

RECRUITMENT AND THE ROLE OF THE RESEARCH COORDINATOR

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AGENDA

- Definitions
- Participant Rights
- UAB Recruitment Regulations (IRB, GCP, HIPPA)
- Barries to Recruitment
- Recruitment Methods
- Recruitment Guidance





DEFINITION OF RECRUITMENT

- The process of identifying, contacting, educating, and enrolling individuals to participate in a research study.
- It involves presenting information about the study to potential participants, gaining their informed consent, and ensuring the recruitment process is ethical and complies with relevant regulations.



RESEARCH PARTICIPANT RIGHTS

- Participant rights in research ensure the well-being and dignity of participants.
- These rights include the right to informed consent, the right to withdraw at any time, the right to privacy and confidentiality, and protection from harm.
- Federal regulations, like the "Common Rule" (45 CFR 46) regulates ethical standards for all human subjects in research conducted or supported by the U.S. Department of Health and Human Services (HHS) and institutional review boards (IRBs) are in place to protect these rights.

RECRUITMENT REGULATIONS (IRB)

UAB Institutional Review Board (IRB)

- A committee established under federal regulations (Common Rule, Good Clinical Practice, and HIPPA) for the protection of human subjects in research. Its purpose is to help protect the rights and welfare of human participants in research conducted under the University of Alabama at Birmingham.
- University policy requires that all research involving human subjects be reviewed and approved by the UAB IRB before the research begins.
- Any changes to an IRB-approved project must be reviewed and reapproved by the IRB before they can be implemented.

RECRUITMENT REGULATIONS (HIPPA)

I. <u>Research Recruitment by Treating Physicians/Staff</u>

Treating physicians and staff within a division who work collaboratively to treat patients in clinic and who are also assigned to work on research protocols may review the clinic patients' records to identify potential research subjects for research protocols.

2. Research Recruitment by Non-Treating Physicians/Staff

•For a researcher and staff to review records or obtain lists of other physicians' patients, medical records, test results or other clinical information when the researcher/staff is not involved in the treatment of the patients, the researcher/staff must include a description of the plan for recruitment in the IRB protocol submission that describes the method of identifying and contacting the individuals.



UABTRAINING

•UAB requires key personnel engaged in human subject research complete training in human subject protections.

- Initial IRB training
- Continued IRB training (every 3 years)
- Initial Good Clinical Practice (GCP)
- Continued GCP training (every 3 years)

<u>https://www.uab.edu/research/home/irb</u>Email: <u>irb@uab.edu</u>

REGULATION TAKEAWAYS..











PARTICIPANTS HAVE RIGHTS UAB IRB IS A COMMITTEE THAT ENSURES OUR RESEARCH AND RESEARCH METHODS COMPLY WITH FEDERAL REGULATIONS (COMMON RULE, GCP, HIPPA) RESEARCH STAFF MUST RECEIVE IRB AND GCP TRAINING (EVERY 3 YEARS) NO MATTER THE METHOD OF RECRUITMENT – ALL RECRUITMENT STRATEGIES AND DOCUMENTS MUST BE APPROVED BY THE IRB PRIOR TO APPROACHING POTENTIAL CANDIDATES RESUBMISSION FOR IRB APPROVAL WHENEVER METHODS OR DOCUMENTS FOR RECRUITMENT NEED TO BE MODIFIED OR UPDATED

REASONS PARTICIPANTS JOIN CLINICAL TRIALS

Access to best care and doctors for their condition

Belief they would benefit future participants

Belief they would get more care and attention

Belief/Hope that they themselves will benefit



RECRUITMENT- BARRIERS

(**\$**5)

Fear of receiving a placebo and misunderstanding of research terminology

Participants reluctance to go against their primary doctor's recommendations

Fear of being treated like a "guinea pig"

Distance patient might have to travel or additional time to participate

What will it cost to participate

RECRUITMENT METHODS



RECRUITMENT – HELPFUL TIPS



Know your protocol and informed consent



Confirm which method(s) or documents have been IRB approved



Practice "recruiting a participant" with a fellow coordinator



Create a checklist



Create a Recruitment Tracker

(Pre-screened, screened, screen fail, eligibility confirmed date, contact date, consent date, on trial date)



RECRUITING Ensure there is plenty of time for potential Use clear and concise Be transparent: clearly state participant to decide and discuss the decision with the trial's purpose, communication - everyday language to explain procedures, and potential family and friends or ask risks and benefits complex concepts questions before signing Show empathy and respect: Be prepared to answer Listen to their concerns Be friendly and questions and address any and acknowledge their approachable concerns they may have experiences Tailor your communication Reassure participants that their information will be Be mindful of cultural to the specific needs and differences and language characteristics of your barriers kept confidential target population





THANK YOU