Informed Consent: Documentation and Processes

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September 17, 2025

Clinical Research Community Meeting

Baystate Health | ADVANCING CARE. ENHANCING LIVES.

Obtaining Continuing Education Credit

Date: September 17, 2025
Title: Documenting Consent forms and procedures;
documenting research enrollment—utilizing systems adequately

ATTENDANCE CODE: **MUBDAW**

- Step 1: Text Attendance Code to 413-200-2444
- Step 2: Complete the Evaluation (from your smartphone, tablet, or computer)
- Step 3: Claim Credit (You must select your professional credit type to receive credit)

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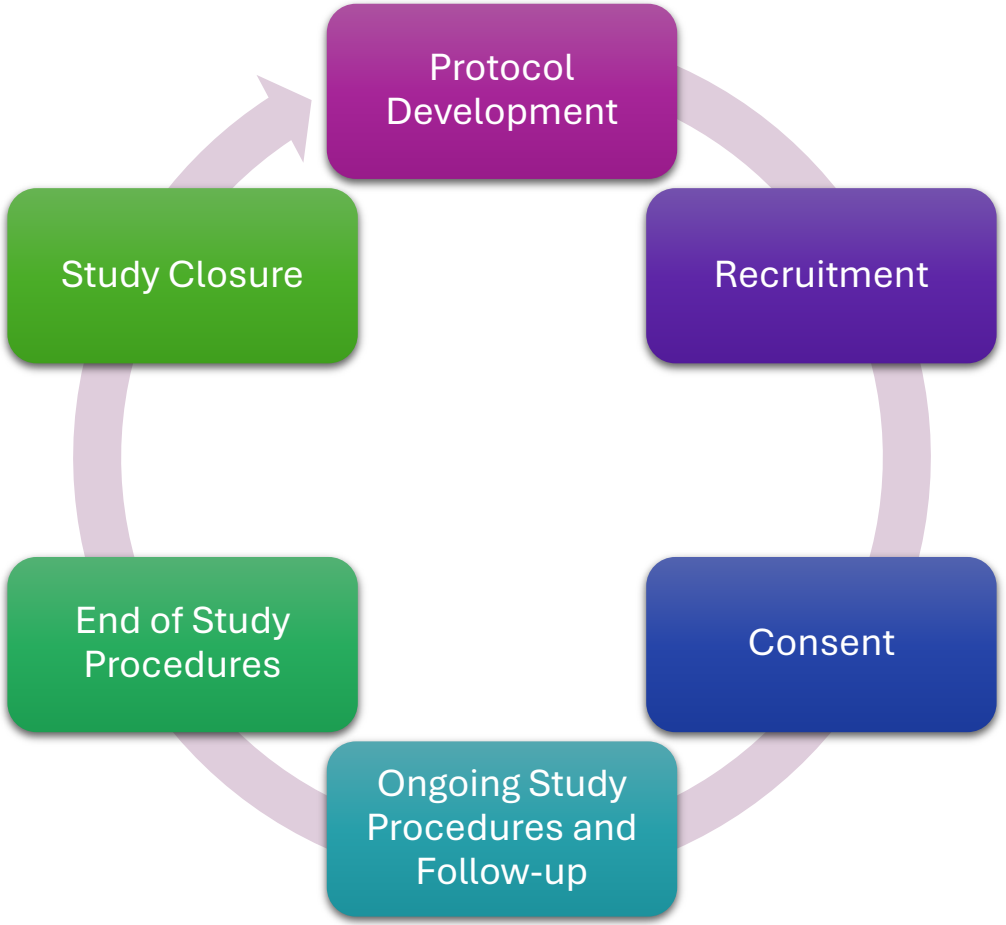
Learning Objectives

- ❑ Differentiate between documentation of consent and the consent process.
- ❑ Identify accepted electronic locations where consent documents may be stored (CIS, Florence).
- ❑ Describe the process of entering consent information into OnCore (on study process).
- ❑ Describe effective methods of documenting informed consent (checklist, if patient has asked questions and how that is included within the process note).

Documentation of Informed Consent

Susan Garrow-Sloan

Study Life Cycle



Informed Consent:
Legally Effective and Prospectively Obtained

1

Presenting information to the subject or Legally Authorized Representative (LAR) needed to make an informed decision.

2

Facilitating understanding of what has been disclosed.

3

Promoting voluntariness of the decision.

What is Documentation of Informed Consent?

Written



- Written documentation of informed consent
- 21 CFR 50.20 General Requirements of Informed Consent and 45 CFR 46.116 General Requirements of Informed Consent
- 45 CFR 46.117 and 21 CFR 50.27 Documentation of Informed Consent

Verbal



- Waiver or Alteration of Documentation of Informed Consent if the research meets the requirements of the regulation
- 45 CFR 46.117 (c) Criteria for Waiver of Documentation of Informed Consent
- 21 CFR 50.22 Exception from Informed Consent Requirements for Minimal Risk Clinical Investigations

Written Documentation of Informed Consent

- A written consent can be either of the following:
  - A **written consent** that meets the requirements of 45 CFR 46.116, FDA 21 CFR 50.20
  - A **short form consent** that states the elements of consent
- The consent is signed by the subject or the subject's legally authorized representative. (This includes electronic formats)
- A copy of the ICF is given to the person signing the informed consent form



Verbal and Implied Consent Process

- **Verbal consent** means that a person obtaining consent reads or explains a verbal version of a consent form. The consent process may take place in person or over the telephone.
- **Implied consent** is an option that may be utilized when a prospective participant has been asked to complete an anonymous survey. Completion of the survey implies consent.



Accepted Electronic Locations for Consent Document Storage

Ensuring Compliance in Clinical Research

Sola Odesina

Introduction

- Importance of informed consent documentation
- Regulatory requirements (21 CFR Part 11, HIPAA, ICH-GCP)
- Electronic Systems available at Baystate Health

Key Regulatory Guidelines

- FDA 21 CFR Part 11: Electronic records/signatures

- ICH E6(R2) Good Clinical Practice: Data integrity

- HIPAA: Protection of personal health information (PHI)

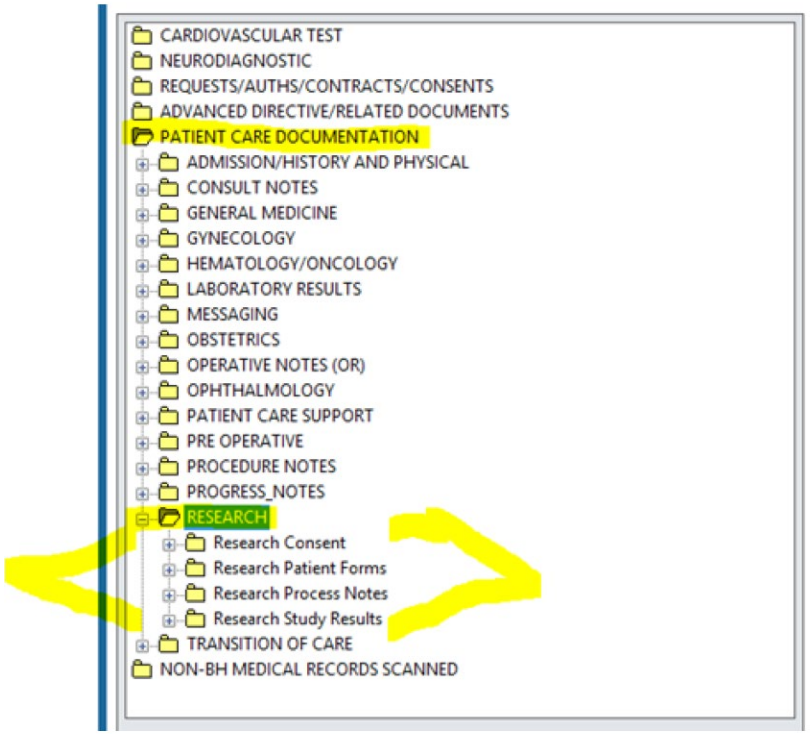
- Institutional Policy

BC 10.190 - Research Consent Process and Documentation

Accepted Electronic Storage Locations

1. eRegulatory Systems
    - Florence eBinders
2. Secure Electronic Medical Records (EMRs)
    - CIS
3. eConsent System
    - REDCap – File Repository

CIS



- Send your research documents to HIM, once your research documents are ready to be filed
- You can email, fax, or send via courier
  - Email:41379558003@fax.bhs.org
  - Fax: 413-795-8003

Features of Acceptable Systems

- Access control and audit trails
- Version control and document locking
- FDA and HIPAA compliance
- Redundancy and disaster recovery measures

Prohibited or Inadvisable Locations

- Personal cloud storage (e.g., Google Drive, Dropbox) without oversight
- Non-secure shared drives
- Unencrypted email attachments
- Local computer storage without backup or access controls

Best Practices



Summary

Electronic consent storage improves efficiency and compliance

Systems must meet regulatory and institutional standards

Avoid unsecure storage methods

Always align with IRB and sponsor requirements

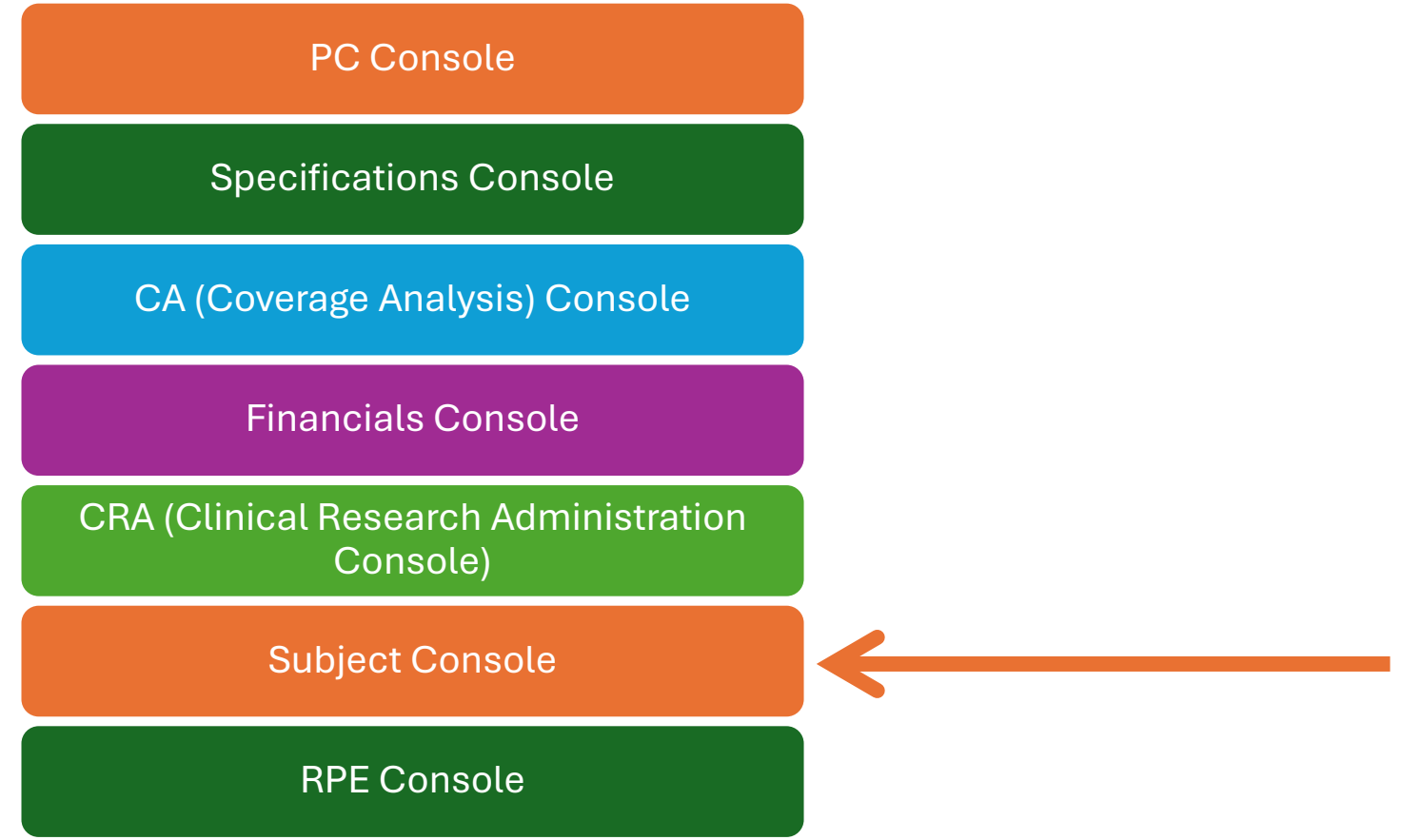
Documenting Consent in OnCore: The ‘On Study’ Process

Vanessa Roxo

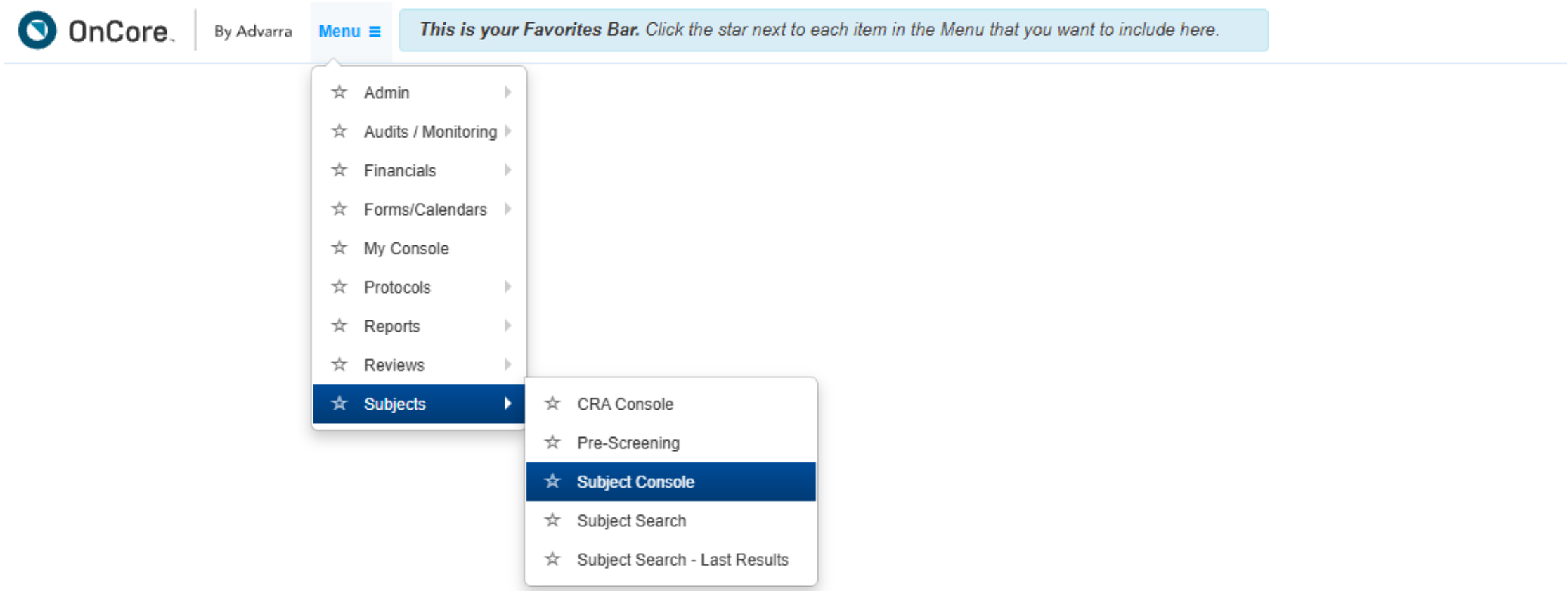
Why is Proper Documentation of Consent in OnCore Important?

- Regulatory Alignment: Ensures accurate recordkeeping and version control
- Audit Readiness: Creates a clear audit trail of the consent process.
- Transparency: Promoted consistency in enrollment tracking.
- Billing Compliance: Prevents protocol-related billing errors
- Institutional Oversight: Enables real-time reporting to leadership.

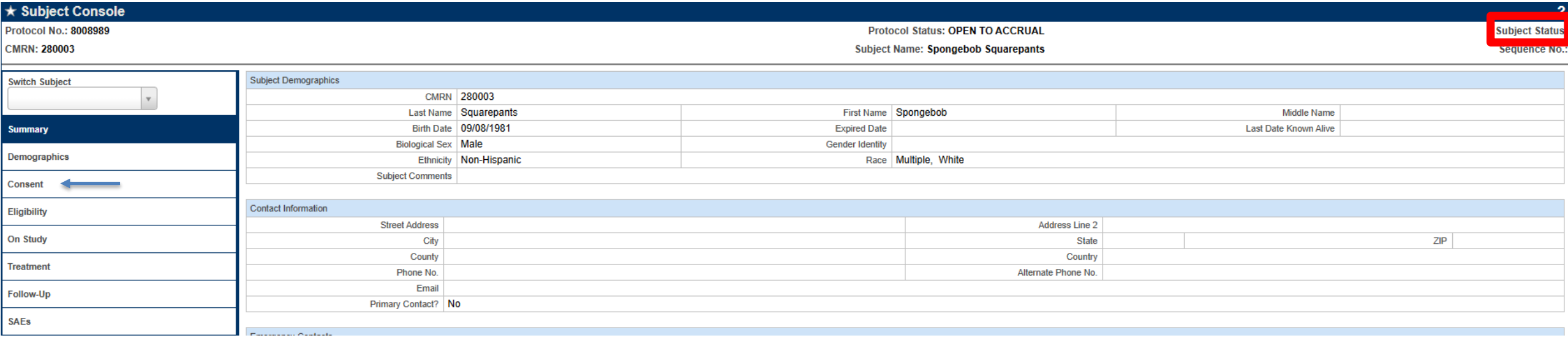
OnCore Consoles



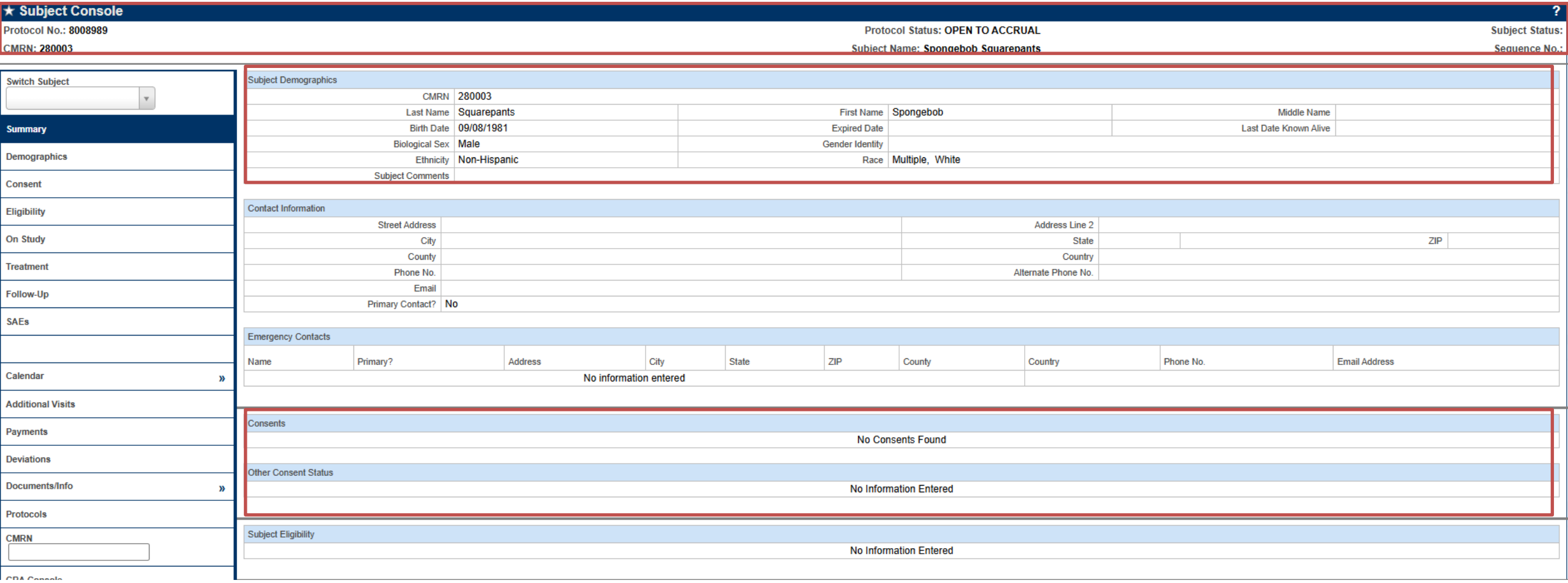
Subject Console



Consent in OnCore

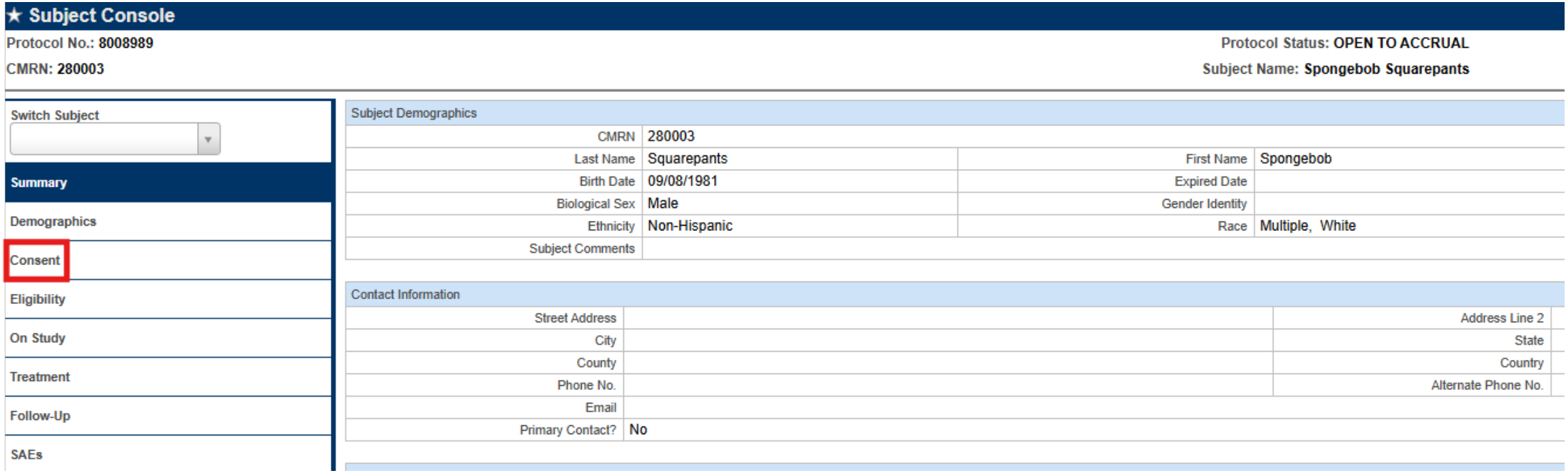


Consent Tab

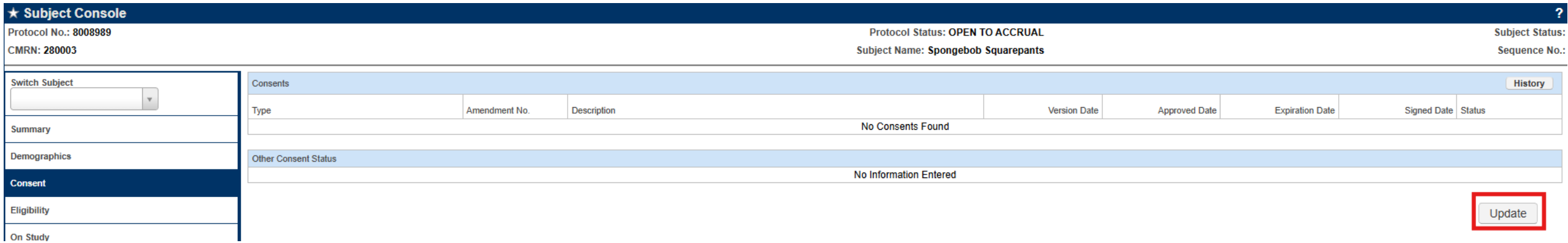

★ Subject Console
?
Protocol No.: 8008989
Protocol Status: OPEN TO ACCRUAL
Subject Status:
CMRN: 280003
Subject Name: Spongebob Squarepants
Sequence No.:
Switch Subject
Summary
Demographics
Consent
Eligibility
On Study
Treatment
Follow-Up
SAEs
Calendar
Additional Visits
Payments
Deviations
Documents/Info
Protocols
CMRN
Subject Demographics
CMRN 280003
Last Name Squarepants
First Name Spongebob
Middle Name
Birth Date 09/08/1981
Expired Date
Last Date Known Alive
Biological Sex Male
Gender Identity
Ethnicity Non-Hispanic
Race Multiple, White
Subject Comments
Contact Information
Street Address
Address Line 2
City
State
ZIP
County
Country
Phone No.
Alternate Phone No.
Email
Primary Contact? No
Emergency Contacts
Name
Primary?
Address
City
State
ZIP
County
Country
Phone No.
Email Address
No information entered
Consents
No Consents Found
Other Consent Status
No Information Entered
Subject Eligibility
No Information Entered

Documenting a New Consent

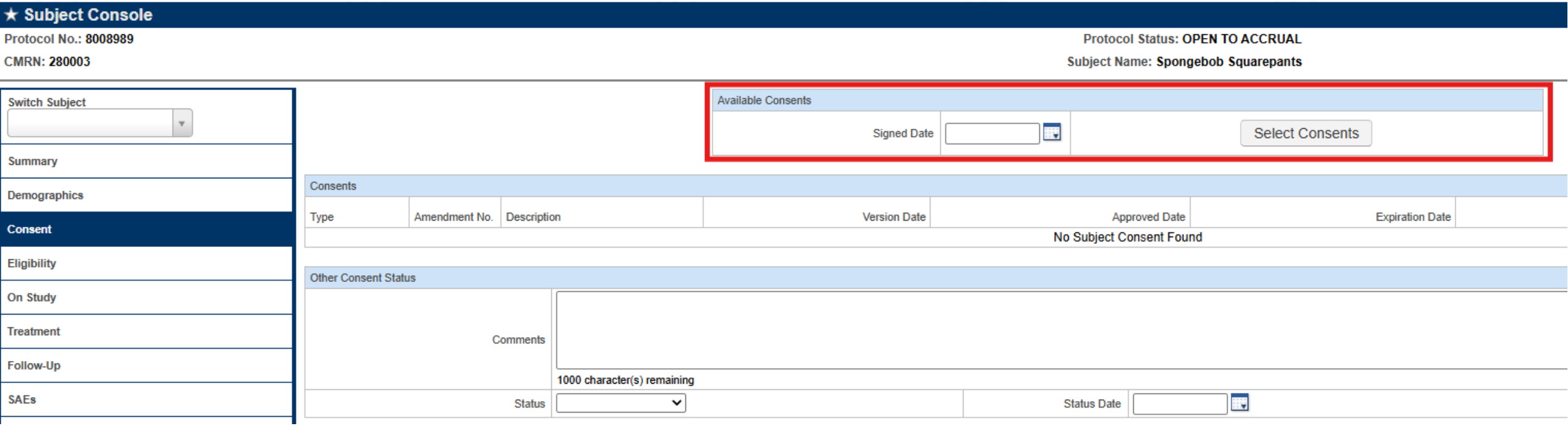
Navigate to the Consent vertical tab



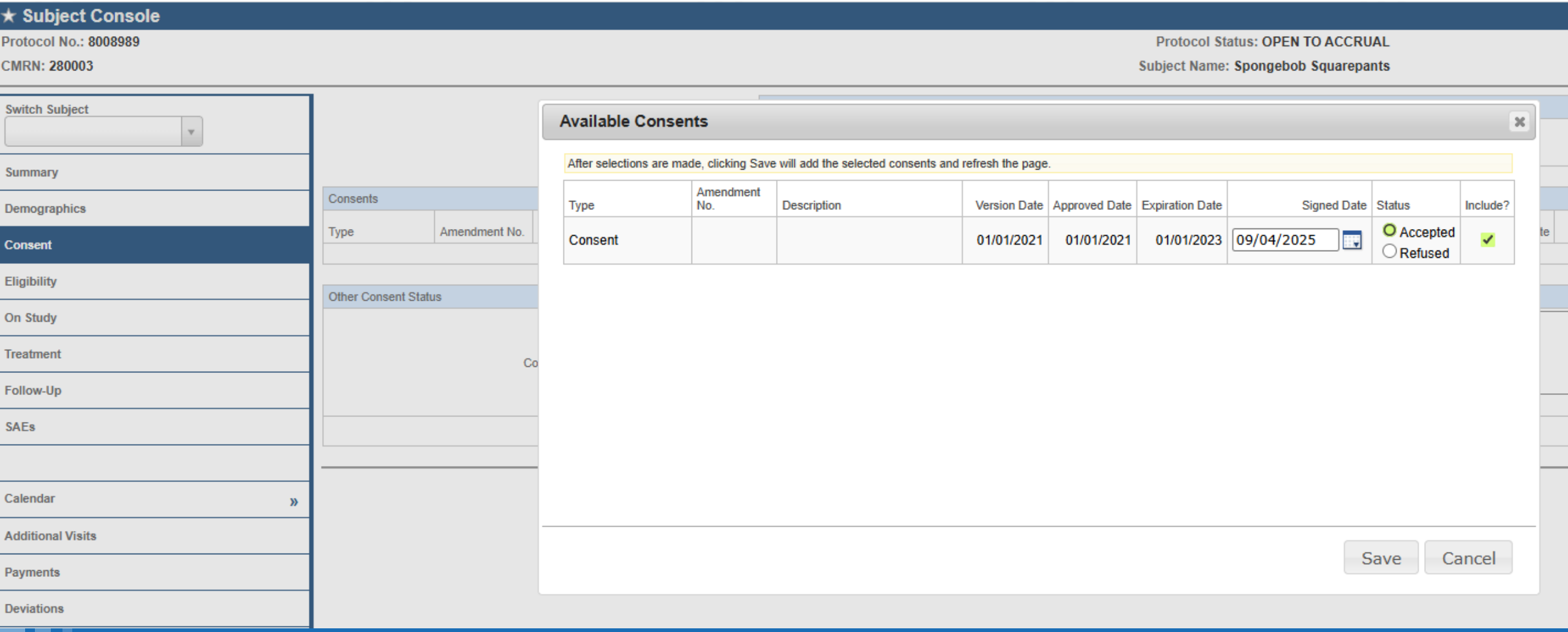
To document a new consent, click UPDATE



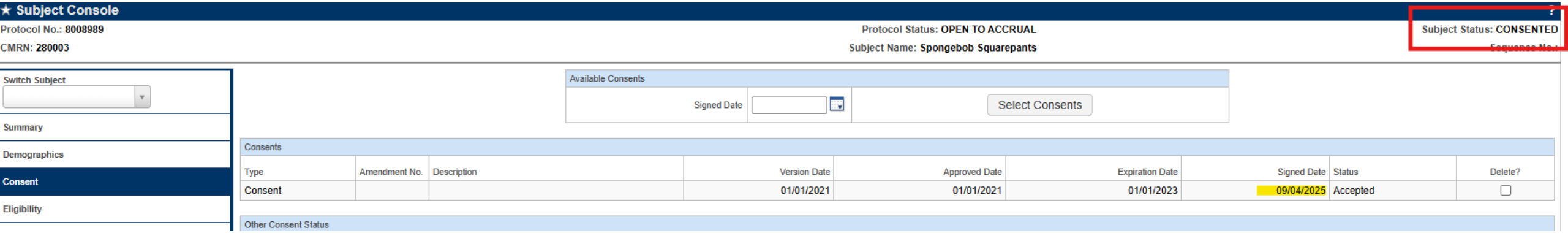
Indicate signed date and click Select Consents



Indicate accepted or refused consents, and click save

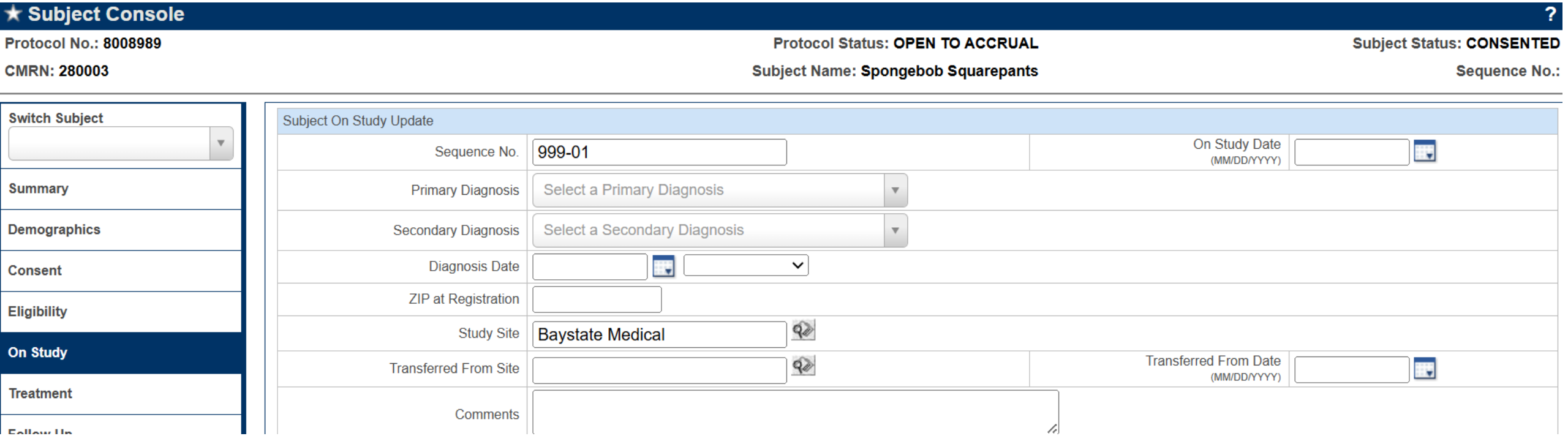


The Consent tab is now updated



Sequence

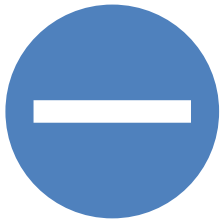
Update the participant sequence # to push the participant into CIS



Important Notes



You will keep all original copies of signed consent forms in Florence, your regulatory binder.

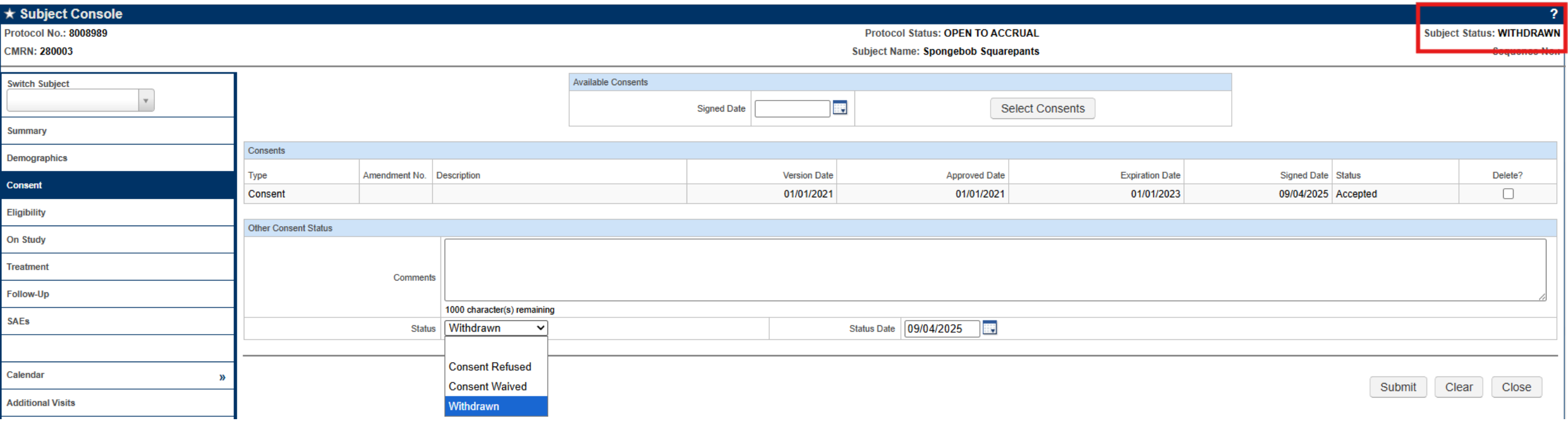


Signed forms do not need to be uploaded in OnCore.



Consent needs to be documented in OnCore as close to **real time** as possible.

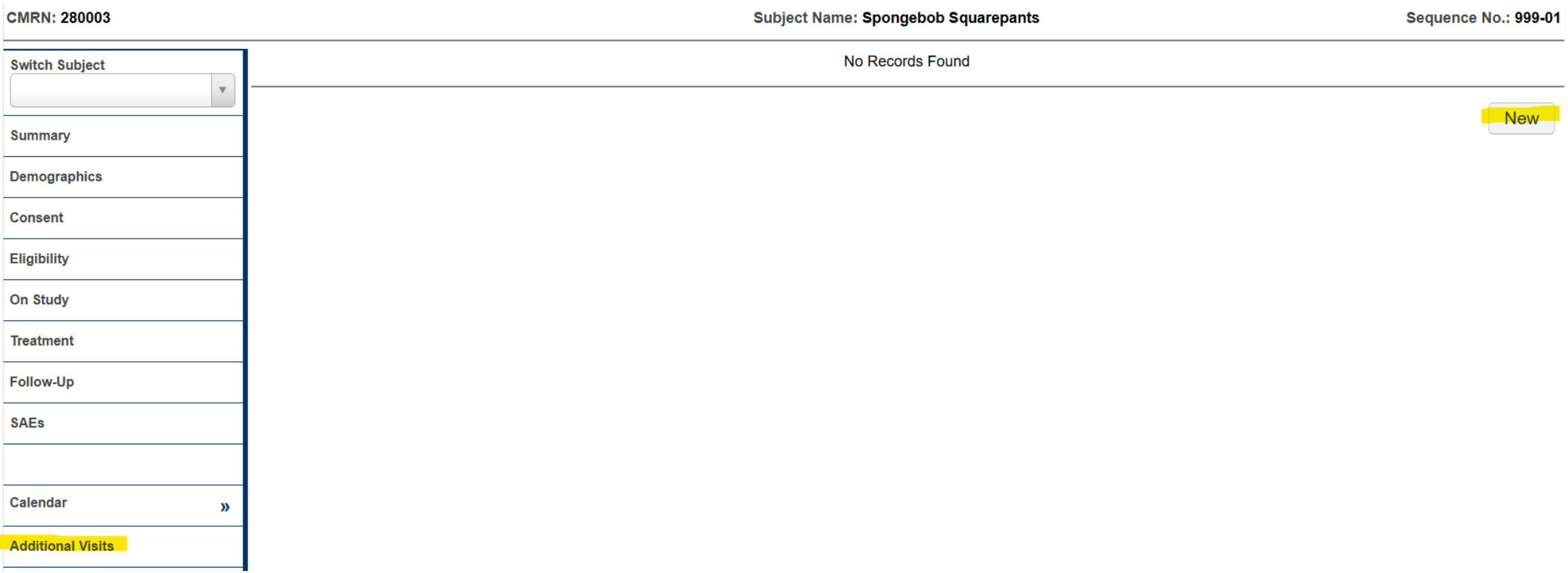
Other Consent Status



Re-Consenting

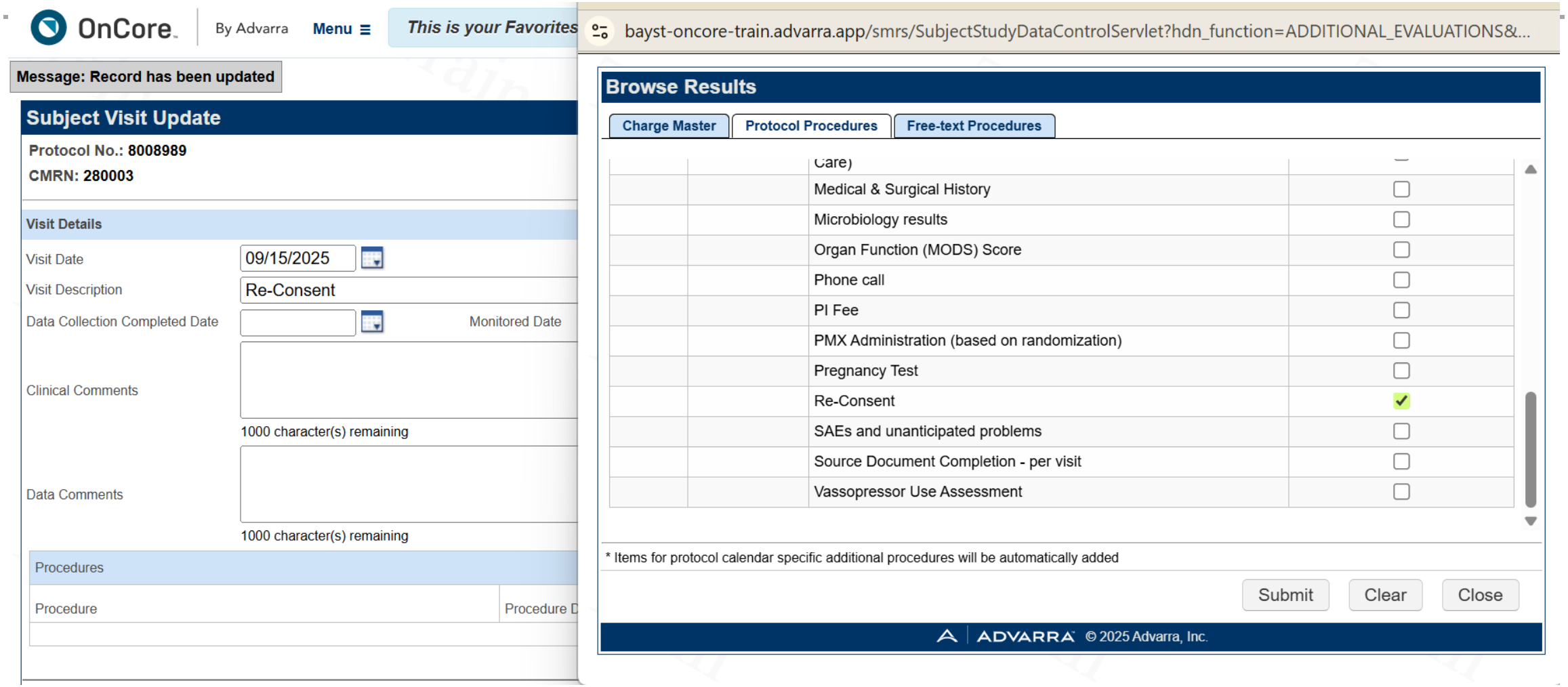
Re-Consenting: Step 1

Add an 'Additional Visit'



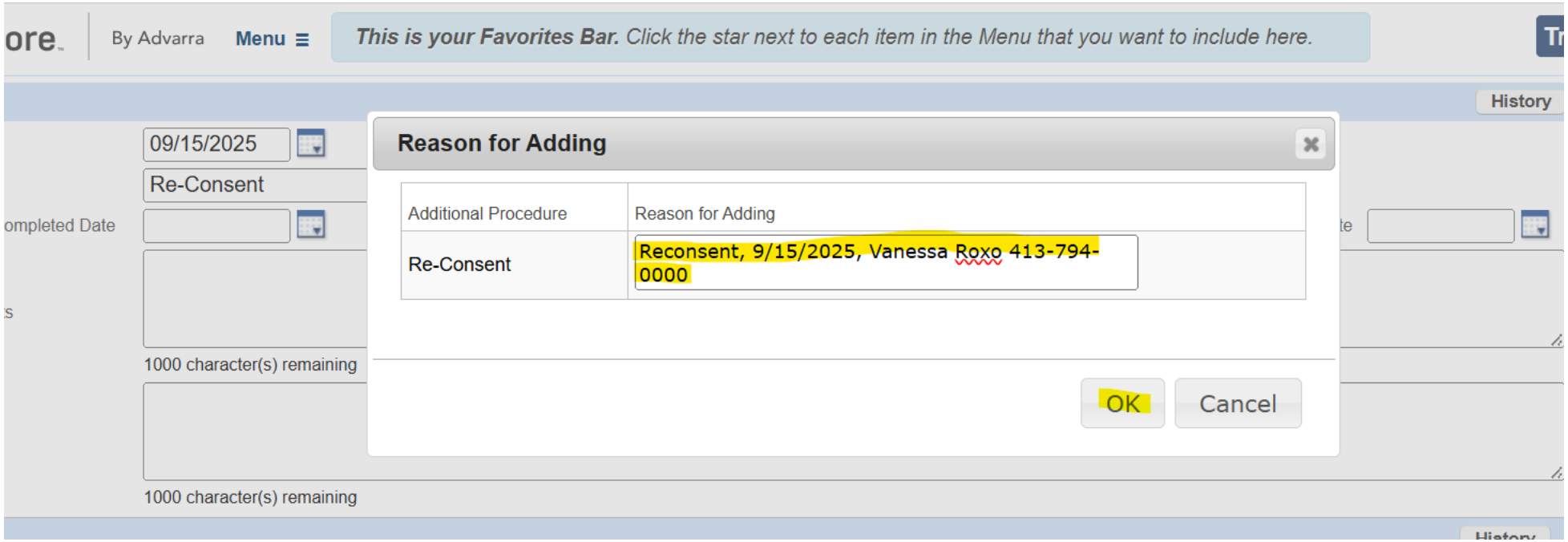
Re-Consenting: Step 2

Select "Re-Consent" from the menu



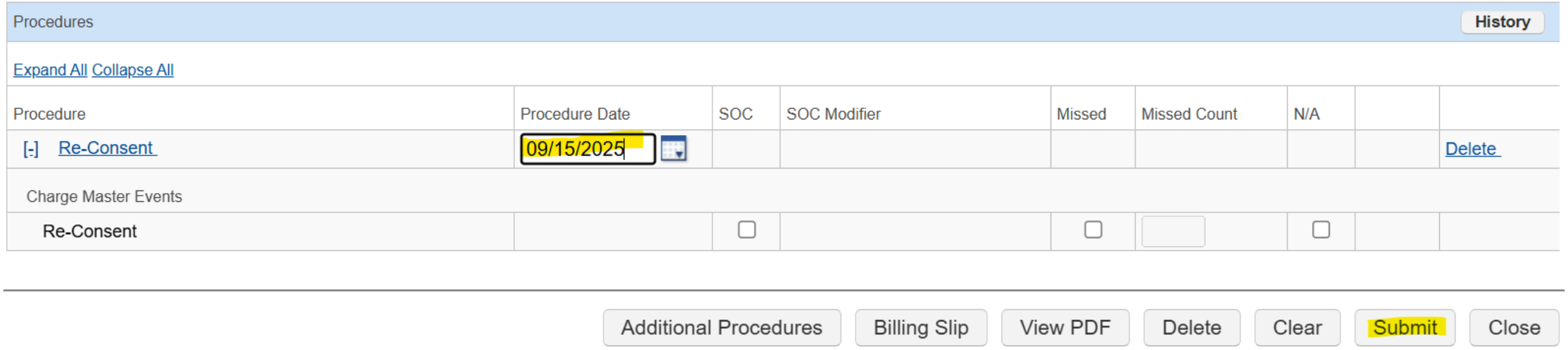
Re-Consenting: Step 3

Document the reason: "Reconsent, Date, Your Name and Phone #



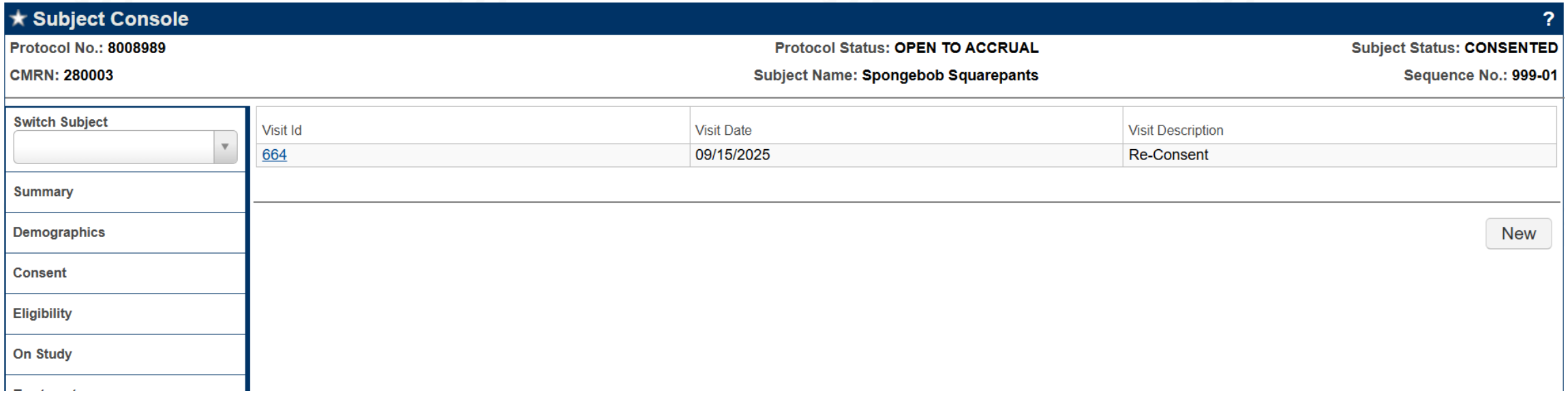
Re-Consenting: Step 4

Add the Procedure Date (Today's Date)



Re-Consenting: Step 5

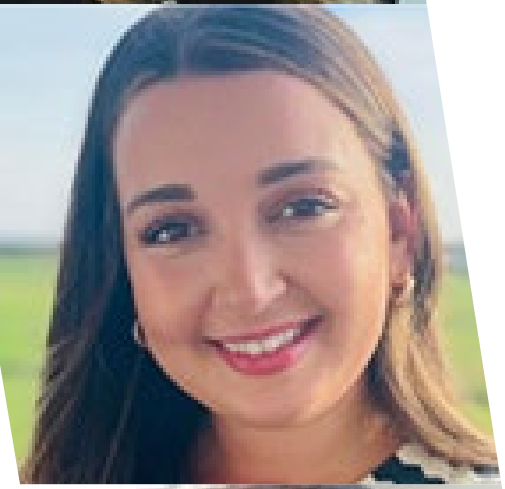
The information goes to billing for invoicing



Examples from the Department of Emergency Medicine

Jillian Tozloski







Why does it matter?

Helps to ensure that all requirements of the informed consent process are met

- HRPP does educational audits – they're here to help!
- Educational audits over the years have led to better documentation processes
- What we learned over the years
  - Be consistent
  - Double check your work! Build in safeguards – protect the patient AND your team

What needs to be included?



Date and time of the consent



Description of the consenting process

Is the consent being done with the subject or an LAR?

Where is the conversation taking place?

What language? Is an interpreter being used?

Is there a witness present? Family at bedside?



Statement that the subject/LAR has received an explanation of the study and the ICF

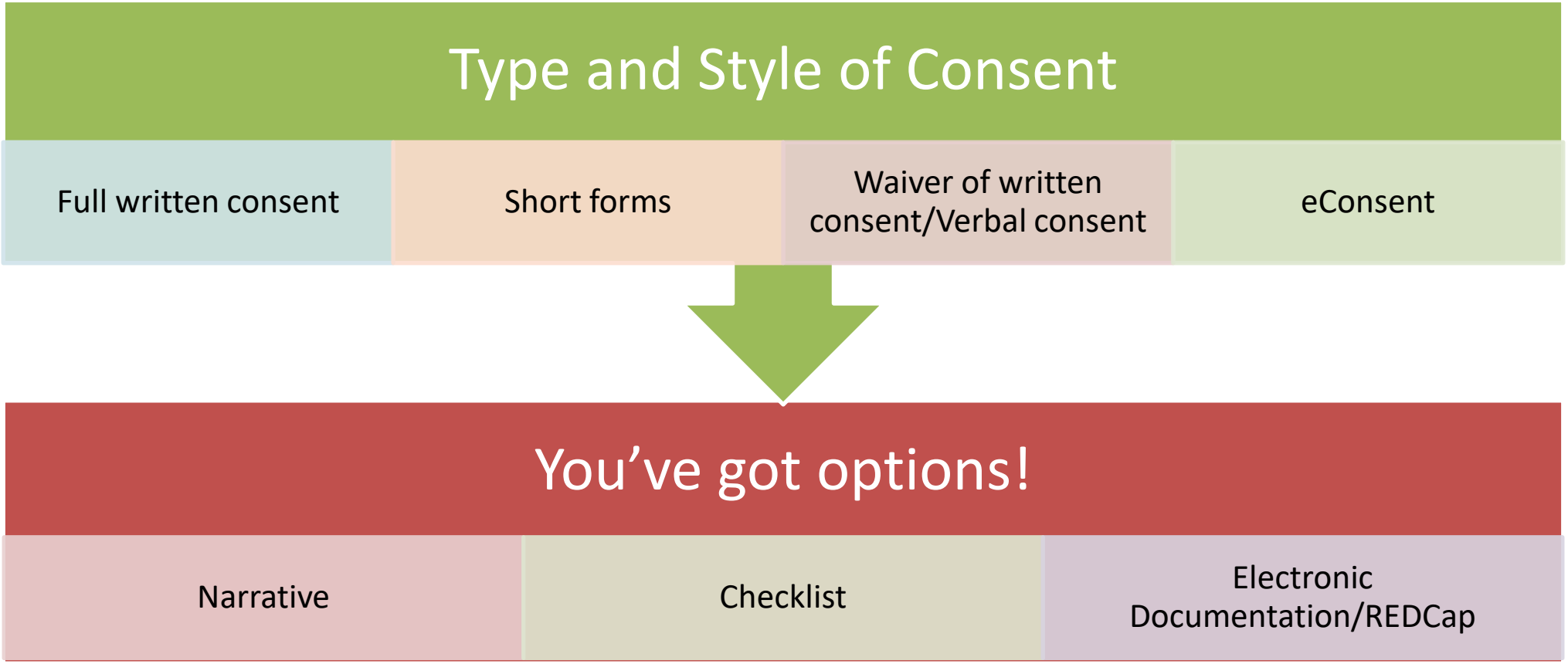


Statement that the subject/LAR participated in teach-back and had the opportunity to read the consent form and ask questions prior to signing



Statement that subject/LAR has received a copy of the signed and dated ICF

How do you document informed consent?



Narrative Format

Pros

- Can be more detailed/specific
- Better for higher risk or more complicated studies

Cons

- Time consuming
- Less standardized

Baystate Medical Center
DEPARTMENT OF EMERGENCY MEDICINE

759 Chestnut Street Springfield, MA 01199 Tel: (413) 794-5375 Fax: (413) 794-3303 baystatehealth.com

IRBNet Number: 1472800

Study Title: Shared Decision-Making for the promotion of patient-centered imaging in the Emergency Department: Suspected Kidney Stones (PHASE 2)

Subject's Name:

_____

The subject was approached for the study reference above. The details of the study were discussed with the subject and/or the subject's legally authorized representative (LAR) (circle one or both). The study and consent form(s) were reviewed and explained in detail. The subject and/or subject's LAR was encouraged to ask questions. All questions and concerns were addressed to the subject's satisfaction. The subject and/or subject's LAR was given time to read, ask questions, and consider participation prior to signing the consent form.

The IRB approved consent form version _____(consent type-written, verbal, etc.- version number, and date) was signed on _____(date) at _____(time).

A copy of the consent form was given to the subject. No study procedures were initiated prior to the subject and/or subject's LAR signing the consent form.

Notes:

_____
_____
_____
_____
_____
_____
_____
_____
_____

Research Staff Signature: _____Date: _____

Research Staff Printed Name: _____

Study XXX Consent Note

Study Name:

Study ID: _____

CONSENT NOTE:

Patient meets all inclusion and no exclusions

Informed consent obtained from ☐**Patient** or ☐**LAR**, if LAR, relation to patient_____

Length of discussion _____minutes

Questions regarding the nature of the study, risks, benefits and participation were asked and answered to satisfaction and the patient (or LAR) agrees to proceed. The informed consent was signed prior to any study participation. A copy of the informed consent was given to the patient (or LAR). For further information please contact Dr. Howard Smithline at 794-8960, or the Emergency Medicine Research Office at 794-4313.

Additional Comments:_____
_____
_____
_____

Study Staff Signature_____ Date/Time__/__/____ __:__



Checklist Format

Pros

- Quick and easy
- Great for simple surveys or interviews that utilize verbal consent

Cons

- Less detailed
- Lacks nuance/context

Informed Consent Documentation Template

To be signed by the person obtaining informed consent.

Date of Informed Consent: ☐ Initial Consent ☐ Re-consent

Participant Identifier: Protocol #:

Was an LAR used? ☐ Yes* ☐ No *LAR Name:

Was a witness present? ☐ Yes* ☐ No *Witness Name:

- ☐ The content of the informed consent document was fully explained.
- ☐ The participant was given adequate time to review the consent form and received an explanation of the content of the informed consent document.
- ☐ If applicable, the participant was provided the following additional information/materials at the time of consent:
  ☐ N/A – No additional materials provided at time of consent
- ☐ The participant had an opportunity to ask questions and all of the participant's questions regarding the study were answered to their satisfaction.
- ☐ The participant completed all sections of the informed consent document and signed and dated the informed consent document.
- ☐ The participant received a signed and dated copy of the informed consent document.

Additional comments:

By signing below, I attest that the informed consent process was conducted as indicated above.

Signature:	Date:
Printed Name:	

Documentation of Verbal Consent from Provider

This documentation will serve as confirmation of provider's verbal consent to both complete the items below.

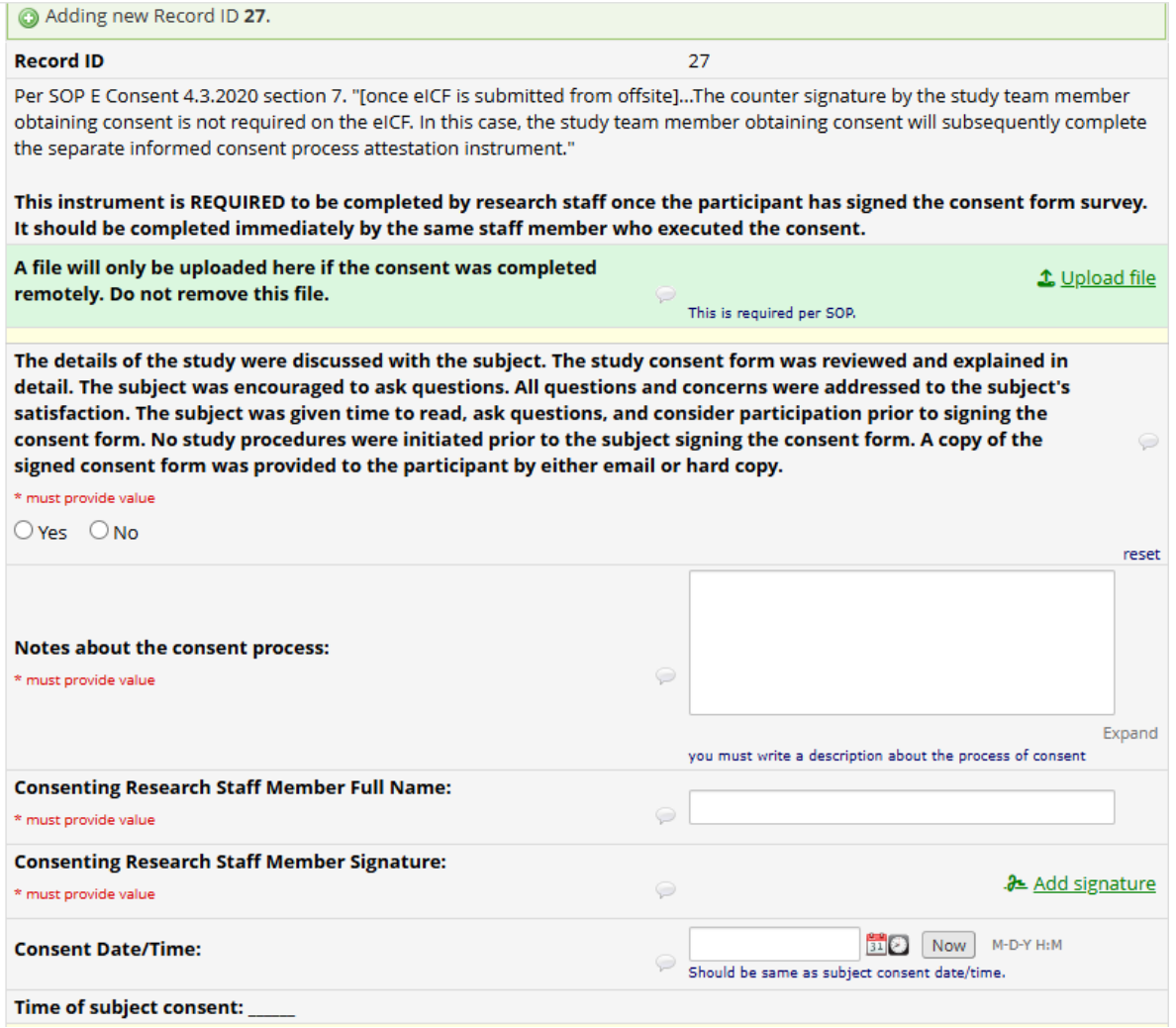
- ☐ Completion of Survey
- ☐ Recording of Conversation and Interview

No survey data was collected and no recordings were made prior to obtaining the verbal consent from the provider.

Printed Name of Research Staff:	
Signature of Research Staff:	
Date of Verbal Consent:	
Time of Verbal Consent:	

In Person eConsent and electronic documentation

- Pros
  - Ideal when using REDCap for eConsent so all records remain in one place
  - Can be narrative or checklist format depending on how you build the REDCap
- Cons
  - Doesn't make sense to use if not utilizing eConsent


Adding new Record ID **27**.

Record ID 27

Per SOP E Consent 4.3.2020 section 7. "[once eICF is submitted from offsite]...The counter signature by the study team member obtaining consent is not required on the eICF. In this case, the study team member obtaining consent will subsequently complete the separate informed consent process attestation instrument."

This instrument is REQUIRED to be completed by research staff once the participant has signed the consent form survey. It should be completed immediately by the same staff member who executed the consent.

A file will only be uploaded here if the consent was completed remotely. Do not remove this file. Upload file

This is required per SOP.

The details of the study were discussed with the subject. The study consent form was reviewed and explained in detail. The subject was encouraged to ask questions. All questions and concerns were addressed to the subject's satisfaction. The subject was given time to read, ask questions, and consider participation prior to signing the consent form. No study procedures were initiated prior to the subject signing the consent form. A copy of the signed consent form was provided to the participant by either email or hard copy.

* must provide value

Yes No

reset

Notes about the consent process:

* must provide value

Expand

you must write a description about the process of consent

Consenting Research Staff Member Full Name:

* must provide value

Consenting Research Staff Member Signature:

* must provide value

Add signature

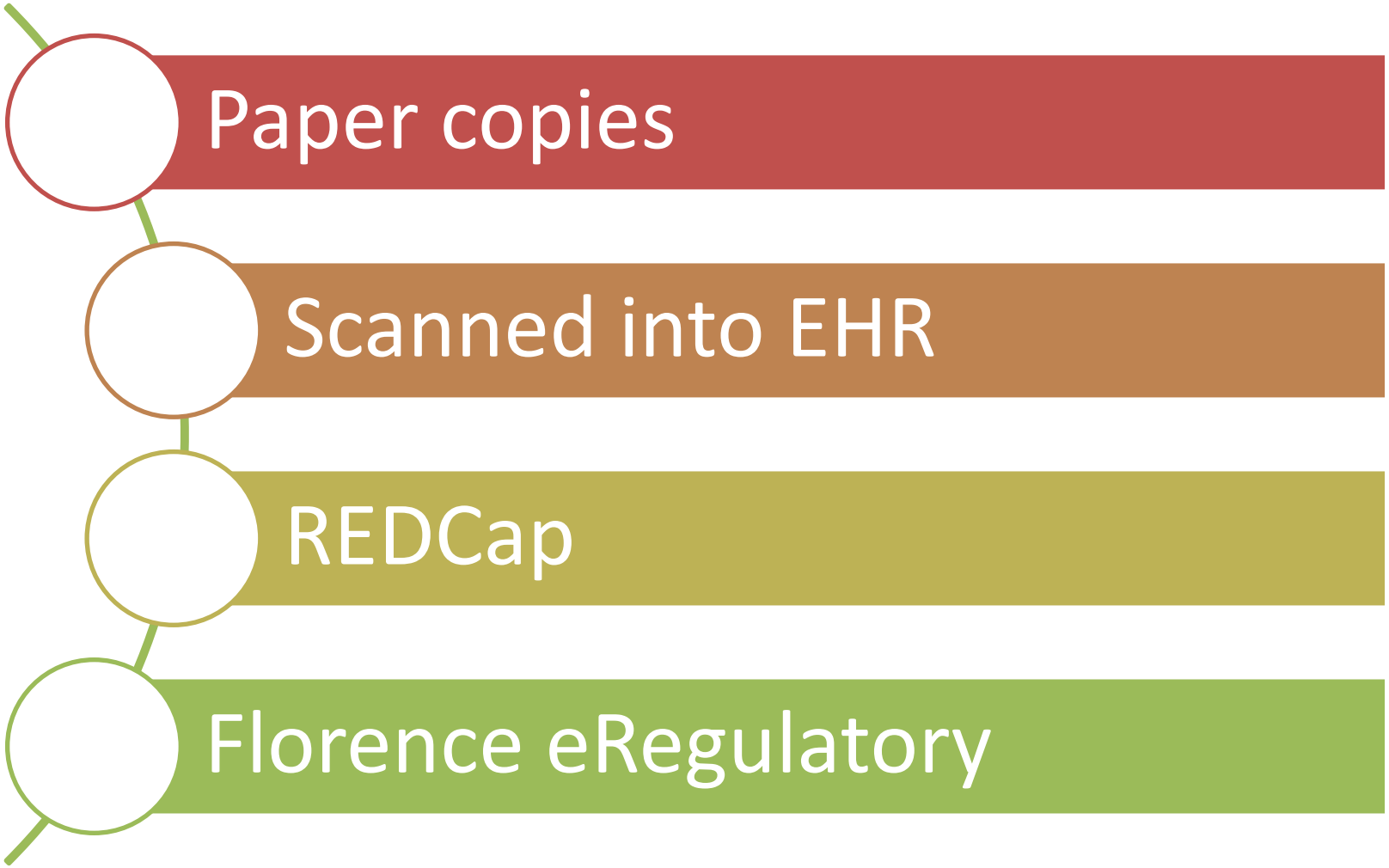
Consent Date/Time:

Now M-D-Y H:M

Should be same as subject consent date/time.

Time of subject consent: ____

Where do you keep the documentation of informed consent?



Ultimately what's important/what will be needed for an audit…

- Pick a format that works best for the type of study and ensures your team is compliant
- Perform internal self-audits over the course of the study
- Take the opportunity to learn from HRPP audits

Resources

- BC 10.190 – Research Consent Process and Documentation
- HRPP SOP Section 5 Obtaining Informed Consent From Research Subjects
- ONCORE “Train” Environment - https://bayst-oncore-train.advarra.app/forte-platform-web/login
- ICH GCP E6R3
- Posting Clinical Trial Informed Consent forms