

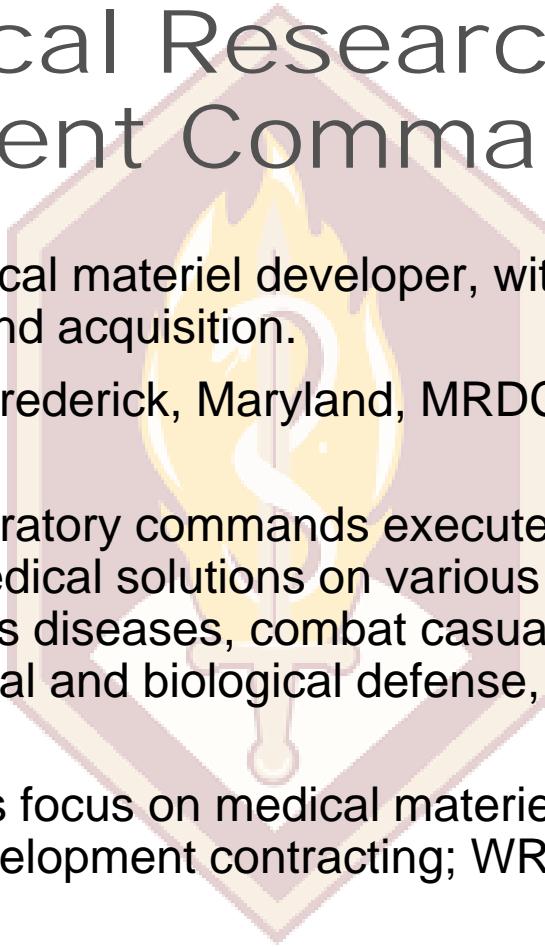
Walter Reed Army Institute of Research (WRAIR) Community Engagement

Information for Community Advisory Board



Medical Research and Development Command (MRDC)

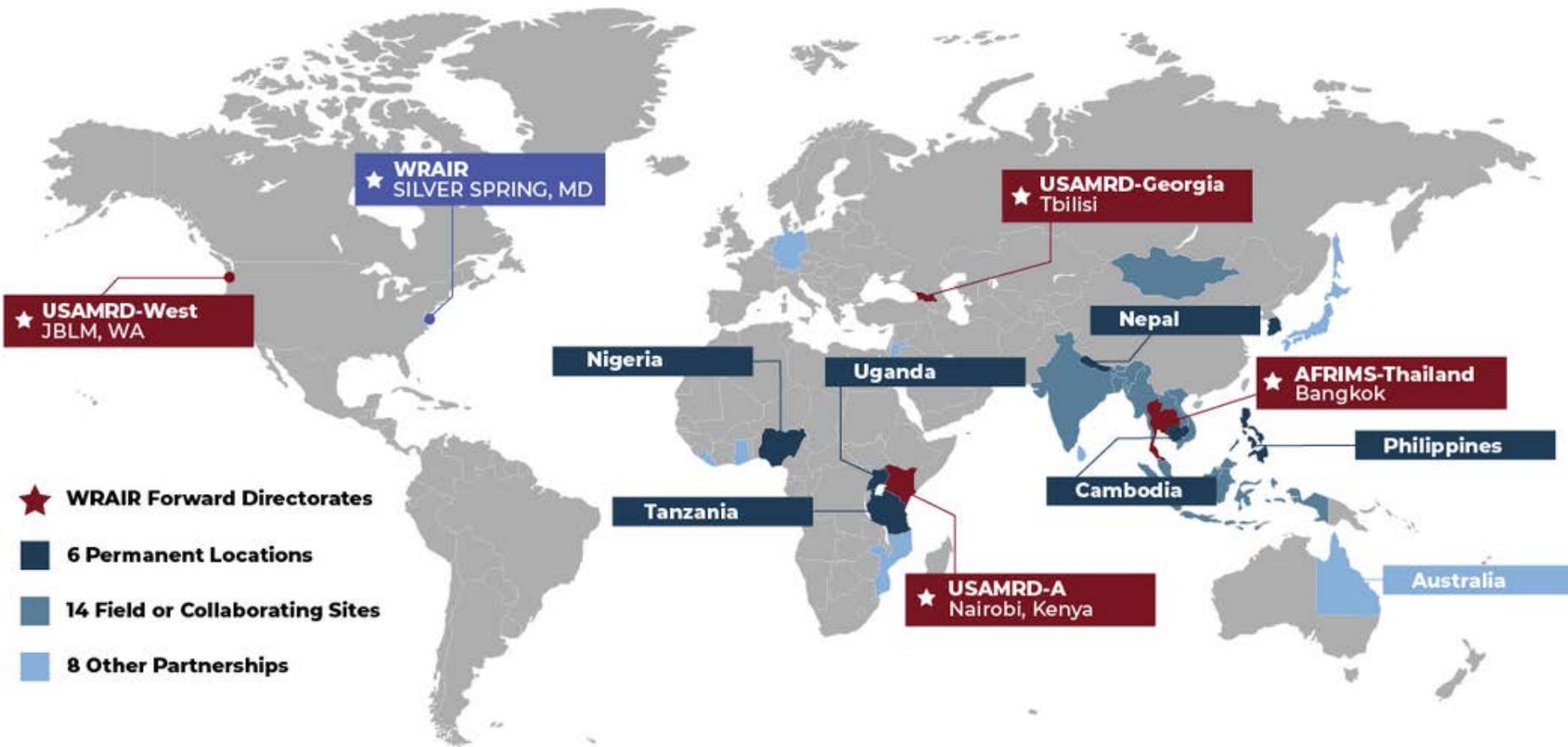
- MRDC is the Army's medical materiel developer, with responsibility for medical research, development, and acquisition.
- Located at Ft. Detrick in Frederick, Maryland, MRDC is the headquarters for eight Army commands.
- Six medical research laboratory commands execute the science and technology program to investigate medical solutions on various areas of biomedical research; including military infectious diseases, combat casualty care, military operational medicine, medical chemical and biological defense, and clinical and rehabilitative medicine.
- Two additional commands focus on medical materiel advanced development and medical research and development contracting; WRAIR is the largest MRDC research command.



WRAIR Introduction

- Since 1893, WRAIR has been a leader in solving the most significant threats to Soldier readiness and lethality such as disease and battle injury.
- WRAIR's research is focused on Soldier health, but its products have important civilian applications, saving countless lives around the world.
- In 1960 and 1969 respectively, WRAIR began operations in Thailand and Kenya with the establishment of the Armed Forces Research Institute of Medical Sciences (AFRIMS) and the U.S. Army Medical Research Directorate - Africa (USAMRD-A).



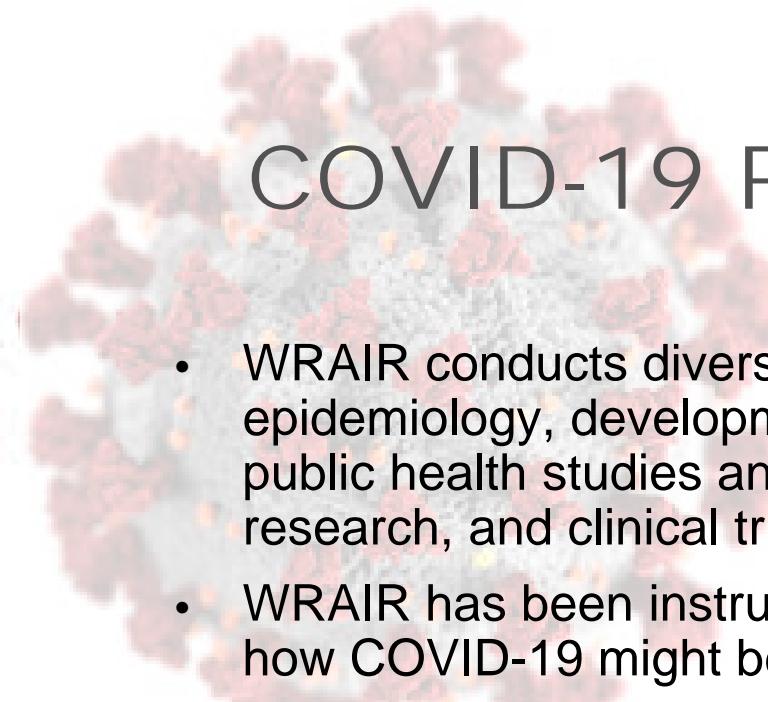


WRAIR Introduction

- WRAIR's Clinical Trial Center has conducted more than 150 studies with over 7,200 annual visits by research subjects.
- For 3 decades, WRAIR's research has been housed on the same campus, allowing seamless scientific discovery in new vaccines and therapeutics.
- WRAIR can move research from basic science to animal models, manufacture pilot-scale material in our pilot bioproduction facility, and test products in human trials in the Clinical Trials Center.

WRAIR Personnel

- WRAIR scientists make our work possible: entomologists, virologists, immunologists, chemists, microbiologists, veterinary medicine specialists, epidemiologists, clinical trial experts, product development experts--WRAIR runs the entire spectrum.
- WRAIR has a staff of more than 2,500, many of whom are civilians or contractors working beside military personnel.
- WRAIR also partners with other government agencies, academia, and private industry to develop and test new interventions to prevent and treat disease.

A large, semi-transparent image of a COVID-19 virus particle, showing its characteristic spike proteins and internal structure.

COVID-19 Research at WRAIR

- WRAIR conducts diverse types of research on COVID-19, including epidemiology, development of new diagnostic tests and assays, public health studies and outbreak investigations, laboratory based research, and clinical trials.
- WRAIR has been instrumental in conducting studies to determine how COVID-19 might be transmitted among military recruits.
- WRAIR's diagnostics laboratory is a leader in the field and has developed and tested new assays, as well as collaborating with industry partners on validation of tests for COVID infection, serology (evidence of prior infection) and viral clearance

COVID-19 Vaccine Research at WRAIR

WRAIR's own COVID-19 vaccine, SpFN, was developed in WRAIR labs and will be tested in an upcoming phase I trial that is set to begin in February 2021.



- WRAIR also participates in clinical trials of COVID vaccines and therapeutics supported by external sponsors through Operation Warp Speed (OWS).
 - To date, WRAIR has plans to participate in vaccine trials from Sanofi Pasteur and Inovio.
 - A COVID-19 treatment study funded by NIH which will include monoclonal antibodies, among other treatments.

A SARS-CoV-2 vaccine candidate would likely match all currently circulating variants

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The magnitude of the COVID-19 pandemic underscores the urgency for a safe and effective vaccine. Many vaccine candidates focus on the Spike protein, as it is targeted by neutralizing antibodies and plays a key role in viral entry. Here we investigate the diversity seen in severe acute respiratory syndrome coronavirus 2

socioeconomic implications. As of July 23, 2020, more than 15 million cases and 622,000 attributable deaths have been reported worldwide (5–8) (<https://coronavirus.jhu.edu/map.html>). Phylogenetic analyses suggest that SARS-CoV-2 is likely derived from a clade of viruses found in horseshoe bats (9). In S, the bat ge-

Community Engagement



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Community Engagement: Background and Rationale

- Community engagement (CE) has become one of the hallmarks of the ethical conduct of clinical research, and in particular, clinical trials.
- CE is valuable for improving ethical conduct, improving research relevance and efficiency, and helping communities to realize full benefits of science
- COVID-19 pandemic has spurred a burst of clinical research activity unfolding at unprecedented speed
- Need to engage the public, inform laypersons and potential trial participants about the research, and to gain and sustain public trust.
- Critical to engage minority communities (Black, LatinX) as well as other affected groups: front line workers and others at high risk

WRAIR CE Project Goals

Goal 1: Increase community knowledge and awareness of WRAIR COVID-19 research and its impacts

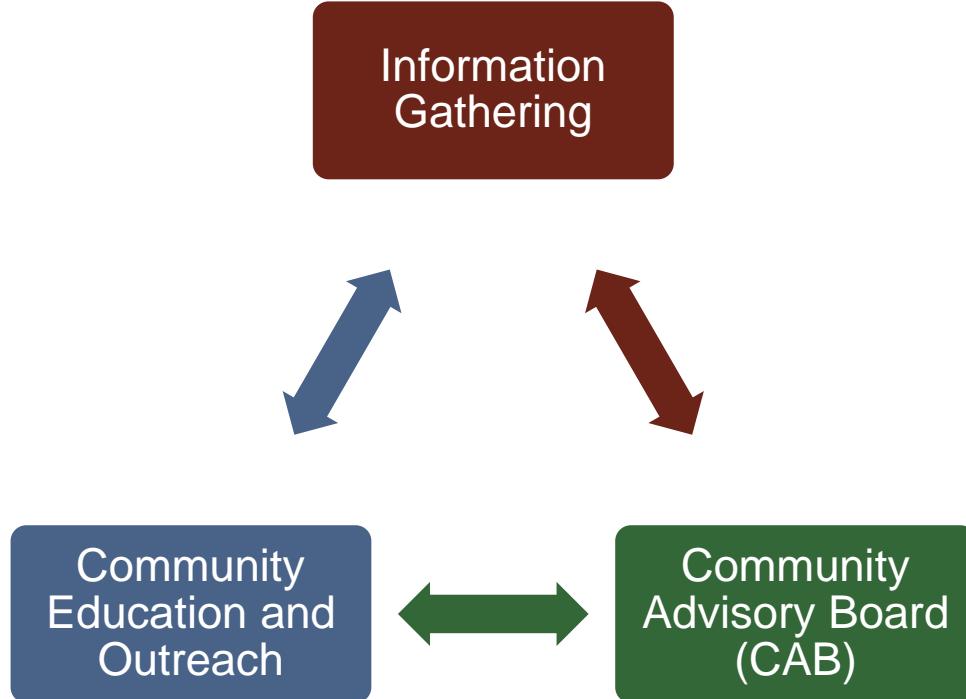
Goal 2: Increase WRAIR researchers' knowledge and awareness of community needs, values, and preferences; increase competency for community engagement in relation to COVID-19 research, with focus on communities most affected by COVID-19

Goal 3: Incorporate community input into design and execution of WRAIR COVID research

Goal 4: Improve trust and address misperceptions/misconceptions about clinical research enterprise and COVID research in particular

Goal 5: Support effective strategies for recruitment and retention in COVID clinical trials

CE Project Activities



Information Gathering

1. Focus groups 4 to 8 groups
 - Current and former trial participants;
 - Members of affected neighborhoods/communities (representing different racial and ethnic groups);
 - Health care providers
 - Researchers
2. Community organization mapping developing lists and contact info of CBOs, health care provider orgs, etc, in MoCo, PG County, DC, for further outreach
3. “On the street” interview in neighborhoods in DC metro area (high COVID impact, overlap with WRAIR catchment area)
4. Photovoice outreach to community members to document attitudes, perspectives on research
5. Discussion groups- more informal than f.g.s, explore relevant perceptions, attitudes, themes

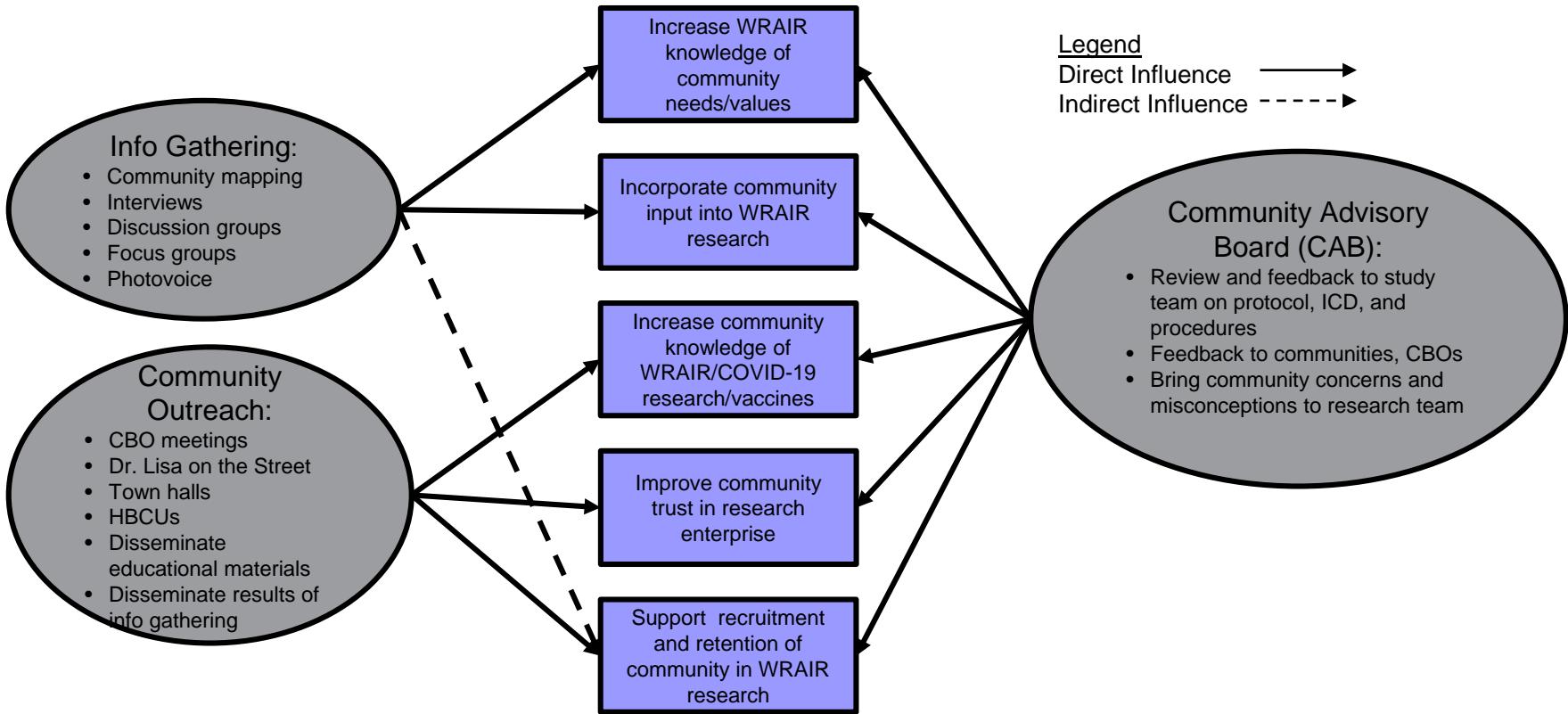
Community Outreach and Education

- Education: preparation of community educational materials and HBCU outreach
- Education for researchers about community-engaged research
- Town Hall: forums and other outreach events (virtual)
- Social media: education, dialogue
- Dissemination: qualitative and quantitative project findings- stakeholder meetings and discussion
- Videos: preparation of videos about WRAIR and WRAIR research

Community Advisory Board (CAB)

- Membership: representatives of lay communities, including CBOs; health care providers; current/former clinical study participants
- Charter, membership, procedures: work jointly with WRAIR ethics team to develop plans and procedures
- Education: receive education on clinical research, how to review a protocol, oversight of clinical trials, etc.
- Input into WRAIR research: will participate in discussion/review of clinical trial plans, including protocol, informed consent, recruitment
- Community feedback: can provide input from their communities and stakeholder groups regarding attitudes towards clinical research and COVID vaccines
- Dissemination: can help feed back information to their constituencies

Activities in relation to CE goals

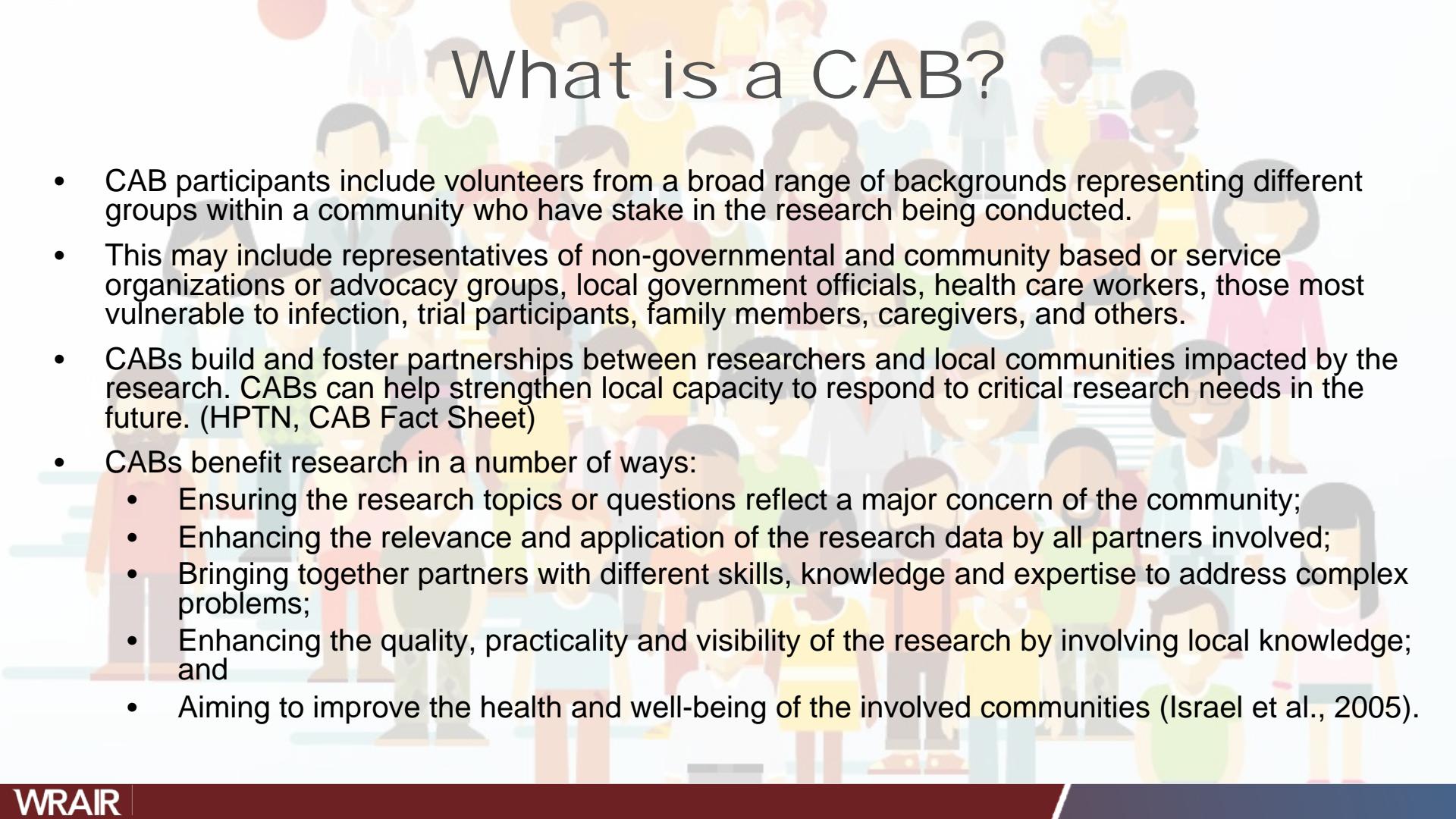


Community Advisory Board



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What is a CAB?

- CAB participants include volunteers from a broad range of backgrounds representing different groups within a community who have stake in the research being conducted.
- This may include representatives of non-governmental and community based or service organizations or advocacy groups, local government officials, health care workers, those most vulnerable to infection, trial participants, family members, caregivers, and others.
- CABs build and foster partnerships between researchers and local communities impacted by the research. CABs can help strengthen local capacity to respond to critical research needs in the future. (HPTN, CAB Fact Sheet)
- CABs benefit research in a number of ways:
 - Ensuring the research topics or questions reflect a major concern of the community;
 - Enhancing the relevance and application of the research data by all partners involved;
 - Bringing together partners with different skills, knowledge and expertise to address complex problems;
 - Enhancing the quality, practicality and visibility of the research by involving local knowledge; and
 - Aiming to improve the health and well-being of the involved communities (Israel et al., 2005).

CAB at WRAIR

Engage Advocate

- Provide leadership for community participation
 - Communicate with members of their community to gauge shared concerns and priorities
 - Participate in community education and advocacy
 - Spread information about the collaboration within the community
- Provide information about community strengths and resources
 - Provide feedback on ethics and relevance of research
 - Share relevant meanings and information from community perspective