Up Next . . .

2–3 p.m.

Breakout Room 2: PRS Beta

Carrie Dykes, University of Rochester

Nachiket Dharker, PRS Beta Product Owner

Moderators:

Stacey Arnold, ClinicalTrials.gov Results SME

Amanda Burton, ClinicalTrials.gov Lead Information Research Specialist

Qiao Chang, ClinicalTrials.gov Registration SME

Summary

Anna Fine, Acting Director of ClinicalTrials.gov

We are currently on a break and will resume at 2 p.m.

PRS Beta Breakout Room

Carrie Dykes

University of Rochester

Nachiket Dharker

PRS Beta Product Owner

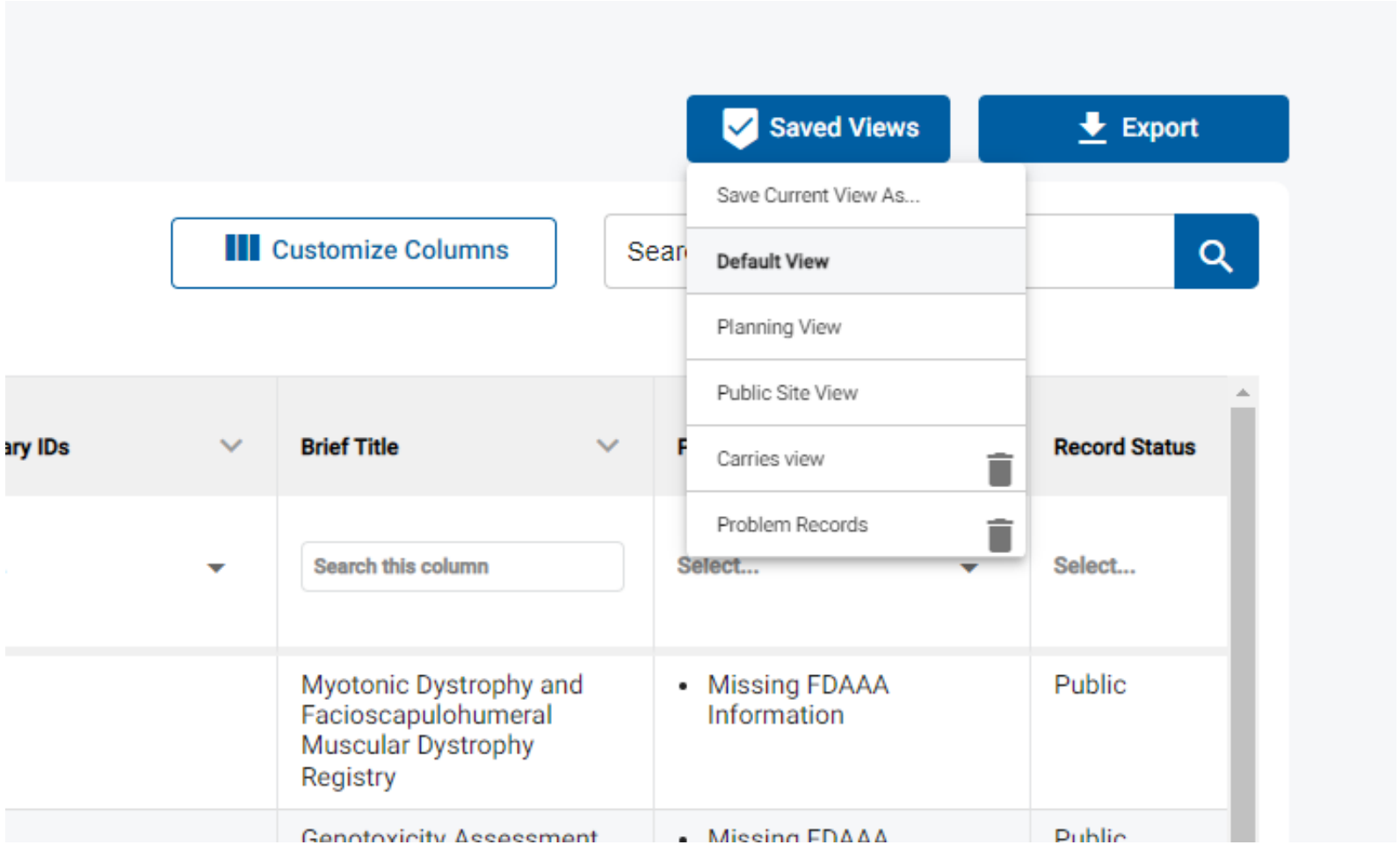
User Comments on PRS Beta

Carrie Dykes, PhD

PRS Administrator

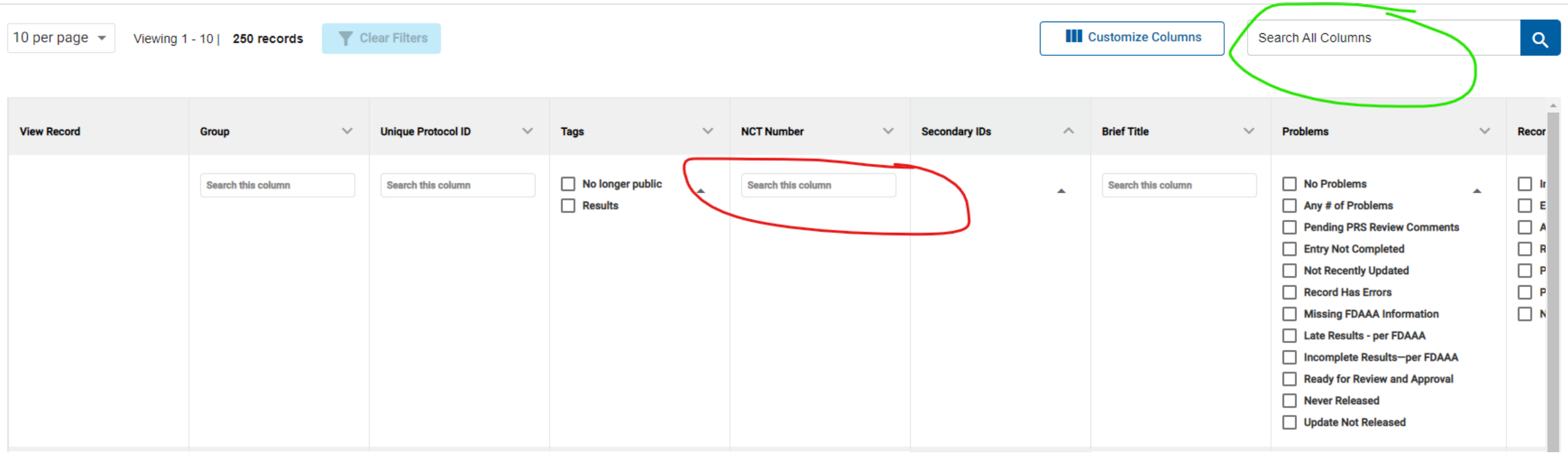
University of Rochester

Homepage: Allows Users to Save a View



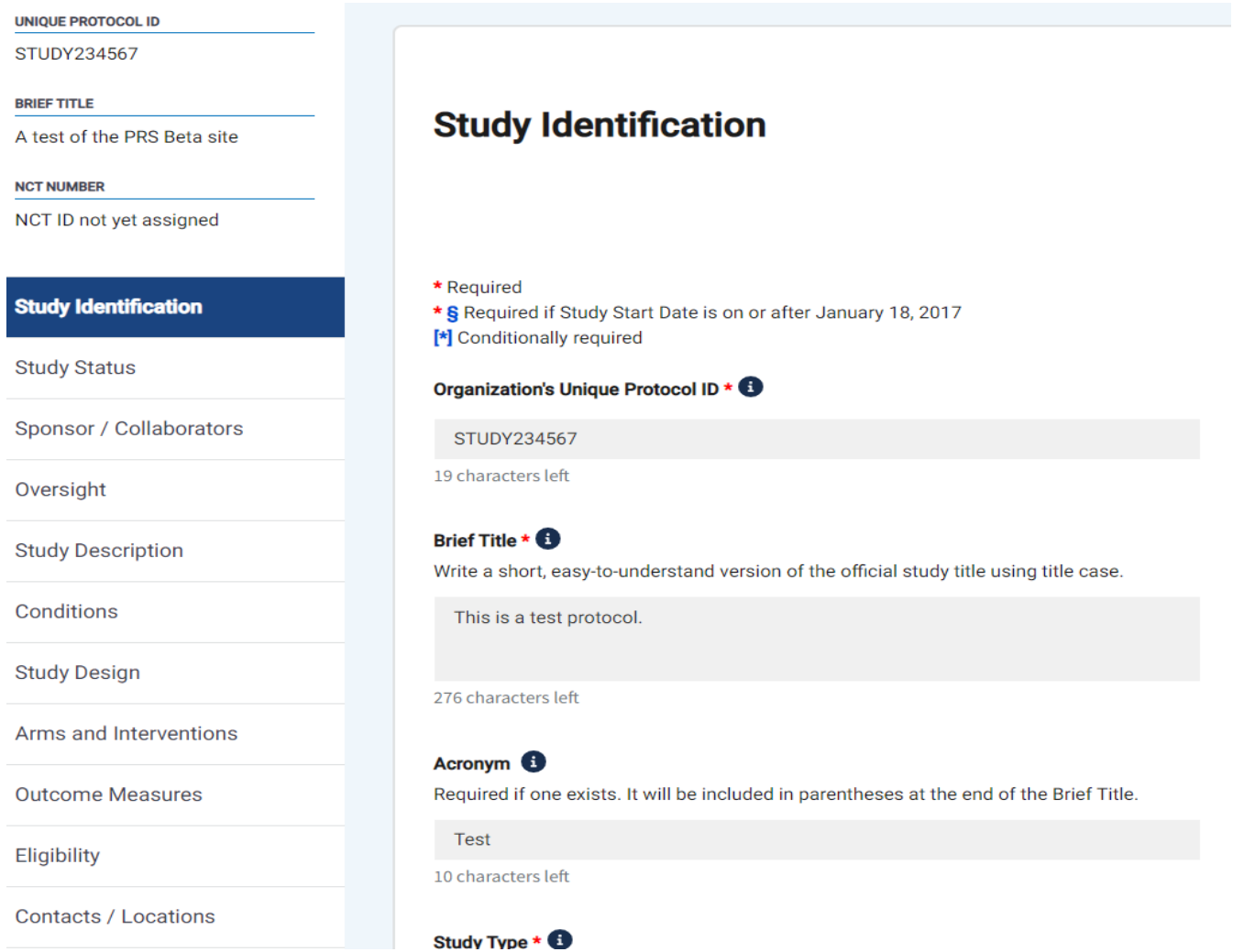
PRS Beta allows users to save a particular view where the columns are customized for a particular purpose.

Homepage: Each Column Is Searchable



Protocol Registration: Easier Navigation within a Record

Users can now click from module to module without having to click out of the modules.



Protocol Registration: Information Buttons

Information buttons for each field bring up additional information and definitions.

Record List

UNIQUE PROTOCOL ID
STUDY234567

BRIEF TITLE
A test of the PRS Beta site

NCT NUMBER
NCT ID not yet assigned

- Study Identification
- **Study Status**
- Sponsor / Collaborators
- Oversight
- Study Description
- Conditions
- Study Design
- Arms and Interventions
- Outcome Measures
- Eligibility

Record Summary | Protocol | Study Documents

Study Status

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required

Record Verification Date *

Month **Year**

Overall Recruitment Status *

If you select "Suspended," "Terminated," or "Withdrawn," an explanation of why the study was stopped is required.

- Select -

Record Verification Date

Enter the date that the study record information was last reviewed and confirmed by the responsible party.

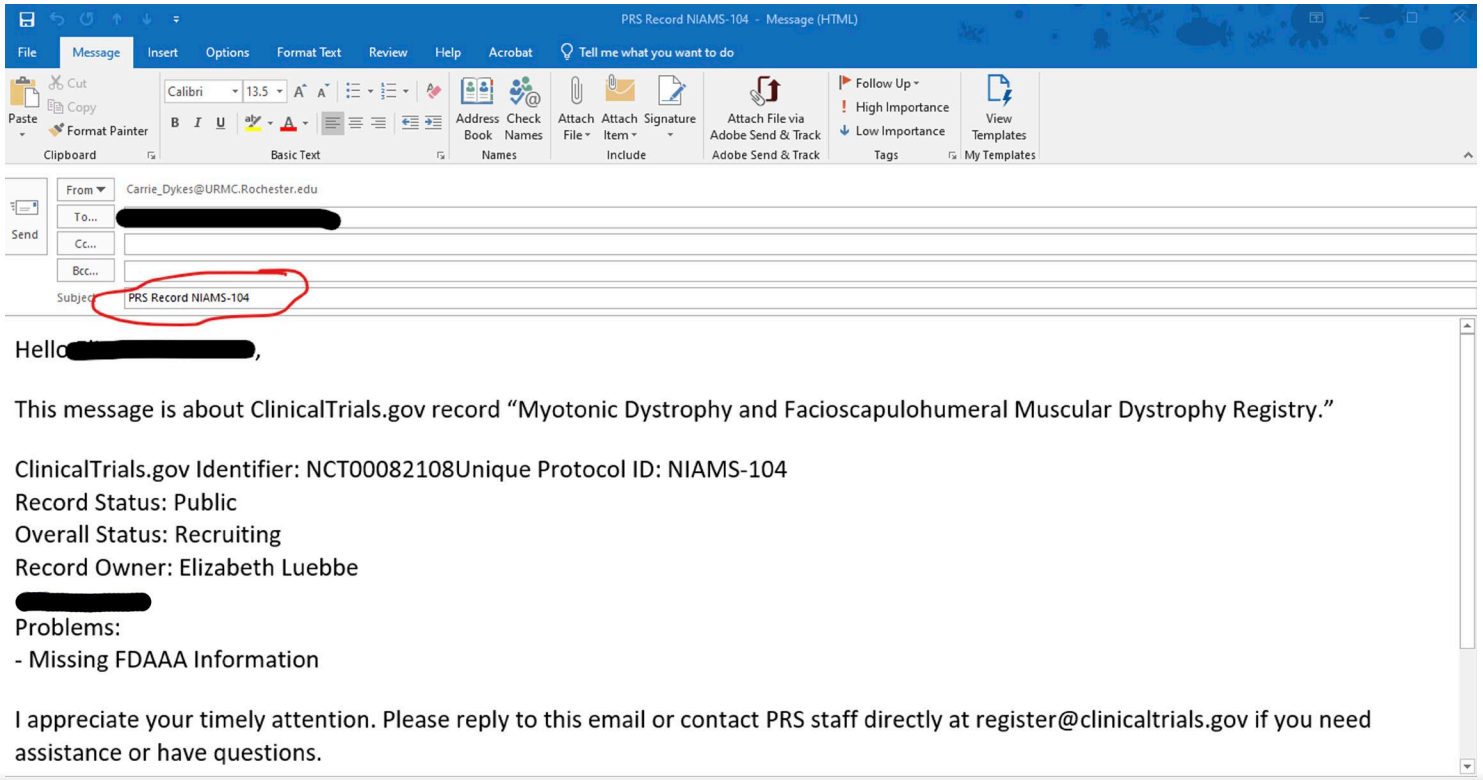
Additional Information +

Data Element Definition +

Feedback

Homepage: Messages to PRS Record Owners

- The NCT Number is a unique identifier used in all my email communications.
- It allows me to search messages using this unique number.
- It would be helpful to include it in the subject line of the beta system's email template.



Problem Records: Email Message Template

- It would be helpful in the future if the template language could be customized by each institution.
- My institution emails the responsible party and record owner.
    - It would be helpful to email them together rather than separately.

Email Notifications and Templates

Request: Include the NCT Number in the subject line.

Response: We can explore adding this information, but we would maintain the Unique Protocol ID in the subject line in all cases (for records without an assigned NCT Number).

Request: Create emails from user-defined templates.

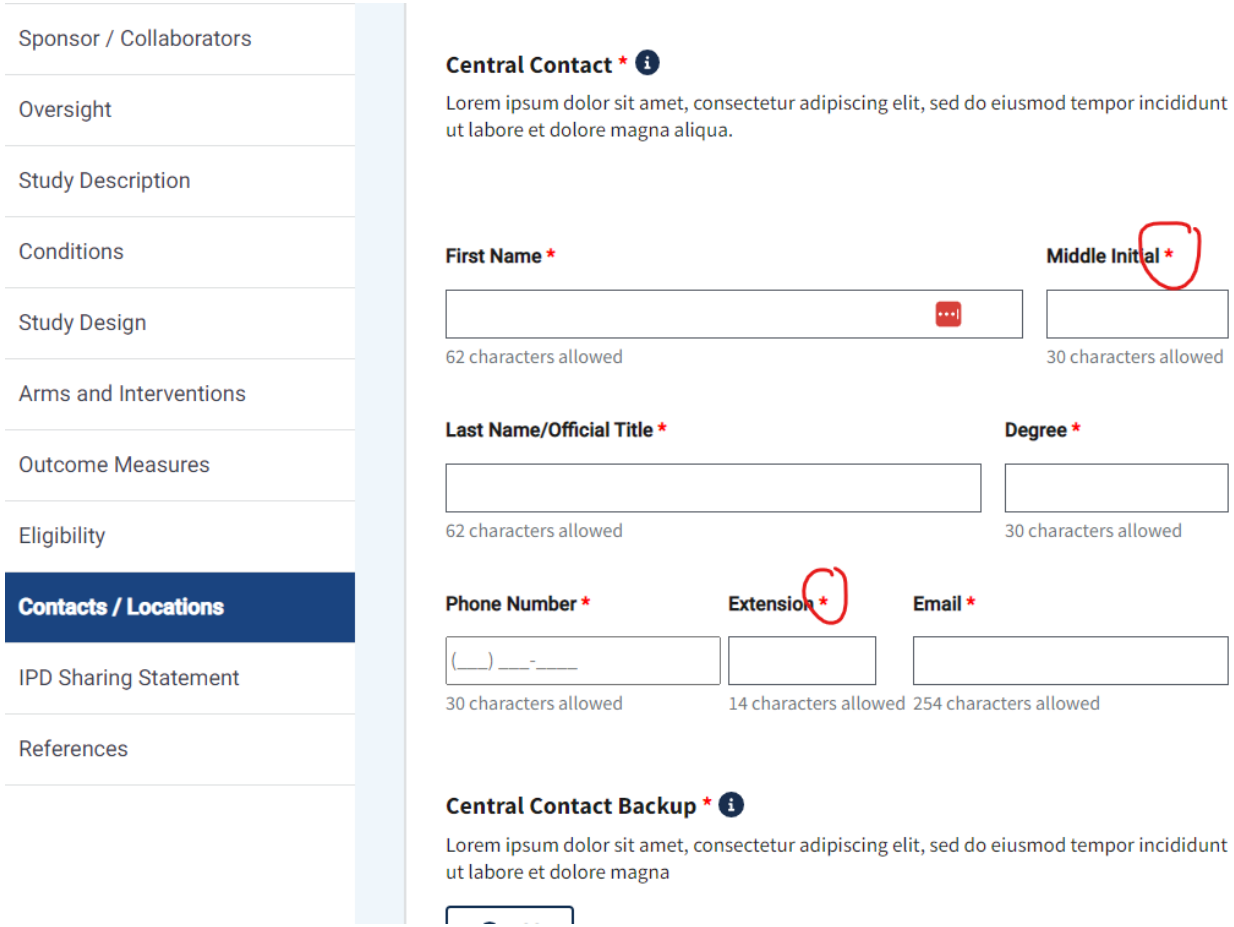
Response: This would require storage in the PRS. We will need to explore our capacity for this storage.

Request: Allow multiple addressees to be emailed at once (e.g., responsible party and PRS Record Owner).

Response: We can explore the potential to select multiple names in the To, Cc, and Bcc fields from the study record's Access List.

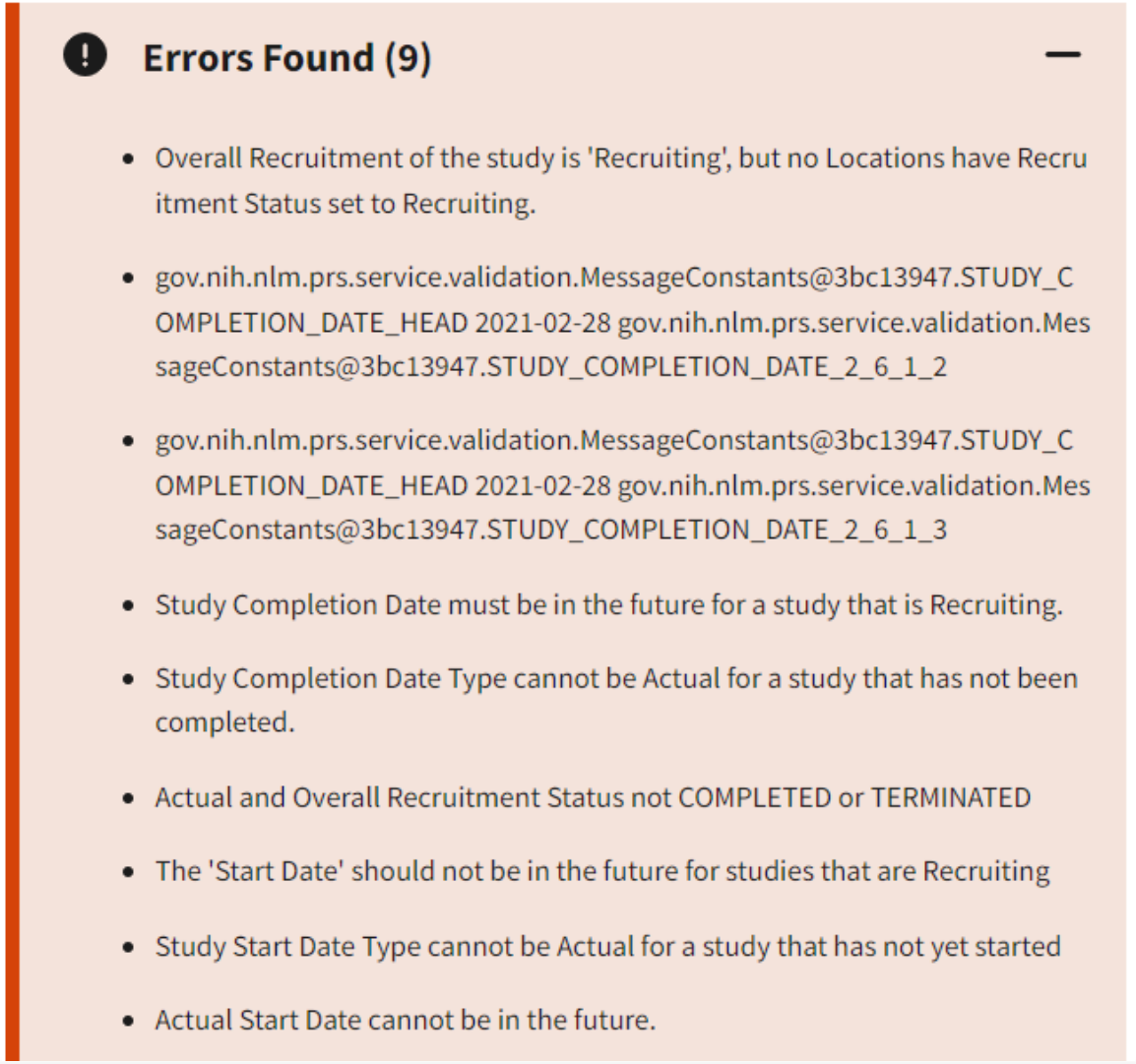
Protocol Registration: Entering Contact Information

- There are several places in the record where red asterisks are not appropriate.
- Red asterisks indicate the field is mandatory to complete.
- For example, the Middle Initial and Extension are mandatory when entering the Central Contact information.



Protocol Registration: How Errors Are Shown

- Having a list of Errors at the top of the record as you complete it is not helpful.
- Just like how most forms on the web are completed, the system should highlight the fields that have Errors, so they are easier to find.
- Errors appear about downstream sections of the record before the record is completed.

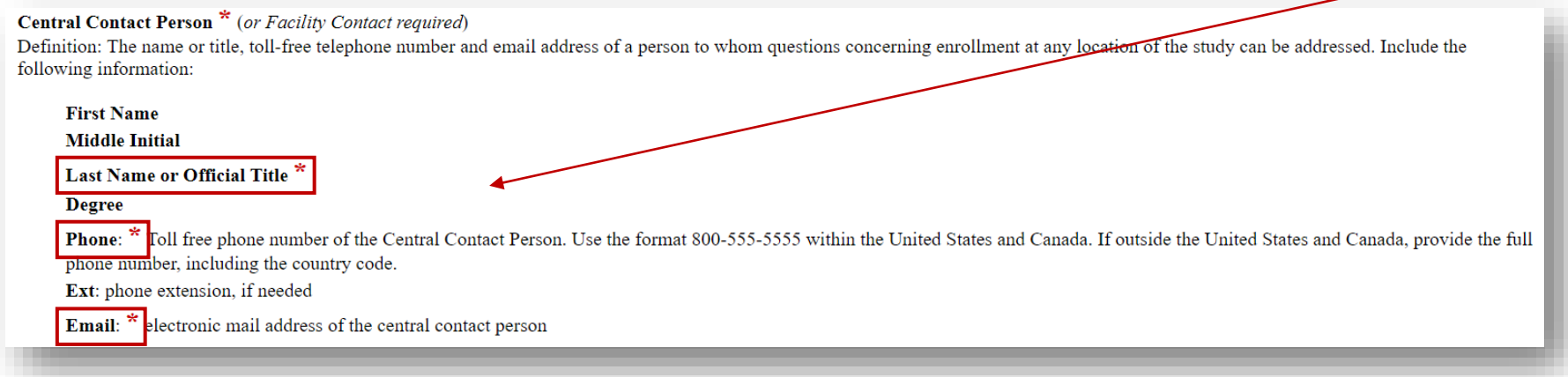


Known Issues

Issue: Inappropriate requirement labeling for data element fields

Response: We are aware of this issue and have been working on a solution.

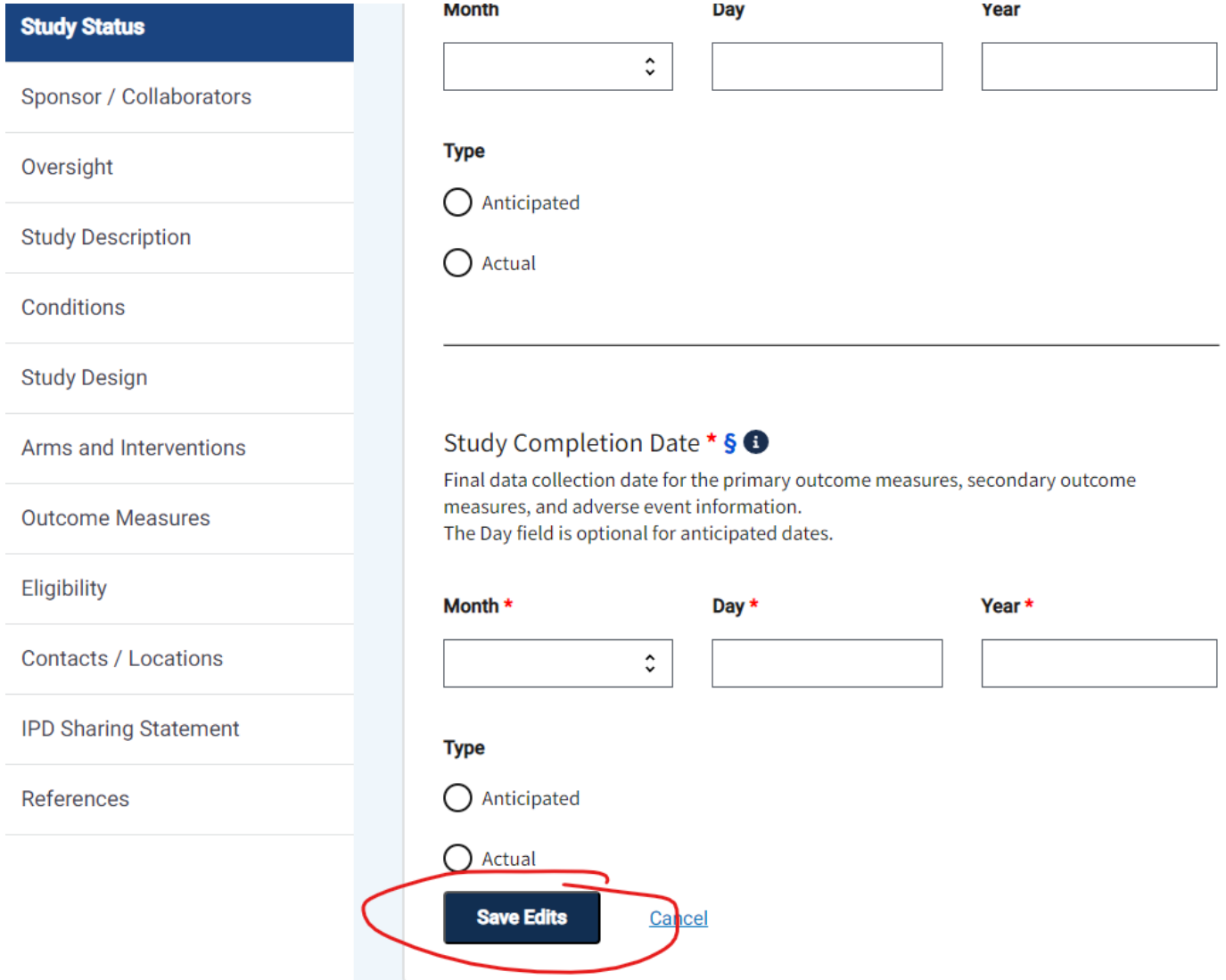
The goal is to label fields according to individual requirements (as is done in the DED).



Issue: Errors appear at the top of the page, instead of near the problem areas, and are sometimes inappropriate.

Response: We are aware of these issues and have been working on solutions.

The goal is to identify errors closer to the relevant fields and to avoid inappropriate errors.

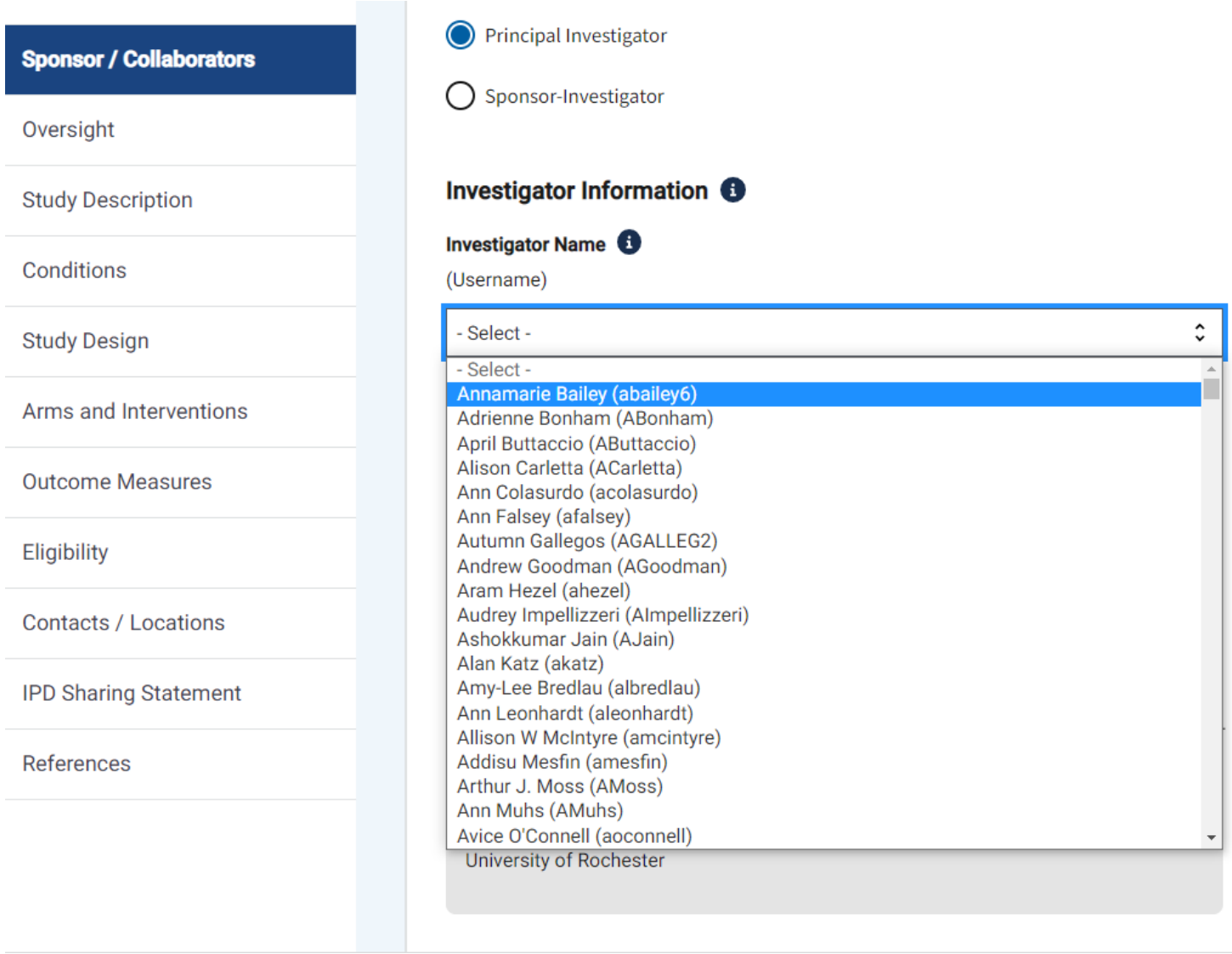


Protocol Registration: Creating a New Record

- "Save Edits" is not an intuitive action button when creating a record for the first time and all the fields are blank.
- "Next," "Save," or "Continue" are more intuitive.

User Accounts

- User lists that populate fields like Investigator Name should be alphabetized by last name, not by username or first name.
- Lists should be searchable.



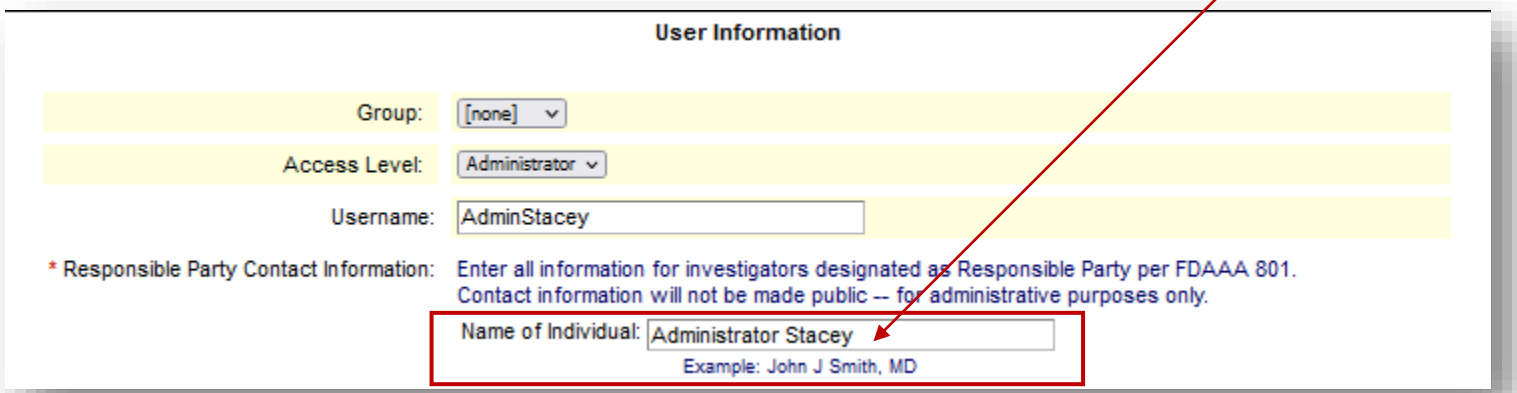
Additional Suggestions

Request: Change the name of the **Save Edits** button to something more intuitive when entering information for the first time.

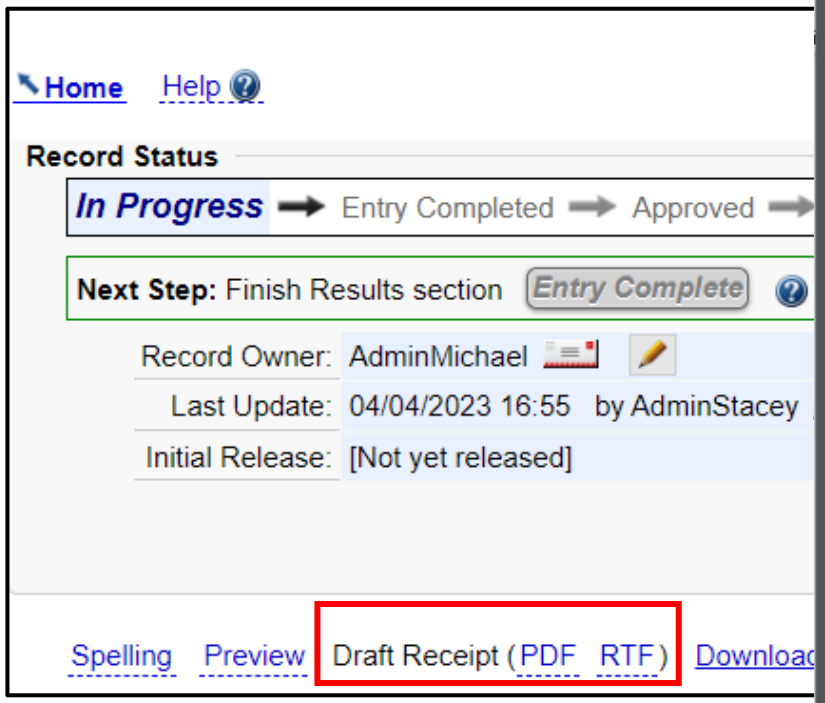
Response: This makes sense, and we think “Save” might work for both first-time entries and revisions.

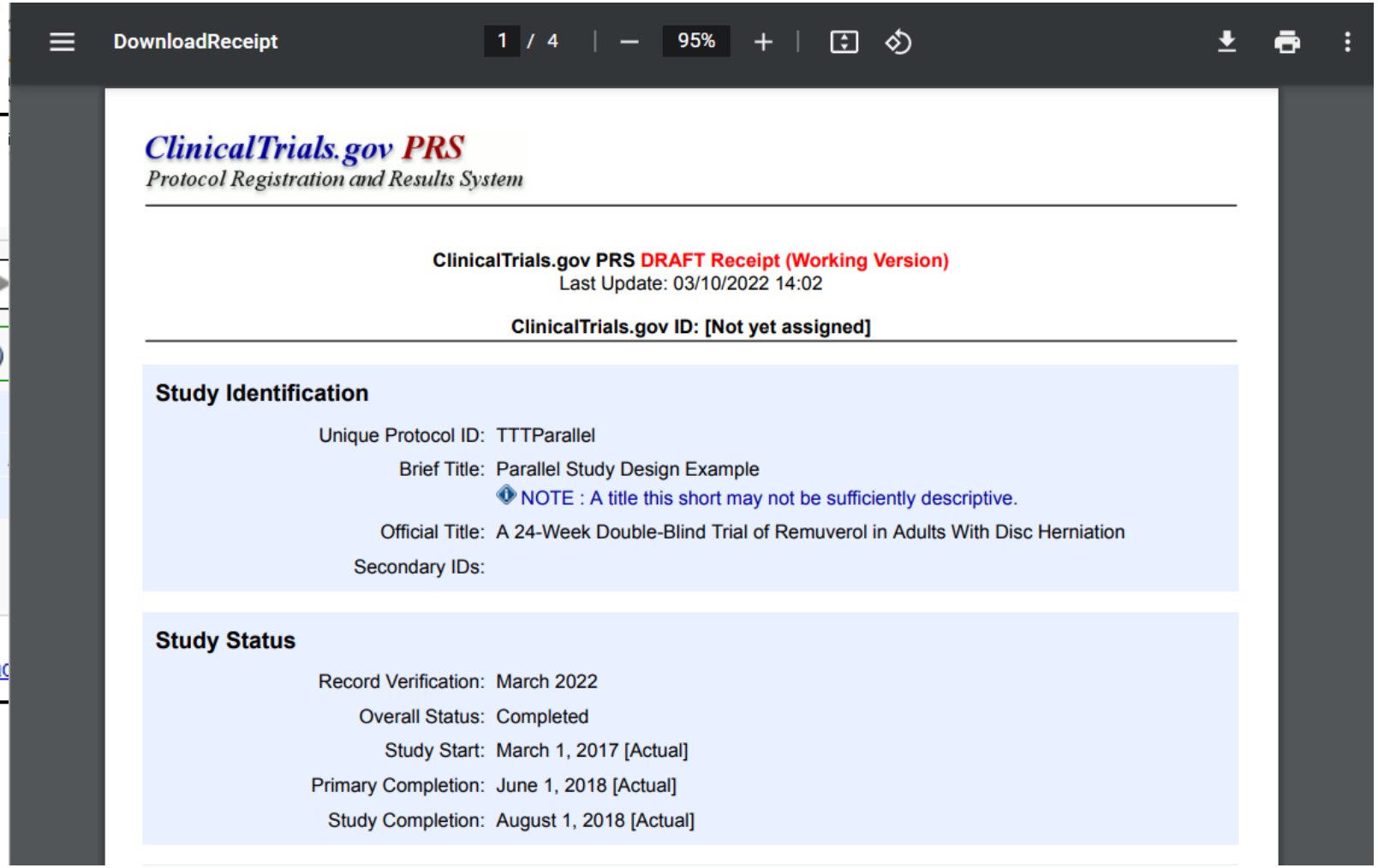
Request: Alphabetize user lists by last name, and make them searchable.

Response: We will explore making lists of names searchable. Alphabetization by last name is trickier because full names are entered in a single field when accounts are created.



Question 1 (Record Summary)—Context



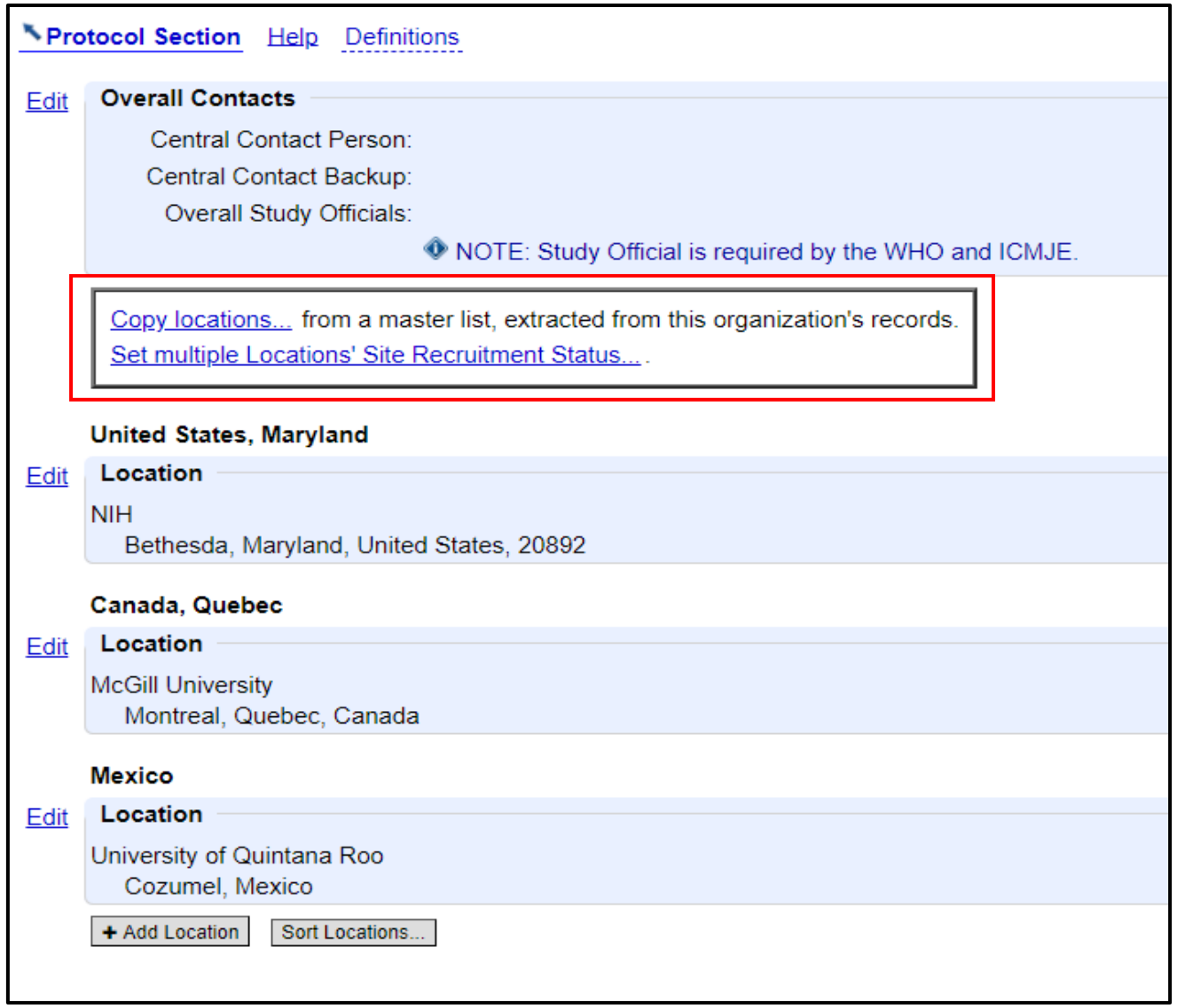


Question 1 (Record Summary)

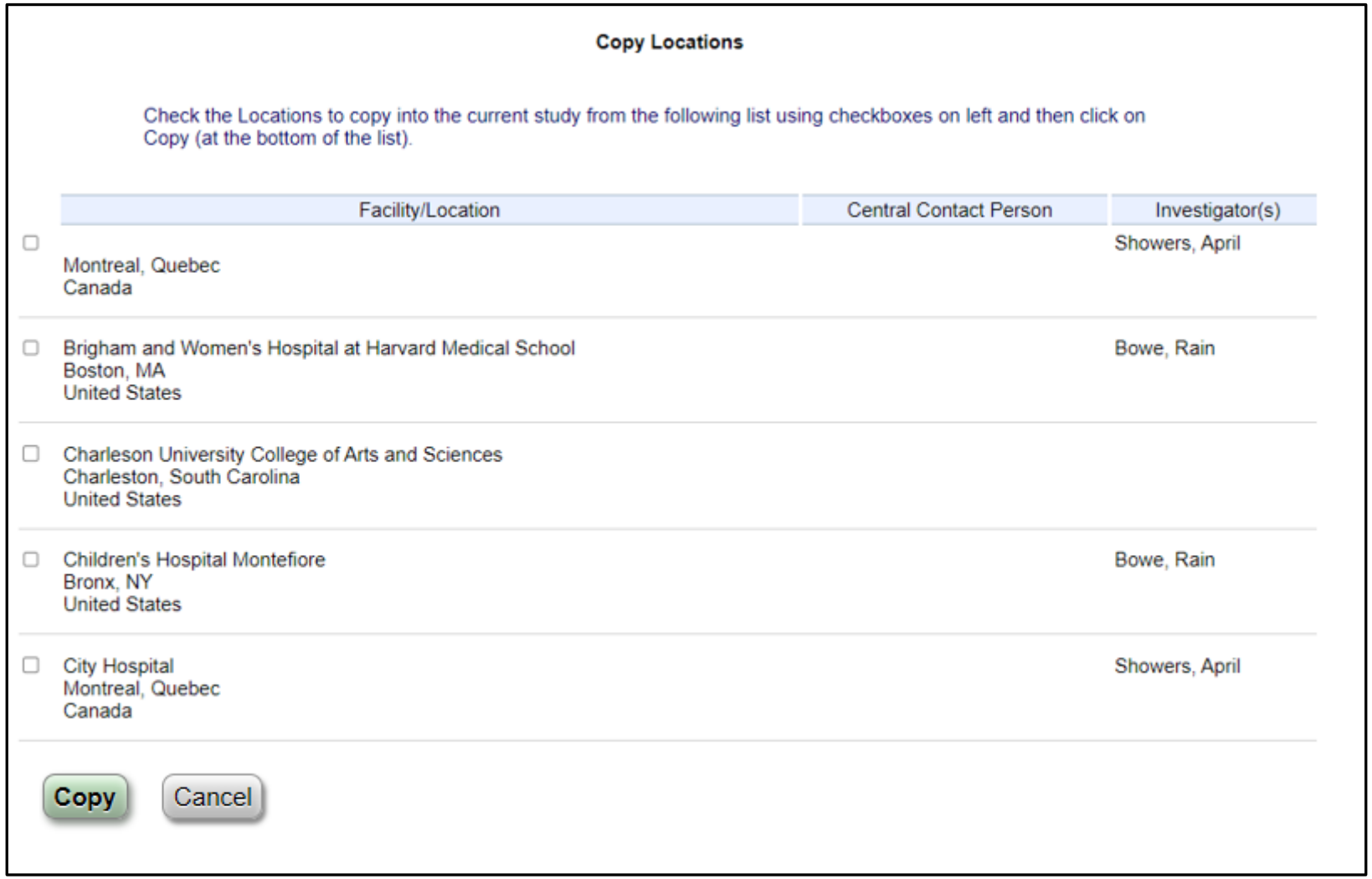
Do you use the Draft Receipt option on the Record Summary page to download the PDF or RTF file?

A. Yes, I use both the PDF and RTF file formats.
B. Yes, I use only the PDF file format.
C. Yes, I use only the RTF file format.
D. No, I don't use this option.

Question 2 (Contacts and Locations)—Context 1



Question 2 (Contacts and Locations)—Context 2



Copy Locations

Check the Locations to copy into the current study from the following list using checkboxes on left and then click on Copy (at the bottom of the list).

Facility/Location	Central Contact Person	Investigator(s)
Montreal, Quebec Canada		Showers, April
Brigham and Women's Hospital at Harvard Medical School Boston, MA United States		Bowe, Rain
Charleson University College of Arts and Sciences Charleston, South Carolina United States		
Children's Hospital Montefiore Bronx, NY United States		Bowe, Rain
City Hospital Montreal, Quebec Canada		Showers, April

Copy Cancel

Question 2 (Contacts and Locations)—Context 3

Site Recruiting Status

Update Site Recruitment Status for multiple Locations.

Tip: It is only necessary to maintain Site Recruitment Status when Overall Recruitment Status for the study is Recruiting.

1. Select the desired Recruitment Status.

* Recruitment Status: --Select--

2. Check the Locations for which Site Recruitment Status is to be changed.

Check all | Check none

	Facility	Location	Current Status
☐	NIH	Bethesda, Maryland, United States, 20892	
☐	McGill University	Montreal, Quebec, Canada	
☐	University of Quintana Roo	Cozumel, Mexico	

CAUTION: This operation can only be undone by restoring Site Recruitment Status for each Location individually.

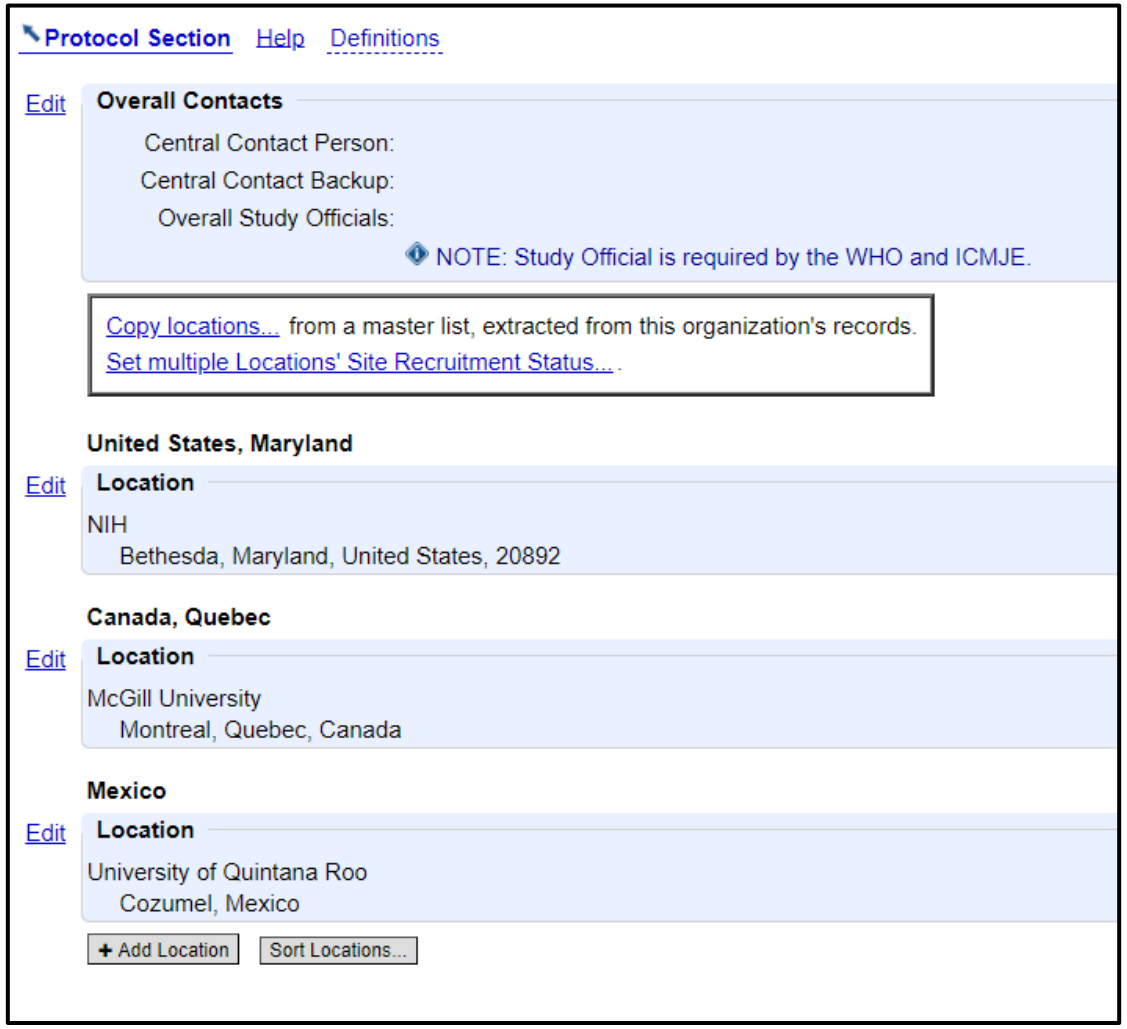
Save | Cancel

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Question 2 (Contacts and Locations)

Which of these features do you use?

A. Both the Copy locations and Set multiple Locations' Site Recruitment Status features
B. Only the Copy locations feature
C. Only the Set multiple Locations' Site Recruitment Status feature
D. Neither of these features



Open Q&A

Please direct your questions in the chat to “Everyone in Meeting.”

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