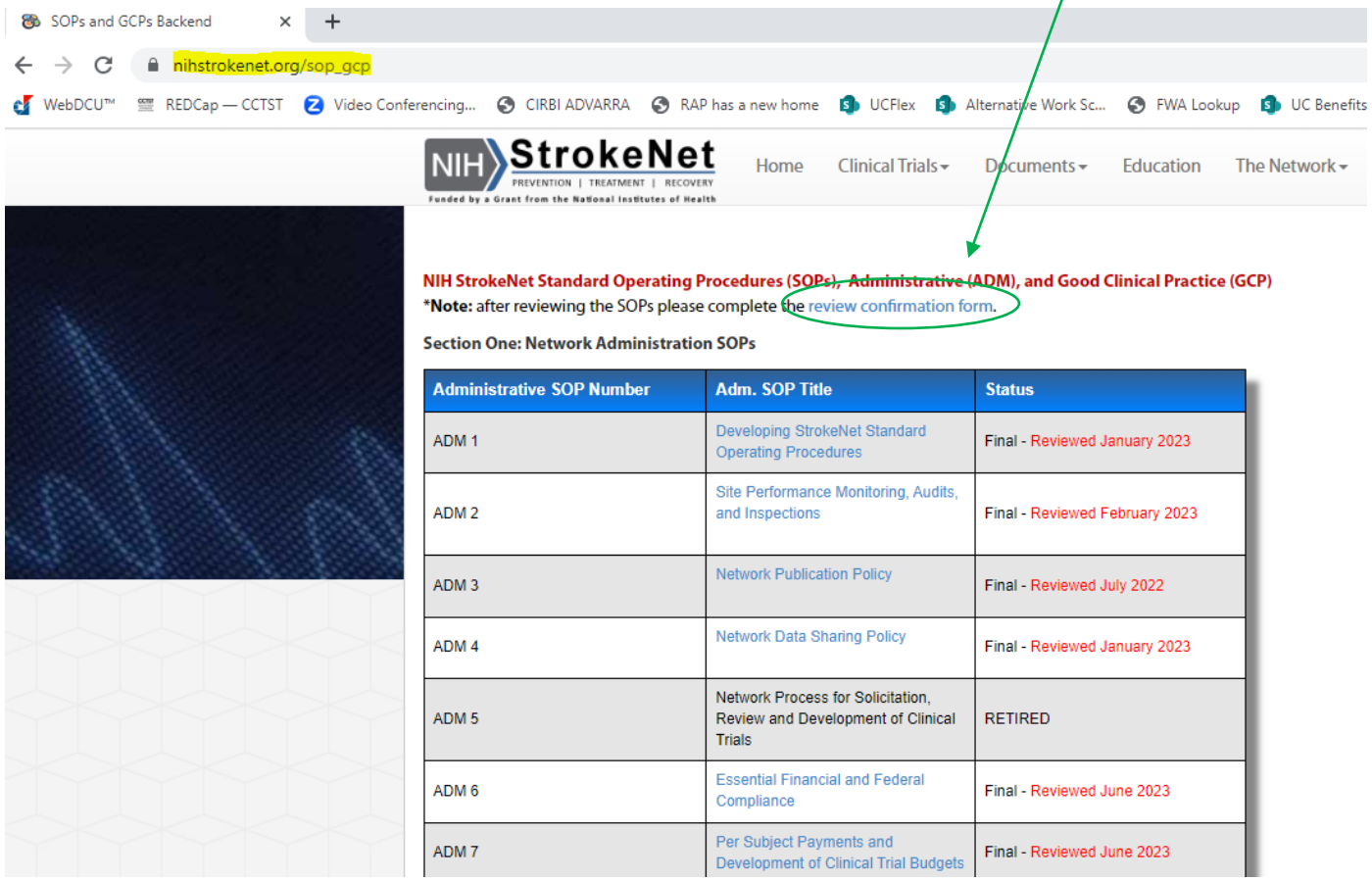
NIH StrokeNet Coordinator Webinar

November 29, 2023

NIH StrokeNet Standard Operating Procedures (SOP) Webinar Series

https://www.nihstrokenet.org/sop_gcp

- Series to review all StrokeNet SOPs
- All **RCC PIs** and **RCC Managers** will be required to review and attest they have reviewed all StrokeNet SOPs



SOP Review – Safety Reporting

SOP #	SOP Title
ADM 12	Central Institutional Review Board (CIRB) Reporting
ADM 13	Safety Monitoring and Reporting
GCP 4	Safety Reporting

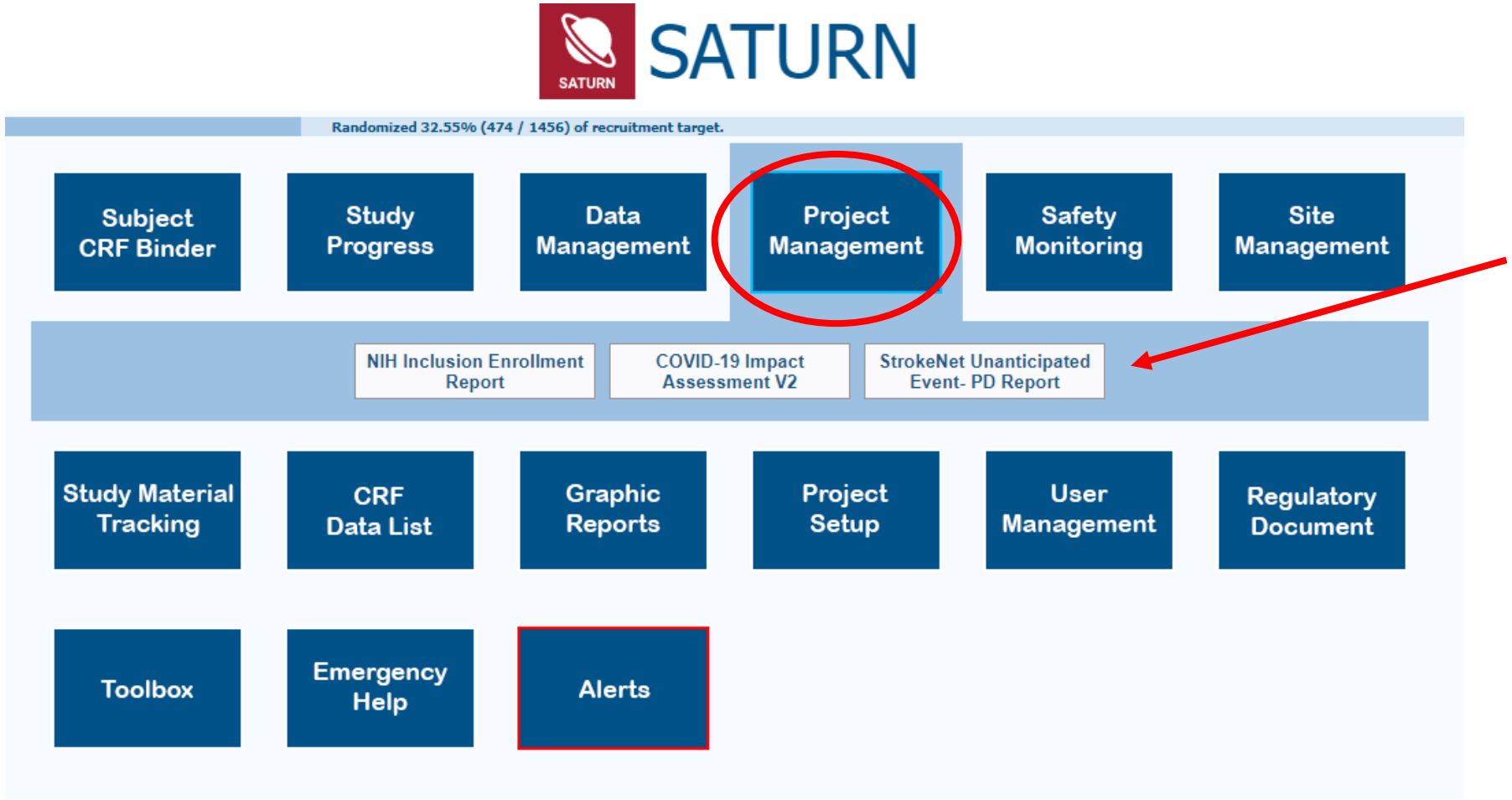
ADM 12 – CIRB Reporting

- This SOP defines the process by the CIRB of record for sites engaged in NIH StrokeNet research for reporting unanticipated events/problems
- Sponsors and sites are required to report unanticipated events (UAE) (UC CIRB terminology) or unanticipated problems (UAP) (Advarra terminology) which meet the CIRB reporting criteria.
- This SOP provides:
  - Description of reportable events
  - Procedures on how sites report events into WebDCU™ > NCC PM reports event to the CIRB of record
  - Defines time frame for reporting
  - Reporting during continuing review (not discussed today)

Events Requiring Prompt Reporting

UC CIRB	Advarra
• AEs that are unexpected, related to research, and involves new or increased risk to participants or others • Unanticipated adverse device effects • Significant protocol deviations • Events requiring prompt reporting according to the protocol sponsor • Complaints made by participants indicating UAEs or complaints that cannot be resolved by the research staff • Unapproved changes made to the research to eliminate an apparent immediate hazard to a research participant • Problems or findings (e.g., breach of confidentiality, loss of study data or forms, etc.) that could influence the safe conduct of the research • Report any new information from written reports (i.e. study monitors, DSMB report, ect.)	• AEs that are unexpected, related to research, and involves new or increased risk to participants or others • Unanticipated adverse device effects • Significant protocol deviations • Event requiring prompt reporting in accordance with the protocol or sponsor • Any complaint by a subject that indicates an unanticipated risk or which cannot be resolved by the research staff/sponsor. • Any change to the protocol taken without prior IRB review to eliminate apparent immediate hazard to a research participant • Any accidental or unintentional change to the IRB-approved protocol that involved risks or has the potential to recur. • UAPs involving risk to subjects or others • Serious or continuing noncompliance • Any publication in the literature, safety monitoring report, interim result, or other finding that indicates an unexpected change to the risks or potential benefits of the research.

Trials using the UC CIRB



ADM 12

Trials using the UC CIRB

WebDCU SATURN

Laura BENKEN Sign Out

List: StrokeNet Unanticipated Event- PD Report

Help

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Page Actions Add New

WebDCU SATURN

Laura BENKEN Sign Out

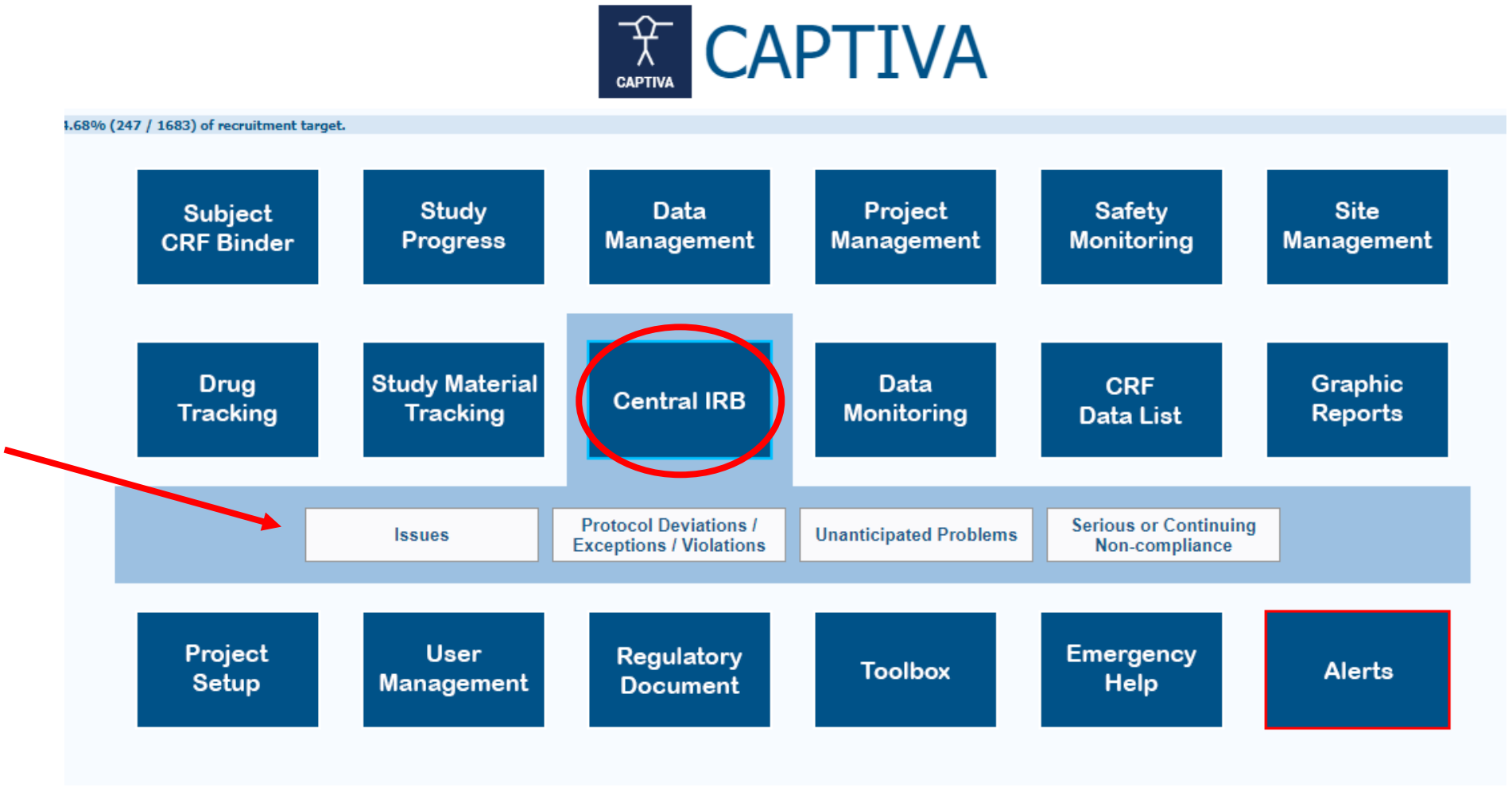
Edit: StrokeNet Unanticipated Event- PD Report

Help

No.	Item Description	Data Value
Q01	Site	Please Select
Q02	Subject ID(s) affected	(50 char.)
Q03	Short Title of Event	(100 char.)
Q04	Date of event	(dd-mmm-yyyy)
Q05	Date of site first awareness of event	(dd-mmm-yyyy)
Q06	Was this event unexpected? *(If Q06, Q07, & Q08 = yes, event meets "prompt" CIRB reporting requirements)*	No Yes
Q07	Is this event related or possibly related to the research? *(If Q06, Q07, & Q08 = yes, event meets "prompt" CIRB reporting requirements)*	No Yes
Q08	Does this event suggest that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized? *(If Q06, Q07, & Q08 = yes, event meets "prompt" CIRB reporting requirements)*	No Yes
Q09	Describe the unanticipated event in detail including date of occurrence and date of site discovery, sequence of events, actions taken (i.e. treatments given or changes in protocol defined procedures) whether the event is resolved, whether the participant remains in the study, and whether the sponsor (if applicable) has been notified.	(8000 char.)
Q10	Describe the corrective measures that have been put in place to prevent similar unanticipated events	(2000 char.)
Q11	Type of event (for versions 1 to 4)	

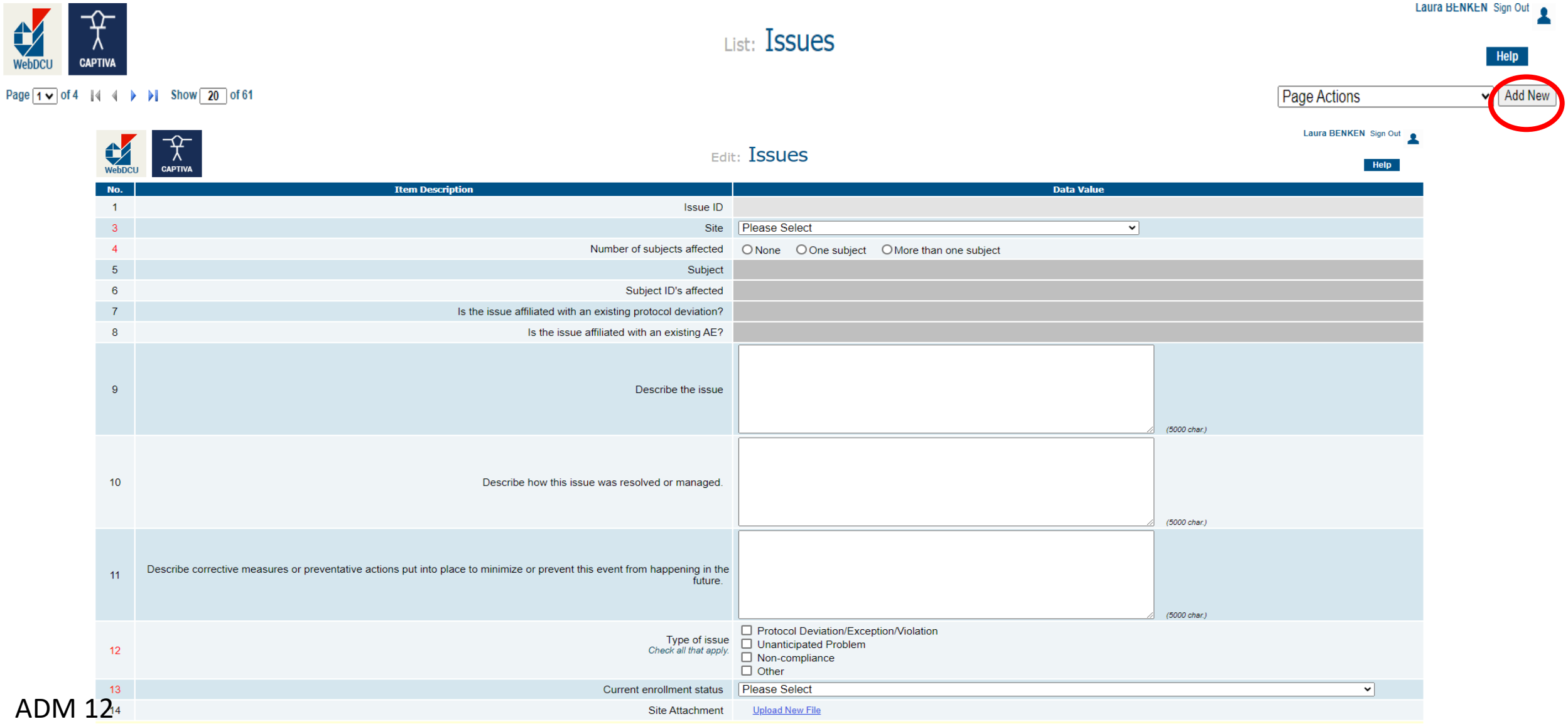
ADM 12

Trials using the Advarra



ADM 12

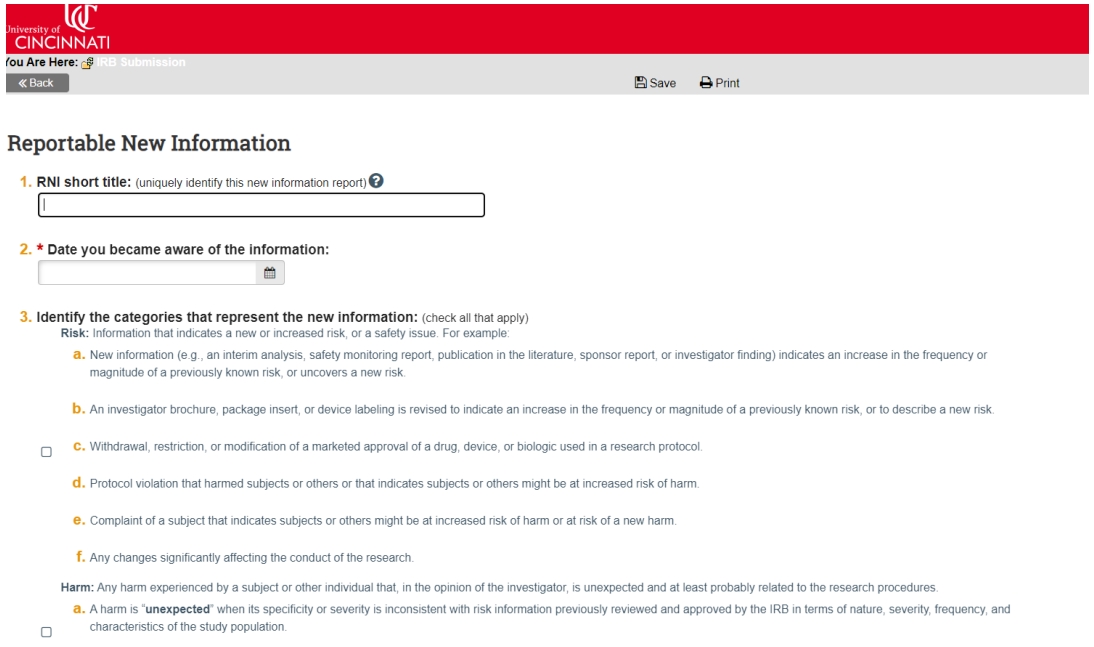
Trials using the Advarra



ADM 12

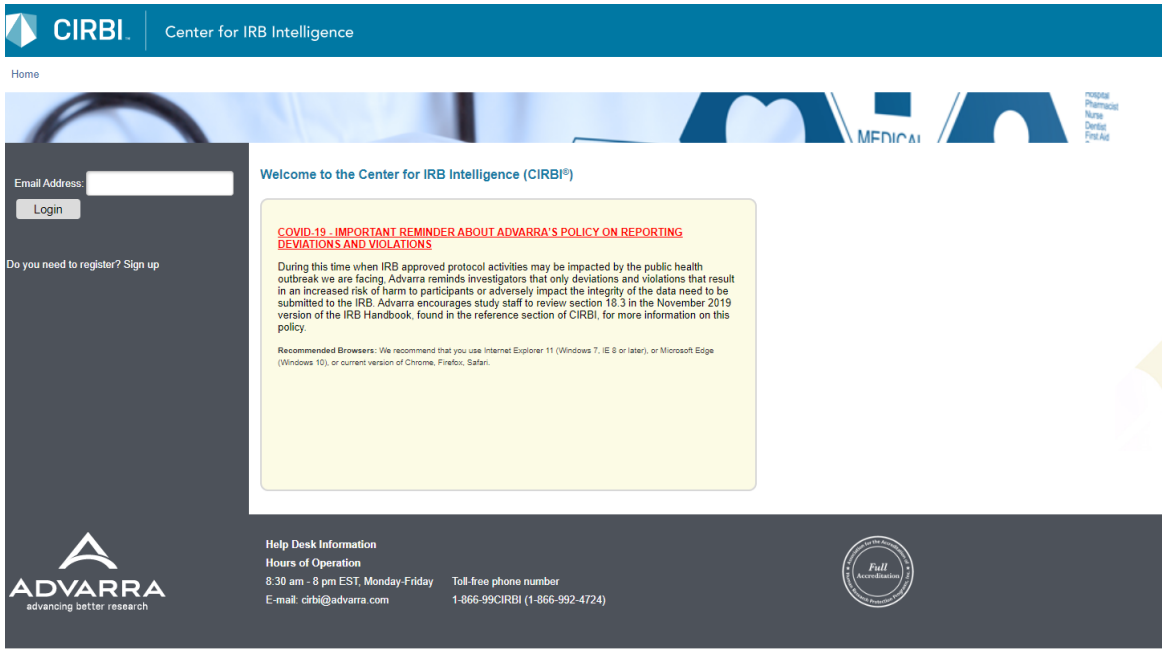
If we are reporting the same types of events, why does the UAE-PD form and the Issues form look different and ask different questions?

UC CIRB → RAP System



NDMC has programed the UAE-PD form to match questions asked in RAP

Advarra → CIRBI System



NDMC has programed the Issues form to match questions asked in CIRBI

	UC CIRB	Advarra
Site event reporting window into WebDCU™	**24 hours** after site's first knowledge of event	**24 hours** after site's first knowledge of event
WebDCU™ table to enter event	Project Management > Unanticipated Event – PD Report	Central IRB > Issues
Site PI responsibilities	• Identify and assess the event • Report any incident, deviation, experience, or outcome that meets the criteria **for prompt reporting** with appropriate documentation via the WebDCU™ "StrokeNet Unanticipated Event-PD Report" form	• Identify and assess the event • Report any incident, deviation, experience, or outcome that meets the criteria **for prompt reporting** with appropriate documentation via the WebDCU™ "Issues" form
NCC PM prompt reporting window to submit event to CIRB	**10 days** after site's first knowledge of event	**10 days** after site's first knowledge of event
Resources if sites have questions about event reporting	ADM 12, Trial specific MOP, NCC PM	ADM 12, Advarra Handbook, trial specific MOP, NCC PM

Reporting Other Events:

- Other deviations/violations, unanticipated problems, and/or complaints not meeting the prompt reporting criteria will be reviewed by the Prime Protocol Principal Investigator (PI) or delegate and the study team regularly in aggregate as prepared by the NDMC team.

- Most individual reports of minor protocol violations which are already documented in WebDCU™ do not need to be re-entered in the UAE-PD/Issues form, unless there is ongoing/egregious noncompliance in which case a single report will be entered.
  - Some exceptions to exist, take NCC Manager's lead if they ask you to enter a minor event into UAE-PD / Issues form.

ADM 13 – Safety Monitoring and Reporting

- This SOP describes the safety monitoring procedures for StrokeNet Trials
  - Broadly states AE of interest and SAEs are entered into WebDCU™ by site > reviewed by Medical Safety Monitor (MSM) > when applicable WebDCU™ will generate safety reports > sent to CIRB
  - Broadly states each trial has a Safety Monitoring Plan > plan names parties responsible for safety reporting to the applicable oversight bodies (FDA, DSMB, CIRB)

GCP 04 – Safety Reporting

- This SOP provides guidelines for timely and accurate reporting of adverse events
- The **Performance Site (PS)** is responsible for ensuring that complete and accurate information regarding Unanticipated Adverse Device Effect (UADEs), Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), Adverse Events (AEs) and Serious Adverse Events (SAEs) is submitted in WebDCU™ within the required time frame per specific protocol requirements. (*References ADM 12 for detailed description*)

Adverse Event Reporting

- The **Performance Site Principal Investigator (PS PI)** or designate is responsible for following CTCAE guidelines for grading the intensity of the event, completing the appropriate sections of the Adverse Event Electronic Case Report Form (eCRF), and submitting the eCRF through the electronic data entry system (WebDCU™).
- Study-specific adverse event reporting instructions for completing and submitting the AE eCRF can be found in each trial's **'Data Collection Guidelines'** document that is located in the associated trial's **Toolbox > Project Documents**.

Form 104: Adverse Event

- Instructions on the top of F104 will include the type of reportable events (i.e., SAEs, Clinical Outcomes, Events of Interest) and the reporting period for the specific study.
- Reportable AEs must be submitted in WebDCU with the appropriate timeframe from first knowledge of the event.
  - Saving the CRF (especially with rule violations) is not considered submitting.
- F104 includes event name, grade, severity, relatedness, outcome, and narratives describing the event in detail.
  - All reported AEs must have their grade, severity, and relationship to study intervention assessed by a site investigator.

Serious Adverse Events (SAEs)

- An adverse event is considered serious if it results in the following:
  - Death
  - Life-threatening
    - Defined as event in which participant was at risk of death at the time of the event.
  - Inpatient hospitalization or prolongation of existing hospitalization
  - Persistent or significant disability/incapacity
  - Congenital anomaly/birth defect
  - Important medical event
    - Defined as medical event(s) that may not be immediately life threatening or result in death or hospitalization, but based upon appropriate medical and scientific judgement, may jeopardize the participant or may require intervention to prevent one of the other serious outcomes listed above.

NOT Serious Adverse Events (SAEs)

- The definition of SAE excludes the following:
  - A visit to the ER or other hospital department < 24 hours, that does not result in admission (unless considered an important medical or life-threatening event)
  - Elective surgery, planned prior to signing consent
  - Hospital admission as per protocol for a planned medical/surgical procedure
  - Routine health assessment requiring admission for baseline/trending of health status (i.e., routine colonoscopy)
  - Medical/surgical admission other than to remedy ill health and planned prior to entry into the study (appropriate documentation is required in these cases)
  - Hospital admission encountered for another life circumstance that carries no bearing on health status and requires no medical/surgical intervention (i.e., lack of housing, economic inadequacy, caregiver respite, family circumstances, administrative reason)

F104 Completion Guidelines

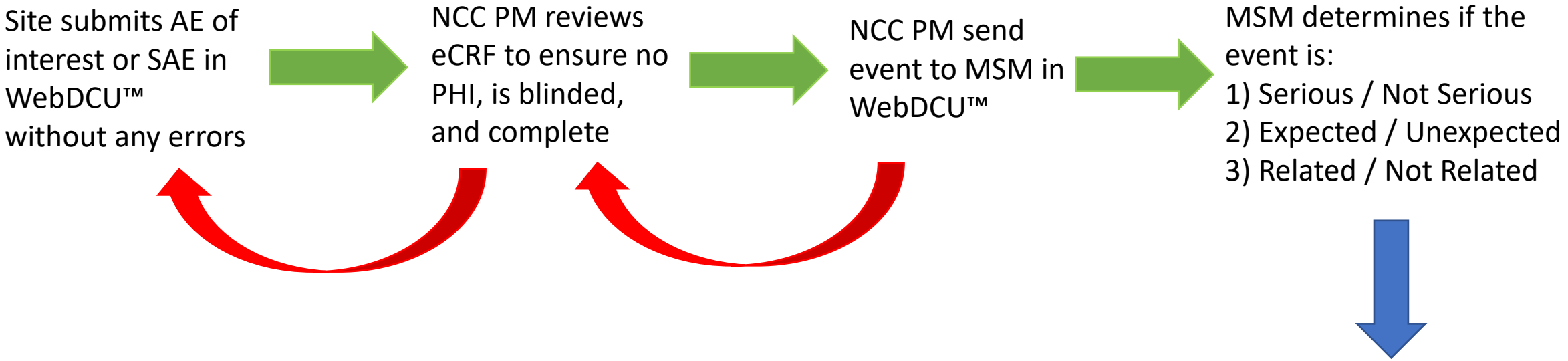
- Adverse Event Name (Q01)
  - Report final diagnosis not individual symptoms (i.e., report ‘pneumonia’ as one AE – not fever, cough, chest pain, crackles as 4 separate events).
  - For hospitalizations, the main reason the subject was hospitalized should be captured as the AE Name with additional diagnoses listed in the narrative.
  - Enter the reason for death, surgery, intubation, etc. as these are outcomes of adverse events.
- AE Narratives (Q15-Q17)
  - Data Collection Guidelines will detail the required information to include and provide examples/templates to use.
  - Do not identify any study participant, physician, or institution by name.

F104 Q15 Describe the event or problem

- The following are specific items to include the AE narrative:
  1. Age, race, gender, most pertinent history, and time and date of enrollment
  2. Dates and times of the event and relevant procedures/clinical assessments
  3. A description of what happened and a summary of all relevant clinical information (i.e., medical status prior to event, signs and/or symptoms)
  4. Differential diagnosis for the event in question
  5. Complete clinical course information including relevant test/lab data (both +/- results with corresponding dates)
  6. All treatment outcomes
  7. Discharge summary (if applicable)

Adverse Event Reporting

- The PS PI participating in NIH StrokeNet trial is responsible for assuring the AEs and SAEs are properly recorded in the study records and entered in WebDCU™ in a timely manner (within 24 hours of first knowledge of event).



If AE is deemed **serious**, **unexpected**, and **study related** by the MSM, WebDCU™ will generate an automated notification for the NCC PM to submit a safety report to the CIRB within 10 days