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SCHOOL OF MEDICINE

The Informed Consent Process

Practical Applications to Elevate The Consenting Experience

Brett Phillips, MA, PMP, CCRP

UNC Blood Research Center

Clinical Research Program Manager

Just a few Housekeeping items:

- This presentation will be recorded and available on the NRP website
- Please keep your lines muted
- You may enter your questions into the chat.
- We are holding questions until the end of the presentation.

Disclaimer

Presentations are intended for educational purposes only. Content shared is the position or opinion of the individual presenter and not representative of the position or opinion of the NRP.

Goals of The Session

- Connect
- Review and apply
- Increase

Nazi Medical Experiments (‘39 – ‘45)

- Unethical & inhumane experiments on concentration camp prisoners without consent.

- Ethical Relevance:
  - **The Nuremburg Code (‘47)**
  - Voluntary & Informed Consent

Tuskegee Syphilis Experiment ('32 – '72)

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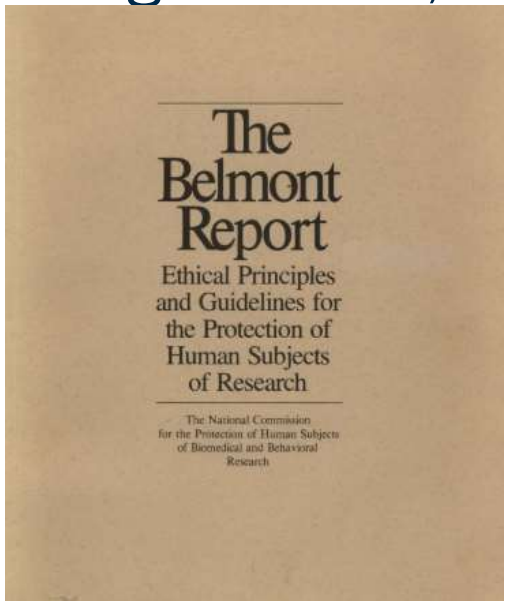
- US gov study of untreated syphilis in African American Men.
  - Without informing them of their diagnosis
  - or providing treatment

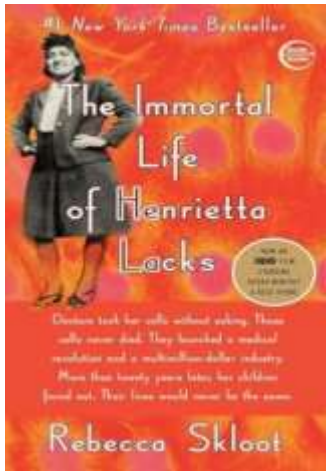
- Public outrage led to **Belmont Report ('79)** and stricter ethical guidelines, including the requirement for ICF.

- Three Core Ethical Principals:
  - Respect For Persons
  - Beneficence
  - Justice



Other Notable Ethical Issues

- Henrietta Lacks (1950s)
  - *A patient owns their tissues*
  - *Need consent for future use of research specimens*



- HSV-2 Vaccine Study in Humans (2011- 2014)
  - *No regulatory oversight*
  - *Don't think unethical conduct can't happen here*

- CRISPR Gene Editing Babies (2018)
  - *Misrepresentation; Highly technical language; financial coercion*
  - *Ethical conduct over reckless innovation*

Ten Elements of T[illegible]Process

"Your relationships with your care team will not change whether or not you choose to participate"

1. Research Statements
   - This is research
   - Participation is voluntary
   - Refusal involves no penalty
   - Withdrawal at any time
2. Purpose(s)
3. Study Duration
4. Participant Expectations
5. Risk & Benefit Disclosure
6. Alternative Treatments
7. Confidentiality
8. Specimens for Future Research Use
9. Compensation & Cost
10. Research Contacts

Chat GPT

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Informed Consent – Before, During, & After

Tips to be Patient-Centered, Ethical, and Confident

Before The Consent

- Study Start-Up (Set yourself up for success)
  - Set realistic goals for enrollment rate, decline %, loss to follow-up %
    - We all have pressure to perform
    - Baseline metrics to measure against
  - Persuade sponsor to incorporate a visit stipend and travel reimbursement
  - Role Play
    - With PI and/or colleague
    - TRACS Recruitment & Retention
  - Consider alternative methods of obtaining consent
  - Checklists

Pre-Consent Checklist

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1. Review Study-Specific Materials

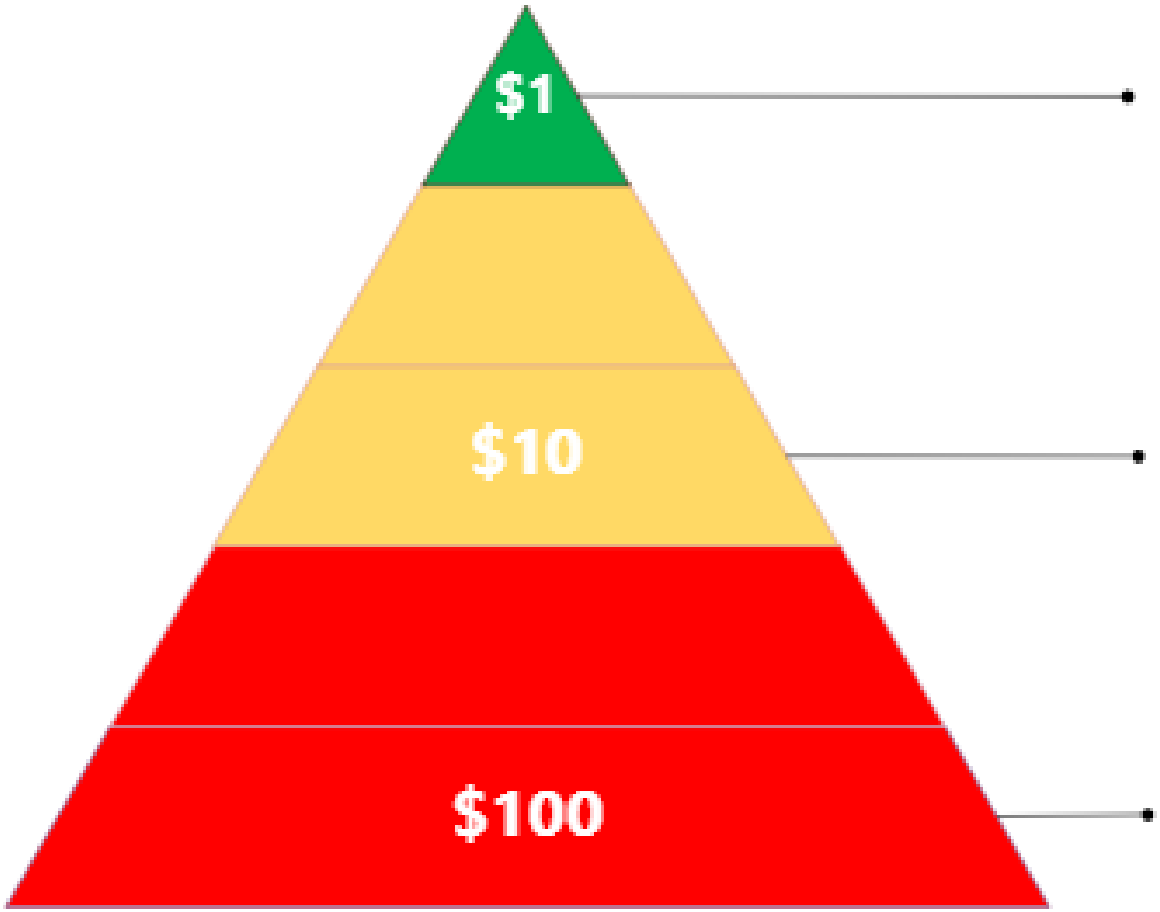
☐ Confirm you have the most up-to-date **approved** ICF.

☐ Review the protocol to ensure you understand key study details (*e.g., purpose, procedures, risks, benefits*).

☐ Verify the patient's eligibility status based on inclusion/exclusion criteria.

☐ Prepare any supplemental materials (*e.g., study brochures, lay summaries, visual aids*).

Risk: The use of an old approved version of an ICF to consent a participant



Pre-Consent Checklist

2. Gather Essential Patient Information

☐ Review the patient's medical history and relevant clinical data.

☐ Check for any prior discussions the patient has had about the study.

☐ Confirm language preference and whether an interpreter is needed.

☐ Identify any potential concerns or barriers the patient may have (*e.g., time commitment, transportation, health literacy*).

Pre-Consent Checklist

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3. Ensure Logistical Readiness

☐ Verify you have a quiet, private space for the conversation.

☐ Confirm you have enough time for a thorough discussion without feeling rushed.

☐ Have a notepad or electronic device ready for documentation (*if required*).

☐ Bring **two extra copies** of the consent form for the patient and their caregiver (*if applicable*).

Pre-Consent Checklist

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4. Prepare for the Discussion

☐ Plan a clear and concise way to introduce the study and its purpose.

☐ Be ready to explain key study aspects in layman's terms.

☐ Anticipate common patient questions and prepare responses.

☐ Know how to discuss alternatives to participation, withdrawal options, and the voluntary nature of the study.

Pre-Consent Checklist

5. Confirm Regulatory and Institutional Compliance

☐ Ensure you are trained and authorized to obtain informed consent for this study.

☐ Confirm documentation requirements for consent (*e.g., whether electronic or paper signatures are used).*

☐ If applicable, ensure a witness is available if required by study protocol or institutional policy.

Pre-Consent Checklist

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6. Mental and Professional Preparation

☐ Approach the conversation with empathy and patience.

☐ Be mindful of body language and tone of voice.

☐ Ensure you can convey all information without coercion or undue influence.

☐ Remember to encourage the patient to ask questions and take their time deciding.

During the Consent

- Build Rapport
  - Acknowledge everyone in the room
  - Point out one non-study related thing
  - Bring yourself into the consent discussion
- The Importance of Framing
- Full Risk Disclosure

"It is a part of my responsibility to assure patient confidentiality. May I speak to Mr. X one-on-one for a few minutes".

"These risks are classified as rare, meaning they are known to occur in <5% of patients on this medication."

During the Consent

- Don’t assume, assess
  - Watch for red flags
  - Comprehension, not just consent
    - Teach-back method
    - 3 question quiz
- Review every page of the consent with the patient
- Double-check form completion
- Anticipate expected questions

Patient FAQs to Anticipate

- ❑ “Would you want your grandma to do this?”
- ❑ “Will this cost me money?”
- ❑ “What are the side effects?”
- ❑ “Does my doctor know about this?”
- ❑ “Who are you again?”

Reflect: What questions have you received?

Situations that Sound Okay That are NOT Okay

- "I don't need to read it, where do I sign?"
  - *It's your job to ensure COMPREHENSION not just consent.*
- "If my doctor wants me to do it, I'll do it."
  - *Autonomy* – The *participant must understand & voluntarily consent.*
- "Give it to my wife and she'll make a decision."
- "Thanks for leaving the ICF. I went ahead and signed it."
  - *Assure comprehension and ask participant to re-sign/date in your presence*
- **Reflect: What conflicting consent situations have you been in?**

After The Consent

- Communicate
  - Celebrate this milestone!
  - Share relevant context
- Document
  - Get that ICF back to the office!
  - Recommendation: leverage smart phrases & smart lists
- Analyze

EPIC Consent Smart Phrase *[sample]*

Header

Eligibility

ICF Process

ICF Process (Every Visit!)

Study Title: **AVA-ITP-401: Measuring Safety and Treatment Satisfaction in Adult Subjects With Chronic Immune Thrombocytopenia (ITP) After Switching to Avatrombopag From Eltrombopag or Romiplostim**
UNC IRB #: 21-1849
UNC PI: Dr. Raj Kasthuri
Subject ID: 121-***

AVA-ITP-401 Screening (Visit 1) and Baseline (Visit 2)

@NAME@ was seen **@FDATE@**, for study visit **{AVA ITP VISIT LIST:93449}**. Study visit occurred **{study visit location:73315}** and was led by **{BRCstudycoordinators:98845}**. Patient checked at the front desk on the 5th floor and was screened for COVID-19.

Study eligibility
Study eligibility criteria was reviewed by coordinator to ensure subject is a candidate. Subject eligibility was confirmed by **PI Raj Kasthuri** prior to consent. A scanned copy of the eligibility checklist is uploaded in the Epic media tab.

Informed consent
Patient provided written informed consent and a HIPAA authorization for the AVA-ITP-401 trial, on *** **at** ***. Consent was led by **{AVA ITP Research Team:93448}**. The study was discussed in detail with the patient. Ample time was allowed for patient to ask questions and all questions were answered. Patient was provided with the signed consent and HIPAA documentation. Notification of the patient's informed consent was documented in SecureConsent (IQVIA).

Travel Stipend
Patient was compensated $50 for travel. Receipt signed by patient, who was then provided a copy.

Prep for Next Encounter
Subject was scheduled for the next study encounter: **{AVA ITP VISIT LIST:93449}**.
Appointment has been confirmed in Epic and will take place on ***date***.

After The Consent

- Communicate
- Document
- Analyze
  - Collect relevant raw data
  - Translate into persuasive stories

Accrual Metrics – ACTIV4c ('21-'22)

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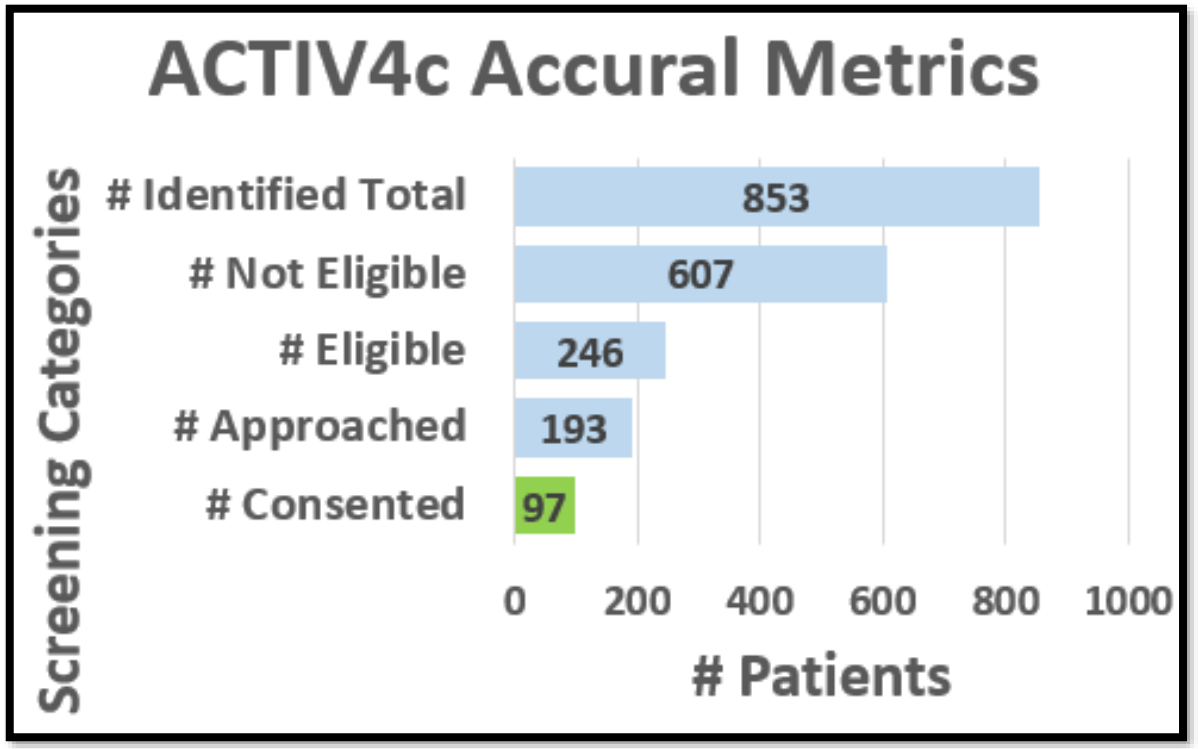
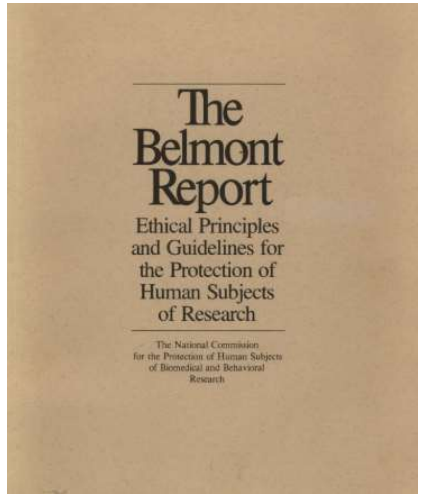
Screening Categories	# Patients
# Identified Total	853
# Not Eligible	607
# Eligible	246
# Approached	193
# Consented	97
# Weekend Randomized	4
# Consented but Ultimately Not Randomized	5
# Declined	96
# Missed or Passed Up	51

Translate To Communicate

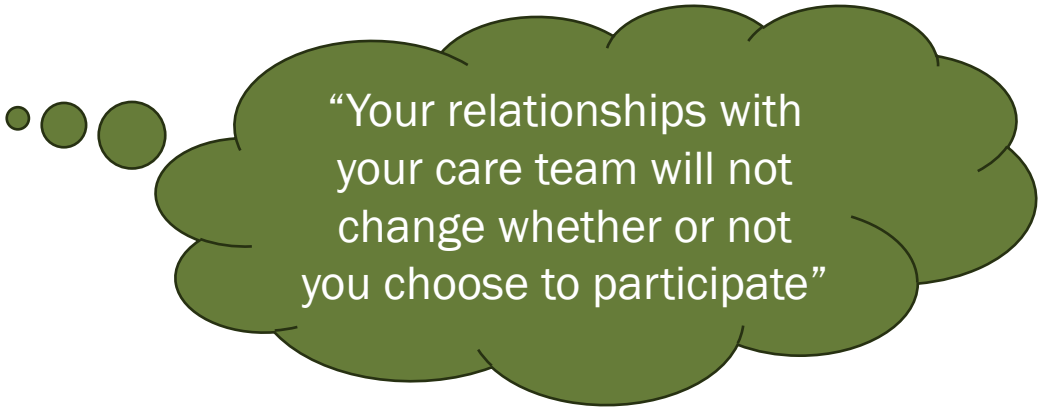


- ✓**40%** of eligible patients admitted to UNC consented
- ✓**48%** of those approached were consented
- ✓**20** Patients requested by sponsor
- ✓**97** Delivered

Recap


The Belmont Report
Ethical Principles and Guidelines for the Protection of Human Subjects of Research
The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research


SOHAM NANAVATI, BSPH
CLINICAL RESEARCH COORDINATOR
soham_nanavati@med.unc.edu
O 919-843-1822 | F 984-279-1911
THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL
SCHOOL OF MEDICINE - HEMATOLOGY
UNC BLOOD RESEARCH CENTER
Suite 50
6340 Quadrangle Dr. | Chapel Hill, NC 27517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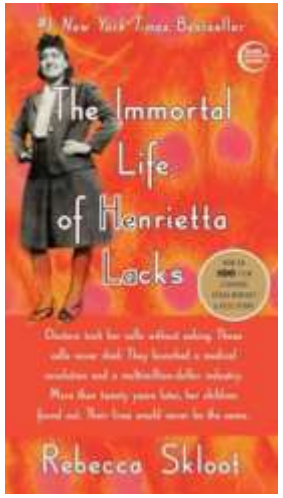
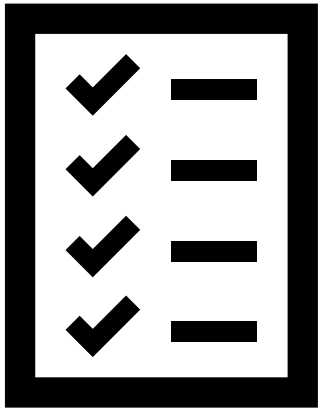
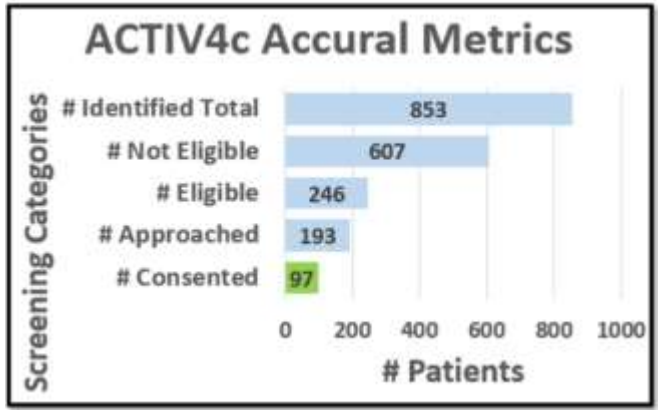

The Immortal Life of Henrietta Lacks
Rebecca Skloot




ACTIV4c Accural Metrics
Screening Categories
Identified Total
853
Not Eligible
607
Eligible
246
Approached
193
Consented
97
0
200
400
600
800
1000
Patients

IRBIS

UNC Research Resources

- NRP – Education & Training
  - https://nrp.tracs.unc.edu/education-training/
- Clinical Research Navigation Hub
  - https://tdx.unc.edu/TDClient/33/Portal/Requests/ServiceDet?ID=219
- Epic Research Informatics
  - https://tracs.unc.edu/index.php/services/informatics-and-data-science/epic-research-informatics

Thank You!

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Brett_Phillips@med.unc.edu

Connect on LinkedIn:

Evaluation

Please complete the post-session evaluation

NRP Post session evaluation_ICF March 5

Email: NRP@unc.edu if further questions or suggestions for future education.