IT TAKES A VILLAGE

Diverse groups of people are involved in clinical trial research

A "stakeholder" in a worker health study is an individual or a group with an interest, or "stake" in the conduct or outcome of the study.

The Institute of Medicine (IOM) states, "Each stakeholder offers a different set of tools to support the essential components of a clinical trial. These resources form the infrastructure that currently supports clinical research in the United States. Time, money, personnel, materials (e.g., medical supplies), support systems (informatics, as well as manpower), and a clear plan for completing the necessary steps in a trial are all part of the clinical research infrastructure. "

Institutional Review Board (IRB)

- A group of scientists, doctors, clergy, and patient advocates who review and approve the detailed plan for every clinical trial.
- IRBs are meant to protect the people who take part in a clinical trial.
- They check to see that the trial is well designed, legal, ethical, does not involve unneeded risks, and includes a safety plan for patients. There is an IRB at every health care facility that does clinical research (3).

Community Advisory Board (CAB)

- A group of non-scientist volunteers who serve as a link between a community and clinical trial researchers.
- A Community Advisory Board may review and monitor clinical trials and help teach the community about the trials (3).

Community Health worker (CHW)

- Trusted members of and/or have an unusually close understanding of the community they serve.
- This trusting relationship enables CHWs to serve as a liaison/link/intermediary between health/social services and the community to facilitate access to services and improve the quality and cultural appropriateness of service delivery.
- CHWs also build individual and community capacity by increasing health knowledge and self-sufficiency through a range of activities such as outreach, community education, informal counseling, social support and advocacy (1).

Research coordinator

- Specialized research professional working with and under the direction of the clinical Principal Investigator (PI).
- The research coordinator supports, facilitates and coordinates the daily clinical trial activities and plays a critical role in the conduct of the study.
- By performing these duties, the research coordinator works with the PI, department, sponsor, and institution to support and provide guidance on the administration of the compliance, financial, personnel and other related aspects of the clinical study.

Nurse / Nurse Practitioner (NP)

- Nurse- A health professional trained to care for people who are ill or disabled (3).
- NP- A registered nurse who has additional education and training in how to diagnose and treat disease. Nurse practitioners are licensed at the state level and certified by national nursing organizations (3).

Patient advocates

- A person who helps a patient work with others who have an effect on the patient's health, including doctors, insurance companies, employers, case managers, and lawyers.
- A patient advocate helps resolve issues about health care, medical bills, and job discrimination related to a patient's medical condition.

All stakeholders

are

critical for the success of the trial!

Principal Investigator

- "A doctor or health professional who leads the clinical research team and, along with the other members of the research team, regularly monitors study participants' health to determine the study's safety and effectiveness." (NIH clinical trials and you)

Research sponsors (industry, academia, government, nonprofit organizations)

- "An individual, company, institution or organization which takes responsibility for the initiation, management, and / or financing of a clinical trial." (ICH)
- "A person who takes responsibility for and initiates a clinical investigation. … The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator." (CFR)
- The commercial manufacturer that has developed a product in which it holds the principal financial interest.
- The sponsor holds the IND (Investigational New Drug) application and files the NDA / BLA (New Drug Application/Biological Licensing Application)

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(1) http://www.roche.com/gb07e07.pdf
(2) http://www.nlm.nih.gov/medlineplus/ency/article/001934.htm
(3) http://www.cancer.gov/dictionary?cdrid=44534
(4) https://research.wustl.edu/Resources/Roles/Pages/CRC.aspx_)
(5) Institute of Medicine (US) Forum on Drug Discovery, Development, and Translation. Transforming Clinical Research in the United States: Challenges and Opportunities: Workshop Summary. Washington (DC): National Academies Press (US); 2010. 3, Challenges in Clinical Research. Available from: http://www.ncbi.nlm.nih.gov/books/NBK50888/
(6) American Public Health Association, 2008- http://www.chwnetwork.org/who-are-chws/definition/?