New Research Recruitment Services

August 26, 2021

UT Health San Antonio

During the Forum:
We ask you to please

- Mute your mic to avoid background noise
- Keep your camera off to conserve bandwidth
- Join via Microsoft App to facilitate identifying UT Health San Antonio domain
- Use the chat feature and a moderator will respond to your question.

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Overview

- Initial Research Feasibility
- Participant Recruitment Marketing Strategies
- Budgeting for Recruitment
- Velos eResearch, Pre-Screening
- UT Health San Antonio IRB Guidance

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Initial Study Feasibility

Jason Bates

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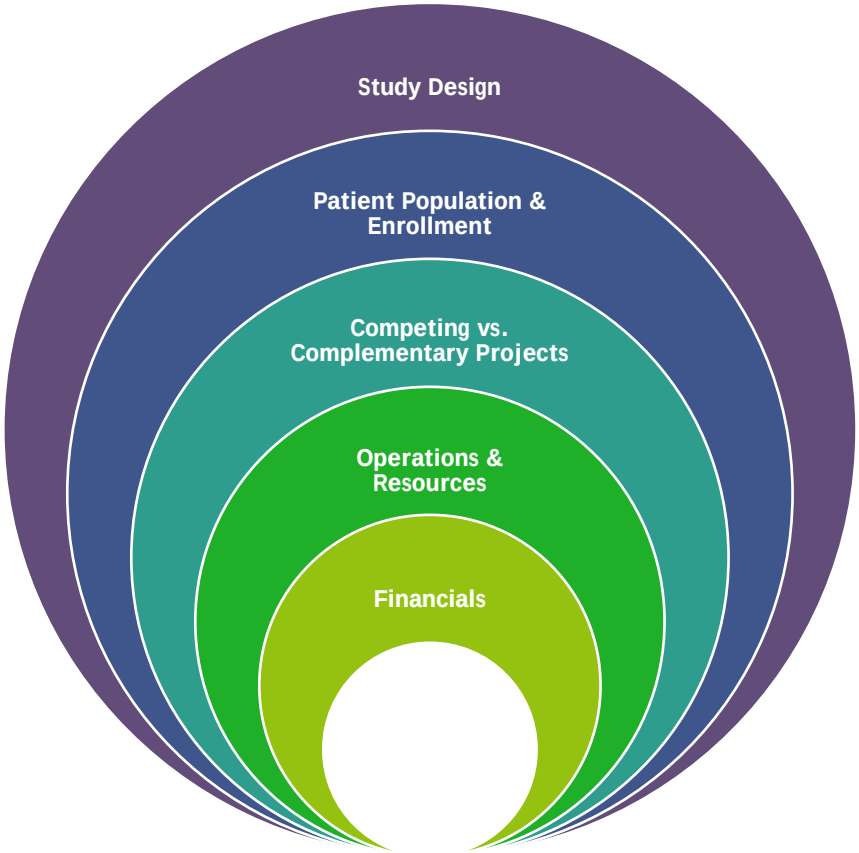
Study Feasibility

When assessing the feasibility of a study, the following should be considered as applicable:

- Study Design
- Patient Population & Enrollment
- Competing vs. Complementary Projects
- Operations and Resources
- Financials



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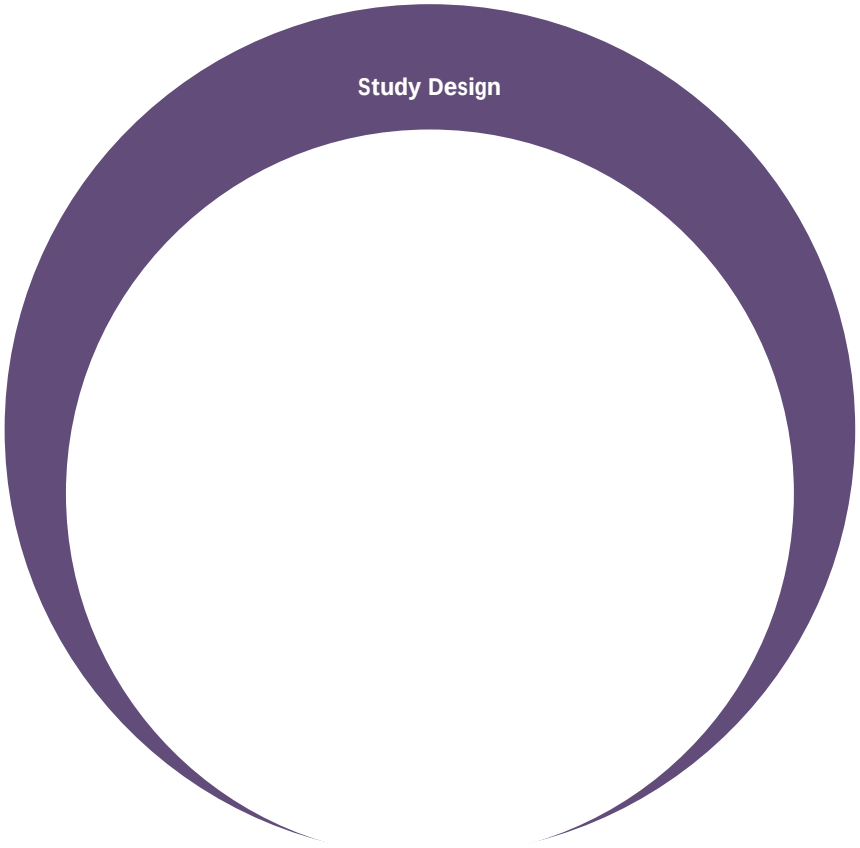
Study Design

- Do we have experience in the therapeutic area or indication being evaluated?
- Is the Study Design considered scientifically sound by the local investigator?
- Does the study have reasonable Inclusion & Exclusion Criteria given the study indication?
- Practical frequency of; visits, events or procedures.



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Patient Population & Enrollment

- Direct access to the patient population being evaluated
- Given inclusion/exclusion do you think you can meet enrollment expectations
- Barriers to enrollment
  - Study Design
  - Alternative treatments
  - Cost to patients
  - Subject time commitment or expectations

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Recruitment & Marketing Strategies for Clinical Trials

Linda Lopez-George , M.A.
Director of Research Marketing, Basic & Translational Science
Marketing, Communications & Media

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THREE WAYS TO INITIATE SERVICE

1. Clinical Trials Portal
2. Service Catalog
3. Email to Linda Lopez-George

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Clinical Trials Portal

CTO Budget Analyst will initiate contact on behalf of the investigator when preparing a budget to negotiate with industry sponsor clinical trial

Recruitment & Marketing Team initiates the Service Request ticket and begins to prepare marketing plan designed to achieve the recruitment goals and provides the quote to the CTO within three (3) weeks.

Communication among the CTO and research team is managed through the service request ticket.

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Service Catalog

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Responsibilities to Attain KPIs

Marketing Team Responsibilities

- Consult with requestor to determine if project aligns with strategic priority and goals.
- Provide scope of work based on project requirements.
- Communicate the status of the project to the requestor as needed.
- Coordinate with the requestor to align project goals with the final product.

Client Responsibilities

- Review checklist to assist in providing a summary of patient recruitment needs.
- Provide project description, trial protocol and supporting documentation.
- Respond to requests for additional information promptly.
- Provide measurable goals and metrics on key performance indicators.

Next Steps

1. Have your information and project ID (PID) ready before submitting the request.
2. You will be contacted in 1-2 business days to discuss your request.

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Client Proposal

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Client Proposal

PROJECT OVERVIEW

TIMELINE

WEEKS 1 & 2

AUGUST 16-29

WEEK 3 & 4

AUGUST 30-
SEPTEMBER 12

REPORT
BY SEPTEMBER 16

BUDGET: $300

SOCIAL MEDIA

Call to Action' driving to the Barshop Institute clinical trials webpage.

A/B test runs Weeks 1 and 2. The ad generating more engagement runs in Weeks 3 and 4.

Campaign metrics will be provided to the research team within 3 business days after the campaign ends. Metrics can support NIA grant budget justification, if required.

SOCIAL MEDIA MANAGEMENT

Facebook ad campaign will be managed by the Marketing, Communications & Media Digital team.

Facebook does not allow comments in sponsored ads to be disabled. Comments will be closely monitored and irrelevant or inappropriate comments can be hidden from view by the Digital team.

Paid ad campaigns can be suspended at any time to allow for evaluation of metrics and review of creative, as needed.

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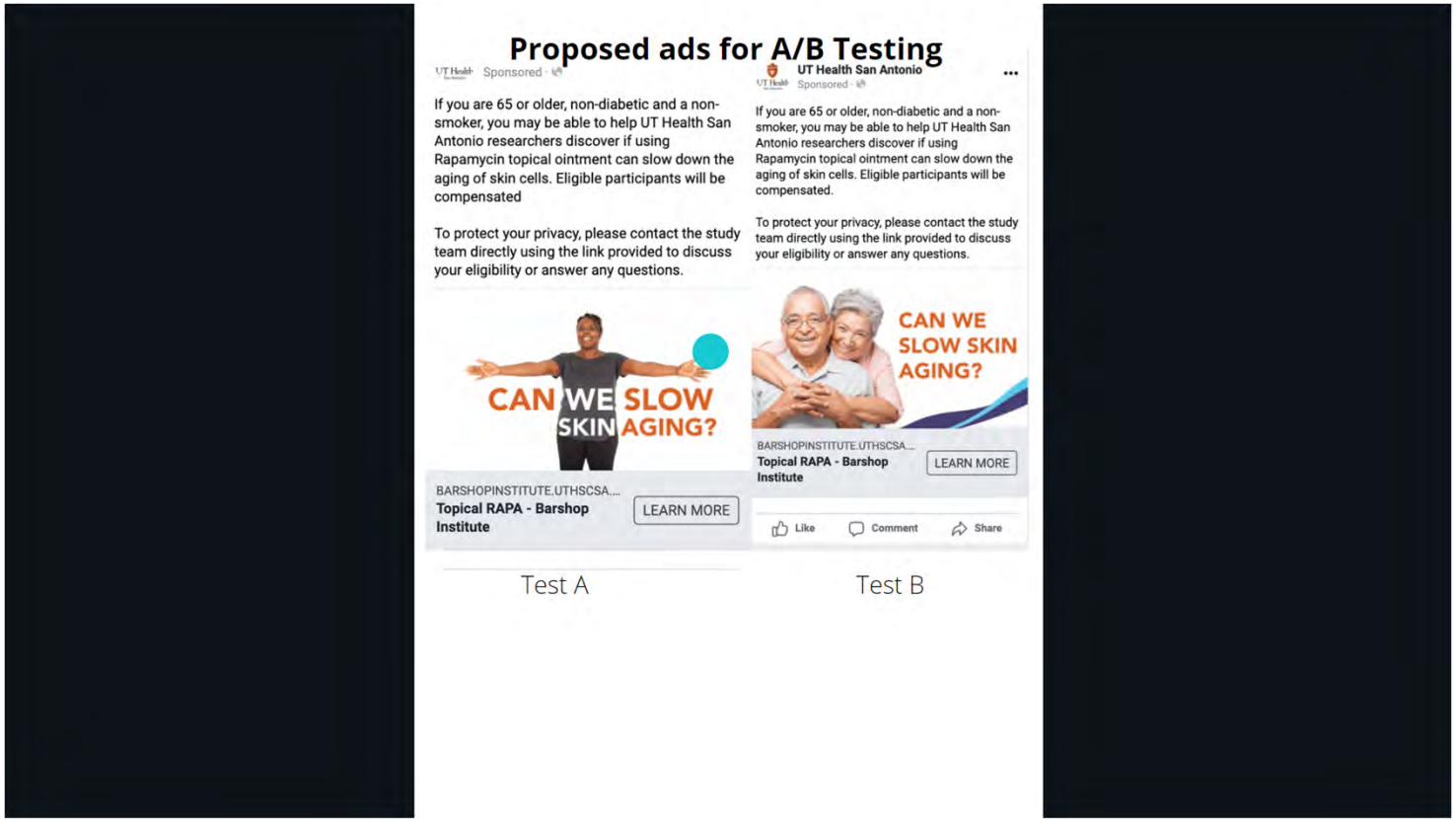
Sponsored Ad Prepared for IRB Review



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Organic Tactics

- Institutional Digital newsletters
- News story pitched to the media
- UT Health San Antonio social media platforms (Twitter and Facebook)
- External digital newsletters (Bexar County Medical Society)
- Outreach Events (UTSA football home game)

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Budgeting for Recruitment

Patricia Miranda
Clinical Trials Office
Manager, Research Operations

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CTO Standard Budget Approach

Draft Coverage Analysis Step – Identification Point

- CTO Budget Team will identify whether a Sponsor's budget includes Advertising Budget
- When Research Teams anticipate the need for advertising funds, CTO Budget Analyst can request funds during negotiation

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Ongoing study financial considerations

…once the study is ACTIVE

When patient enrollment is reached, **patient retention** is the next challenge!

Budget Amendments can be site initiated

Timing is key

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Velos eResearch, Pre-Screening

Jason Bates

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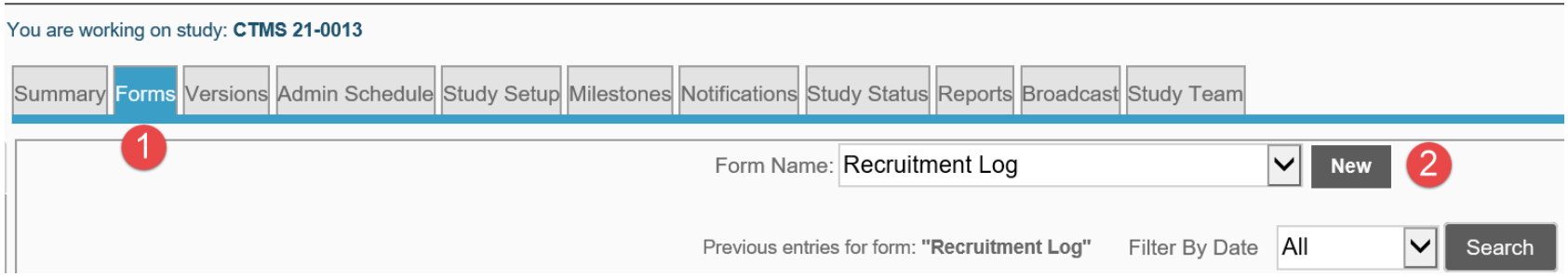
Tracking Recruitment Effort in eResearch

eResearch provides functionality to track recruitment efforts under each study:

After navigating to your study

1. Navigate to the Forms Tab
2. Select Recruitment Log and New



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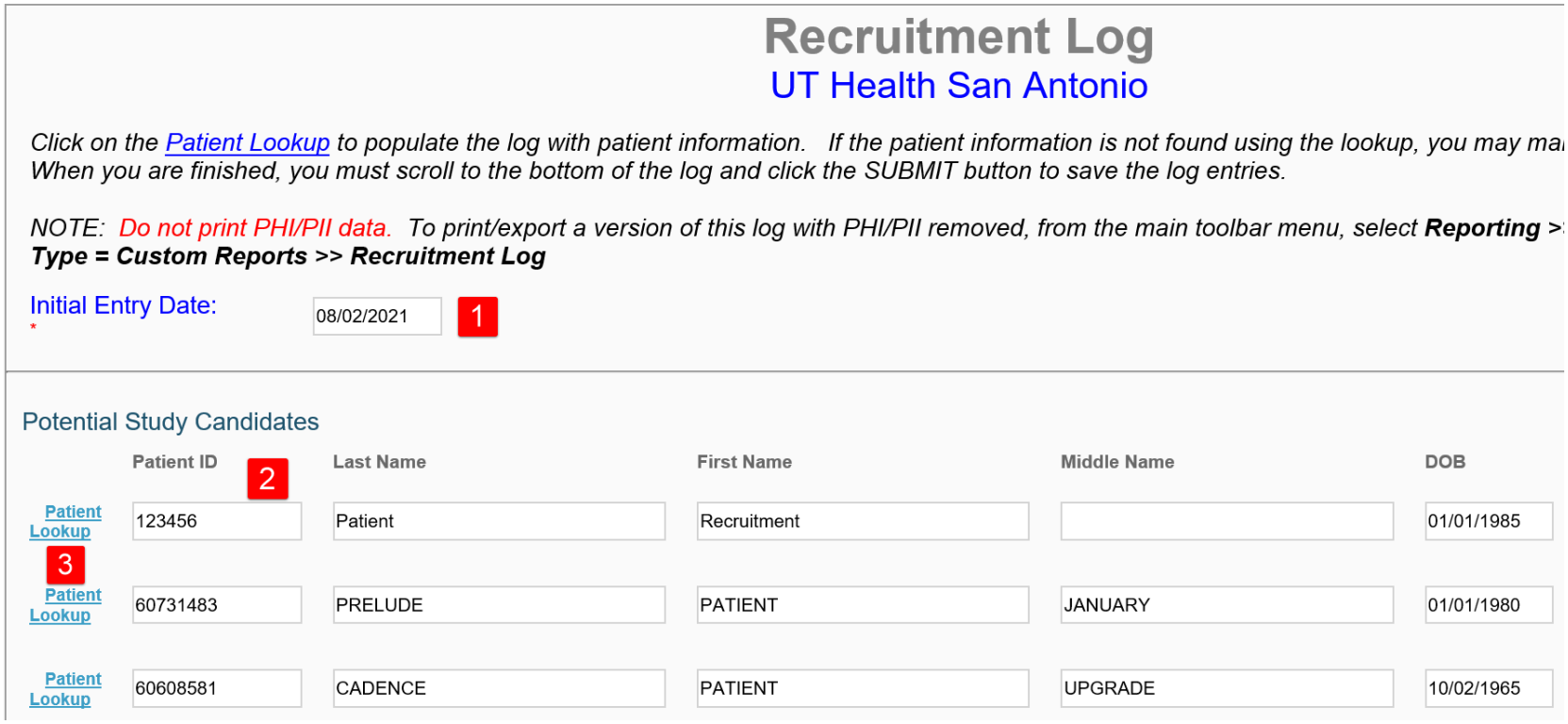
Utilizing Recruitment Logs

1. To Start you will need to insert a start date
2. Patients can be entered by typing in the row, or
3. Users can use the search function to pull the patient in from Velos or EPIC



Recruitment Log

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Click on the Patient Lookup to populate the log with patient information. If the patient information is not found using the lookup, you may ma
When you are finished, you must scroll to the bottom of the log and click the SUBMIT button to save the log entries.

NOTE: Do not print PHI/PII data. To print/export a version of this log with PHI/PII removed, from the main toolbar menu, select ***Reporting >***
Type = Custom Reports >> Recruitment Log

Initial Entry Date: * 08/02/2021 1

Potential Study Candidates

	Patient ID	Last Name	First Name	Middle Name	DOB
Patient Lookup	123456	Patient	Recruitment		01/01/1985
Patient Lookup	60731483	PRELUDE	PATIENT	JANUARY	01/01/1980
Patient Lookup	60608581	CADENCE	PATIENT	UPGRADE	10/02/1965

2

3

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Utilizing Recruitment Logs

1. Document the subject status and date
2. Include a reason
3. And comments as applicable
4. To save any update scroll to the bottom of the page and select submit.

DOB	Patient Study ID	Status Date 1	Status	Reason 2	Comments 3
01/01/1985	N/A	08/18/2021	Excluded	Inclusion/Exclusion Criteria	does not meet qualifications
01/01/1980		08/19/2021	Qualified for Screening	N/A	Subject scheduled for screening on 9/1/2021
10/02/1965	N/A	08/20/2021	Excluded	Subject Not Interested	

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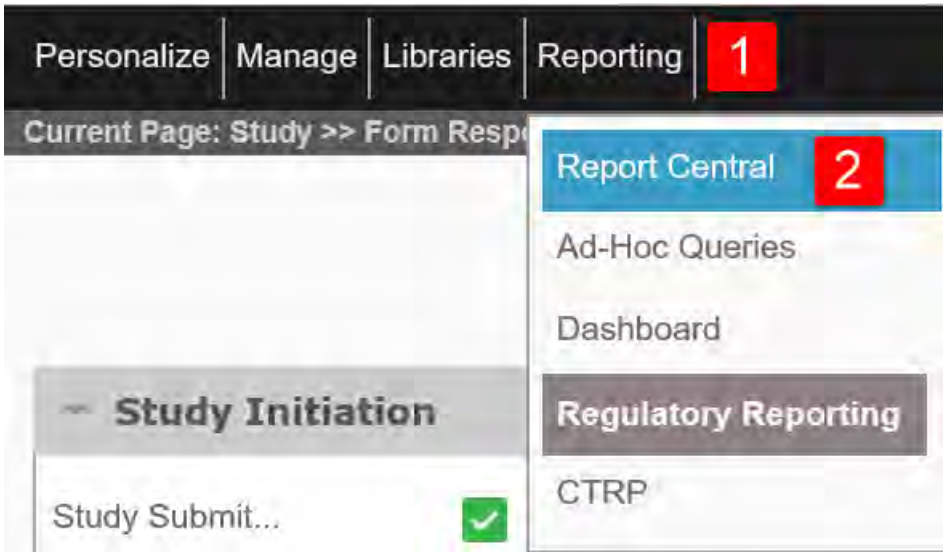
Recruitment Log – Reports

Pull De-Identified list to share with sponsor or for invoicing supporting documentation.

1. Navigate to Reporting from the Velos eResearch top menu
2. Select Report Central



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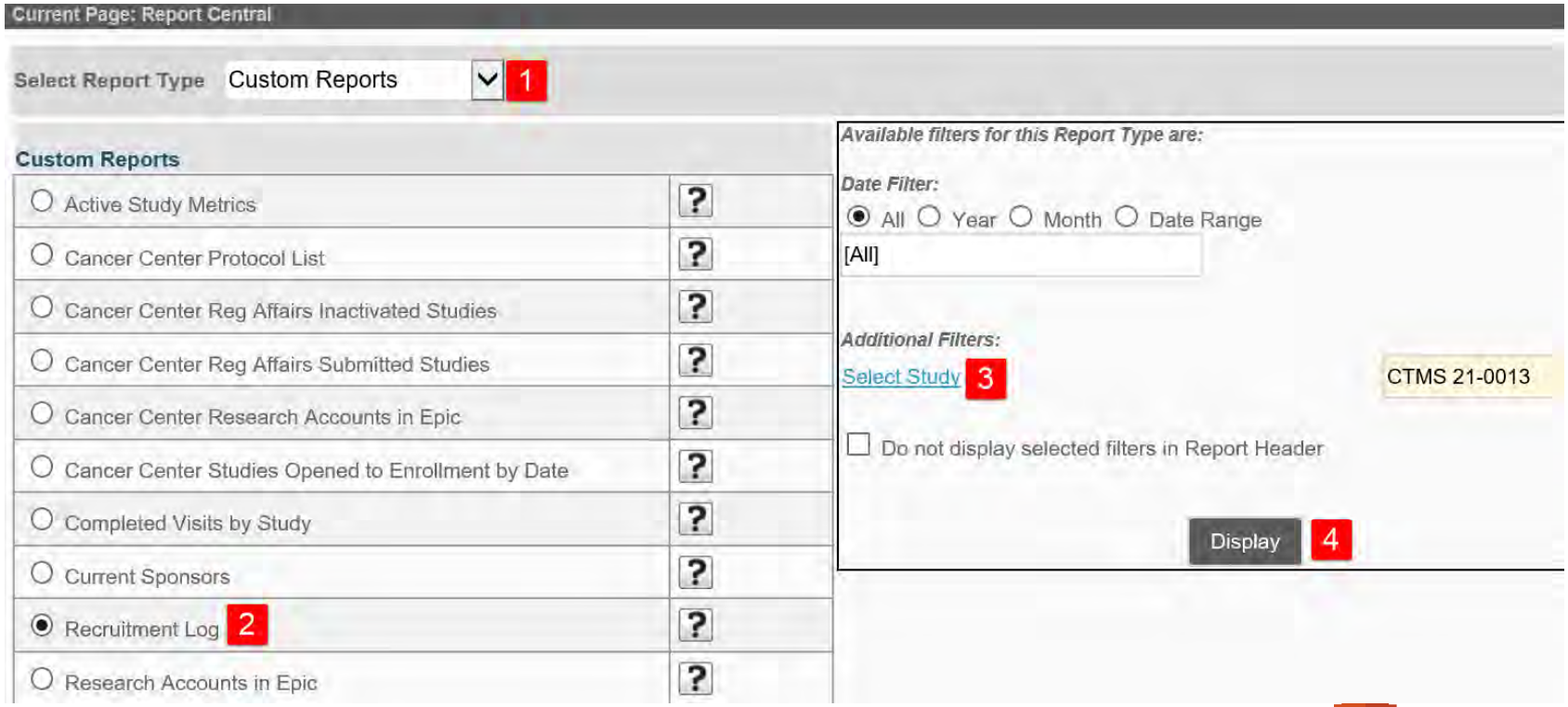
Recruitment Log – Reports

Within Reports Central

1. Select Custom Reports from the dropdown list
2. Select Recruitment Log
3. Select the study
4. Display



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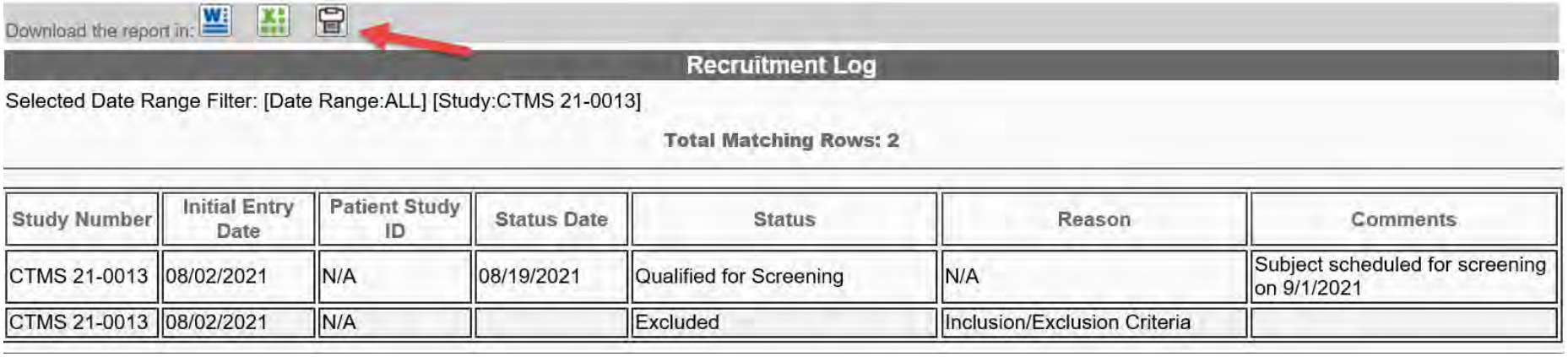
Recruitment Log – Reports

De-Identified report is rendered which allows several download options.



Download the report in:

Recruitment Log

Selected Date Range Filter: [Date Range:ALL] [Study:CTMS 21-0013]

Total Matching Rows: 2

Study Number	Initial Entry Date	Patient Study ID	Status Date	Status	Reason	Comments
CTMS 21-0013	08/02/2021	N/A	08/19/2021	Qualified for Screening	N/A	Subject scheduled for screening on 9/1/2021
CTMS 21-0013	08/02/2021	N/A		Excluded	Inclusion/Exclusion Criteria	

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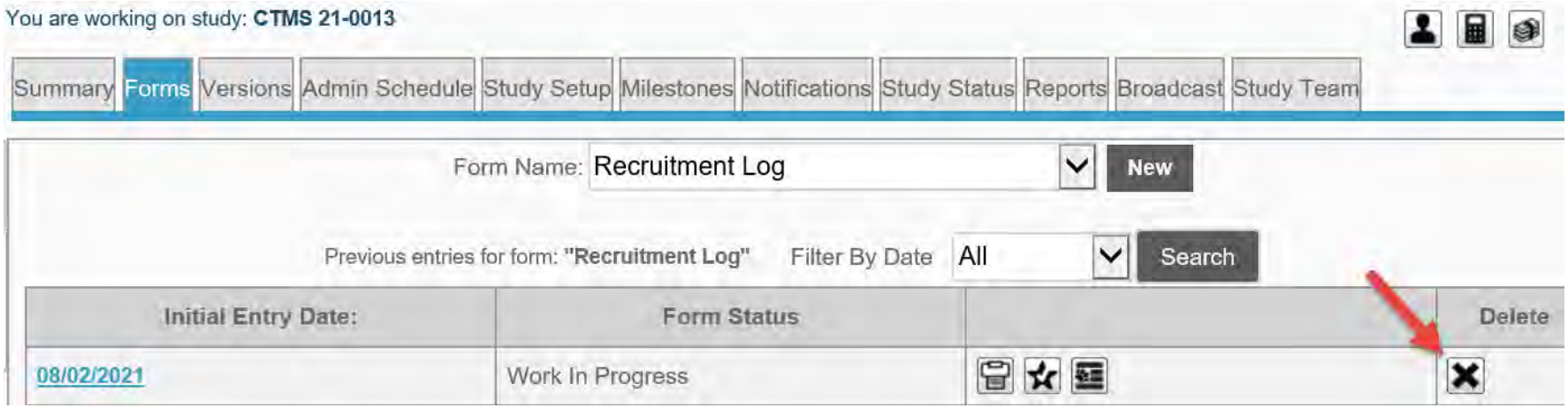
Recruitment Log – End of Study

It is important to delete the report at the end of the study, as these are not subjects who consented for the trial.

1. Navigate to the Forms Tab
2. Select Recruitment Log and New
3. Select Delete and enter your e-Signature to save



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UT Health San Antonio IRB Guidelines for Advertising to Research Participants

Meyad Baghezza

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IRB Requires Review of Recruitment Material

The information contained in the advertisement

The mode of its communication

The final copy of printed advertisements

The final audio/video taped advertisements

Amount and schedule of any payments

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Intent of IRB Review

- Identify misleading or coercive language
- No claims that the treatment is safe, effective, equivalent, or superior to any other treatment
- Do not state or imply favorable outcome or benefits that may be different from protocol/consent form
- For vulnerable populations, additional considerations are made

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Advertisements

The name and address of the investigator and/or research facility
The purpose of the research
Basic eligibility criteria
A brief list of participation benefits, if any (e.g., a no-cost health examination)
The time or other commitment required of the subjects
The name and phone number of the person to contact for further information
May include statement that compensation for participation will be provided

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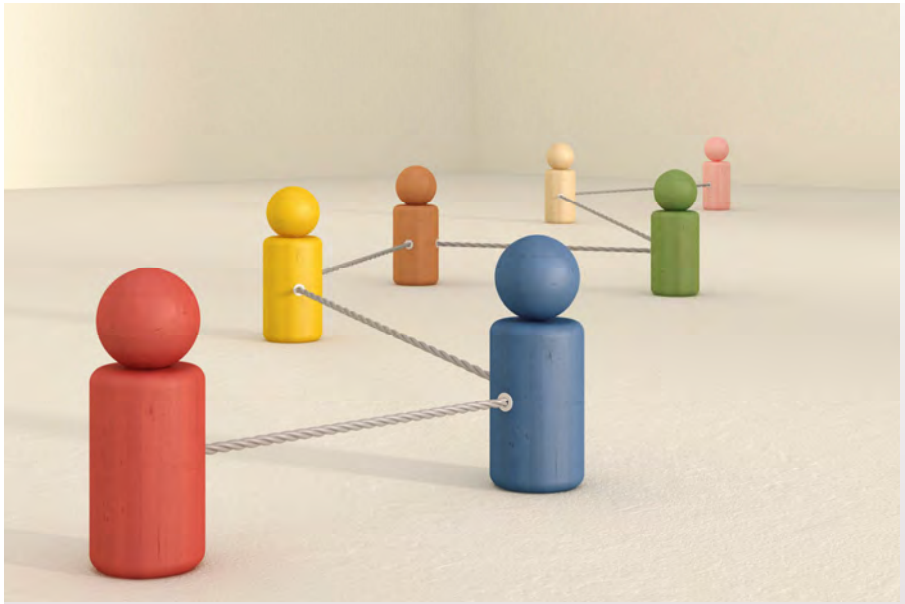

Using Social Media to Recruit Participants

Identifying a list social media sites that are planned to be used

If public and private group interaction is planned, that a moderator has approved the interaction (or confirmation that there is no moderator)

Identifying how the research team will respond to group member messages

If additional sites will be used, providing the IRB with contents of the information

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Recruitment using Social Media

A plan to address privacy, confidentiality, data security, and identity verification for private messaging

Include a description of any identifiable data that will be collected

Include roles/responsibilities for posting, monitoring, and responding to recruitment communication– may be a service provided through third party contract

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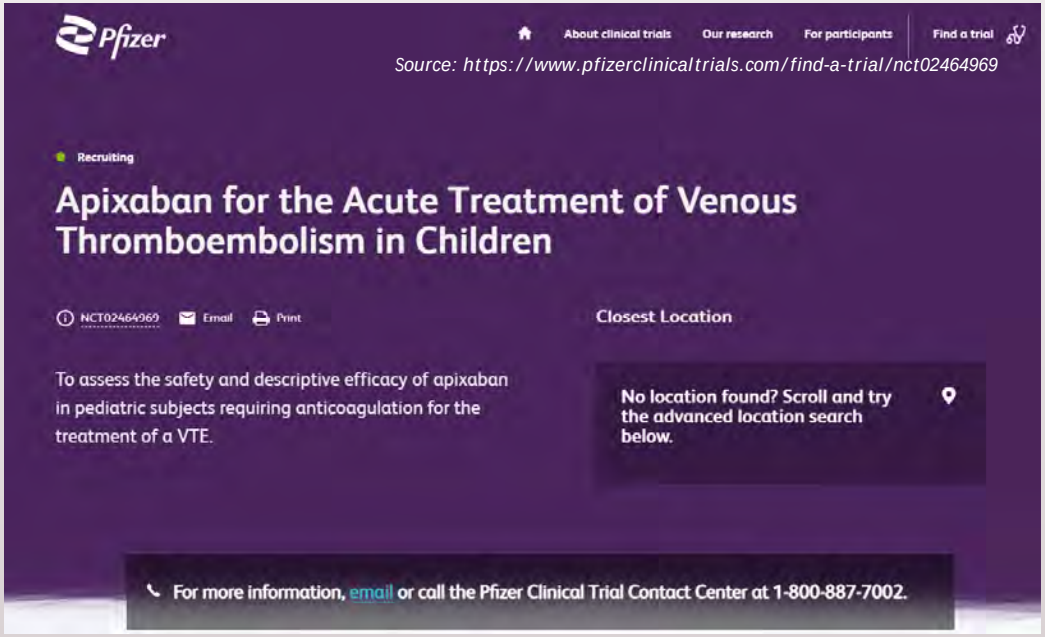
Advertisement that do **not** need IRB review

CLINICAL TRIALS WEBSITES



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Advertisement that do **not** need IRB review

COMMUNICATIONS INTENDED TO BE SEEN OR HEARD BY HEALTH PROFESSIONALS

Source: https://www.cfp.ca/content/cfp/suppl/2010/12/08/56.12.1375.DC2/Appendices_A-F.pdf

Appendix A: Sample Study Invitation Letter to Recruit Practices for Waiting Room Surveys

[Insert date]

Dear Sir/Madam,

The University of Ottawa has been funded by the Ontario Ministry of Health and Long Term Care to conduct a study that examines the way primary health care is organized in Ontario. Primary Health Care can be defined as the first point of contact for health care, such as the care you receive from your family doctor. The goal of this study is to understand what is working well in the primary health care system and to identify those areas that need improvement.

Patients provide very insightful information about our health care system. I am writing to request your participation in this study. With your help we can meet the study goals, creating a better health care system for you and your community.

If you agree to participate, we will ask you to complete a survey questionnaire (which will take approximately 15 minutes) regarding your experience in this medical clinic. Most of it can be filled out while you wait for your turn to visit the doctor. One page will need to be completed after the visit

Participation is voluntary. You may withdraw from the study at any time and this would not affect your care in any way. The information you provide will be kept confidential. It will not include your name or any other identifying information, and no one at the practice will see your answers.

If you would like more information about the research, please speak with the Survey Administrator. We look forward to your involvement.

Sincerely,

_____

Investigator Name
Principal Investigator
Study Name
Signature of Investigator

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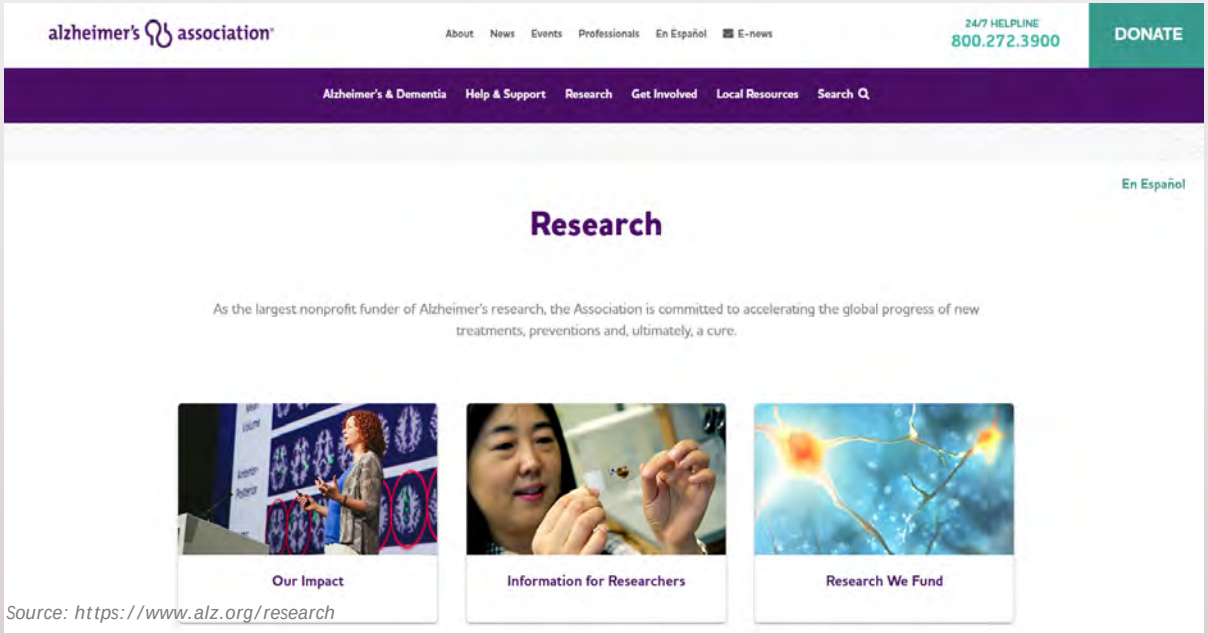
Advertisement that do **not** need IRB review

PUBLICITY INTENDED
FOR OTHER AUDIENCES
– FINANCIAL INVESTORS



Source: https://www.alz.org/research

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Advertisement that do **not** need IRB review

PRESS RELEASES/NEW STORY

Young adults show serious complications from Type 2 diabetes

Published On: August 2, 2021
Shared by Will Sansom

UT Health San Antonio, University Health enrolled area children in TODAY studies. *Source: https://news.uthscsa.edu/young-adults-show-serious-complications-from-type-2-diabetes/*

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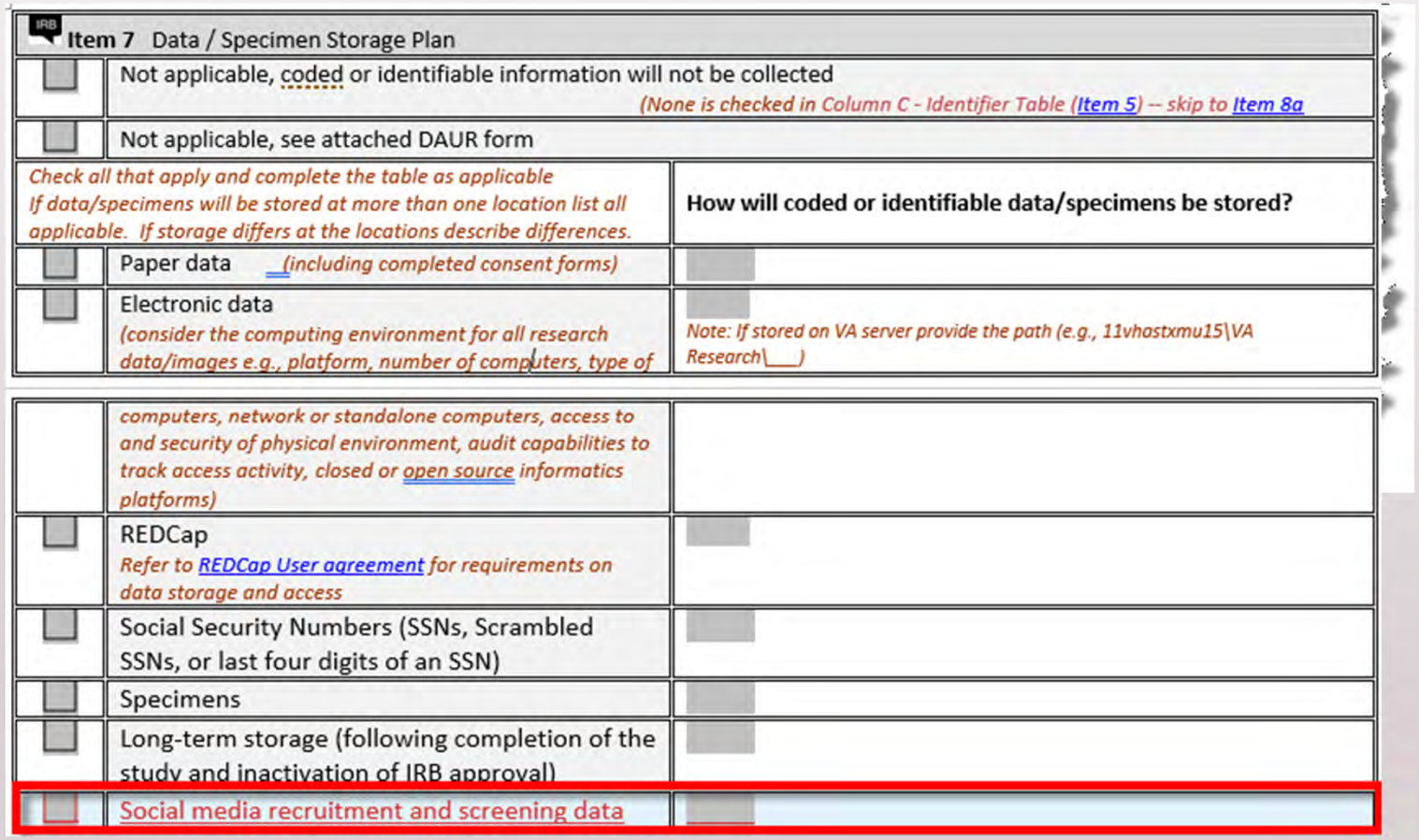
Institutional Form



Item 7 Data / Specimen Storage Plan	
☐	Not applicable, coded or identifiable information will not be collected *(None is checked in Column C - Identifier Table (Item 5) -- skip to Item 8a*
☐	Not applicable, see attached DAUR form
Check all that apply and complete the table as applicable *If data/specimens will be stored at more than one location list all applicable. If storage differs at the locations describe differences.*	**How will coded or identifiable data/specimens be stored?**
☐	Paper data *(including completed consent forms)*
☐	Electronic data *(consider the computing environment for all research data/images e.g., platform, number of computers, type of computers, network or standalone computers, access to and security of physical environment, audit capabilities to track access activity, closed or open source informatics platforms)* *Note: If stored on VA server provide the path (e.g., 11vhastxmu15\VA Research___)*
☐	REDCap *Refer to REDCap User agreement for requirements on data storage and access*
☐	Social Security Numbers (SSNs, Scrambled SSNs, or last four digits of an SSN)
☐	Specimens
☐	Long-term storage (following completion of the study and inactivation of IRB approval)
☐	Social media recruitment and screening data

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Institutional Form & IRB Forms

Item 32 Research Team - Roles and Activities *Note: Submit Inst-M Personnel Form (list of all research team members by name)*

☐ **Not applicable – this is an exempt protocol or chart review study**

Column A
Build your research team below by **identifying key position titles**

At a minimum, all studies must have a Principal Investigator.

Other suggested positions have been inserted below. Delete positions as appropriate to your study.

Position Title (DO NOT MODIFY POSITION TITLES)

Column B
For each key position, list the roles & responsibilities that could be assigned to research team members in this position.
Use the following codes to identify the responsibilities that are applicable for the role you created in Column A.
Not all roles are applicable to every study

General research responsibilities

1. recruitment
2. assess inclusion and exclusion criteria
3. obtain informed consent
4. assist with the consent process
5. source documentation or case report form completion
6. perform physical examination
7. perform physical assessment
8. obtain medical history or evaluate concomitant medications
9. prescribe intervention being tested
10. administer intervention being tested
11. perform study procedures
12. adverse event inquiry and reporting
13. laboratory or other specimen handling
14. specimen shipping **
15. investigational product dispensing & accountability
16. regulatory & essential documents, other record keeping or admin function
17. review private identifiable information
18. Direct REDCap access to identifiable study data (other than data entry)
~~18.~~19. posting, monitoring, responding to social media recruitment communications

Oversight responsibilities

~~19.~~20. directing the research team members and assessing compliance with study protocol
~~20.~~21. Lead PI - direct the study site PI(s) at other locations
~~21.~~22. determine significance of subject safety indicators (e.g., AE/SAEs, UADEs, SUSAR, UPs, etc.)
~~22.~~23. determine the significance of protocol deviations or violations
~~23.~~24. ensure the integrity of the data
~~24.~~25. Sponsor-Investigator monitoring and reporting ***
~~25.~~26. REDCap Study Administrator
~~26.~~27. Other:
~~27.~~28. Other:
~~28.~~29. Other:
~~29.~~30. Other:

** Requires IATA Training / Safety-Shipping Infectious Substances, Clinical Specimens, and Dry Ice
*** Requires GCP for investigator initiated studies of drugs, biologics or devices

Column C
For each position, list the minimum credentials and training required for any person assigned to this role.
Use the following codes to identify the credentials & training for the role you created in Column A.

- **A.** Medical license (US)
- **B.** Dental license (US)
- **C.** RN license (US)
- **D.** RPH license
- **E.** ____ license (US)
- **F.** Good Clinical Practice (GCP) training
- **G.** Research related certification (e.g., CCRC)
- **H.** Advanced academic degree
- **I.** ____ certification
- **J.** ____ certification
- **K.** Specialized training for the use of a device
- **L.** Other:
- **M.** Other:

Training requirements

Scope of Practice requirements

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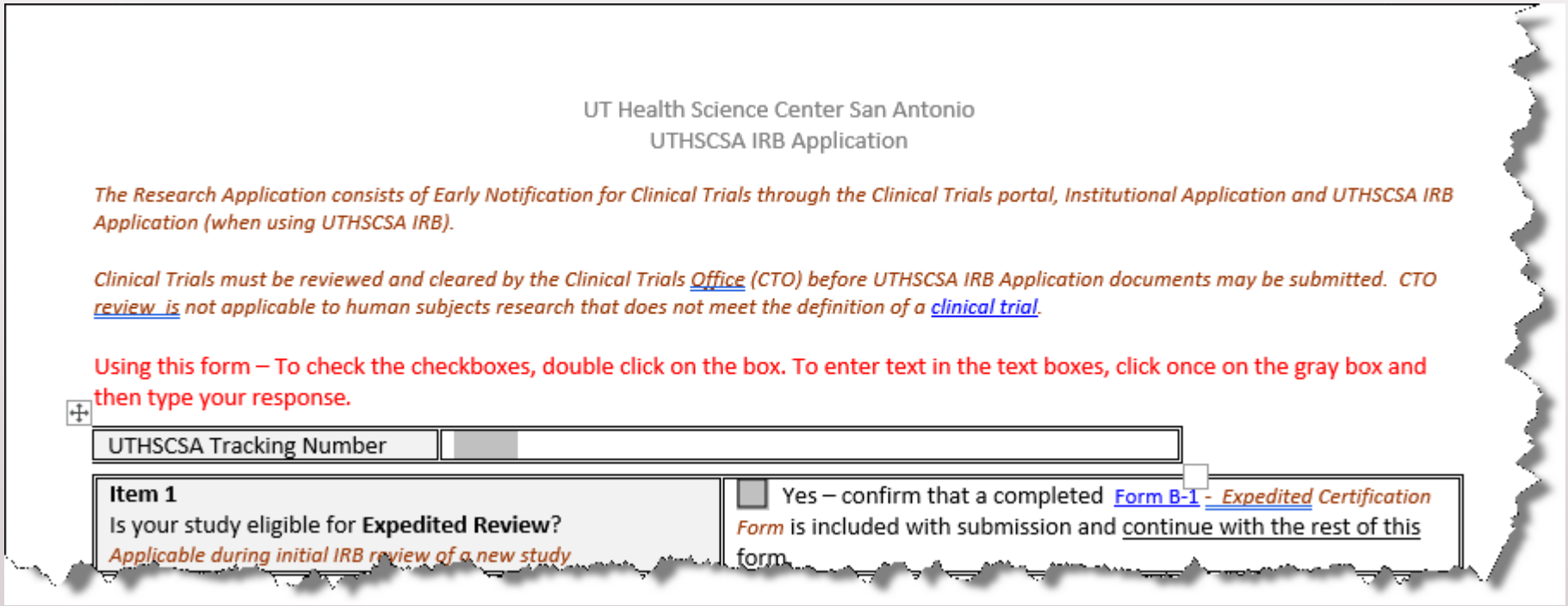
IRB Forms



UT Health Science Center San Antonio
UTHSCSA IRB Application

The Research Application consists of Early Notification for Clinical Trials through the Clinical Trials portal, Institutional Application and UTHSCSA IRB Application (when using UTHSCSA IRB).

Clinical Trials must be reviewed and cleared by the Clinical Trials Office (CTO) before UTHSCSA IRB Application documents may be submitted. CTO review is not applicable to human subjects research that does not meet the definition of a clinical trial.

Using this form – To check the checkboxes, double click on the box. To enter text in the text boxes, click once on the gray box and then type your response.

UTHSCSA Tracking Number	
Item 1 Is your study eligible for **Expedited Review**? *Applicable during initial IRB review of a new study*	☐ Yes – confirm that a completed Form B-1 - *Expedited Certification Form* is included with submission and continue with the rest of this form.

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Institutional Form & IRB Forms

Item 10
First Contact - Recruitment
select how and where initial contact will be made with potential subjects; list all applicable

☐ N/A – this study does not involve interaction with living individuals *continue to Item 17*

How will contact be made:	From study staff to participants	From participants to study staff	Briefly describe the plan to contact subjects including differences between groups (if any) --*include details regarding relationship with subjects (i.e., members of treatment team will contact…)*
Telephone call	☐	☐	
Email	☐	☐	
Mail	☐	☐	
Waiting room (public)	☐	☐	
During scheduled visit (private)	☐	☐	
Other method:	☐	☐	

Will Social Media be used for recruitment?
☐ No *continue to Item 11*
☐ Yes *(check all which apply and the remainder of this section)*
☐ Facebook
☐ Instagram
☐ Twitter
☐ Other:

Indicate the type of recruitment activity using social media
☐ Static *(a post or advertisement where there is **no** anticipated interaction)*
☐ Interactive *(a post or advertisement where interaction **is** anticipated)*
☐ Interactive with public group(s):
  ☐ Moderator approval is attached
  ☐ A Moderator does not exist
☐ Interactive with private group(s) – Include evidence of the group's moderator approval
☐ Private messaging

If interaction is planned, describe plans for responding to messages:

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Questions?

UT Health
San Antonio

Concierge

September 1, 2021

Wednesday from 9am -12pm

September 7, 2021

Tuesday from 1pm - 4pm

September 15, 2021

Wednesday from 9am-12pm

September 29, 2021

Wednesday from 9am-12pm

Register online for virtual concierge:
https://redcap.uthscsa.edu/REDCap/surveys/?s=FDYWD3JFJD

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