
STRATEGIC PLAN

Legacy Project 2011-2014



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Executive Summary

The Legacy Project works nationally to address factors that influence participation of traditionally underrepresented communities in HIV prevention and treatment clinical research through engagement, education, and scientific investigation. The Legacy Project works to cultivate partnership and relationship development among the National Institute of Allergy and Infectious Diseases (NIAID)-funded HIV clinical research networks, community-based organizations and affiliates engaged in HIV prevention and treatment, while ensuring a commitment to capacity building for communities and populations most impacted by the United States HIV epidemic. As the Legacy Project builds on its work within the HIV Vaccine Trials Network (HVTN) to expand across other HIV trials networks, a plan to support this transition, foster collaboration and communication, and improve efficiency is essential.

Methods

In December 2010, a strategic planning taskforce comprised of twelve members of the Legacy Project Working Group and an external facilitator convened to recommend a set of goals and objectives to guide the Legacy Project's work over the next three years (Appendix A). The taskforce met weekly to gather and discuss information related to organizational operations, stakeholder ideas and views, and to identify the perceived role of the Legacy Project in the landscape of national HIV clinical trials. The participatory strategic planning process began with an environmental scan to identify and assess gaps, challenges and opportunities for the Legacy Project to strengthen outreach to underrepresented communities disproportionately affected by HIV.

Part of this process included a comprehensive review of the Legacy Project's target communities and the broader environment in which the Legacy Project operates, as well as identifying strategic partners that support its objectives and goals, including funders, government agencies, national institutes and policymakers. In addition, the taskforce reviewed the Legacy Project's internal documents and conducted eighteen interviews with stakeholders. The sample of stakeholders that were interviewed was stratified across four axes: 1) current collaborator (e.g., pilot projects and NHVREI partners), 2) historical perspective (e.g., member of LPWG since inception), 3) affiliated with NIAID networks or sites (e.g., network representative and trial site staff or community members), and 4) working group member not captured in any of the other categories. On average, interviews were completed in 45-60 minutes, and interview responses were summarized and synthesized thematically. The information gathered from the needs assessment was integrated and used to help the group conceptualize and establish the vision, mission, organizational values, goals, and objectives of the strategic plan.

Findings

National HIV Strategy & Funding Trends

Enrollment and representation of Black, Latino and other communities of color in HIV clinical trials (and scientific research in general) is often lower than their respective demographic proportions within the population affected by the disease.^{1,2} Low enrollment of ethnic and sexual minority groups in HIV clinical trials and other research compromises the generalizability of research to the entire population for which interventions are intended. A study conducted to determine the barriers to participation in trials of African American women found that nearly 33% of Black

women agreed that scientists cannot be trusted, compared to just 4% of White women. This issue of mistrust is common to many other underrepresented communities and illustrates one of the main obstacles in increasing broader demographic participation in clinical trials.

The local, state and national HIV agenda for the next five years will be greatly influenced by the National HIV/AIDS Strategy, which was introduced by the Office of National AIDS Policy (ONAP) in July 2010. There are three primary goals in this strategy: 1) reduce the number of people who are infected with HIV, 2) increase access to care and optimize health outcomes for people living with HIV, and 3) reduce HIV-health related disparities.⁴ Legacy's focus and efforts to address issues underlying participation of underrepresented groups in HIV clinical trials and other research are aligned with and work toward all three goals. Legacy's vision, mission and operating principles strategically reflect national HIV/AIDS priorities and agendas. Legacy is committed to partnering with national, state and local agencies that support community engagement work, and plans to build on the momentum of successful campaigns to continue work in these areas.

The Patient Protection and Affordable Care Act will have a profound impact on biomedical research, AIDS service organizations (ASO), and target populations that Legacy serves. The act will expand healthcare coverage, increase funding for biomedical research and expand access to healthcare for many individuals in Legacy's target population. Through healthcare reform, the Medicaid threshold will rise to 133% of the federal poverty level (around \$30,000 for a family of four), and healthcare exchanges and subsidies will provide health insurance coverage for individuals and families who make up to 400% of the federal poverty level. Over \$11 billion will be spent over the next five years to build community health centers which will provide primary care health services to over twenty million patients.⁹

The Division of AIDS (DAIDS) is a division of the National Institutes of Health's NIAID that sponsors a portion of Legacy's efforts. DAIDS was established in 1986 in order to tackle the HIV/AIDS epidemic. While the final FY 2011 budget for NIH has not yet been published, preliminary estimates indicate a significant continued investment in HIV-related biomedical research. The FY 2011 OAR budget estimates show NIH's continued commitment to the area of HIV/AIDS research. Biomedical interventions represent an important component in the battle against the HIV/AIDS epidemic.

Interview Findings

All interviewees recognized the importance of Legacy's work and identified a number of assets Legacy can leverage and build on in its future work, including staff; community engagement, education, and pilot projects success; and visibility at conferences. All interviewees also identified some challenges they perceived Legacy to face, either internally or externally. Internal challenges focused on branding (including networks), partnership development, and evaluation. External challenges focused on lack of communication between and diversity within networks, and community issues surrounding research funding distribution and capacity, youth engagement, and scientific literacy.

A number of recommendations addressed Legacy's work broadly and offered strategies to mitigate the challenges outlined above. These recommendations targeted Legacy's relationship to NIAID networks, cultural competence within networks, Legacy's research agenda, and community engagement. Within these broad areas, recommendations focused on branding and communication, technical assistance and capacity building, education and mobilization.

Vision, Mission, & Organizational Values

Vision

The Legacy Project envisions accurately informed communities actively engaged in clinical research with culturally sensitive research environments and processes.

Mission

The Legacy Project's mission is to build trust and collaboration between historically underrepresented communities most impacted by the domestic HIV epidemic, researchers, and research institutions; enhance cultural competence; and initiate scientific investigation to increase clinical research participation.

Organizational Values

Legacy Project Values:

Inclusion: Participants in HIV research should be proportionate to those populations most impacted by the epidemic.

Leadership Diversity: Cultivation of leaders among communities most impacted by the epidemic.

Innovation and sense of urgency: New ideas, scientific generation of knowledge, and recognizing the importance of expediently addressing the HIV epidemic.

Justice & Equity: Parity, inclusion, and representation of all.

Collaboration: The power of teamwork and cooperation.

Priority Areas, Goals, & Objectives

Capacity Building

1. Build the capacity of communities and researchers to partner in the research enterprise
 - 1.1. Increase cultural awareness and community engagement skills among researchers in networks and sites most challenged in recruiting Black and Latino participants
 - 1.2. Increase representation of minority researchers within networks and sites with the least diversity
 - 1.3. Increase scientific literacy among Black and Latino communities most impacted by the epidemic

Engagement & Collaboration

2. Facilitate community involvement throughout the research process
 - 2.1. Increase knowledge in communities about research, biomedical interventions, and safety issues
 - 2.2. Decrease barriers related to participation in clinical trials

2.3. Facilitate partnerships between sites and national and community organizations

Research

3. Influence the creation of scientific agendas and science that is responsive to community priorities. Conduct and support primary research on community engagement and clinical trial participation and the relationship between them
 - 3.1. Review network governance to understand generation of scientific agendas and protocols to determine processes that support and/or hinder input
 - 3.2. Produce manuscripts and materials targeting scientific community and funders focused on the utility of community participation and engagement
 - 3.3. Develop research priorities germinating from priority populations
 - 3.4. Evaluate key opinion leader approach to community engagement to determine if it results in different levels of community engagement in research compared to direct community marketing campaigns
 - 3.5. Inform NIH research priorities, trial protocols, and target population focus domestically

Evaluation

4. Demonstrate Legacy's impact and effectiveness
 - 4.1. Monitor and evaluate Legacy programs, initiatives, and activities

Research & Evaluation

4. Influence the creation of scientific agendas and science that is responsive to community priorities.
 - 4.1. Conduct community-engaged and community-responsive research that increases clinical trial participation among traditionally underrepresented communities
 - 4.2. Contribute scientific expertise, and translate community expertise, to the generation of scientific agendas and protocols within NIAID-funded clinical trials networks
 - 4.3. Publish and disseminate results of community-engaged and community-responsive research among traditional clinical researchers
 - 4.4. Evaluate the efficacy and effectiveness of various approaches to community-engaged research on clinical trial participation and network responsiveness to traditionally underrepresented communities

Strategies

1. Enhance and expand efficient and effective communication with networks, sites, partners, and the general public
2. Develop a rigorous scientific agenda and an expert scientific base within the Legacy Project and coordinating partners that (i) addresses trial participation among traditionally underrepresented communities, and (ii) promotes and enhances community-engaged and community-responsive research within the networks
3. Engage in bi-directional translational research (translating scientific knowledge to external communities and translating community knowledge to scientific communities).
4. Develop and enhance new and existing partnerships with national and community-based organizations, and formal and informal groups
5. Build coalitions across groups and organizations and mobilize communities
6. Facilitate coordination with and cooperation of NIAID networks and U.S. sites
7. Provide capacity building and technical assistance to networks, sites, partners, and the general public that improves scientific literacy, promotes collaboration and partnerships, and translates advances in HIV biomedical research
8. Provide technical assistance and infrastructure development focused on target populations
9. Coordinate with federal, state, and local agencies, centers, and institutes to influence HIV research and practice priorities, policies, and funding

Introduction: Purpose & Rationale

The Legacy Project works nationally to address factors that influence participation of traditionally underrepresented communities in HIV prevention and treatment clinical research through engagement, education and scientific investigation. The Legacy Project is committed to addressing historic inequities and to overcome the socioeconomic disparities that threaten all NIAID-funded HIV clinical research. As the Legacy Project builds on its work within the HIV Vaccine Trials

The strategic planning process sought to focus Legacy's purview, generate new ideas and assist new leadership with developing systems of accountability. The planning process was ultimately intended to clarify what Legacy can do to increase participation of traditionally underrepresented communities in research. This strategic plan provides a basis for monitoring progress, and for assessing results and impact. It sets goals to guide the organization and provides a clear focus to staff for program implementation and program management.

Methods

In December 2010, a strategic planning taskforce, comprised of 12 members of the Legacy Project Working Group and an external facilitator, was formed to recommend a set of goals and objectives for the Legacy Project, covering the next three years (2014). The taskforce met weekly to gather and discuss information related to organizational operations, stakeholder ideas and views, and to identify the perceived role of Legacy in the landscape of HIV clinical trials nationally. The participatory strategic planning process began with an environmental scan to identify and assess opportunities and threats in the external environment and assess organizational strengths and challenges. The external component of the environmental scan included a review of Legacy's target communities and the broader environment in which Legacy operates: funders; national offices, institutes, centers and new laws.

Forces, trends and political considerations in the broader community included structural and psychological barriers to research participation of ethnic and sexual minority groups, national HIV/AIDS priorities and agendas, and health reform. Community values, status, and the needs of Black, women, and gay populations related to participation in research; Patient Protection and Affordable Care Act implications for organization partners; and NIH Office of AIDS Research and Division of AIDS priorities, were all examined. The internal component of the environmental scan included a review of Legacy's internal documents and semi-structured interviews conducted by the facilitator with Legacy staff, leadership, working group members, partners, and collaborators to evaluate organizational performance, critical success factors, and strategic relationships. The documents reviewed included working group meeting minutes from the past year, the HIV/AIDS Network Coordination (HANC) Project Year 5 work plan and quarterly report from June 2010 – August 2010, and the Legacy Project logic model.

The interview guide topics included programming, top achievements and challenges, and resources (Appendix B). The sample of stakeholders that were interviewed was stratified across four axes: 1) current collaborator (e.g., pilot projects and NHVREI partners), 2) historical perspective (e.g., member of LPWG since inception), 3) affiliated with NIAID networks or sites (e.g., network representative and trial site staff or community members), and 4) working group member not captured in any of the other categories. Eighteen interviews were conducted in person or via phone, and all interviewees were encouraged to comment candidly and think expansively (Appendix C). On average, interviews were completed in 45-60 minutes and responses were summarized and synthesized thematically.

The next phase of the process involved the identification of key issues, questions and choices to be addressed as part of the planning effort. This included answering the questions: Should Legacy expand, contract or stay the same? Who should Legacy be targeting? Based on discussion derived from the environmental scan and responses to these questions, the taskforce established priority areas and defined the organization's mission, vision, and values. The process of articulating Legacy's mission, vision and values included providing evidence for the need for Legacy and its role in integrating underrepresented communities in HIV clinical research; detailing Legacy's outcomes and goals; and building a cohesive message for what Legacy stands for and the communities it serves. The taskforce identified organizational values that reflect Legacy's guiding principles. The vision reflects the image of Legacy's targeted communities and the impact Legacy will have if the mission is achieved.

Lastly, the taskforce developed a series of goals, objectives and strategies that describe where Legacy wants to be and how it will get there. The strategic planning process enabled Legacy to

develop a clear focus, harmonize priorities and devise evaluation methods for measuring progress.

Environmental Scan Findings

Barriers to Minority Communities' Participation in Research

Often HIV clinical trials and other research studies enroll lower percentages of Black, Latino, and other minority participants than are represented in communities where research takes place.^{1,2} Low enrollment of ethnic and sexual minority groups in HIV clinical trials and other research compromises the generalizability of research to the entire population for which interventions are intended. This challenge highlights the need for Legacy's work to address the issues underlying barriers to participation of underrepresented groups in research. Below we briefly outline some of the primary factors related to HIV research participation barriers that Legacy seeks to tackle.

The majority of available information on the psychological and structural barriers to HIV trials and research participation is focused on Black and gay communities. There is a need for more research focused on women, Latino and transgendered populations. The lack of information on these groups and the reasons for their underrepresentation in scientific research provides an opportunity for the Legacy Project to play an instrumental role in the production and dissemination of new knowledge related to HIV trials and research participation, while continuing to address research targeting Black and gay populations. Investigations among Black and gay communities on participation in various clinical trials have centered on interest and barriers related to mistrust of scientific research and government, safety concerns of biomedical interventions, and misunderstandings about clinical trials. Legacy has identified the need to also address and incorporate the concerns and needs of women, Latinos and transgender communities into HIV-related clinical research.

A study conducted to determine the barriers to participation in trials of African-American women found that nearly 33% of Black women agreed that scientists cannot be trusted, compared to just 4% of white women. Additionally, researchers found that Black women were more likely to believe researchers did not care about them, clinical research was unethical, and participating in research prevented them access to better care.¹ Researchers leading a study investigating the perceptions of Black men about prostate cancer trials reported similar findings. Minority communities' mistrust of the scientific and medical establishment may in part stem from a general fear of being used for medical experimentation.

Perhaps the most commonly stated reason for lack of participation in scientific or medical research in Black communities is a cultural remembrance of the Tuskegee syphilis study. In a focus group study of African Americans' attitudes and beliefs about medical research, participants cited other instances of government abuse that contributed to their mistrust. Many participants shared that other "experiments" and "conspiracies" validated their trepidation growing out of the Tuskegee syphilis study. These conspiracies were related to Agent Orange (manmade creation of the AIDS virus), the distribution of crack cocaine in the inner city by the Central Intelligence Agency, and target marketing of cigarettes to African Americans.³

Studies focusing on HIV vaccine trial participation and gay subpopulations found safety concerns to feature prominently. Many participants expressed concerns about contracting HIV from the study, the stigma associated with testing positive, fears of side effects, and not wanting to be a “guinea pig.” Moreover, one study found that older men were more open to enrolling in HIV vaccine trials than younger men.⁴ This suggests there is needs to better engage young men, one of Legacy’s target populations.

In order to increase the participation of underrepresented populations in clinical trials, a number of underlying factors must be addressed. Education focused on the implications and process of participation, and making the language and ideas of science more accessible, is needed. To minimize safety concerns, more culturally responsive practices for guiding research, from question generation to protocol development and findings dissemination, could help minimize perceived consequences from minority groups. Furthermore, it is essential to increase transparency, foster inclusion and build common language and understandings between the research establishment and communities in order to repair trust and adequately convey research intentions.

To address the ethical concerns of communities, culturally attuned considerations throughout the research process may assuage feelings of distrust and increase the participation of underrepresented communities in HIV clinical trials. Fear of experimentation and origins of conspiracy theories should be addressed and not dismissed, and agency and participation of communities as co-investigators ought to be encouraged and supported through the creation of culturally sensitive research environments. Finally, HIV-related stigma can be tackled through social marketing and culturally appropriate institutional policy changes. Community and coalition building and mobilization, and enhancing cultural awareness of researchers and the research establishment will be required to address all of these issues. Through these efforts, Legacy addresses and corrects common misconceptions about scientific research, effectively communicates the risks and rewards of participation and rebuilds trust.

National HIV/AIDS Priorities, Agendas, & Health Reform

The local, state, and national HIV agenda for the next five years will be greatly influenced by the National HIV/AIDS Strategy (NHAS) which was introduced by the ONAP in July 2010. There are three primary goals in this strategy: 1) reduce the number of people who are infected with HIV, 2) increase access to care and optimize health outcomes for people living with HIV, and 3) reduce HIV-health related disparities.⁵ These goals will guide programmatic, policy and funding priorities related to the HIV epidemic in the US. Legacy’s focus and efforts to address issues underlying participation of underrepresented groups in HIV clinical trials and other research are in line with and works toward all three goals. The strategy also focuses on three target populations, gay and bisexual men, and Black and Latino communities, all of whom are also a focus for Legacy.

Currently, the Legacy Project partners with a number of national and community-based organizations to: share information and materials about all NIAID networks; co-sponsor conferences, meetings and events to educate communities about HIV, research, and clinical trials; and promote involvement in the research process (Appendix D). Through the NHAS, the national government has prioritized establishing and promoting community-level approaches to reducing the HIV epidemic in highly impacted groups.⁶ This gives the Legacy Project an opportunity to work across NIAID networks, national and community organizations to enhance their work with educating communities about potential HIV biomedical research and clinical trials, and to support organizations and research sites in the promotion of culturally appropriate research participation and assist partner organizations in creating and implementing more innovative and effective strategies and messaging around testing, care and research. Moreover,

federal agencies acknowledge that service organizations have a deep reach and great knowledge of communities highly impacted by HIV.⁷ Therefore, it is important for Legacy to partner with organizations that have both a nuanced and broad awareness of target populations.

As the Legacy Project continues to build and develop new and existing partnerships, potential areas of collaboration could include informing partner organizations of best practices on service delivery; promoting HIV research advocacy and policy changes to non-governmental organizations outside of its networks; developing trainings for NGO staff on biomedical interventions, research and testing recruitment strategies; and linking clients to research. To accomplish these objectives, a possible strategy could include developing a stronger online presence using blogs, newsletters, digests, webinars and social media to raise awareness about the Legacy Project, educating targeted communities on HIV biomedical research, and linking network organizations. One of the most significant recent developments in HIV prevention from the Centers for Disease Control and Prevention (CDC) and the White House has been the implementation of a five-year national social marketing initiative known as the Act Against AIDS Campaign.⁸ The campaign's aim is to combat complacency and mobilize specific communities around HIV prevention as well as educate and raise awareness of prevention options.

This campaign can serve as a guide for Legacy's potential social marketing efforts that target myths and mistrust, and raise awareness of biomedical and other interventions, trials, and research, particularly in geographic hotspots such as the Northeast and the South. Lastly, the proposed congressional reduction of non-security related discretionary spending for FY2011 to FY2008 levels would cut HIV/AIDS funding programs from \$7.58 billion to \$7.09 billion, a decrease of 6.5%.⁹ This, along with cuts at the state and local levels impacting CBOs, could cause a decrease in services offered, restructuring and changes in current plans for both organizations and agencies, which could impact Legacy's ability to collaborate with partners and achieve goals as partner priorities change due to resource limitations. Legacy's vision, mission, and operating principles are strategically aligned with national HIV/AIDS priorities and agendas, and with national, state and local agencies that support community engagement work.

Patient Protection and Affordable Care Act (PPACA)

The Patient Protection and Affordable Care Act will have a profound impact on biomedical research, AIDS service organizations and Legacy's target populations. The act will expand healthcare coverage, increase funding for biomedical research and expand access to healthcare for many individuals in Legacy's communities. Many ethnic and sexual minority communities disproportionately lack health insurance and come from socioeconomically disadvantaged backgrounds. Through healthcare reform, the Medicaid threshold will rise to 133% of the federal poverty level (around \$30,000 for a family of four) and healthcare exchanges and subsidies will provide health insurance coverage for individuals and families who make up to 400% of the federal poverty level.

Providing healthcare coverage for individuals and families who are uninsured or underinsured will help alleviate some of the burden of many AIDS service organizations. Having more people covered by health insurance will lead to a greater awareness and ability to address health issues that impact many ethnic minority communities, such as AIDS, obesity, heart disease, and cancer. This will ultimately lead to more individuals interfacing with the healthcare system, which will hopefully translate into more HIV testing, treatment and clinical research opportunities. Even if increased availability to health care expands, access to quality resources for Legacy's target population is often limited.

To this point, the health care bill will also increase the amount of funding dedicated to community health centers across the country. Over \$11 billion will be spent over the next five years to build community health centers which will provide primary care health services to over twenty million patients.¹⁰ Many of the health centers will be located in urban and rural areas, where many of Legacy's target communities are concentrated. Establishing these new community health centers will provide new opportunities for collaboration with Legacy and its partners, such as expanding HIV testing and providing primary care for HIV-positive individuals. The centers could also serve as valuable spaces to raise awareness and encourage enrollment into HIV biomedical clinical trials.

The Healthcare Reform Act will also have implications for biomedical research. Through the act, NIH will have a new funding stream known as the Cures Acceleration Network (CAN). This new funding stream will provide up to \$500 million per year to translate basic research into treatments.¹¹ These funds would be ideal for HIV biomedical prevention research, but are not likely to be allocated for this purpose. Moreover, CAN mandates close collaboration between the FDA and NIH, which should streamline licensing and the rollout of new successful HIV biomedical prevention research products.

However, some states may face difficulty in increasing their primary healthcare delivery for the millions of new patients who will be added into the insurance rolls by the expanded Medicaid coverage and other healthcare subsidies. A recent article in the *New England Journal of Medicine* highlighted this issue as researchers examined all 50 states' primary care capacity and the number of new people estimated to receive healthcare as a result of the new act. Eight states (Oklahoma, Georgia, Texas, Louisiana, Arkansas, Nevada, North Carolina, and Kentucky) are predicted to have the greatest difficulties in responding to the increased number of patients as a result of the Medicaid expansion.¹² This poses a particular problem as many of the states on this list have a great number of individuals from the target population that Legacy serves. Furthermore, many of these states have high rates of HIV and other STI infections. Lastly, there is currently an effort in Congress to repeal health care. If the repeal is successful, many of the proposed reforms are in danger of not being fully implemented during the next five years.

NIH Office of AIDS Research (OAR) & Division of AIDS (DAIDS)

The Division of AIDS (DAIDS) is a division of the National Institutes of Health's National Institute of Allergy and Infectious Diseases that sponsors a portion of Legacy's efforts. DAIDS was established in 1986 in order to tackle the HIV/AIDS epidemic. The current mission of the division is to "help ensure an end to the HIV/AIDS epidemic by increasing basic knowledge of the pathogenesis and transmission of the human immunodeficiency virus (HIV), supporting the development of therapies of HIV infection and its complications and co-infections, and supporting the development of vaccines and other prevention strategies".¹³ While DAIDS works to carry out its mission through its eight research programs and offices, most strategic planning of the National Institutes of Health's HIV/AIDS agenda is conducted by the NIH Office of AIDS Research (OAR).

As of late, OAR has been placing increasing emphasis on its support of biomedical interventions as a means of combating the HIV/AIDS epidemic. HIV vaccine clinical trials, HIV microbicides, the use of therapeutics as a means of decreasing spread of the virus, and further study of the HIV virus itself are all top priorities on OAR's research agenda.¹⁴ Biomedical interventions will continue to be one of Legacy's main focuses. The purpose of the NIH OAR is to "coordinate the scientific, budgetary, legislative and policy elements of the NIH AIDS research program".¹⁵

Each year, OAR conducts a process of "planning, budgeting, and portfolio assessment"¹⁶ in order to ensure emphasis is placed on those areas of research that show the greatest promise. The products of this process include the annual Trans-NIH Plan for HIV-Related Research, and the NIH AIDS Research Budget, both of which are instrumental in decision making in all areas of NIH's HIV-related research portfolio. Lessons learned from Legacy's work, findings from Legacy pilot projects, and Legacy's connection to communities and national and community-based organizations could prove valuable to the development of the Trans-NIH Plan for HIV.

The annual Trans-NIH Plan for HIV-Related Research is congressionally mandated under the Public Health Service Act. It functions as the strategic plan for OAR and NIH HIV-related activities. Legacy has the capacity to contribute to the framing of the document by outlining issues that should be addressed: how to assess and measure community engagement and culturally sensitive research environments, what infrastructure and capacity needs communities have to effectively engage in and contribute substantively to research, and factors related to recruit, enrollment and retention. The FY 2011 Trans-NIH plan includes several overarching priorities to be considered when conducting NIH HIV research. Each priority includes several objectives of interest. Outlined below are those Trans-NIH priorities for 2011 that directly relate to biomedical interventions¹⁷:

Expanding Basic Discovery Research: Objectives include investigating the biology of HIV transmission, HIV virology and pathogenesis, HIV immunopathogenesis, the pathogenesis of opportunistic infections and co infections, the pathogenesis of metabolic and body composition change, and the pathogenesis of malignancies, organ and tissue disorders, and neurological disease.

Reducing New Infections: Great emphasis is placed on vaccine development with objectives including: vaccine research, development and testing, investigation into pediatric vaccines, conduction of vaccine clinical trials, and development of strategies to prepare populations for vaccine trials (i.e. underrepresented populations). Emphasis is also placed on the research and development of HIV microbicides including pre-clinical and clinical trials. A third area of emphasis is behavioral and social science research.

Improving Disease Outcomes for HIV-Infected Individuals: Primary objectives under this priority include drug discovery, development, and treatment, to conduct clinical trials of anti-HIV treatments, development of therapeutic strategies for preventing and treating complications of HIV infection, prevention and treatment of HIV-related co-infections, novel treatments of AIDS-related cancers and neurologic disease, and research into immune reconstitution approaches.

Legacy is uniquely positioned to inform the development of the Trans-NIH plan for HIV, based on Legacy's knowledge and experience working to build trust in communities and investigating factors related to participation in trials and research. Legacy may be able to provide insight to answer pivotal questions, such as: On which communities should the plan focus? How does the plan support inclusion of underrepresented groups at all stages of the research process? What mechanisms does the plan put in place to assure that the research protocols, methods and environments are cultural sensitive? OAR is also responsible for creating and presenting the annual Trans-NIH AIDS Research Budget and presenting it to congress. While the final FY 2011 budget has not yet been published, preliminary estimates indicate a significant continued investment in HIV-related biomedical research.

The FY 2011 OAR budget estimates show NIH's continued commitment in the area of HIV/AIDS research. Legacy can assist in determining how resources are allocated within these areas. In light of the significant investment in areas of biomedical interventions, including vaccines and

microbicides, significant opportunities may exist or become available in the near future. These represent potential areas of growth for Legacy to expand efforts to provide technical assistance related to organizational systems of both research establishments and organizations, knowledge, and human resources; and share research findings, best practices, and skills related to building trust, educating communities, and factors related to research participation. These also represent potential areas to expand efforts to raise cultural sensitivity and awareness among networks, sites and researchers, and to collaborate with partners on building capacity and infrastructure of organizations to become more involved in research and to strengthen the testing, treatment, research links.

DAIDS-Supported HIV/AIDS Clinical Trials Networks

Biomedical interventions represent an important component in the battle against the HIV/AIDS epidemic. One of the most promising interventions being investigated is HIV microbicides. Current research is investigating the use of microbicides as a primary prevention tool administered topically, orally or through other modalities. HIV vaccines are another strongly supported potential biomedical intervention. Current vaccine pre-clinical and clinical trials are being conducted globally, with strong support from government and interest groups. Immunological studies are also being performed in order to gain insight into possible new vaccine strategies.

A third biomedical intervention causing great excitement among the HIV prevention community is the use of Pre-Exposure Prophylaxis (PrEP).¹⁸ PrEP studies require HIV negative persons at high risk for infection to take antiretroviral drugs in order to decrease their infection risk. Studies are being conducted worldwide on the effectiveness of this strategy. Recent data from the NIH-sponsored "iPrEx" study has shown the promise in PrEP as an effective prevention strategy. However, more information will be needed to determine the effectiveness of PrEP among a broad range of populations,¹⁹ which again highlights the crucial importance of Legacy's work in ensuring that all populations, especially those traditionally underrepresented, have equal, ethical and culturally appropriate access to research development and participation.

AIDS Clinical Trials Group (ACTG) – ACTG was established by the National Institute of Allergy and Infectious Diseases (NIAID) in 1987. The mission of the ACTG is to conduct research and clinical trials to investigate: pathogenesis of HIV-1 and its complications, evaluate treatment and prevention strategies targeting HIV-related co-infections and co-morbidities, and to reduce HIV-related morbidity and mortality by disseminating results. "The ACTG established and supports the largest network of expert clinical and translational investigators and therapeutic clinical trials units in the world." The current principal investigator overseeing the network is Dan Kuritzkes, M.D.

HIV Prevention Trials Network (HPTN) – HPTN was established under NIAID in 2000. HPTN consists of a worldwide network of clinical trials focusing on the testing and evaluation of non-vaccine prevention strategies. HPTN focuses mainly on the use of preventative antiretroviral medications, work focusing on co-infections, risk reduction, and structural interventions applied to HIV prevention. The current principal investigator overseeing the network is Sten Vermund, M.D., Ph.D.

HIV Vaccine Trials Network (HVTN) – HVTN is supported by NIAID and consists of 27 trial units located at various institutions around the world conducting research with the goal of finding an "effective and safe HIV vaccine." "The mission of the HVTN is to enhance the discovery and drive the development of a safe and globally effective vaccine for the prevention of HIV through well-designed clinical research trials which objectively and ethically address the critical questions of the field." The current principal investigator overseeing the network is Lawrence Corey, M.D.

International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) – IMPAACT was formed as a merger between two former clinical trials networks: the Pediatric AIDS Clinical Trials Group and the Perinatal Scientific Working Group of the HPTN. IMPAACT is funded by several divisions within NIH. The purpose of IMPAACT is to evaluate “potential therapies for HIV infection and its sequelae in the infant, pediatric, adolescent and pregnant women populations.” The current principal investigator overseeing the network is Jay Brooks Jackson, M.D., M.B.A.

International Network for Strategic Initiatives in Global HIV Trials (INSIGHT) – INSIGHT was funded in 2006 by NIAID. The mission of INSIGHT is to “define optimal strategies for the management of HIV and other infectious diseases through a global clinical research network.” The current principal investigator overseeing the network is James D. Neaton, Ph.D.

Microbicide Trials Network (MTN) – MTN was funded in 2006 by NIAID. MTN is the newest of the six DAIDS-funded clinical trials networks. MTN works through its research network to develop and evaluate “products applied topically or administered orally” with the goal of reducing HIV transmission. The current principal investigator overseeing the network is Sharon Hillier, Ph.D.

All networks and sites should be successfully and appropriately engaging, recruiting and enrolling minority communities in trials. All networks have successes and challenges that can be shared to assist each of the networks in their efforts. Legacy is uniquely positioned to assist with this information sharing, as well as to assist networks in evaluating their own efforts, providing guidance and training regarding community engagement and participant retention, and connecting networks and sites to community leaders and organizations. Legacy can help coordinate networks and provide protocol development assistance.

Interview Findings

Of those on the LPWG, most described their contribution as having been previously involved in projects organized by Legacy or through a partnering organization. Many also characterized their role as assisting the Legacy Project with ideas and advisement. Of Legacy collaborators and network affiliates, most described their involvement with Legacy as stemming from relationships they have developed with Legacy staff or working group members, a project organized by or co-organized with Legacy, or through participation on conference calls or at annual meetings. Of those familiar with Legacy’s work, nearly everyone identified the pilot projects and education as areas where Legacy has had the most success. Legacy’s success in these areas was attributed to personnel, resources and staff’s ability to develop relationships with key individuals in communities and within partnering organizations.

Though the vast majority of those interviewed felt that Legacy has made a positive impact toward increasing the participation of African Americans and Hispanics in HIV prevention and treatment clinical research, they could not determine whether Legacy met its goals, either because they were unsure of what Legacy’s specific goals were or did not know of any evaluation data to suggest Legacy met its goals. Several of those interviewed assessed that the inequities Legacy seeks to address are so great that they will require additional staff to meet programming and organizational needs. Legacy collaborators and network affiliates indicated that areas of expansion for Legacy should include the development of new and untraditional partners, as well as the continued expansion of its community education and pilot projects. LPWG members pointed to increased involvement and engagement of networks, sites and researchers as important areas of expansion for Legacy.

Legacy collaborators and network affiliates expressed a desire for improved communication from Legacy about current projects, how to get more involved and partnership opportunities. LPWG

members suggested that refining Legacy's organizational structure and better engaging NIAID networks would strengthen and enhance the group's work. Roughly half of the LPWG members articulated a need to focus trainings on researchers and principal investigators.

Strengths

All of those interviewed recognized the importance of Legacy's work and identified a number of assets Legacy can leverage and build on in its future work including staff; community engagement, education, pilot project's success and visibility at conferences.

- Legacy has highly motivated, knowledgeable and organized staff that are well regarded and effective at developing relationships.
- Legacy has demonstrated community engagement success, particularly with the Ball community.
- Legacy has demonstrated success in its education, campaigns and pilot projects efforts.
- Legacy is present and visible at conferences.
- Legacy is skilled at explaining, interpreting and making science accessible.

All of those interviewed identified some challenges they perceived Legacy to face either internally or externally. Internal challenges focused on branding (including networks), partnerships and evaluation. External challenges focused on lack of communication between and diversity within networks, and community issues surrounding research funding distribution, research capacity, youth engagement and science literacy.

Internal Challenges

- Legacy has been challenged in clearly communicating its structure and the relationships between Legacy, HANC, HVTN, Networks and NIAID.
- Legacy has been challenged in expanding messaging outside of vaccines.
- Legacy has been challenged in moving beyond staff relationships with leaders of organizations to organizational partnerships.
- While Legacy has had success establishing relationships with national and more well known community leaders, Legacy has not done as well connecting with more grassroots and informal groups doing work on the ground. While Legacy is present and visible at conferences, Legacy is less visible in community settings.
- Legacy plenaries are not as well attended by principal investigators.
- Lack of clarity about who partners are, what constitutes partnership and how organizations and groups become partners.
- Lack of rigorous and robust evaluation measures, tools and activities prevent Legacy from clearly documenting its success.

External Challenges

- Networks are not always aware of each other's efforts.
- There is a lack of diversity among principal investigators and among leadership within the networks.
- Some principal investigators have not been as active and visible in communities, which threatens or limits credibility and trust.
- Research funding distribution between communities and research establishment is a community concern. Recruitment and retention is underfunded.
- Many organizations don't have sufficient research capacity.
- Some local agencies have not been able to reach youth and young adults.
- Communities are challenged in understanding and sometimes intimidated by the science.

Recommendations

A number of recommendations addressed Legacy's work more broadly while others focused on specific challenges. These recommendations targeted Legacy's relationship to NIAID networks, cultural competence within networks, Legacy's research agenda and Legacy community engagement. Within these broad areas, recommendations focused on branding and communication, technical assistance and capacity building, education and mobilization. Most interviewees suggested that Legacy should clarify its focus on all networks, for example, by including all networks in Legacy presentations, co-branding and materials, and communicating more effectively with networks regarding how Legacy is representing and assisting them. Other discussions centered on expanding faith-based initiatives to focus on all biomedical interventions, focusing some conference calls on the needs and activities of networks, and highlighting how Legacy's work is directly relevant to networks. Many interviewees thought engaging in these activities would solicit more input, participation and buy-in from networks.

There was also widespread agreement that researchers and networks need to focus beyond just recruitment for particular studies by building relationships with communities, engaging in cross-cultural exchange and evaluating their cultural responsiveness. It was suggested that data and information Legacy already possesses and new data Legacy can generate can help researchers, networks and sites in this area by providing training, monitoring tools and protocol review, among other forms of technical assistance. Associated discussions focused on the need to identify key individuals within networks who are committed, motivated and see the value in these efforts, and who will bring their knowledge of networks to the group. It was acknowledged that these efforts will engage different networks to varying degrees based on the strengths, challenges and needs of particular networks.

Legacy collaborators and network affiliates proposed that Legacy undertake research projects to study enrollment successes in trials, documenting what works and what doesn't work and dropout characteristics of sites and participants, among other issues. Conversations addressing this point centered on recruitment challenges, conducting community assessments and recognizing that the diversity within larger communities will require initiatives designed to engage particular segments of marginalized groups. Further, interviewees recommended that Legacy collaborate with

networks and other entities external to NIAID to raise awareness, disseminate information and train community members and others to talk about biomedical interventions through webinars, social marketing campaigns and publications. Conversations to this point focused on Legacy serving as a hub of lessons learned and best practices from all stakeholders, connecting organizations and groups in cities around biomedical issues through national capacity building and community mobilization, and developing tool kits for community engagement.

To achieve Legacy's vast research and evaluation goals, it was suggested a full-time rather than a part-time social scientist would be needed. In the words of one interviewee, "There is nothing part-time about Legacy's work." Additional ideas proposed during the interview process that highlight important issues and contribute substantively to the themes covered above include:

- Networks should contribute funding to Legacy and/or figure out how to fund cross network support.
- The re-competition should prioritize or mandate collaboration with Legacy to outline a plan to reach recruitment goals and related issues.
- Partner with schools (Parent Teacher Associations, Gay-Straight Alliances, K-12, colleges/universities, and student groups) and artists or arts organizations.

Vision, Mission, & Organizational Values

Vision

The Legacy Project envisions accurately informed communities actively engaged in clinical research with culturally sensitive research environments and processes.

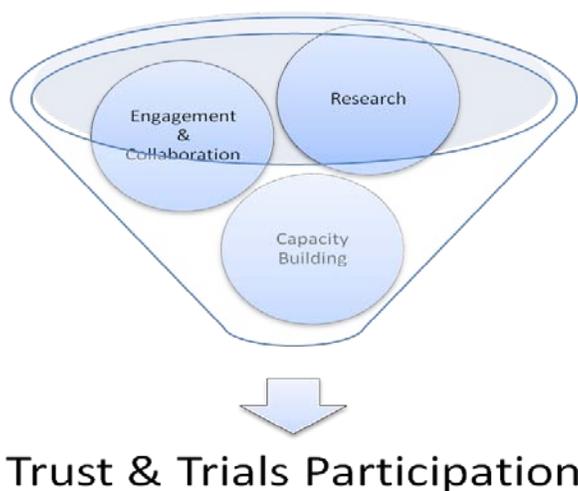


Figure 1

Mission

The Legacy Project’s mission is to build trust and collaboration between historically underrepresented communities most impacted by the domestic HIV epidemic, researchers, and research institutions; enhance cultural competence; and initiate scientific investigation to increase clinical research participation.

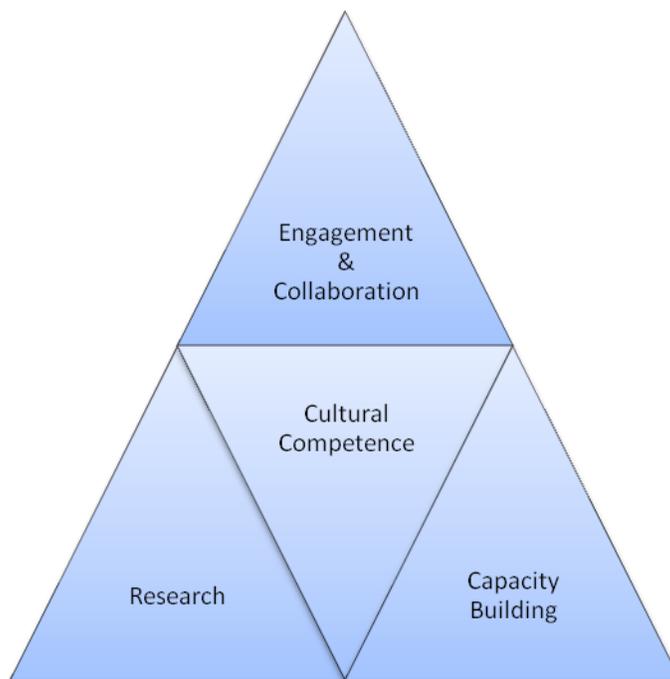


Figure 2

Legacy Project Values:

Inclusion: Participants in HIV research should be proportionate to those populations most impacted by the epidemic.

Leadership Diversity: Cultivation of leaders among communities most impacted by the epidemic.

Innovation and sense of urgency: New ideas, scientific generation of knowledge, and recognizing the importance of expediently addressing the HIV epidemic.

Justice & Equity: Parity, inclusion, and representation of all.

Collaboration: The power of teamwork and cooperation.



Figure 3

Summary

Legacy aims to produce the science that will help networks better understand institutional cultural awareness, sensitivity and responsiveness issues in order to design measurement tools, conduct trainings and recommend policy and practice changes within networks, sites and the research process as a whole. Legacy also aims to identify, through rigorous scientific investigation, community needs and best practice models of community engagement and collaboration for particular subgroups within target communities that could be adapted for use in a variety of settings, including sites and community-based organizations. The knowledge and information gained from these research activities will be disseminated, translated and used to help achieve capacity building and engagement goals.

Legacy aims to use the best available information and tools to improve cultural awareness and sensitivity, and community engagement skills among network, researchers and clinical sites. This includes targeting policies, practices and attitudes to promote culturally sensitive leadership that inform protocol design and implementation, as well as successfully promote HIV clinical research careers to ethnic and sexual minority doctoral students and early career investigators.

Legacy seeks to engage and collaborate with communities to facilitate their involvement throughout the research process. This includes reaching out to communities through formal and informal groups and organizations to increase knowledge about research, biomedical interventions and safety issues. This also includes identifying and creating opportunities for community participation throughout the research process, decreasing barriers to communities

becoming more involved and linking sites with national and community-based organizations for collaboration and trials recruitment.

In order to demonstrate Legacy’s effectiveness and impact, programs, initiatives and activities will be monitored and evaluated; which will require the development of measures and tools. Better understanding cultural competency and community engagement to build capacity within networks and enhance engagement and collaboration between communities, researchers and sites will realize Legacy’s vision to build relationships of trust with communities to increase their participation in all HIV clinical trials and ultimately eliminate HIV/AIDS.

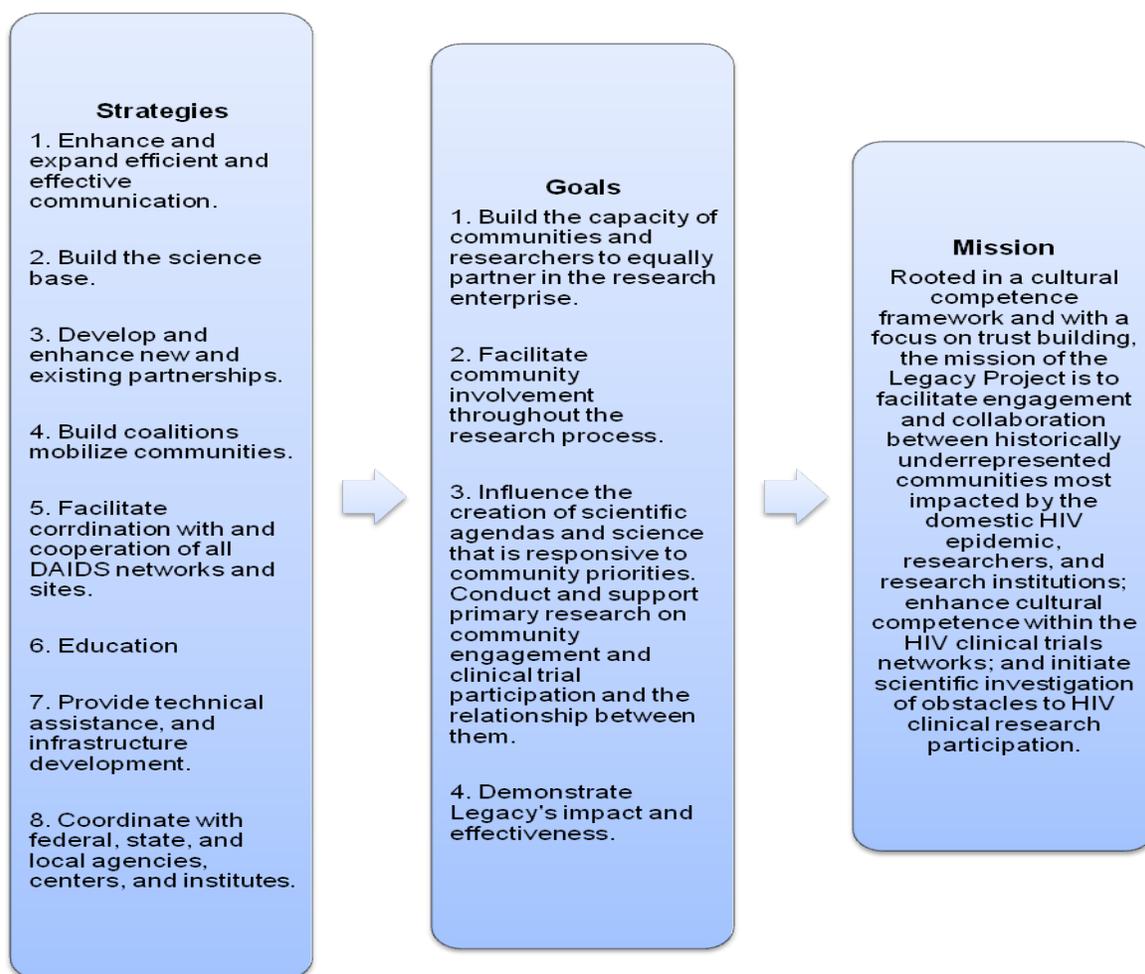


Figure 4

Strategies, Tactics, & Actions

1. Enhance and expand efficient and effective communication with networks, sites, partners, and general public.

1.1. Coordinate with Communications Working Group

1.2. Increase visibility and branding

1.2.1. Promotional materials, newsletters, issue briefs, greater web presence and social media sites

1.2.2. Press packets

2. Build the science base.

2.1. Assess strategies for increasing participation of historically underrepresented and/or most impacted communities in HIV clinical research

2.2. Assess impact of social media in communities historically underrepresented and/or most impacted by HIV

2.3. Coordinate with Behavioral Sciences Working Group

3. Develop a rigorous scientific agenda and an expert scientific base within the Legacy Project and coordinating partners that (i) addresses trial participation among traditionally underrepresented communities, and (ii) promotes and enhances community-engaged and community-responsive research within the networks.

3.1. Help design and participate in one or more community-engaged research projects within network studies

3.2. Evaluate the impact of community engagement in study development and/or implementation on trial participation

3.3. Evaluate the impact of alternative community outreach approaches on increasing and sustaining community engagement within network trials

3.4. Assess the extent of enrollment and retention disparities in network trials and identify approaches to increase participation of traditionally underrepresented communities

3.5. Coordinate with the HANC Behavioral Sciences Working Group to promote greater incorporation of social scientific theory and methodology within biomedical research

4. Engage in bi-directional translational research (translating scientific knowledge to external communities and translating community knowledge to scientific communities).

4.1. Assess attitudes, perspectives, knowledge, and capacity of various communities with respect to clinical trial participation, study design, participation, and interpretation of results

4.2. Disseminate community knowledge to network scientific leadership and staff

4.3. Disseminate network scientific progress to communities in a readily accessible manner

5. Develop and enhance new and existing partnerships with national and community-based organizations, and formal and informal groups.

5.1. Determine and use criteria to select groups and organizations with which to cultivate relationships

5.2. Determine standards for official partnership and if formal agreements will be sought

5.3. Co-sponsor conferences, meetings, and events with partners to enhance communication and community and researcher engagement, education, and training

6. Build coalitions across groups and organizations and mobilize communities.

7. Facilitate coordination with and cooperation of DAIDS networks and U.S. sites.

7.1. Create cultural competency plan for networks

7.1.1. Identify representatives from networks and engage researchers

7.2. Coordinate with Site Coordinators Working Group

8. Education

8.1. Disseminate research findings, best practices, and other information from and to Legacy initiatives, trials, sites and partners

8.1.1. Consult with communities about implications of science and research findings

8.1.2. Establish a clearinghouse for best practices and information sharing between Legacy, networks, sites and partners

8.1.3. Establish a speaker's bureau

8.2. Address relevant current events, news, and issues in the media (e.g., NYT article on vaccine safety)

8.2.1. Develop and implement a scanning and response plan

8.3. Implement social marketing campaign targeting HIV stigma

9. Provide technical assistance and infrastructure development focused on target populations.

9.1. Develop and distribute community engagement, site environment, trials recruitment and readiness examination tools for site and network use

- 9.2. Develop or adapt cultural competence models, materials, and trainings (curricula) for clinical settings focused on Black and Latino communities
- 9.3. Offer culturally appropriate practices and considerations for community engagement and recruitment
- 9.4. Develop accessible dissemination guidelines for researchers and practitioners
- 9.5. Foster continuum and linkages from testing, to care or prevention services, and an awareness of the opportunities to participate in clinical research for those who are both HIV-negative and positive

10. Coordinate with federal, state and local agencies, centers, and institutes to influence HIV research and practice priorities, policies, and funding.

- 10.1. Inform NIH research priorities, trials protocols, and target populations focus domestically
- 10.2. Research advocacy

Summary

Legacy's ability to brand and present itself in a way that facilitates the development of new partnerships, cooperation of NIAID networks and sites, and coordination with agencies, centers and institutes, in part, is a function of how efficiently and effectively Legacy communicates with networks, sites, partners and the general public. One of Legacy's strategies is to enhance and expand efficient and effective communication through the diversification of communication media (e.g., newsletters, issue briefs, social media.). This communication will include information on current Legacy Projects, how potential partners can get involved and information on all networks. This increased visibility and branding will include materials representing and relevant to all NIAID networks as well as target populations of interest.

To build its scientific agenda, Legacy will investigate questions such as how and who is best to approach? How do historical issues of mistrust present themselves today? What needs do communities have to prepare for involvement in research? Building the scientific agenda is critical in informing all of Legacy's work.

Legacy gains access to and develops relationships in communities by partnering with national and local community-based organizations as well as groups. These partnerships enable Legacy to conduct research, share information, and discover and address barriers to engaging in the research process. Future partners may include think tanks, foundations, and community health centers. It will be important to determine what "partnership" entails for Legacy. Partners can be connected to networks and sites for further engagement, follow-up, and potential collaboration and recruitment. These partnerships are also the units that comprise Legacy's mobilization and coalition building efforts.

Legacy will work across partnerships to mobilize communities and resources in particular areas around research advocacy, structural and institutional inequalities, educating communities and other important issues. Legacy will help coordinate, form alliances and organize various segments of communities for specific causes, as well as help build bridges between subgroups within target populations.

Legacy's success depends on the buy-in, support and cooperation of the networks. Legacy will work to coordinate activities across its three primary goals with and through networks when strategically appropriate. This includes co-programming and co-sponsoring.

Legacy produces and has access to research findings, best practices and other information from a variety of sources (e.g., partners, sites, all trials). Legacy is uniquely positioned to organize, store, disseminate, translate and make this information accessible in numerous forms (e.g., clearinghouse database, speaker's bureau, presentations, discussions, publications). This information could be useful to partners, researchers, networks and sites related to engagement and cultural competence. This information will also be used to help explain the science of biomedical interventions, correct misunderstandings about clinical trials and motivate communities to get involved in research.

One of the main strategies Legacy will employ is to provide technical assistance and infrastructure development focused on target populations to networks, sites and partners. This will include developing and distributing community engagement, site environment, trials recruitment and readiness examination tools for site and network use. Community partners could also use the community engagement tools and Legacy could assist partners in expanding their research capacity. This strategy also includes developing and adapting cultural competence models, materials and trainings for clinical and partner organization settings focused on Black and Latino communities broadly as well as particular groups within these overarching communities. Legacy will offer culturally appropriate practices and considerations for community engagement and recruitment, as well as develop accessible dissemination guidelines for researchers and practitioners.

These strategies are interrelated and are applicable to multiple goals. Many of these strategies will be drawn on simultaneously to work toward achieving a particular goal.

Priority Populations

Primary

Black & Latino

Secondary

Women

Youth

Transgendered, Gay, & Bisexual Communities

Given the vast diversity within communities, it will be important to identify subgroups within primary and secondary populations to assure that highly impacted communities are not overlooked or left out (e.g., low socioeconomic status, House/Ball communities, and communities in the Southern and Northeastern regions).

Definitions

Community Education

The provision of information to communities about research in order to increase awareness and knowledge about science to a level where individual informed consent can be obtained in an ethical manner. Community education addresses cultural attitudes and beliefs that present barriers to trial participation or to supporting participants.

Community Engagement

The development and maintenance of partnerships and quality relationships with a variety of stakeholders to develop trust and engage those partners in a shared vision. Community engagement requires commitment to a process of developing shared principles and values for the mutual benefit of all parties.

Cultural Competency

A set of behaviors, attitudes, activities, and policies that come together to address racial, ethnic and cultural characteristics in order to increase participation of populations disproportionately affected by the HIV epidemic. A culturally competent research enterprise should have the capacity to educate, recruit and retain individuals regardless of each participant's core beliefs, values and differences. To achieve cultural competency throughout the research enterprise, all participants must embrace this goal as fundamental in the pursuit of HIV clinical research.

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Appendices

A: Taskforce Members

Borris Powell
Damon Humes
Georgette King
Jeff Schouten
Karl Shaw
Michael Lanier

Michele Andrasik
Paris Mullen
Stephan Oxendine
Steve Wakefield

B: Interview Guides

1.1 Individual Interview Guide & Questions

I want to thank you for taking the time to meet with me today. This interview is one of several ways of gathering information that will inform Legacy Project's strategic planning efforts. My name is Louis Graham and I am part of a taskforce charged with facilitating Legacy's strategic planning process. I would like to talk to you about several topics today including your knowledge, perspectives, and ideas regarding Legacy, its staff and programming, and its future. This information will be used along with other data to help ensure a successful future for Legacy.

The interview should take about one hour. Because I don't want to miss any of your comments, I will be taking notes. All sensitive responses will be kept confidential. This means that sensitive interview responses will only be shared in aggregate with taskforce members and we will ensure that any information we include in our report does not identify you as the respondent.

Do you have any questions?
Are you willing to participate in this interview?
Thank you. Let's start the interview questions.

Interview Questions

1. **What is your role on the LPWG?**
 - a) What has your contribution to the LPWG been?
 - b) Describe how Legacy makes decisions and goes about its work.

2. **What does Legacy do best related to programming, management, and communication?**
 - a) What is working best within Legacy involving primary research, pilot projects, and administrative operations and sustainability?
 - b) How does Legacy engage its collaborators related to cultural competence?

3. **Describe Legacy's primary successes and top achievements related to increasing the participation of African-Americans and Hispanics in HIV prevention and treatment clinical research?**
 - a) How did Legacy achieve these goals?
 - b) What accounts for Legacy's success?
 - c) To whom and what would you attribute these accomplishments?
 - d) When and where were these successes achieved?

4. **In your view, has Legacy met its goals related to addressing inequities?**

- a) Why/why not?
 - b) What challenges does Legacy face in meeting its goals?
 - c) How can these challenges be addressed?
5. Looking ahead, what are the most likely factors that could prevent Legacy from fulfilling its mission?
- a) E.g. activities, attitudes, assumptions, etc.
6. Does Legacy have all of the resources it needs to meet its goals?
- a) E.g. staff, funding, etc.?
7. In what ways should the LPWG expand or contract its work, if at all?
- a) Who would be key players in this effort?
 - b) To what end would this expansion or contraction serve?
8. Based on your role and contribution to the LPWG, what would strengthen, improve, or enhance your and the groups work?
9. What could Legacy do better regarding training and community education?
10. Is there anything else you would like to add that we have not already covered?

Closing

The taskforce will be analyzing the information you and others have provided and compiling findings. Thank you for your time!

1.2 Individual Interview Guide & Questions

I want to thank you for taking the time to meet with me today. This interview is one of several ways of gathering information that will inform Legacy Project's strategic planning efforts. My name is Louis Graham and I am part of a taskforce charged with facilitating Legacy's strategic planning process. I would like to talk to you about several topics today including your knowledge, perspectives, and ideas regarding Legacy, its staff and programming, and its future. This information will be used along with other data to help ensure a successful future for Legacy.

The interview should take about one hour. Because I don't want to miss any of your comments, I will be taking notes. All sensitive responses will be kept confidential. This means that sensitive interview responses will only be shared in aggregate with taskforce members and we will ensure that any information we include in our report does not identify you as the respondent.

Do you have any questions?
Are you willing to participate in this interview?
Thank you. Let's start the interview questions.

Interview Questions

11. **In what ways or in what capacity do you partner/collaborate with Legacy?**
 - a) Describe your working relationship with Legacy.
 - b) How does Legacy operate in a partnership?
 - c) Characterize your collaboration with Legacy.
 - d) When did you begin partnering with Legacy and for what primary reasons?
12. **What does Legacy do best related to programming, management, and meeting partners' expectations?**
 - a) What is working best within Legacy to help meet partners' needs?
 - b) How does Legacy engage its collaborators and build and maintain its partnerships?
13. **Describe Legacy's primary successes and top achievements related to increasing the participation of African-Americans and Hispanics in HIV prevention and treatment clinical research?**
 - a) How did Legacy achieve these goals?
 - b) What accounts for Legacy's success?
 - c) To whom and what would you attribute these accomplishments?
 - d) When and where were these successes achieved?
14. **In your view, has Legacy met its goals related to addressing inequities?**
 - a) Why/why not?
 - b) What challenges does Legacy face in meeting its goals?
 - c) How can these challenges be addressed?
15. **Looking ahead, what are the most likely factors that could prevent Legacy from fulfilling its mission?**
 - a) E.g. activities, attitudes, assumptions, etc.
16. **Does Legacy have all of the resources it needs to meet its goals?**
 - a) E.g. staff, funding, etc.?
17. **In what ways should Legacy expand or contract its work, if at all related to partnership and relationship development?**
 - a) Who would be key players in this effort?
 - b) To what end would this expansion or contraction serve?
18. **As a Legacy collaborator, what needs do you or your organization have that Legacy may be able to help with?**
 - a) Capacity and infrastructure needs related to clinical research participation
19. **What could Legacy do better regarding training and community education?**
20. **Is there anything else you would like to add that we have not already covered?**

Closing

The taskforce will be analyzing the information you and others have provided and compiling findings. Thank you for your time!

C: Interviewees

Andrew Spieldenner
Borris Powell
Katharine Kripke
Cornelius Baker
Damon Humes
Edwin Sanders
Gary Daffin
Georgette King
Jeff Schouten
Kimberly Parker
Marjorie Hill
Michael Keefer
Michael Lanier
Paris Mullen
Sharon Lettman-Hicks
Sheldon Fields
Stephan Oxendine
Steve Wakefield