UNC
THE NORTH CAROLINA
TRANSLATIONAL & CLINICAL
SCIENCES INSTITUTE

Join the Conquest – What's New?

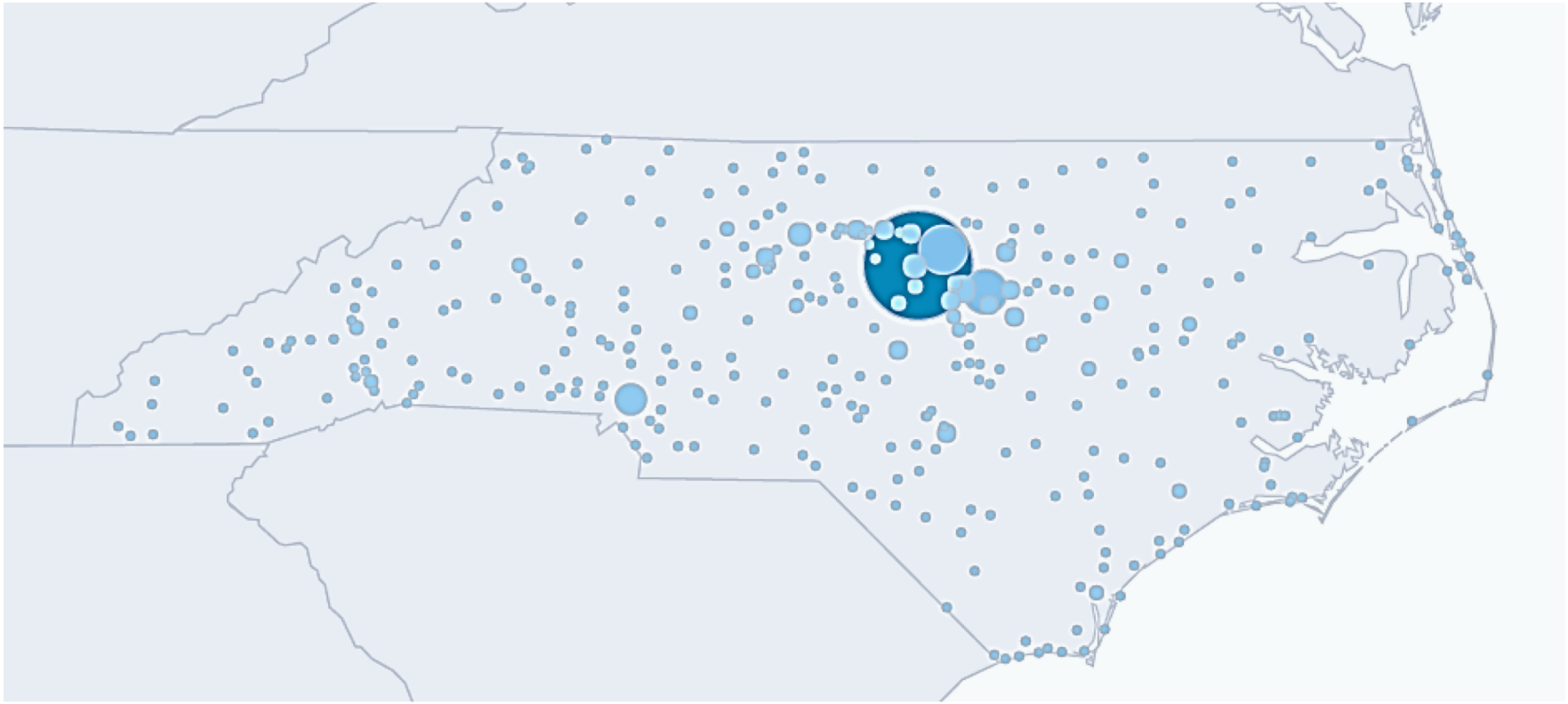
Information and Feedback Session

North Carolina Translational and
Clinical Sciences (NC TraCS) Institute
Carol Breland, Research Recruitment Director

December 13, 2017

Thanks to you, 274 studies have been listed on JTC !

And all over the state, folks were interested! Great job!



Google Analytics:
www.jointheconquest.org;
Sept 2014 to Nov 2017

But, it's time for an update to our system!

- In June 2017, a new IRB SOP gave clarification on compensation in study listings
- Study listings that include compensation require IRB approval
- In JTC, compensation is popular feature!
- Needs assessment: Put our thinking caps on to create a better study listing workflow to include compensation

UNC IRB SOPS- Effective June 2, 2017

2.4.10.1

- Advertising on clinical trial websites. OHRP issued guidance on internet advertising on September 20, 2005. Clinical trial websites that provide only directory listings with basic descriptive information about clinical trials in general do not need to be reviewed by an IRB. Examples of clinical trial listing services that do not need IRB review and approval include the National Institutes of Health (NIH) ClinicalTrials.gov website, the NIH National Cancer Institute's cancer clinical trials listing (Physician Data Query [PDQ]), and the government-sponsored AIDS Clinical Trials Information Service (ACTIS).

- In keeping with the DHHS and FDA guidance, the UNC IRB has determined that the IRB review/approval for brief internet advertisements (e.g., listing of studies on department or research website) is not necessary provided that the information is limited to:
    - study title
    - purpose of the study
    - protocol summary
    - basic eligibility criteria
    - study site location(s), and
    - contact information for the study site

- When information posted on a clinical trial website goes beyond directory listings with the basic descriptive information given above, such information is considered part of the informed consent process and therefore requires IRB review and approval.
- Information exceeding such basic listing information includes:
    descriptions of clinical trial risks and potential benefits, or
    solicitation of identifiable information from potential research subjects.

From FDA: Recruiting Study Subjects Information Sheet

- IRB review and approval of listings of clinical trials on the internet would provide no additional safeguard and is not required when the system format limits the information provided to basic trial information, such as: the title; purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and how to contact the site for further information.
- Examples of clinical trial listing services that do not require prospective IRB approval include the National Cancer Institute's cancer clinical trial listing (PDQ) and the government-sponsored AIDS Clinical Trials Information Service (ACTIS).
- However, when the opportunity to add additional descriptive information is not precluded by the data base system, IRB review and approval may assure that the additional information does not promise or imply a certainty of cure or other benefit beyond what is contained in the protocol and the informed consent document.

- https://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm

From DHHS: (NIH)

- Considerations and Recommendations Concerning Internet Research and Human Subjects Research Regulations, with Revisions
- Q19: What forms of online recruitment are used and what is reviewable by an IRB? Recruitment tools include Web ads, Twitter streams, blog postings, YouTube videos, and —push‖ methods, such as email solicitations and texts. Links to online recruitment sites (e.g., Patients Like Me, Inspire) may also be provided in other media (television, newspaper, classified, public transit posters, robo-calls, etc.).
- OHRP considers direct subject recruitment part of informed consent, which is subject to IRB review. Note that, per FDA guidance, prior IRB review is not necessary for simple listings of clinical trials on websites where the system format limits the provided information to basic descriptive information, including study title, purpose of the study, protocol summary, basic eligibility criteria, study site location(s), and how to contact the study site for further information.
- Any recruitment plan must receive IRB review and approval prior to initiation if additional information is provided, including description of research risks, potential benefits, incentives (monetary or non-monetary), or where identifiable information is solicited to determine eligibility.

- https://www.hhs.gov/ohrp/sites/default/files/ohrp/sachrp/mtgings/2013%20March%20Mtg/internet_research.pdf (see page 17)

Solution: Here's Phase 1 of our new process!

1. Take form out of CRMS and put in more flexible REDCap application

2. Embed REDCap - based JTC submission form in IRBIS

3. Ensure access to NC TraCS for listing consultations and assistance

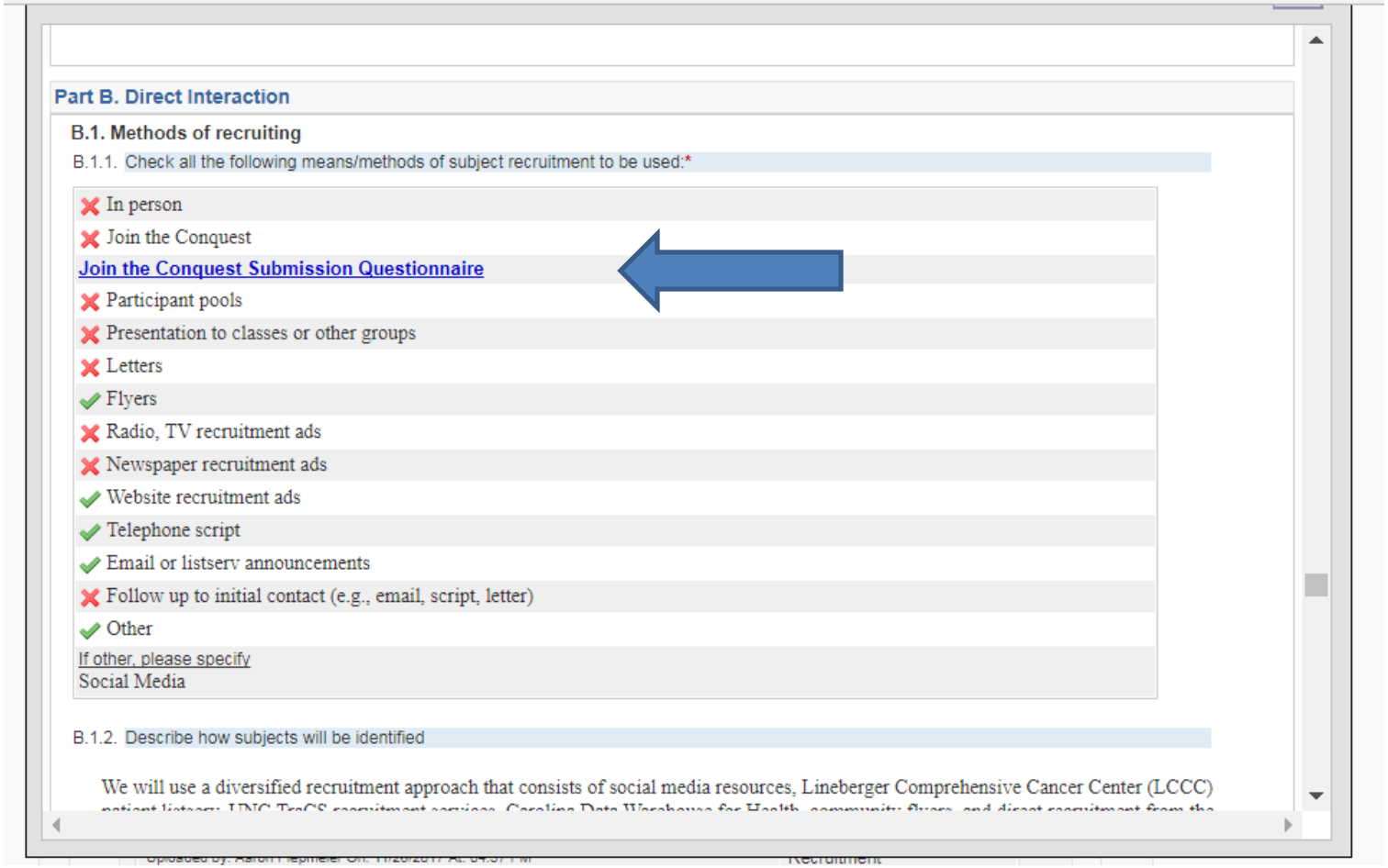
Take form out of CRMS and put in REDCap application

- Why take it out of CRMS?
  - CRMS is an older system; REDCap has more features
- What is REDCap anyway?
  - An online data management application hosted by CTSAs – UNC has free access for all users
- Will the form look different?
  - Not much, just some cosmetic changes
  - The submission and approval process is different
  - You'll be able to make form changes via your REDCap code
- Other questions?

Embed JTC submission form in IRBIS

- Where will it be in IRBIS?
  - Within the IRB application form, section B.1.1
- When can I submit the form?
  - You can submit it anytime!
- How long will it take to get approval?
  - Standard IRB review times will apply
- Will I get a copy of the listing form?
  - Yes, via email to the contact person and the PI
  - You'll receive a PDF of the form with a code that will allow you to return to the form to make changes
- Other questions?

Navigate to B.1.1 to see the JTC submission link



Part B. Direct Interaction

B.1. Methods of recruiting

B.1.1. Check all the following means/methods of subject recruitment to be used:*

- ✗ In person
- ✗ Join the Conquest
- Join the Conquest Submission Questionnaire
- ✗ Participant pools
- ✗ Presentation to classes or other groups
- ✗ Letters
- ✓ Flyers
- ✗ Radio, TV recruitment ads
- ✗ Newspaper recruitment ads
- ✓ Website recruitment ads
- ✓ Telephone script
- ✓ Email or listserv announcements
- ✗ Follow up to initial contact (e.g., email, script, letter)
- ✓ Other

If other, please specify
Social Media

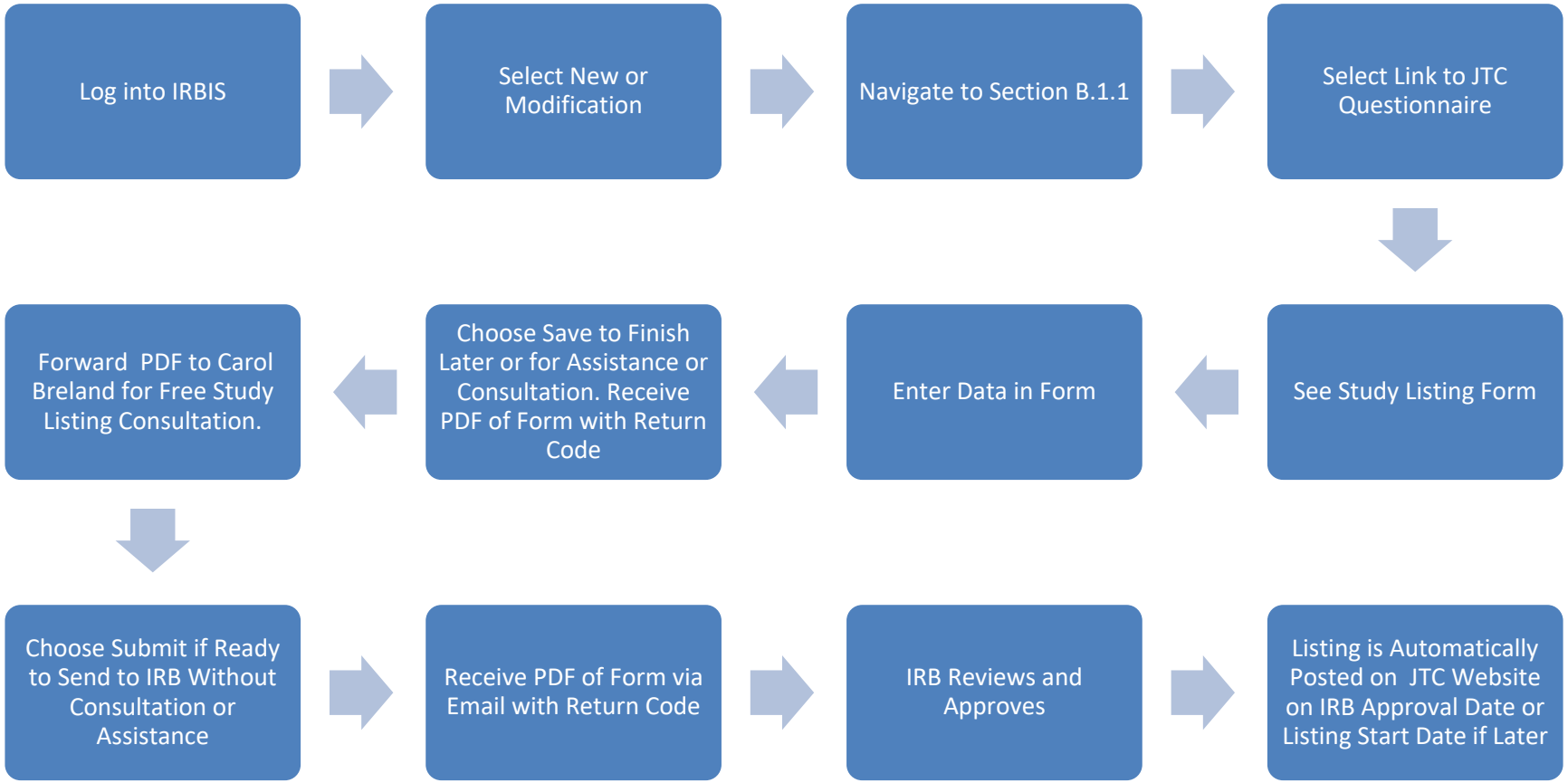
B.1.2. Describe how subjects will be identified

We will use a diversified recruitment approach that consists of social media resources, Lineberger Comprehensive Cancer Center (LCCC)

Contact NC TraCS for listing consultations and assistance

- If the form is in IRBIS, will the IRB review it or NC TraCS?
  - IRB will review and approve. Listing consultations are available at any time with Recruitment Services
  - For listing consultations, contact Carol Breland
- How do I get help if I have a problem with the form?
  - For techical issues, contact NC TraCS at nctracs@unc.edu
- Will listing in JTC and consultations still be at no cost?
  - Yes!
- Other questions?

New Workflow!



FAQs:

- What about studies that are using a central IRB?
  - The IRB will assist you
- How do I check my listing approval status?
  - Check your application status in IRBIS
  - Contact the IRB at 919-966-3113
- What happens if I can't find my email with the return code?
  - Contact our JTC admin support team at nctracs@unc.edu
- How do I submit after getting a consultation ?
  - Follow the instructions in your PDF to return to RedCap, put in your code and make your updates, then hit Submit.
- How do I make changes after I have approval?
  - If you are making changes to compensation, you will need to submit a modification through IRBIS. Follow the usual procedure.
  - Otherwise, return to the REDCap form, enter your return code, and make your changes and hit Submit.

Who to Contact?

- Study Listing Consultations
  - Carol Breland at carol_breland@med.unc.edu
- Technical Assistance with the Form or Codes
  - NC TraCS at 919 966-6022 or nctracs@unc.edu
- IRB Questions
  - IRB at irb_questions@unc.edu or 919-966-3113
- General questions or assistance
  - NC TraCS at 919 966-6022 or nctracs@unc.edu

More Training Opportunities and Slide Availability

- Another training is planned for January, 2018.
- More details to follow
- Slides and webinar recording will be posted on the NC Recruitment Services website

Suggestions? Concerns? Solutions?

- Send an email to Carol Breland at carol_breland@med.unc.edu
- Please complete an evaluation of this training at:
  - https://unc.az1.qualtrics.com/jfe/form/SV_bQNBRVHXFkQtGe1

Thank You!

Thank you!