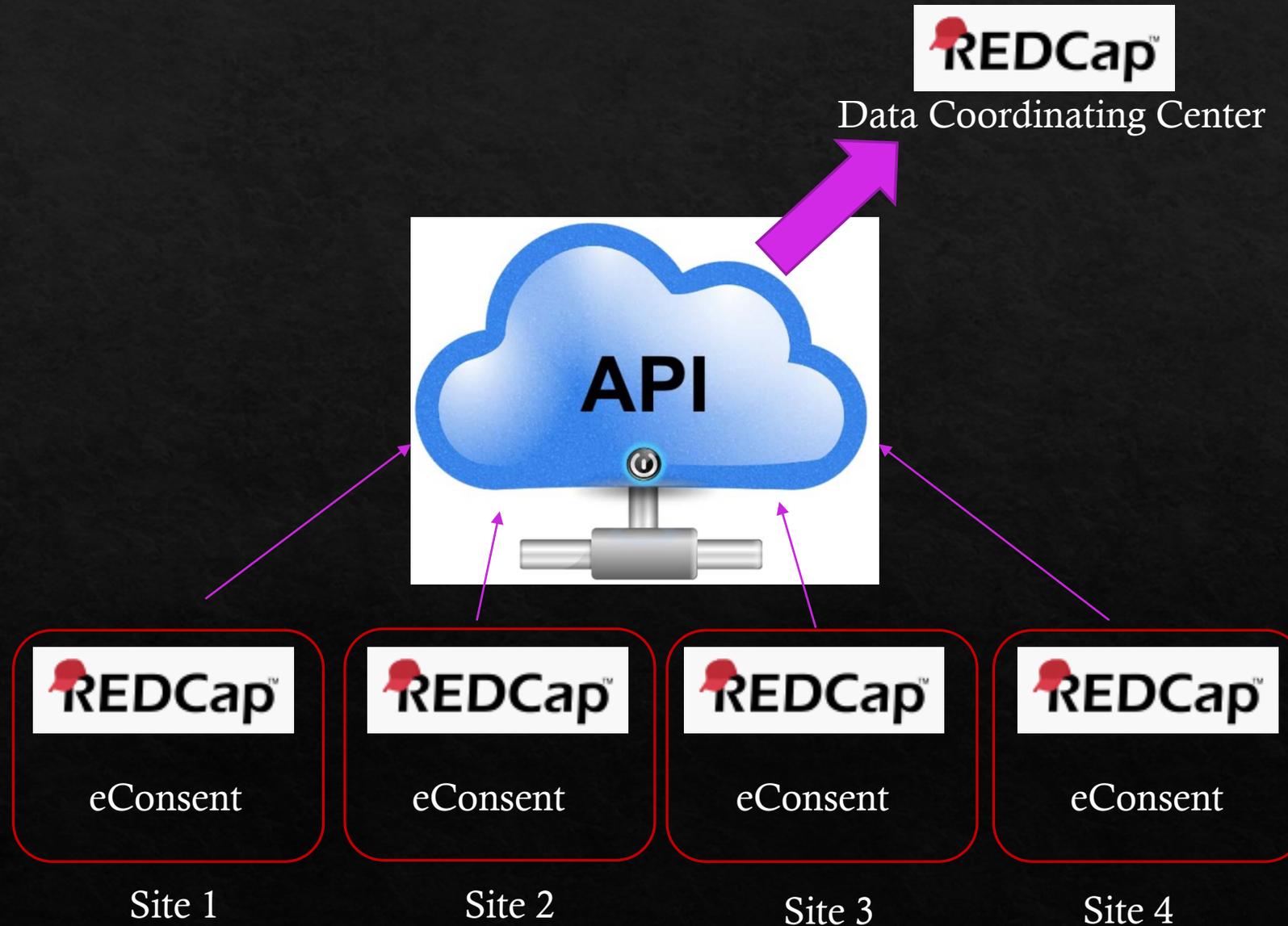


Consent Form

- ◇ The fields on the consent form will be driven by branching logic to generate site specific consent language.
- ◇ Once saved and eConsent is complete the PDF will store with site specific language.

**** Data Dictionary for 2-part consent is available for download from the sharing survey:
<https://redcap.link/econsent2020>

eConsent for multi-site studies model where a single site (VUMC) might organize eConsent with implementation at local sites. (Separate REDCap Installations)



Key Features & External Modules

Videos

Common Research Procedures and Informed Consent Elements in the eConsent Video Library.	
Biopsy (English and Spanish versions)	Genetic Test
Blood Sample	Lumbar Puncture (LP)
Computed Tomography (CT) scan (with/without contrast)	Mammogram
Data Privacy	Magnetic Resonance Imaging (MRI)
Echocardiogram	Positron Emission Tomography (PET) scan

- ❖ Identified 8 key procedures and/or research themes as topics for the video library (10 videos)
- ❖ Videos are short (1-4 minutes in length), and represent specific procedures with a voiceover explanation to describe each step
- ❖ Prior to filming, scripts were reviewed by our local IRB.

External Modules

- ◆ REDCap external modules may be built and deployed by any REDCap Consortium partner to extend existing REDCap functionality in novel ways not currently possible in the standard distribution version of REDCap.
- ◆ Modules are typically created and maintained by developers at REDCap Consortium partner institutions, rather than the central REDCap development team at VUMC responsible for the standard software distribution.
- ◆ External module creators may choose to disseminate their work for use by any other REDCap consortium partner with the publishing in REDCap Repo (i.e. a centralized repository of curated External Modules that can be downloaded and installed to local instances of REDCap).

Hover and Click

- ◆ This external module is a customizable tool that allows researchers to define supplemental information (e.g. text definitions, pronunciations, explanatory images or video) for review by research participants.
- ◆ Supplemental information is registered to individual words or phrases, highlighted within an eConsent document, so that hover-based supplemental information is displayed for either the first instance of a key word or any time the registered word or phrase is found.

 **STRIDE** CONSENT FORM V1
TREATMENT OF INTRACEREBRAL HEMORRHAGE
(PAGE 3 OF 10)

1) What is the purpose of this study?

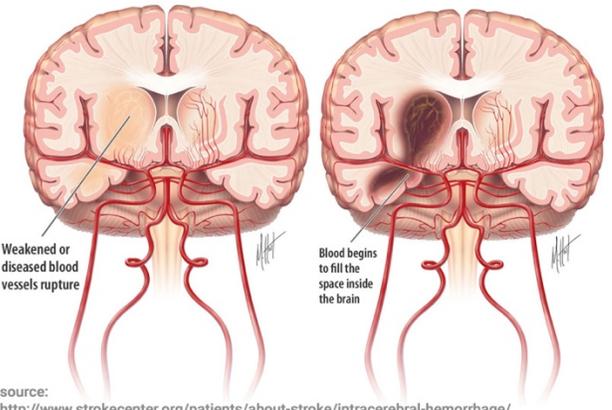
You are being asked to take part in this research study because you have been diagnosed with an [intracerebral hemorrhage](#). [Intracerebral hemorrhage](#), or [ICH](#), is when bleeding occurs inside the brain because a blood vessel has burst. [ICH](#) typically occurs in patients with high blood pressure or older individuals due to fragile blood vessels.

This research is a phase 3, randomized, controlled trial comparing a minimally invasive surgical approach to a standard medical approach. The study drug is currently not available in the United States and has not been approved by the U.S. Food and Drug Administration.

The rate of disability at 90 days post-stroke is related to the size of the hemorrhage. This treatment is being studied to see if it can improve recovery.

Recent studies have shown that minimally invasive surgery can help reduce the amount of blood that is removed from the brain, which may lead to better recovery. This study will allow us to compare the results of surgery to standard medical care, which does not involve surgery.

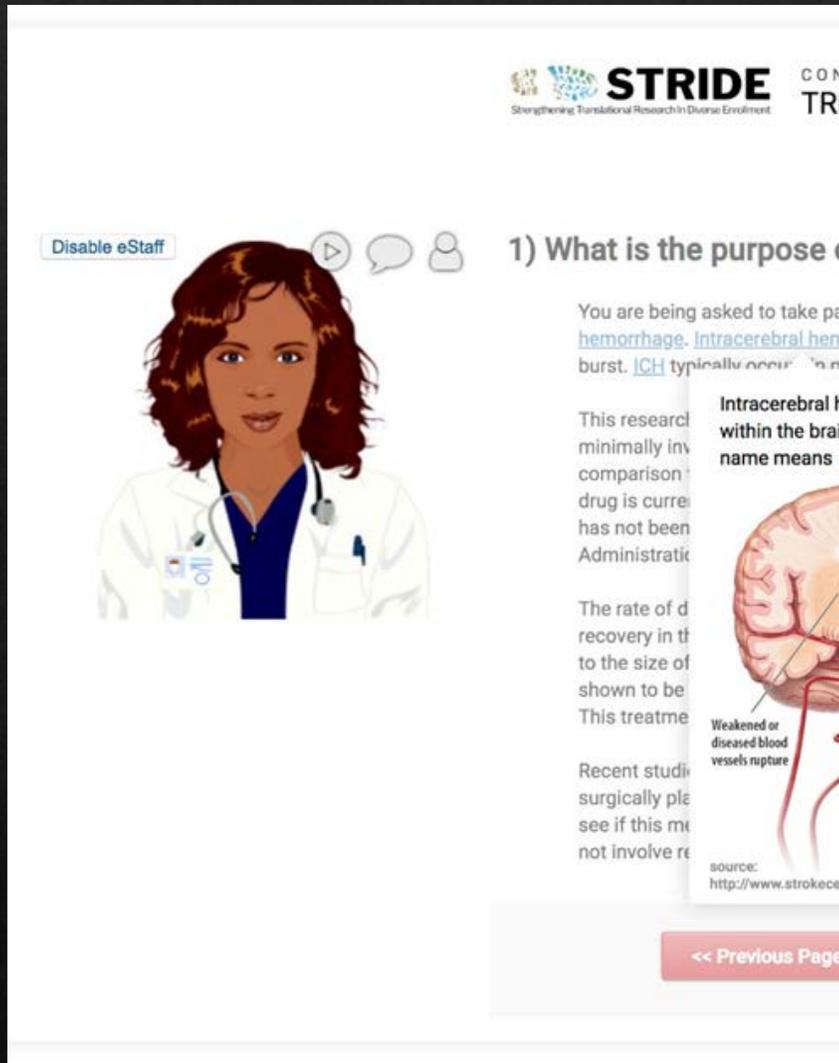
Intracerebral hemorrhage occurs when a diseased blood vessel within the brain bursts, allowing blood to leak inside the brain. (The name means *within the cerebrum* or brain).



source:
<http://www.strokecenter.org/patients/about-stroke/intracerebral-hemorrhage/>

<< Previous Page Next Page >>

Avatar



The screenshot shows a digital consent form interface. At the top left, there is a logo for "STRIDE" (Strengthening Translational Research in Diverse Enrollment) and "CONSENT" (CONTRIBUTOR). Below the logo is a "Disable eStaff" button. To the right of the button are icons for play, speech, and a person. The main heading is "1) What is the purpose of...". The text below explains that the user is being asked to take part in a study about "hemorrhage. Intracerebral hemorrhage" (ICH), which is a type of stroke. It mentions that ICH typically occurs in the brain and that the research is a "minimally invasive comparison" of a "drug is currently" used. It also notes that the "Administrative" rate of recovery is related to the size of the hemorrhage and that the treatment is "Recent studies" showing that "surgically placed" devices may not involve re... An anatomical diagram of a brain shows "Weakened or diseased blood vessels rupture". A source link is provided: "source: http://www.strokecenter.org". At the bottom, there is a red button labeled "<< Previous Page".

- ◆ We used Oddcast media software studio to create scripted avatar messaging for use with eConsent.
- ◆ This external module can be distributed for use at other institutions but requires the adopting institutions to also license and support Oddcast media software locally.
- ◆ When deployed for an individual REDCap project, avatars can be customized in both appearance and voice.
- ◆ The avatar can be utilized to help guide a participant through a consent document with voiceover instruction, clarification, or additional information.

Help Me

Resources & Contacts

- ◆ Contacts:

- ◆ colleen.lawrence@vumc.org

- ◆ leah.dunkel@vumc.org

- ◆ redcap@vumc.org

<https://redcap.link/econsent2020>

Includes videos, data dictionaries, manuscript re-print option, and Part-11 documentation

Acknowledgements

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 - ◇ STRIDE – (STRENGTHENING TRANSLATIONAL RESEARCH IN DIVERSE ENROLLMENT(5 U01 TR001812)
 - ◇ VUMC CTSA (UL1 TR002243)
 - ◇ The Recruitment Innovation Center – RIC (5U24 TR001579-02)



REDCap eConsent: eConsent Framework



Watch later



Share





REDCap eConsent: Additional Features



Watch later



Share





REDCap eConsent: Multi-Site Studies



Watch later



Share



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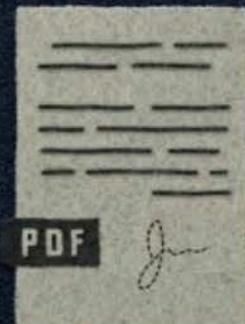
1

Creation of New Instruments

2

Branching Logic







Part 11

Table of Contents

Signature Page	2
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1.5 Out of Scope.....	7
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4.2 Training	9
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Demo

- ◇ https://redcap.vanderbilt.edu/redcap_v9.3.2/ProjectSetup/index.php?pid=95132