

Carol Breland, Research Recruitment Director NC TraCS Updated Aug 21, 2017



Let's Get Started! Open the Study Listing Template in CRMS





Open the Study Listing Template **★** For OnCore Users Only **★**

CLINICAL RESEARCH MANAGEMENT

HOME MY DASHBOARD HELP ADMIN REPORTING LOGOUT

Clinical Research Dashbo				- Chape
Start New Clinical Study	On the	Homo tob		
My CRMS Records	click the	e My Studies by	IRB#	
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Study Listing & Enrollment		<u>C09-0004</u> C09-0007	0.0-203	97 te Bi
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Enter Study Enrollment Dates and Recruiter Contact Info

To list your study in the Research Studies Gallery on the *Join the Conquest* website, please comp and approve the listing. Upon approval, NC TraCS will upload the information to the Research Stud

Test Study IRB Number:

C.

Instructions	Detailed Instructions link			
Status Not yet entered Working copy modifie Study is in the recruiti Recruiting ends 0.	Last Approved: Never Approved ww) TraCS Approved. d on: 0 by: 0. ing phase.		Ente date date begi	r your study recruitment ranges. Start date is the you want the listing to n being shown to the public and date is the date you
Enrollment Status The study will begin sho has expired. Recruitment start	owing a listing in the Gallery on the recrui	itment st	from date	t the listing to be removed t the public view. <i>The end</i> will be shown to the public.
Recruitment end	date	1	r	Enter your contact
Contact:				person listed on your IRB application.
Email: Optional link to stud	dy or department website:			Include a study or department website if available.

Describe Your Study to a Layperson

Descriptive Information about the study.

The Study will have a "Public Name" this is made up of 3 parts:

- 1. Population/Indication
- 2. Length of time a participant will spend in the study
- A very short (30 characters or less) description or acronym for the study. This should be something meaningful to a member of the public, and not neces For example: Older Adult Smokers - 10 weeks - GOODLIFE

Study Population/Indication Adults with Eye Disease Due to Diabetes

Length of Participation (Months/Weeks) 2 years

Acronym/Very Short Description DRCR V

Describe your study in one or two sentences to a layperson:

Eye researchers want to learn more about what treatments work best for patients with eye disease caused by diabetes. You may receive laser therapy, a drug, or no therapy.



The Study Population/Indication should describe the subject population you want to recruit.

No medical or research jargon!

Describe why you are doing this study using plain (9th grade level) language.

Enter Demographics and I/E

Demographics & Inclusion/Exclusion					
Gender Male O Female O No Preference O	Volunteers will see I/E listed as "Participant Qualifications and Not Eligible If"				
Age Range (years) Lower Limit: 18	Use plain language!				
Upper Limit: 99	Define medical terms on the layperson level				
Inclusion/Exclusion Criteria					
1st Inclusion Type I or Type II Diabetes					
2nd Inclusion Vision 20/25 or better					
1st Exclusion Patients who have had a kidney transplant or are on dialysis.					
2nd Exclusion Patients who are currently receiving treatment for their diabetic eye disease.					



Enter Location, Visits and Compensation

	Be Specific! Use "Other I	Location" for studies not
Locations, Visit Types, and Participant Compe	nsati located on the UNC Chap	oel Hill main campus.
Enter the location where subjects will go for most vi	sits: It's ok to enter more that same field. Use semi-col	n one location in the ons to separate.
On UNC CH Campus: UNC Kittner Eye Center	If study has locations bo use both location fields.	th on and off campus,
Other Location:	Write out name (e.g., Cl Research Center, not "Cl	inical and Translational TRC".)
	"Other" Study visit types in line questionnaires, texts, o	nclude gym visits, on- etc.
Enter the estimated number of visits by Type:		
Screening: 1 Clinic:	Phone: Other:	
Describe the participant compensation:		If Compensation is entered, the study listing
Amount: De	scription:	IRB! Otherwise, write
25.00 p	er completed visit, provided by sponsor	"Contact the research team for details."
	NORTH CAROLINA	

SCIENCES INSTITUTE

Create the Search Details

Search Categories	Fo	or Categories, choose	only one.
Choose ONE category that best matches	your study:		,
O Survey Device	 Lifestyle/I Procedure 	Focus Group es	Drug Medical Treatment Outcomes
 Phase I Drugs - Healthy Volunteers Check this box if healthy volunt 	eers will be needed	Don't forget to check volunteer box if applie	the healthy cable, especially if
Keywords (Check all that apply.) Allergy Alcohol Abuse Alzheimer's	 Ears Eating Disorde Eyes 	only healthy voluntee the study. If your study is sure to chose that category	ers are required in a Phase I drug study, be and also check the box.
 Arthritis Asthma Autism Spectrum Behavior 	 Genetics Hearing Heart/Cardiova High Blood Prese 	Pregnancy Sight Skin Ssure	
 Bones Brain/Head Breastfeeding Breathing Cancer Diabetes 	 HIV/AIDS Kidneys Lungs Men's Health Mental Health Mouth/Nose/Th 	Smoking Stomach Stroke Thyroid Tooth/Dental	Choose all keywords that apply to your study
 Digestion Drug/Substance Abuse 	Muscles Nutrition	□ Women's Health☑ Other	

You're Almost Finished! Save or Submit



Volunteers View the Studies Gallery

- KEYWORD SEARCH -

Allergy
Alcohol Abuse
Alzheimer's
Arthritis
Asthma
Autism Spectrum
Behavior
Bones
Brain/Head
Breastfeeding
Breathing
Cancer
Diabetes
Digestion
Drug/Substance Abuse

Ears
Eating Disorders
Eyes
Genetics
Hearing
Heart/Cardiovascular
High Blood Pressure
HIV/AIDS
Kidneys
Lungs
Men's Health
Mental Health
Mouth/Nose/Throat
Muscles
Nutrition

🗆 Obesity
🗆 Pain
Pediatrics
Pregnancy
🗆 Sight
🗆 Skin
🗆 Sleep
Smoking
Stomach
Stroke
🗆 Thyroid
Tooth/Dental
🗆 Urinary
🗆 Women's Health

Other

Volunteers can view studies without registering or signing in. However, to send an email to you through the JTC system, they must be registered and logged in.

Healthy Volunteers (check this box to search studies that need Healthy Volunteers)

CATEGORY SEARCH

Survey
 Lifestyle/Focus Group
 Drug
 Device

Procedures
Medical Treatment Outcomes
Phase I Drugs - Healthy Volunteers

SEARCH TERM (OPTIONAL)

They choose studies of interest by keyword, category or search term, then they click "Search the Gallery."

SEARCH THE GALLERY

Your Short Study Description

STUDIES GALLERY

This first view shows the short description of your study that you created. This is really critical!

Be sure you have entered what the study is designed to do and why it is important.

The volunteer clicks DETAILS to see the full study listing information you entered. They can send you an email on the Details Page or click "New Search" to return to the Studies Gallery.

NEW SEARCH

Study Name	ŧ	Length	ŧ	Туре	ŧ	Study Description	
Pediatric Sickle Cell (The EPIC Study)		Variable Participa Time	tion	Drug		This study will test a new drug for patients who have sickle cell disease and have had to be admitted to the hospital to treat pain. The goal of this new drug is to shorten the amount of time that sickle cell patients are in pain.	DETAILS
Adults with Eye Disease Due to Diabetes (DRCR V)		2 years		Drug		Eye researchers want to learn more about what treatments work best for patients with eye disease caused by diabetes. You may receive laser therapy, a drug, or no therapy.	DETAILS

Individual Details Page Layout

TAN WINGOLD





More Information and FAQs!





Terms of Researcher Participation

- Researchers are required to provide metrics to NC TraCS on # of volunteers contacted and enrolled in listed studies (not names, just metrics) as requested
- Researchers are obligated to abide by all IRB regulations and maintain research privacy standards
- Researchers are responsible for ensuring the listing information matches their protocol
- Researchers are required to update their study listing as study recruitment requirements change (amendments, study hold, study closure, etc.)
- Researchers are responsible for all prescreening and screening activities.



Frequently Asked Questions

- Is there a cost to the researcher to use the system?
 - Join the Conquest.org is funded by NC TraCS CTSA grant— there is no charge to UNC researchers or volunteers
- Why do we need to use plain language?
 - The Join the Conquest website was created to help those with limited research and medical knowledge
- Why do I need to limit my inclusion/exclusion criteria?
 - Your study listing creates a simple "Reader's Digest" version of the study purpose, inclusion/exclusion, and participation details
- Why don't I need IRB approval unless I list compensation?
 - The UNC IRB has determined that this type of listing does not require review as long as it does not list compensation. The template is designed to ensure the listing is compliant and has been approved by the UNC IRB
 - If compensation is listed, then it must be treated as advertising and requires that the complete study listing be reviewed by the IRB and approved prior to submission to JTC administrators.



Frequently Asked Questions

- Why do I need to enter enrollment dates?
 - This feature allows you pick the start/stop dates of the listing. If you need modify the end of the enrollment, just change the date!
- My study is approved by the non-medical IRB. Can I still list it?
 - All types of studies that require human volunteers to participate can be listed
- How long does it take to complete the listing template?
 - The approximate time to complete the listing is 10-15 minutes
- What happens if I get a protocol amendment and need to change the study details?
 - You can update the information at any time for any reason. Your current details will continue to show until the updated information is approved by NC TraCS administrators
 - Your study listing is linked to IRBIS through CRMS, so as long as your study continues to be approved by the UNC IRB, you will be able to list it on Jointheconquest.org



Key Website Take-aways!

- Join the Conquest incorporates our formative research results and change theory
- Addresses barriers to research participation to reach that 53% of Americans unfamiliar and uncomfortable with clinical research
- Aims to increase participation from 10% by listing studies in a central location and in plain language
- Builds trust and lasting relationships between researchers and volunteers



For More Information

- Contact NC Tracs at <u>nctracs@unc.edu</u>
- Go to <u>https://tracs.unc.edu/index.php/services/recr</u> <u>uitment-services</u>
- Contact:
 - Carol Breland, Research Recruitment Director
 - NC Tracs Recruitment Services
 - brelandc@email.unc.edu
 - 919 966-6274





More FAQs: What Happens after I List My Study?

- You get automatic alerts via email from volunteers who view your listing and express interest in learning more
- In the email, you will receive volunteer contact information as provided by volunteer
- NC TraCS website administrators do not participate in screening volunteers for studies and does not assist volunteers with choosing studies.
- NC TraCS will contact you from time to time
- The website is being promoted to the public via the MyUNCChart portal



How Will Volunteers Find My Study?

- From the Studies Gallery, the volunteer will be able to search for your study several ways:
 - Study Category
 - Key Word
 - Free text field (Search Term)
- The volunteer will review the studies from the search results
- If the volunteer is interested, the volunteer will click button
- The system will automatically send you a email with the volunteer's information
- The system also send a email to the volunteer confirming their interest in your study and that you will be in contact with them shortly
- All volunteers must be adults age 18 or older to join. All persons can request information on pediatric studies
- Volunteers will also receive a monthly newsletter via email with information about Join the Conquest and highlighted studies.



What Security and Access Rules Apply?

- Volunteer contact information is stored on a secure server at UNC and administrated by NC TraCS
- No medical information from volunteers is requested by or stored on jointheconquest.org
- The volunteer registration database is not available to researchers
- Researchers only receive volunteer contact information if the volunteer authorizes it
- While the UNC IRB does not require separate approval, your study sponsor may require approval prior to submission of the listing and if you list compensation you are required to get IRB approval
- The researcher is obligated to adhere to Good Clinical Practices and all applicable privacy regulations when storing volunteer information
- Volunteer information is not to be shared with other researchers unless permission obtained from the volunteer



What If I Want to Change My Study Details?

- You can save your work at any time prior to submission. Just click the Save button
- When you are ready, hit the Submit button to send to NC TraCS administrators for review
- NC TraCS will review your submission for basic wording and appropriateness, not to ensure the content matches the protocol. Self evident corrections (typos) may be corrected if minor.
- You may receive a modification request via email for your listing. Once approval is granted from NC TraCS, the study listing will immediately show on in the public view assuming IRB approval is active.
- Updates can be made to the listing after approval is granted.



How Do I Update My Approved Listing?

- You can make an update any time after the submitted version is approved.
- You make the changes to your template just as you did in the original submission.
- You will click Submit, and NC TraCS will review your updates.
- As soon as the new version is approved, it will show on the Studies Gallery.
- Until the new version is approved, the old version will show.



How do ResearchMatch.org and Jointheconquest.org compare?

- On ResearchMatch.org, the researcher drives the engagement with the volunteer
 - Volunteer enters medical information and the researcher enters details about their study
 - The system matches volunteer profiles to study profiles
 - The system notifies the researcher of the possible match
 - The volunteer waits for the researcher to review their information and make contact
 - Studies in 62 CTSA sites and affiliates are eligible to be listed
- On JointheConquest.org:
 - Volunteers JOIN using basic contact information and then use a search engine to see all studies listed at UNC that interest them and make a decision if they want to learn more
 - Study listings are linked to Jointheconquest.org , a promotional website with videos, stories, educational tools and more
 - Listings are in plain language- 9th grade reading level
 - Listings are shown only during the recruitment period
 - Volunteers can notify researchers of interest with the click of a button
 - Volunteers are encouraged to remain engaged with newsletters, promotions and events
 - Allows UNC IRB approved studies only -
 - Study listing is created in CRMS and reviewed locally at NC TraCS

