ADDRESSING SUB-SAHARAN AFRICA'S BURDEN OF ENDEMIC DISEASES: A CASE FOR MANDATORY CITIZEN PARTICIPATION IN RESEARCH ON MALARIA AND TYPE 2 DIABETES

by

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Abstract

Driven by a passion for ethical compliance in health practices and research in sub-Saharan Africa (SSA), this thesis explores how Indigenous African bioethics can align with and enhance global moral principles to improve health outcomes. SSA bears a heavy disease burden, with endemic conditions like malaria and Type-2 Diabetes Mellitus (T2DM) posing significant health crises. These issues, responsible for over half a million annual deaths in SSA from malaria-related illnesses alone, should be recognized as health emergencies requiring urgent action.

The thesis advocates for mandatory participation in research-based interventions targeting malaria and T2DM across SSA, given malaria parasite's unpredictable behavior and SSA's low health literacy. While acknowledging concerns about personal autonomy and privacy, it argues that the ethical imperative to save lives and reduce suffering outweighs these concerns. The work also proposes safeguards, grounded in SSA's culturally embedded values and ethos, to protect participants and communities from exploitation during and after these interventions.

General Summary

Malaria and Type 2 Diabetes Mellitus (T2DM) are widespread in sub-Saharan Africa (SSA), contributing significantly to the region's heavy disease burden. Each year, malaria alone causes over half a million deaths in SSA, mostly among children under five. The global health community and SSA governments are alarmed by this crisis, which I believe should be declared an international health emergency to spur urgent action.

Persistent poverty and low health literacy in the region worsen the situation. Malaria parasites often behave unpredictably, and many people with T2DM are unaware of their condition. In this thesis, I advocate for the mandatory participation of all SSA populations in research-based interventions to improve efforts to control and eradicate malaria and T2DM. My proposed eradication framework includes strong protections to prevent abuse and exploitation of research participants and host communities during and after the intervention.

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List of Abbreviations

AMS	Anti-Microbial Stewardship
CAB	Community Advisory Board
CDC	Centers for Disease Control and Prevention
CIOMS	Council for International Organizations of Medical Sciences
COVID-19	Coronavirus Disease 2019 pandemic
CRF	Constitutional Rights Foundation
CSOs	Civil Societies Organizations
DSMB	Data and Safety Monitoring Board
EDCTP	European and Developing Countries Clinical Trials Partnership
GDA	Gestational Diabetes Mellitus
GDP	Gross Domestic Product
GDPR	General Data Protection Regulation (of the European Union)
GTS	General Technical Strategy (for malaria eradication)
HIV/AIDS	Human immunodeficiency Virus/Acquired Immunodeficiency Syndrome
IDF	International Diabetes Federation
IRB	Institutional Review Board
LMICs	Low- and Middle-Income Countries
MDA	Mass Drug Administration
MDGs	Millennium Development Goals
NCDs	Non-Communicable Diseases
RBM	Roll Back Malaria
REB	Research Ethics Board
REC	Research Ethics Committee

SDGs	Sustainable Development Goals
SSA	Sub-Saharan Africa (comprises all 54 African countries except the five North African countries - Egypt, Algeria, Libya,Tunisia, and Morocco)
TCPS2	Tri-Concil Policy Statement 2
T2DM	Type 2 Diabetes Mellitus
UNDP	United Nations Development Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNICEF	United Nations Children's Fund (formerly United Nations International Children's Emergency Fund)
WHO	World Health Organization
WMA	World Medical Association

Dedication

This work is dedicated to Bill Gates for his exceptional dedication and ongoing efforts toward eradicating endemic diseases and abject poverty in sub-Saharan Africa.

Chapter 1

Introduction

1.1 General Introduction

This thesis argues in favour of mandatory, population-wide participation in health research in sub-Saharan Africa (SSA). The main compelling reasons for this drastic step in research ethics are the catastrophic impact of endemic infectious and chronic diseases in the region, coupled with extreme poverty and weak health systems.

The African continent bears the world's highest burden of infectious diseases, a situation exacerbated by its fragile health system infrastructure (WHO Africa, 2022; Leone et al., 2022). By 2030, unless urgent action is taken, the total healthcare cost for diabetes in SSA will reach US$35-59 billion (IDF, 2021). Globally, malaria is responsible for about 600,000 annual deaths (2019), with about 90% occurring in Africa; and children under the age of five are its main victims (Roser & Ritchie, 2019). Type 2 Diabetes Mellitus (T2DM) is another major health challenge for SSA. It affects about 24 million adults (aged 20–79) in the region, a number that is estimated to grow to 47 million by 2045 (WHO Africa, 2022), with most of those affected undiagnosed and unaware of their critical health condition (WHO, 2021).

The scourge of SSA with the world's largest endemic disease burden (Leone et al., 2022) is not only limited to malaria and T2DM diseases. In addition to malaria, the life-threatening endemic communicable diseases in SSA include lower respiratory tract infections, polio, tuberculosis, HIV/AIDS and diarrheal diseases, which together are estimated to cause over three million deaths annually (WHO, 2023). However, my choice of malaria for the infectious disease case study in this work is characterized by its particular tenacity, which, unlike many other communicable diseases, defies measures to eradicate it. Likewise, I selected T2DM for the noncommunicable diseases (NCDs) case study in this work alongside other endemic NCDs in SSA (such as cardiovascular disease, kidney disease, cancer, and mental disorders due to substance abuse) to demonstrate that T2DM’s prevalence in SSA is increasing disproportionately beyond the global average and that it requires urgent attention for improved health outcomes in SSA. Implementation of appropriate public health measures to combat the menace of malaria, T2DM and other endemic diseases has therefore become a health priority for SSA countries.

1.2 SSA's Disproportionate Burden of Endemic Diseases – Causes and Effects

Many factors have been cited as responsible for poor health in SSA. These include, for example, the pervasive multidimensional poverty in Nigeria (second only to India’s), which is estimated to affect over 133 million Nigerians, accounting for over 60% of the citizenry (Ahmad, 2022). Multidimensional poverty illustrates the complexity of poverty in developing economies like India and Nigeria where income alone does not capture the full extent of deprivation. It reflects the interconnected challenges that prevent people from achieving a minimum quality in living standards - nutrition, housing, health, and education. It is commonly assessed using the Multidimensional Poverty Index (MPI), developed by the Oxford Poverty and Human Development Initiative (OPHI) and the United Nations Development Programme (UNDP).

SSA's population is among the fastest growing in the world, growing at over 2.6% annually (about three times the global average) and is predicted to double by 2050 (The Economist, 2023). Ironically, SSA's GDP growth rate is the opposite of population growth, which accounts for the poor socioeconomic and fiscal outlook and rapidly declining per capita income. SSA is home to approximately 579 million poor people living on less than US$1.90 per day, with more than half of them under the age of 18 (UNDP, 2022). Paradoxically, low- and middle-income countries (LMICs), of which SSA is an integral part, account for approximately 8% of the world's population, yet control less than one percent (1%) of global wealth (UNDP, 2022). Part of the overall impact of all this on SSA is the poor health profile and increasing burden of disease.

The United Nations and several well-meaning non-governmental organizations are unsettled by this situation and appear determined to change the narrative for a fairer world health order. South Africa’s former President Nelson Mandela summed up this situation when he said that “overcoming poverty is not a gesture of charity. It is an act of justice. It is the protection of a fundamental human right, the right to dignity and a decent life” (Guterres, 2018, p.1). In addition to the unequal distribution of global wealth between regions and its reinforcement through structures such as globalization, the lack of health care and general socioeconomic inadequacies in SSA are also consequences of endemic corruption and poor governance practices (Sobrinho & Thakoor, 2019; Roese-Ackerman, 2004).

The United Nations’ Sustainable Development Goals (SDGs) and their predecessors, the Millennium Development Goals (MDGs), are ongoing and current efforts towards a fairer and more prosperous world free of hunger, ignorance, poverty and disease. Part of the SDG health agenda is health for all by 2030 through universal health coverage (United Nations, 2015). The United Nations recognizes in its SDG agenda that eradicating extreme poverty is a prerequisite for achieving global health equity and well-being (United Nations, 2015). In SSA, where extreme poverty is pervasive and chronic, one can rightly conclude that poverty is both a cause and a consequence of the region's high disease burden. Governments in SSA countries and their foreign partners and donors, in a move to improve health infrastructure, have made concerted efforts over the years to reduce the burden of disease in SSA, but these are hardly sufficient (WHO, 2023; WHO Africa, 2022). Some of the successes achieved in this regard are more pronounced in the control of infectious diseases (as opposed to non-communicable diseases), as primary health care has been significantly improved and has led to the effective eradication or control of polio and other communicable diseases throughout the SSA region (EDCTP, 2018).

Eradication of malaria and several other SSA-endemic diseases, including T2DM, would require more than just sufficient financial and human (medical) resources (Oleribe et al., 2019). As outlined in the Global Multidimensional Poverty Index 2022 report, education, health and living standards are co-dimensions of poverty, all of which need to be adequately addressed through interventions aimed at eradicating poverty or improving the overall health of the population (Ahmad, 2022; UNDP, 2022). Because disease is a cause, not just an effect of poverty, attempts to alleviate poverty alone may not be effective without appropriate efforts to control and eradicate disease. Health research must be part of this effort. For example, eradicating malaria in SSA is a multidimensional task that requires preventive, diagnostic and curative measures that are collaborative and well-coordinated in a sustainable manner to achieve optimal outcomes (WHO, 2017a). This requires a certain level of health literacy in the population or a targeted subpopulation (McClintock et al., 2020). In SSA, where resource scarcity is a chronic problem, preventative measures such as controlling mosquito vectors through proper sanitation and the use of insecticide-treated bed nets are typically a priority. No matter how cost-effective and effective these may be, people need a certain level of health literacy and self-discipline for these measures to make a significant impact.

The same applies to T2DM control in SSA. The task of controlling the prevalence of T2DM in a predominantly illiterate population is even more complicated and challenging. Since it is a disease that is often asymptomatic, especially at the onset, regular check-ups and other diagnostic measures are usually required to diagnose, treat and manage the disease (Khan et al., 2020). For people who have already been diagnosed as prediabetic or diabetic, treatment and management protocols include regular blood glucose testing, diet, regular physical activity, medication, and maintaining a stress-free lifestyle to keep blood sugar within normal range, to ward off fatal complications (Cleveland Clinic, 2022). Therefore, low health literacy is a major barrier to improving health care in SSA (McClintock et al., 2020).

1.3 Thesis Position

SSA's low health literacy is a barrier to the voluntary participation by its citizens in clinical trials and research to improve the health situation and general well-being of citizens. Relying on the definition of health literacy by the National Academy of Medicine, McClintock et al. (2020, p. 907) defined health literacy as "the degree to which individuals have the capacity to obtain, interpret, and understand basic health information and services necessary to make appropriate health decisions". Despite the advent of social media and the associated ease of mass dissemination of information around the world, the poor literacy status of many SSA countries prevents most of their citizens from benefiting from readily available health promotion on various social media platforms. For example, in Europe and North America, diseases such as T2DM can be effectively self-treated or managed by many sufferers, supported by publicly available digital health resources (Zhang et al., 2023). However, the situation is different in SSA as many T2DM patients are undiagnosed and unaware of their health condition, which may require urgent medical attention (WHO, 2021).

Superstition plays a significant role in shaping health habits and behaviors in SSA societies. As a psychological construct, superstition involves culturally transmitted irrational beliefs or behaviors that arise from uncertainty, fear, ignorance, or habit formation (Mandal, 2018). These beliefs hinder health literacy and can have significant health and cost implications for decision-making among adherents, especially in low education environments such as SSA (Ukpabi, 2021; Umar, 2014). Superstition often leads individuals to neglect evidence-based facts, favoring irrational or mystical explanations for health conditions, pestilence, public health disasters, or natural occurrences such as accidents, deaths, thunderstorms, and tornadoes (Uwayezu et al., 2022; Ukpabi, 2021). This is why many people in SSA societies and other LMICs seek instant healing for their ailments from spiritual healers and traditional soothsayers instead of orthodox health facilities (Sharma et al., 2021; Sarkar et al., 2014). Faith healing, when used as a complement to conventional medical therapy, can be considered both innocent and ethical, respecting the patient's right to choose their treatment options. However, it should not irrationally expose patients to harm or exploitation by spiritual charlatans and merchants (StudyCorgi, 2020; Nyiribakwe, 2019).

Aside from low health literacy and superstition, widespread poverty significantly impacts health outcomes in SSA populations. Many citizens lack health insurance coverage, resulting in the need to pay medical bills out of pocket. This is often unaffordable, particularly for those with chronic conditions such as diabetes and recurrent malaria, who typically have low or unstable incomes (Barasa, 2021).

Given the prevailing enormous burden of T2DM and malaria in SSA countries and the need to curb their further worsening, the need to improve health care in SSA through research has never been more urgent. The World Medical Association recognized the critical importance of research in improving health by stating that

> "the purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease. In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research. Medical progress is based on research which ultimately must rest in part on experimentation" (1997, p. 925).

Therefore, it is worthwhile and laudable to implement every possible intervention that can change the narrative in the shortest possible time to protect lives from endemic deadly diseases in SSA.

Research-oriented interventions have proven to be effective in eradicating malaria in several countries such as China and Morocco. Accordingly, in this thesis, I will argue for mandatory citizen participation in health research in SSA as an expedient measure to mitigate the threats posed by endemic deadly malaria and T2DM diseases to the populations of the SSA region.

Mandatory citizen participation in health-related research, as proposed in this work, would require a mandatory commitment from citizens of SSA countries to participate in one or more health-related investigations, such as clinical trials and health (behavioral) surveys, within specified time periods. The clinical trials and surveys offer valuable opportunities for general health screening to identify participants who may be infected with malaria or other endemic diseases prevalent in SSA, as well as those with health conditions such as T2DM.

These research initiatives would be administered by designated government agencies or partners under the overall supervision of the Minister for Health and in accordance with an existing statutory health research policy and framework designed to achieve sustainable improvement in public health. In such a planned environment for health research in SSA, the persistent challenge of a shortage of volunteers for research on endemic diseases such as malaria and T2DM would be alleviated to achieve quicker and better outcomes in health research. Mandating the involvement of SSA populations in health research will also create greater public awareness about diseases, including how to prevent and treat them. A wise African proverb says that preventing a disease is better than curing it. This adage is even more compelling in the SSA health context, where low health literacy among citizens and the government's recurring budgetary constraints represent chronic barriers to improving public health (Amu et al., 2022).

The choice of mandatory citizen participation in health research as a pathway to alleviate the disproportionate burden of endemic diseases in SSA is based on other context-specific health realities of SSA as a developing region. There is ample evidence that the health research agenda of high-income countries prioritizes the study of diseases relevant to their country by approximately 700% over diseases of interest to developing regions (Alemayehu et al., 2018; Rottingen, 2013). Similarly, the health research agenda for SSA should prioritize strategies that ensure widespread and sustained citizen involvement in all efforts to eradicate and control endemic malaria and T2DM. These two diseases have persistently and increasingly caused more deaths and suffering than any other to SSA populations for decades. This approach is crucial for achieving the region's overall health objectives.

Furthermore, it is clear from the standard treatment and management protocols for malaria and T2DM that they share many similarities with typical global health research and clinical trial protocols. These include screening and regular monitoring (diagnosis), mass drug/medication administration (treatment), and diets and regular physical activities (prevention), which are based on a ‘test and treatment’ research model in accordance with the ‘common rule’ and other ethical research guidelines (Shapiro & Meslin, 2001). Many people in SSA who develop diseases such as HIV/AIDS, tuberculosis, or T2DM are eligible for therapeutic research or clinical trials when available. Voluntary participation would minimize its own costs and provide access to some level of health care. However, this is not always the case in many SSA societies, where poverty, ignorance, fear of stigma, and societal norms often pose serious barriers to participation or retention in clinical trials and health research (Mesic et al., 2019). Mandating citizen participation in health research will foster a culture of health awareness among the SSA population. This, in turn, will increase their involvement and enable them to benefit from current and emerging clinical trials and research.

Considering the above-mentioned anomalies in SSA, the reality of public health management inadequacies highlights the ethical imperative to find an urgent solution to this health emergency and save lives. This is particularly important in light of the poor prospects for improvement in managing the rising incidence and virulence of endemic diseases and their rising death toll, which collectively reaches three million per year for malaria, HIV/AIDS and tuberculosis (WHO, 2023).

Mandatory citizen participation in health-related research in SSA holds enormous promise as a starting point for addressing its high burden of diseases. In this thesis, I aim to demonstrate how promoting active citizen participation in health research and measures can create synergies to address various socio-economic challenges in the region, such as resource scarcity, inadequate health infrastructure and human resources, low health literacy, widespread poverty, and poor governance practices. While participation alone cannot fully resolve issues like resource limitations and governance shortcomings, it can contribute to fostering awareness, collective action, and more informed policymaking.

Furthermore, through a test-and-treat investigational model for malaria, mandatory participation would achieve constructive collaboration toward cost-effectiveness, targeted and sustained health capacity improvement, population-wide health literacy promotion, and rapid and optimized health outcomes (EDCTP, 2018; Shapiro & Meslin, 2001). Additionally, it would promote the scientific validity of study results on SSA endemic diseases by ensuring sustained participation and retention of human research participants (Barreto, 2009). This would also minimize attrition rates and enable optimal results for longitudinal endemic disease studies conducted in low literacy areas such as SSA (Mesic et al., 2019).

Most importantly, mandatory citizen participation remains the best option for effective and rapid eradication of endemic diseases whose epidemiological characteristics require a unified and coordinated control or eradication intervention mechanism for all target populations. Malaria and Ebola belong to this category of endemic diseases due to their high infection and reinfection rates (Tasman et al., 2022; WHO, 2017a). Therefore, it makes logical and economic sense to prioritize an agenda to eradicate malaria and similar endemic diseases in SSA that enables a collective and population-wide eradication effort.

I prioritize research-oriented strategies for the rapid eradication and control of endemic malaria and T2DM in SSA because such strategies are crucial for success.

Malaria pathogens and the rising prevalence of T2DM due to changing lifestyles in the region's urbanizing societies have an unpredictable epidemiology (Juma et al., 2020; Khan et al., 2020). Original research is crucial for discovering novel approaches to tackle current and emerging challenges in disease eradication and control. It also provides a means to understand public preferences, which can inform the development of health policies and other areas that significantly impact health (Savulescu et al., 2021).

Endemic disease eradication in SSA, through mandated citizen participation in research-based interventions, provides multiple individual and social benefits. Eradication of malaria in any constituency is usually the result of concerted efforts by the leadership and members of the constituency. To achieve optimal effectiveness, activities must be well planned, coordinated, implemented and carefully monitored for collective compliance. All of these steps can be supported by research in general and by mandatory research participation in particular. Many endemic disease eradication protocols typically include therapeutic activities for participants, such as free screening for malaria infections, free insecticide-treated nets, and mass drug administration (WHO, 2017a). Mandatory participation in such community tasks provides citizens with the double benefit of free healthcare and the opportunity to create their own personalized (precision) medicine. It also means huge cost savings for the government, whose health research spending will also be used to provide free or subsidized treatment to its citizens, improve its research capacity and infrastructure, and improve its overall public health.

Mandatory citizen participation in health research enables the research community to collect detailed epidemiological data on diseases of interest at the population level (WHO Africa, 2022), to support accelerated characterization of diseases and the timely translation of research findings into clinical practices for effective disease control (Scanlon et al., 2021). The importance and desirability of addressing the SSA endemic disease burden through research-based programs is reinforced by the WHO World Malaria Report 2022, which highlights global malaria surveillance, country-level case studies, and research and development as core strategies in the fight against malaria (WHO, 2022). The importance of malaria surveillance through sustained research (to prevent re-transmission) is further highlighted by the fact that WHO has made it a core requirement for malaria-free certification for countries (WHO, 2017 & 2017a).

Additionally, over the past eight decades, most conventional interventions to control malaria in SSA have focused on preventive measures and treatment regimens. However, an effective eradication strategy must include systematic and sustained basic science research on malaria pathogens, including studies on multiple drug resistance and their socio-environmental determinants (Oladipo et al., 2022; Gates & Chambers, 2015). Such research is essential for understanding and addressing the recurring challenges of treatment resistance and other control efforts. In regions with low health literacy, such as SSA, where voluntary participation in clinical research and surveys is persistently low, mandated participation may become necessary to ensure the successful implementation of such research and the realization of its intended health outcomes.

1.4 Concern for the Safety, Effectiveness and Value of Proposed Health Research

Human health research is highly regulated worldwide due to the many atrocities committed against humans by researchers and their sponsors in the past. Notable among these infamous studies with human subjects are the studies with

Jewish Holocaust victims of World War II (The Nuremberg Code, 1996). The atrocities became known after the war and led to the historic Nuremberg Trial and the conviction of the perpetrators in 1947. This episode also inspired the creation of the Nuremberg Code (1949) as an ethical guideline for conducting research on humans (The Nuremberg Code, 1996).

Many of the existing bioethics codes and guidelines originated from efforts to address specific ethical challenges caused by particular historical atrocities or persecutions involving human research subjects. For example, the Belmont Report of the United States arose in response to the scandalous Tuskegee Syphilis Study (1932–1972), which violated the natural right of poor study participants to benefit from the newly discovered and more effective penicillin treatment for their syphilis infection within the forty years that the study lasted (Emanuel et al., 2000). As expected, the Belmont Report provided guidelines for protecting vulnerable populations from research harm and exploitation by ensuring a favorable risk-benefit ratio (Emanuel et al., 2000).

Similarly, the SSA's critical endemic disease burden of malaria and the prevalence of T2DM requires a new ethical response that addresses the region's contextual inadequacies in health literacy, health financing, pervasive multidimensional poverty, and the endemicity and virulence of the diseases. The current burden of disease in SSA is a regional health emergency that requires accelerated ethical and technical responses, as was the case with the HIV/AIDS and Ebola epidemics and the COVID-19 pandemic. In the case of the Ebola epidemic (2014–2016) in the three SSA countries namely, Guinea, Sierra Leone and Liberia, health emergency protocols were activated by the WHO, which allowed the use of not-yet approved (unapproved) vaccines, medicines and medical procedures to combat and quell the health catastrophe (EDCTP, 2018).

In the three SSA countries struck by the Ebola virus, approximately 11,000 people died in 2015, resulting in an estimated GDP loss of US$2.2 billion (EDCTP, 2018). The endemic burden of malaria in SSA alone causes over half a million deaths annually and has an estimated annual economic cost to Africa of US$12 billion (Voices for Malaria-free Future, 2023). A comparison of the two health threats (Ebola and malaria) justifies the call for the WHO to urgently recognize the endemic-malaria disease burden of SSA as an uncommon epidemic and a health emergency of global concern. A public health emergency declaration would facilitate the region's efforts to raise funds from international donor agencies and development partners to implement the region-wide mandated health research being proposed here.

Addressing the endemic burden of disease through mandated citizen participation in therapeutic, research-based interventions would provide several long-term benefits to SSA. It would provide SSA countries with the opportunity to develop capacity for clinical trials and research-based interventions and build a sustainable research and clinical preparedness and surveillance network to address future disease outbreaks, control existing endemic disease challenges, protect lives, and to promote well-being and minimize economic losses for the region (EDCTP, 2018).

Governments in SSA must intensify efforts to develop and sustainably upgrade their health infrastructure, including strengthening their research capacity. Building robust research capacity goes beyond recruiting research participants; it requires skilled researchers who can design and implement research protocols effectively to produce meaningful results. This necessitates comprehensive training programs for SSA scientists and personnel to equip them with the skills needed to conduct research and interpret findings accurately.

Because protecting the lives of citizens is a primary duty of every government and its health system, SSA countries should be committed to reducing the prevalence of the deadly diseases of malaria and T2DM in their territories, even at the risk of violating the autonomy and privacy of citizens (Osseni, 2020). Personal autonomy and privacy rights are mostly characterized by key bioethical principles and guidelines as measures to protect and enhance the human dignity and personal freedom of individuals (CIOMS, 2016). However, when such rights (despite the exclusive hype they enjoy in the Western bioethics literature) come into conflict with the more fundamental right to life of the individual, it becomes compelling and ethically justified for the right to life to take precedence over autonomy and privacy rights (Beauchamp & Childress, 2019; Brody, 1997). Compromises between competing ethical principles and values inevitably arise, which, in the context of the prevailing endemic disease burden in SSA, requires that priority be given to protecting human lives from killer endemic diseases that cause over three million deaths annually in SSA (WHO, 2023).

The tension between personal autonomy and prioritizing communal welfare in ethical reasoning and research decision-making has been extensively explored in the literature, particularly regarding differences in the practice of the informed consent doctrine between Euro-American and non-Euro-American jurisdictions (Brunger, 2016). Despite these differences, there is general agreement across all bioethics jurisdictions on the importance of prioritizing life-saving, socio-centric policies and practices over strict adherence to individual autonomy and privacy rights in population health matters (Savulescu, 2021). The recent COVID-19 pandemic exemplifies this consensus, as nearly all countries enforced measures such as social distancing and the wearing of face masks, which were supported by strong evidence of their effectiveness in reducing disease transmission. However, for diseases like Ebola, malaria, or T2DM, the challenges are more complex, as comparable measures may not exist, and the effectiveness of interventions often requires sustained, context-specific research and a nuanced approach to balancing individual and public health priorities.

Overall, concern for the effectiveness and safety of citizens participating in proposed health research could be adequately addressed by comparing the implementation framework with global ethical principles and guidelines. Such measures would require participants to be treated with medications and procedures that are better or are as good as the existing standard treatments for endemic diseases of research interest (Emanuel et al., 2000).

A proposal of this type for mandatory citizen participation in health research in SSA is likely to face challenges related to ethics and cultural norms. Questions such as: What is the benefit of research to society?; What constitutes a fair risk-benefit ratio or fair subject selection?; How does one manage enrollment among segments of the target population while respecting individuals' personal autonomy and participation in research?; and, How can we protect vulnerable groups from harm and the community from exploitation?, will need to be addressed (Emanuel et al., 2000; Ezeome et al., 2010). My discussions in the following chapters of this work will focus on showing how the above ethical concerns are addressed in the highlights of the policy and implementation frameworks of this proposal for mandatory citizen participation in health-related research and how, overall, they lead to optimal health outcomes in the SSA region.

To address the ethical concerns that may arise from the proposal, a practical framework for the implementation of such a regional strategic health initiative will be established, which includes an analysis and mitigation of the ethical and cultural consequences of such a program. For example, many countries have adopted this remedial approach to address the challenge of personal autonomy in the COVID-19 pandemic protocols. Such protocols mandated strict public health measures such as mandatory wearing of face masks in public places, lockdowns and solitary confinement of COVID - 19 affected people for a certain period of time to control the spread of the viral disease (Ayouni et al., 2021). In the next section, I will highlight the themes of each of the five chapters of this work as a prelude to their more detailed discussions in the main chapters that follow.

1.5 Chapter Summaries

In Chapter 1, I provide an overview of the main agenda of this work, namely the highlights of the disproportionate burden of endemic diseases in SSA and how the situation can be improved through mandatory citizen participation in health-related research. I identified key ethical concerns that may arise, what is at stake and the need to address them to avoid preventable deaths and improve the well-being of the SSA populations.

Chapter 2 consists of two sections in which malaria and T2DM are discussed separately as case studies of communicable and non-communicable endemic diseases in SSA. The aim is to highlight the dynamics of human participation in research on these endemic diseases within the framework of an ethical risk-benefit ratio for participants and society. This chapter also highlights the enormous health and financial benefits of such altruistic research participation for citizens and society at large, including improving citizens' health literacy, host country research capacity, and opportunities in a rapidly changing digital world.

In Chapter 3, I discuss the ethical concern of personal autonomy and how it accommodates mandated citizen participation in health research proposed in this thesis without invalidating the proposal on ethical grounds. Highlighted here is an analysis of competing ethical principles and values that leads to an ethical balancing discourse that prioritizes the prevention of avoidable deaths from endemic diseases over minimal violation of personal autonomy, for the benefit of the common good.

In Chapter 4, the proposal for mandatory citizen participation in research-based interventions against malaria and T2DM is discussed in the context of the requirements for ethical and scientific rigor. The chapter is also about how to manage large pharmaceutical companies as research sponsors and partners in planned health research. Large pharmaceutical companies have been heavily criticized in the literature for their profit-oriented behavior in research, which often leads to the exploitation of human participants and host communities. I consider large pharmaceutical research collaborations to be a necessary evil because they have extensive research expertise and financial strength and are often required to complement the generally stringent public sector research and development regulations.

There is ample evidence that, under a well-designed research framework and conditions of collaboration, large pharmaceutical companies can be encouraged to operate more transparently and efficiently in research partnerships, resulting in more equitable benefit-sharing with other stakeholders, including human research participants and host communities. Initiatives like the Drugs for Neglected Diseases Initiative (DNDi) provide examples of successful partnerships in research on neglected diseases. DNDi, a not-for-profit organization, has demonstrated expertise and resources for the research and development of drugs for diseases that disproportionately affect impoverished communities. For instance, DNDi collaborated with Sanofi-Aventis to develop and deliver AS/AQ (artesunate/amodiaquine) for malaria treatment at an affordable cost of less than one US dollar per adult dose (DNDi, 2024a).

Furthermore, DNDi is actively working with the Coalition for Local and Regional Production, Innovation and Equitable Access to advance research and development of new therapeutics for diseases like dengue, a climate-sensitive ailment with no known treatment (DNDi, 2024). Such partnerships highlight the potential for pharmaceutical companies to align their research efforts with global health priorities under the right frameworks.

While large pharmaceutical companies may show more immediate interest in diseases like T2DM, which affect populations in both Africa and high-income regions like North America and Europe, the solutions for these regions often differ significantly. This is due to varying socio-economic, cultural, and environmental factors. Addressing these differences requires research partnerships grounded in ethical compliance, transparency, and a commitment to equitable access.

A robust framework for research compliance, guided by ethical principles and international codes such as GDPR, CIOMS, and TCPS2, is critical for ensuring that these partnerships protect the health and well-being of research participants and their economic interests. These examples underscore the feasibility of engaging pharmaceutical companies in research on neglected diseases when incentives, transparency, and ethical guidelines are well-integrated.

Chapter 5 is the conclusion and aims to highlight the reasons for proposing mandatory citizen participation in health research as a viable solution to the endemic disease burden in SSA and the increasing death toll from preventable diseases. It concludes that protecting human life and minimizing human suffering from preventable endemic deadly diseases takes precedence over all other considerations, including personal autonomy and the right to privacy.

Chapter 2

2.0 **The Growing Burden of Endemic Malaria and T2DM in SSA**

In this chapter, I delve into the ethical and socioeconomic dimensions of mandatory citizen involvement in health research in SSA, focusing on malaria and T2DM. Within the scope of this study, health research, also known as medical or clinical research, aims to deepen our understanding of human health and wellbeing. Its goal is to discover improved methods for preventing, treating, or managing diseases that directly or indirectly affect people (Harvard Countway Library, 2020).

The disproportionate burden of endemic diseases in SSA is typically exemplified by the persistent menace of malaria and T2DM in the region, which would require a rebalancing of efforts in health system reforms toward prevention. Research-based interventions that can effectively control these two diseases are essential for addressing the region's current healthcare challenges (WHO, 2023a; Pastakia et al., 2017). This need forms a key rationale for this thesis.

2.1 **Case Study 1: Malaria Disease**

Malaria is a tropical disease that can be contracted and transmitted from one sufferer to another through mosquito bites (WHO, 2022a). *Anopheles gambiae* mosquito species, deadly and exceedingly difficult to control, is widespread in SSA and is the main vector for malaria transmission in the region (Vogel, 2022). Africa bears the heaviest burden of malaria disease globally with 95% of global malaria cases and 96% of malaria-related deaths occurring in SSA (WHO, 2023a). Nigeria and the Democratic Republic of Congo jointly account for an estimated 40% of malaria's global mortality, while children under five years of age are its highest victims, accounting for about 80% of its mortality in SSA (WHO, 2022a).

The above portrait of malaria's menace and endemicity in SSA has been a cause of persistent worry to the global health community and the SSA governments. In response, however, there have been a series of globally coordinated interventions towards eradicating malaria globally (WHO, 2015). It is essential to recognize that strategies successful in other regions, such as China's '1-3-7' approach (to be elaborated upon later in this section), might not be effective for malaria elimination in SSA due to unique environmental and socioeconomic factors (Huang et al., 2022; WHO, 2017a). In this effort, investments in research and development, such as those managed by organizations like the Roll Back Malaria Partnership (RBM, 2022), are crucial for the global eradication of malaria.

Successful malaria elimination in countries like China and Morocco underscores the pivotal role of research in prevention, diagnosis, and treatment (WHO, 2020) as well as the imperative to adapt malaria elimination strategy to the region's unique ecosystem and disease characteristics (WHO, 2017a). For SSA, malaria interventions are inherently in the form of research and development investments, given that malaria in SSA is paradoxically both a cause and a consequence of prevalent multidimensional poverty in the region (Badmos et al., 2021; WHO, 2021).

Several global initiatives on malaria eradication were commissioned in the past three decades with some of them still ongoing, including the *Roll Back Malaria (RBM) Partnership to End Malaria,* funded by the United States, Japan, and their EU partners through *Global Funds* (RBM, 2022). On the technical and implementation side, some frameworks were developed to guide the diverse ongoing and pipeline activities for global malaria elimination. Aside from the *U.S President's Malaria*

Initiative directly handled by USAID and CDC with implementation sites in Tanzania, Kenya and Malawi, the most prominent global malaria eradication frameworks are WHO's *Global Technical Strategy (GTS) for Malaria 2016-2030* (2015) and *A Framework for Malaria Elimination* (2017). The former aims to eliminate malaria by at least 90% by 2030, from a minimum of 35 countries where malaria was transmitted in 2015. The latter (WHO Manual, 2017) is meant to guide regions and countries in their local adaptation of the global strategies for malaria elimination via vector control, preventive chemotherapies, vaccines, case management, mass drug administration, elimination, and surveillance (WHO, 2022a). I shall be referring to these WHO frameworks for global malaria elimination as I proceed further to explore the feasibility and ethics of malaria elimination in SSA through mandated citizen participation in health research.

2.1.1 How Mandated Citizen Participation in Malaria Research Will Facilitate its Eradication in SSA

Malaria, a stubborn, life-threatening, and vector-borne parasitic disease requires concerted and persistent effort to tackle (Oladipo et al., 2022b). The global effort to eliminate or eradicate malaria is hinged on breaking its transmission chain from its mosquito vectors to humans, which is achieved through combining two or more of preventive, diagnostic, and treatment malaria interventions (WHO, 2017). For countries where malaria was eliminated or eradicated, these interventions were applied in diverse combinations and timing depending on the prevailing dynamics of their peculiar vector-human ecosystems and the level of national priority accorded it. China, Algeria, and Morocco are part of the latest WHO-certified, malaria-free countries, signifying that they are free from indigenous malaria transmission (Raman & Oliver, 2022).

Recent malaria elimination in several countries (including Morocco, Sri Lanka, and China) revealed a strong reliance on research as a baseline measure in malaria prevention, diagnosis, and treatment (WHO, 2020). Specifically, there was strong political will in the recent malaria-free countries to mobilize the population for effective engagement in diagnostic screening (research), therapeutic, and vector control programs. For instance, China's adaptive strategy for malaria elimination spanned the years 2010 to 2020. It involved a '1-3-7' approach, which mandates the reporting of all suspected malaria cases within 24 hours, their investigation within three days of case onset, and the implementation of appropriate responses in form of quick treatment of confirmed cases and risks (outbreak) containment within seven days (Huang et al, 2022). In Costa Rica, their successful ongoing malaria strategy includes a network of over a hundred laboratories and embedded malaria activities in the healthcare system for quick detection (via screening) and attention to cases and outbreaks; while in malaria-free Malaysia, there is a mandatory online registration of malaria cases and outbreaks and their prompt investigation (via screening) and classification (WHO, 2020). China's '1-3-7' approach involved extensive mass screening and mass drug administration (Huang et al, 2022). This was necessary, based on the distinctive unsteady epidemiology of malaria infection.

Several other factors are also at play in the success stories of malaria elimination or near-elimination in different countries. These include free healthcare at least at the primary healthcare level (Algeria, Costa Rica, Iran, Paraguay), strong political will and adequate local funding for malaria control (Algeria, Iran, China, Morocco, Mauritius, El Salvador), and high literacy level and strong community engagement (El Salvador, Mexico, Paraguay) (WHO, 2020). These malaria elimination enablers are regrettably lacking in most SSA countries, and they constitute key barriers to the wholesale adoption by SSA countries, of malaria elimination strategies that worked effectively in the above-mentioned malaria-free countries. For instance, there is no functional primary health care system in most SSA countries to allow for mandated reporting, investigation, and free (or subsidized) treatment of confirmed malaria cases within 1-3-7 days, respectively, as is the case in China.

Also, the average low literacy level in SSA is a key barrier to enforcing mandatory online registration of malaria cases and outbreaks by citizens for investigation as required in malaria-free Malaysia (WHO, 2020). Therefore, effective malaria elimination strategies for SSA must be contextualized to the region's particular socioeconomic realities. A 'test and treat' malaria elimination strategy as represented by the present proposal for mandated citizen participation in therapeutic malaria intervention offers a distinctive pathway to accelerate progress towards achieving a malaria-free SSA soonest.

Mass poverty and perversive illiteracy are common features of SSA countries. Nigeria's population living below the poverty threshold in 2022 is estimated at 95.1 million (WHO, 2022c). This is an inconvenient truth, made even worse by Nigeria's estimated over 10.2 million out-of-school children, where also 75% of those below the age of 14 and in school are unable to read appropriately (UNICEF, 2022). This is typical of the SSA region where one in every five poor persons resides in Nigeria. It also explains why it is unrealistic to expect most SSA populations to appreciate the need for, and to voluntarily engage in, health-related research as a crucial measure toward the elimination of endemic diseases such as malaria and T2DM for society's well-being. Mass illiteracy and low health education for the masses are more prevalent in the rural areas and hard-to-reach countryside where significant patronage of indigenous (traditional) healthcare practices exist side-by-side with the orthodox healthcare system.

Part of the reason for SSA's poor educational attainment and weak healthcare systems is the chronic inadequate budgetary provision for education and health (Ifeagwu et al., 2021; Lewin, 2020). However, if SSA countries should make a poor decision to postpone giving due attention to the requisite malaria elimination strategy for the region, pending such a time when the region's literacy level improves appreciably for most citizens to freely cooperate with public health measures to eliminate malaria, the region may never be malaria-free any time soon. This will mean more malaria-related deaths and harm to the region's economic productivity and school learning outcomes due to frequent malaria infection of the workforce and school children (Chinkhumba et al., 2022; Lukwa et al., 2019). On the contrary, where the region commits to embark on accelerated reduction of malaria transmission through mandated citizen participation in therapeutic, research-based elimination interventions, the endemic malaria burden of the region and its associated patchy development will give way to a new malaria-free socioeconomic landscape with a healthier workforce and brighter educational attainment and opportunities for SSA's children and youths.

Resistance to some malaria vector control measures by many in SSA populations has been identified as a key barrier to malaria elimination efforts. In Botswana, where impressive progress is underway towards attaining malaria-free status, many people, especially in rural areas, are hesitant to use mosquito-treated nets even when freely provided (WHO, 2020). Such behaviors are often caused by cultural beliefs, poor public health awareness, illiteracy, and sheer indolence (Oladipo et al., 2022).

Given these challenges, SSA requires a unique approach to achieve malaria-free status and to rapidly reduce its disproportionate malaria burden, along with the associated rising mortality and morbidity rates. The framers of the *Global Technical Strategy* (GTS) guidelines for malaria elimination in areas with high and persistent infections are mindful of the special difficulty such multi-dimensional challenges can pose. As a remedy, they recommend that "new legislation may be required to support elimination programmes" (WHO, 2017a). China and Malaysia made new laws to compel official and prompt registration of malaria cases. In the SSA context where mass illiteracy and widespread apathy towards elimination programs exist, a more fundamental challenge to address through legislation is the low uptake in citizens' participation in malaria elimination programs due to ignorance and poverty (Grant et al., 2022).

The importance and urgency of enhanced citizen participation in malaria-related research are further demonstrated by the prolonged development of the *RTS,S* malaria vaccine (the first approved malaria vaccine), which took about 30 years to materialize due to challenges including those related to human subject participation in clinical trials (Effiong et al., 2022; Arama & Troye-Blomberg, 2014). Meanwhile, the WHO has set a target for improving the efficacy of the new malaria vaccine from 60% to over 75% by 2030 to ensure steady progress in global malaria elimination strategies, especially during rising resistance to malaria vector control measures (Oladipo et al., 2022). Other promising malaria vaccine candidates such as *R21* and *PfSPZ* are vigorously being pursued to provide multi-component vaccines for optimal efficacy and treatment sustainability (Moamly & El-Sweify, 2023). This will invariably require sustained human subject participation in malaria-related vector control and therapeutic programs.

It is important to emphasize, in line with the central message of my thesis, that research involving human subjects is essential for effective malaria control strategies and vaccine development. It forms the foundation for public health practices tailored to each malaria zone. *The Global Framework for the Elimination of Malaria* (WHO, 2017a) has identified certain interventions towards effective malaria elimination, which can be classified into, *prevention* (vector control, preventive chemotherapies, mass drug administration [MDA], vaccine, and surveillance), *diagnosis* (case detection via screening), and *treatment* (case management). The *Framework* (WHO, 2017a) recommends population-wide screening and mass drug administration as the appropriate strategies for areas approaching malaria elimination. For areas with high transmission intensity (as in most countries of SSA), the use of vaccines and additional vector control may be required. Specifically, *GTS*'s pillar, *'Transform malaria surveillance into a core intervention',* recommends for high and moderate transmission settings, an early step of surveillance strengthening as part of malaria elimination intervention. This should include "testing all individuals with suspected malaria and recording all confirmed cases … including community case detection, confirmation and reporting of malaria cases" (WHO 2017a, p.18). This is achievable in the SSA environment only under a malaria elimination policy and implementation framework that mandates citizens' participation in such 'core interventions' surveillance (screening), which approximates the present proposed biomedical and behavioral research intervention for malaria eradication in SSA.

Furthermore, there are cases where malaria infection is asymptomatic, thus creating situations whereby infected individuals or groups can harbor malaria pathogens for a long time without knowing but infecting those around them (WHO, 2017a). For such situations, the standard protocol recommends population-wide parasite elimination through mass screening and mass drug administration (WHO, 2017a). Such asymptomatic malaria cases may have contributed to SSA's endemic malaria burden and can be effectively tackled through population-wide malaria screening and chemotherapies as recommended by WHO's standard protocol.

There is no one-fit-for-all combination of elimination interventions for all malaria transmission settings. Each malaria zone adapts its elimination strategy depending on its peculiar malarial characteristics (WHO, 2017a). For Turkey, Iran, and Algeria, where citizen health literacy is high or moderate and malaria transmission is low, it may be unnecessary to compel citizens to participate in malaria elimination programs, given that they would do so voluntarily when required or even as a routine. However, for the SSA region, where malaria transmission is high and the population health literacy is poor, the elimination strategy should include mandated citizen participation in malaria research, if population-wide interventions (such as mass screening) are to be effective and impactful. This mandatory provision is a precautionary measure against expected cases of non-compliance by a considerable proportion of the population due to illiteracy, cultural norms, or other reasons (Oladipo et al. 2022).

There are other reasons why continuous human subject participation in research for malaria eradication in SSA is paramount. The swift mutations observed in malaria parasites indigenous to SSA, along with the emergence of the resistant *Anopheles Stephensi* mosquito strain (with resistance to insecticides as well as its all-seasons breeding and activities), present a growing challenge in malaria management (Phillips & Jasmer, 2018). Their genetic intricacy results in the creation of numerous potential antigens, substances that provoke an immune response. Consequently, continuous original research is needed to understand and address the specific challenges posed by these mutations in malaria treatment and control efforts (CDC, 2022).

Research on malaria drug treatment, vaccines, and other preventive interventions - including gene-drive modified mosquitoes - requires continuous human subject participation in clinical studies. For example, the *RTS,S* malaria vaccine developed by GSK took approximately 30 years of clinical research to complete. Gene-drive modified mosquitoes represent a novel approach to malaria control, where male mosquitoes are genetically engineered to carry specific mutations that can spread through the population, either reducing their ability to transmit malaria or causing a population collapse. This cutting-edge technology holds significant promise but also underscores the need for steady participation in health research to ensure sufficient human subjects for long-term studies and trials (Okumu et al., 2022).

WHO's recent 'high burden to high impact' malaria eradication initiative is hinged on tailored interventions based on local data and local disease characteristics, requiring regular malaria research for different demographic areas and their populations, for optimal efficacy and cost-effectiveness in malaria control measures (WHO, 2022; CDC, 2022). This underpins the tone of this proposal in emphasizing the importance of implementing research-based interventions involving citizens in their natural residential locations to optimize the efficacy of anti-malaria measures.

Furthermore, as the SSA region is yet to record its first country to attain the WHO-certified, malaria-free status, it is indicative that the region should double down on its efforts to wage the toughest battle against the malaria scourge in the region. In this critical fight against malaria, aimed at protecting lives - especially among vulnerable populations in SSA -, Shretta et al. (2017) acknowledge that the region will likely require more potent tools and stronger health systems. Evidently, measures to improve sustainable, population-wide participation in malaria vector control and therapeutic programs will invariably involve mass participation in research-based diagnostic (screening) and treatment programs for optimized outcomes (Grant et al., 2022; Bell et al., 2020). If such programs are to be implemented effectively for optimal impact in SSA's low health literacy landscape, a mandated population-wide-participation-informed strategy becomes expedient and ethically justifiable.

In conclusion, combating malaria in SSA evidently requires innovative strategies that acknowledge the region's unique challenges. Mandating citizen participation in malaria research offers a veritable pathway to accelerate progress towards malaria elimination, safeguarding lives and promoting socioeconomic development in the region.

2.2 **Case Study 2: Type-2 Diabetes Mellitus (T2DM)**

2.2.1 Definition & Significance in SSA's Public Health

Type 2 Diabetes Mellitus (T2DM) is a non-communicable disease (NCD) characterized by the body's impaired ability to use and regulate blood sugar (glucose) as fuel, which results in elevated blood sugar levels and can lead to several serious complications if not effectively managed (Mayo Clinic, 2021). T2DM has no known cure but can be controlled or managed, often through regular physical exercise and healthy dieting at the initial stages (Cleveland Clinic, 2022). Other variants of diabetes disease are Type 1 Diabetes and Gestational Diabetes Mellitus (GDM), which share the same symptoms and complications as T2DM but differ in their causes (Cleveland Clinic, 2022).

As part of the global effort to minimize the harm and risks from diabetes to public health, research has yielded promising results. Wearable devices, such as *iLet* (a bionic pancreas that automatically dispenses the correct dose of insulin), have emerged to manage blood glucose levels more efficiently than existing standard methods (Russell et al., 2022). The *iLet* project is being further explored to develop a version that stops blood glucose levels from dropping below the healthy range (Russell et al., 2022). These innovations, as helpful as they may be in the better management of T2DM, are however less helpful to most of its sufferers in SSA and other low- and middle-income countries (LMICs) who are financially handicapped to afford them.

2.2.2 How Mandated Citizen Participation in T2DM Research in SSA Will Aid its Prevention and Control

Over 70% of the countries reporting stable or declining T2DM prevalence are high-income countries (IDF, 2021). This implies that LMICs are disproportionately experiencing rising or unchanging T2DM prevalence. It is no surprise therefore that about 90% of all undiagnosed T2DM sufferers globally reside in Africa (WHO, 2021). SSA's slow progress in controlling T2DM stems from lack of adequate attention to its modifiable risk factors namely, poor diabetes education, insufficient physical activities, obesogenic environment, and unhealthy dietary practices (Issaka et al., 2018). This situation underpins the need for frequent and sustainable research and other interventions on the disease and its social determinants toward closing the global gap against SSA in the management and control of T2DM.

Clinical and behavioral research on T2DM involving human subjects becomes a sine qua non for promoting improved control of T2DM in SSA. This is better achieved in the SSA setting through individual-based and mandated population-wide interventions (Maiyaki & Garbati, 2014). The rationale for mandated citizen participation in T2DM research-based interventions in SSA is similar to that already advanced for improving malaria control in SSA as dictated by the region's distinctive socioeconomic circumstances (Oladipo et al. 2022). In addition, however, mandated citizen participation in T2DM research will help to address the fundamental low health literacy prevalent in SSA populations, including physical inactivity, dietary inadequacy, and obesogenic environment (Maiyaki & Garbati, 2014).

Mandated citizen participation in research-based interventions for T2DM in SSA has the potential to address critical issues such as mass poverty and chronic budgetary inadequacy in health and environmental sectors (Ifeagwu et al., 2021). By actively involving citizens, these programs can leverage community insights, enhance resource allocation efficiency, and foster shared ownership of solutions. For instance, such participation could facilitate the development of cost-effective, locally relevant strategies to combat T2DM, reducing financial strain on both individuals and healthcare systems.

Furthermore, addressing fundamental deficiencies in health literacy and environmental conditions is crucial for SSA to fully benefit from global advancements in managing T2DM and preventing its severe complications (CDC, 2022b). Citizen participation can play a pivotal role in this by raising awareness, promoting preventive measures, and advocating for systemic changes that improve access to resources and enhance health literacy. Without these efforts, SSA risks falling behind in the fight against this pressing health challenge.

The effort to control T2DM in SSA populations calls for sustained and rigorous indigenous research on the disease's modifiable risk factors and how to mitigate against them; for instance, by using indigenous natural resources such as indigenous fruits, vegetables, nuts, grains, and tubers as dietary interventions for blood glucose regulation (Soh, Damndja & Yanou, 2023; Ebere, Imungi & Kimani, 2021).

Establishing and sustaining enhanced health research capacity across SSA countries is key to optimizing the outcome of this initiative. As some of these indigenous functional foods are seasonal, the studies could address avenues of ensuring their all-season availability, including ways of preserving them. Such studies could also incorporate a review of indigenous (traditional) therapies that have sustained SSA's past generations against the disease. The influence of urbanization should not be overlooked in the studies. Urban living often leads to a sedentary lifestyle, whereas rural lifestyles typically involve more physical activity, movement, and a do-it-yourself mentality (Juma et al., 2020; Khan et al., 2020).

Comparative studies of this nature would require sustainable citizen participation in behavioral research, including in longitudinal studies that may run for years and decades (Shamshirgaran et al., 2020; Schunk et al., 2017). Although further research is essential to determine the prevalence of T2DM among rural versus urban populations in SSA, it is clear that low health literacy is a significant barrier to effective self-management of the condition.

The financial burden associated with T2DM management for its sufferers in SSA is of great concern considering that the average income of people in the region may not cover the cost of effective management of the disease, more so as most of the SSA populations have no health insurance coverage (Barasa, 2021). There is therefore a compelling need to explore alternative avenues of protecting T2DM sufferers and the entire SSA populations from the disease and its complications.

Some may argue that as an NCD, T2DM is a personal health burden for its sufferers with no direct health implications for public health, unlike malaria, which is transmissible. While it is true that the direct financial burden of managing T2DM rests with its sufferers, there are wider socioeconomic implications for the public. The complications from untreated T2DM are many, including diminished quality of life for its sufferers, disabilities such as amputation, blindness, cardiovascular diseases, and renal disorders (Mayo Clinic, 2021).

Disabilities from T2DM create the need for special caregiving for its victims in homes and communities. This will result in a loss of economic productivity by T2DM sufferers and their caregivers, thereby depressing the GDP of SSA. Apart from individual and collective economic losses, when T2DM leads to the premature death of its sufferers, families are often affected in many ways including the loss of the family’s breadwinner and disrupted parenting with implications for the children's upkeep and education. In some cases, the children are rendered orphans. Responsible governments in SSA should therefore be keenly concerned about the social determinants of T2DM and its other endemic NCD cousins and should spare no efforts at combating the diseases for a healthier and more prosperous population.

To this end, legislation is usually made for the control of alcohol consumption and substance usage, both of which are considered key risk factors for T2DM and its complications (American Addiction Centers, 2023; Poznyak et al., 2014). Such legislation is normally evidence-based and purposed to achieve the deterrence of alcohol and substance abuse (including rehabilitation of abuse victims) and the generation of additional tax revenues from alcohol surcharges and advertising, as well as fines from violations of anti-abuse statutes. The additional revenue realized can be channelled towards the development of public leisure parks and pedestrian/cycling sidewalks to promote increased outdoor activities and to support orphaned children (Maiyaki & Garbati, 2014). It is noteworthy that for such anti-abuse legislation to be effective, the evidence for it could be an outcome of citizens' participation in behavioral research on alcohol and tobacco as risk factors of T2DM, as canvassed by this thesis.

In conclusion, the health and economic impacts of the increasing prevalence of T2DM in the SSA region are too significant to ignore. As a non-communicable and progressive disease, T2DM demands that SSA governments and health communities prioritize vigorous efforts to combat it. These efforts should include increased budgetary allocations and research-based measures that promote greater awareness for the disease and leverage the region's indigenous resources. This could involve promoting the market and consumption of functional local foods that enhance blood glucose regulation, as well as creating environments that encourage outdoor physical activities for citizens.

Chapter 3

3.1 The Principle of Respect for Personal Autonomy (The Informed Consent Doctrine) - Its Centrality in Contemporary Research Ethics

Respect for personal autonomy as one of the core principles of bioethics has been a priority in bioethics literature since at least the 1960s due to cultural and historical reasons. Western culture is fundamentally rooted in the idea that the individual has an inalienable right to freedom to pursue his or her personal goals and chosen happiness without undue censure or interference from others (CRF, 2009).

Historical events such as the Holocaust during World War II and the Tuskegee Syphilis Study (US Holocaust Memorial Museum, 2021; Curran, 1973) highlighted egregious violations of individual rights and dignity. These atrocities underscored the critical need for ethical safeguards in clinical practice and research, leading to the global recognition and reinforcement of the principle of autonomy. By exposing the consequences of disregarding individual rights, these events catalyzed the development of ethical codes, guidelines, and frameworks, such as the informed consent doctrine and ethical oversight, ensuring respect for personal autonomy in healthcare and research.

The overarching objective of the present study is to establish an ethically justifiable framework that will underpin mandated citizen participation in an integrated research proposal to address the scourge of endemic malaria and T2DM in SSA (Morain & Largent, 2021). I will also refer at times to this integrated model of research as the 'intervention'.

Malaria and T2DM have a devastating impact on the population of SSA, with malaria alone accounting for over half a million deaths annually (WHO, 2022a). This alarming situation constitutes a critical public health emergency. To address this crisis effectively, I argue that it is both crucial and ethically justifiable to mandate citizen involvement in large-scale research initiatives targeting the entire population, particularly when voluntary participation cannot be guaranteed (Busisiwe et al., 2023; Diress et al., 2021).

Furthermore, the success of malaria eradication efforts in SSA relies on their timely and comprehensive implementation. These interventions must reach all residents within the malaria-endemic zone and follow a defined timeline to achieve maximum impact. A region-wide eradication framework for malaria in SSA is necessary because focusing a containment strategy on a single country, like Nigeria, is impractical. Many border communities in SSA countries live in close proximity, where cross-border trade and socio-cultural interactions are common daily occurrences. Endemic communicable diseases like malaria do not adhere to political borders. To ensure effectiveness and sustainability, a malaria containment strategy for SSA must adopt a framework that addresses the entire malaria-endemic region.

A potential ethical concern with mandating citizen participation in the proposed research is the risk of violating autonomy rights (Beauchamp & Childress, 2019; CIOMS, 2016). The autonomy issue is the focus of this chapter. The research I am proposing suggests that SSA residents would not be required to provide individual consent for participation. Instead, an ‘informed assent’ agreement would be established, where the governments of SSA countries, along with their constituent communities, as constitutional representatives of their peoples, would collectively ratify a robust policy and implementation framework for research into malaria, T2DM, and other endemic diseases in the region.

However, recognizing the importance of public engagement, a comprehensive and inclusive enlightenment campaign would be integral to this framework. This campaign would aim to educate the population about the purpose, importance, and benefits of their participation in the research. It would employ multiple channels, such as community outreach programs, town hall meetings, educational materials in local languages, and media campaigns through radio, television, and social media. These efforts would focus on fostering trust, addressing concerns, and ensuring that the public understands the ethical safeguards in place against privacy violation, abuse, and exploitation. By prioritizing public engagement, the campaign seeks to maximize voluntary cooperation and reduce the number of individuals compelled to participate. This approach not only enhances transparency and trust but also aligns with ethical principles, ensuring the research respects the dignity and agency of SSA communities.

The regional, national and sub-national dialogues preceding the ratification of such interventions would be rigorous and inclusive, involving all stakeholders and their representatives - policymakers, public health experts, researchers, community leaders and representatives, funding agencies, bioethicists, civil society organizations and international observers - from the conception phase to the start of the research through to post-implementation processes.

Recruitment into different research sections (prevention/promotion, diagnosis, and treatment) would be based on individuals' health requirements, prevalent health risks within diverse sub-populations, and the researchers’ specific interests in research areas related to the two endemic diseases.

The research would involve multiple approaches across various locations, encompassing research into health promotion, diagnosis, and treatment for the identified diseases. People would be enrolled in the research based on their individual healthcare needs and the necessity for generating data to better understand and effectively manage or eliminate these diseases. Regardless of their specifics, all proposed sets of interventions in the research must undergo thorough review and approval by ethics committees at all levels before implementation. I will discuss the various oversight and review mechanisms later on in this chapter. The goal of oversight is to reduce the risk of harm and eliminate exploitation of participants.

In the context of the research program I propose, there are grounds for mitigating the violation of the respect for autonomy constraint in research involving human subjects. As important as the respect for autonomy principle is in human-related research, it should never represent an insurmountable obstacle to achieving greater societal health and well-being. No single ethical principle is sufficient to determine the ethical validity of a research or intervention when tensions exist between relevant ethical principles (Emanuel et al., 2000).

My research proposal aligns with three core ethical principles: beneficence, non-maleficence, and justice. The principles of beneficence and non-maleficence drive initiatives that aim to prevent harm and enhance well-being, as reflected in the study's goals of reducing deaths and suffering caused by malaria and T2DM while promoting overall health in the SSA region (Nuffield Council on Bioethics, 2020; Beauchamp & Childress, 2019). The principle of justice ensures fairness and equity in programs and processes affecting public well-being. In the context of this study, which involves mandated citizen participation in research, the principle of justice supports the approach as long as it avoids exploitation. Later in this chapter, I will outline procedures and oversight mechanisms designed to prevent exploitation and safeguard individual rights and privacy, even in the absence of traditional informed consent requirements.

Respect for personal autonomy is another critical ethical principle, encompassing the protection of individual rights, including privacy and informed consent before research participation. The Euro-American interpretation of personal autonomy emphasizes the need for individuals to explicitly execute informed consent protocols before participation. However, my proposal seeks to adapt this requirement to the SSA socio-cultural context, where personal autonomy in health decision-making is less prioritized. This adaptation still ensures the protection of participants' rights and privacy. The remainder of this chapter focuses on explaining how the SSA perspective on personal autonomy - and its adaptation of the informed consent protocol - can achieve a robust and ethically sound approach suited to the SSA regional context.

To navigate the ethical challenges surrounding the proposed research against endemic diseases in SSA, it is crucial that other ethical principles endorse mandated citizen participation in the research and take priority over the principle of respect for autonomy (Ayouni et al., 2021; Richardson, 1990). In this context, a principle-based approach would prioritize and justify the research, even if it means compromising on autonomy while aligning with the other three ethical principles (Savulescu, 2021; Beauchamp & Childress, 2019). This prioritization aims to enhance overall well-being by fostering fairness, mutual respect, preventing exploitation, and diminishing avoidable deaths and suffering among the population (Nuffield Council on Bioethics, 2020).

Another argument supporting the idea of mandatory research participation in this context is that one of the primary duties of the government is to protect its citizens from imminent and potential health hazards through solutions that improve public health outcomes and optimize public safety (WHO, 2008). Healthcare providers and policymakers are required to act in the best interests of their patients and the public (Beauchamp & Childress, 2019).

Mandating participation in health-related research can sometimes be argued as justifiable if robust oversight and safeguards are in place, and the research is expected to result in significant health benefits for individuals or the broader population (Savulescu, 2021). One context often cited is public health emergencies, such as outbreaks of highly contagious and deadly infectious diseases like coronavirus or Ebola virus. In such emergencies, governments may advocate for mandatory citizen compliance with public health measures or participation in health-oriented research, asserting that these actions are necessary to protect the population from significant risk of harm (Savulescu, 2021).

By and large, it is important to mention that there is considerable debate about the best course of action in such scenarios. While mandates may be informed by scientific evidence and expert recommendations, these measures are not universally accepted as the singular or definitive approach. Scientific evidence is often complex, and interpretations may vary, leading to diverse perspectives on the appropriateness and ethics of mandates in public health and research contexts.

However, in the SSA context on malaria and T2DM scourge, I argue that mandated citizen participation in research on the diseases is the most feasible approach and ethically justifiable. The situation with malaria and T2DM scourge in SSA is troubling and requires swift and sustained attention. Public health safety is required to be enhanced in situations of endemic diseases, such as SSA's malaria disease burden that causes about half a million annual mortalities (WHO, 2021 & 2022a). SSA governments would fail in their primary duty if they did not take all feasible measures within their capacity to address health threats like malaria and T2DM. Such inaction could be seen as negligence, potentially amounting to culpability by default, given the avoidable annual loss of about half a million lives in the region due to malaria-related illnesses (Sween et al., 2022).

As the custodian of the citizens' collective safety and well-being in modern societies, it is within the remit of governments to mandate research that will enable individuals to receive vital information or screening that will assist them in making informed choices about their health and well-being (WHO, 2008). As the Hastings Center COVID Framework 2020 states, “ensuring the health of the population, especially in an emergency, can require limitations on individual rights and preferences. Public health ethics guides us in balancing this tension between the needs of the individual and those of the group” (Berlinger et al., 2020, p. 2). During public health crises, such as (I argue) the endemic malaria situation in SSA, rapid and extensive participation in research becomes vital in discovering effective treatments or vaccines.

Governments worldwide have imposed restrictive measures on their populations to stem the spread of deadly diseases like coronavirus (Ayouni et al., 2021). While similar urgency is warranted for addressing the increasing burden of endemic malaria and T2DM in SSA countries, research requires a more rigorous ethical standard than measures aimed solely at immediate population protection.

Declaring these diseases as public health emergencies could justify extraordinary measures, such as mandatory population-level research as proposed in this study. Such a research-based approach is distinct in its ability to provide a rigorous and foundational investigation of the issues, ensuring that interventions are evidence-based, effective, and ethically optimized. By leveraging the structured methodologies of research, the study aims to develop precise and sustainable solutions to combat these deadly endemic diseases more effectively and sustainably.

The SSA situation of the endemic malaria scourge, for instance, has lingered for too long and is fast deteriorating unless some uncommon remedy is applied to stem the tide. The malaria burden in SSA is so concerning globally that the Bill & Melinda Gates Foundation has projected that it would require about US$120 billion to eradicate malaria by 2040, to save 11 million lives from malaria-related death (Gates & Chambers, 2015). To imagine that the malaria scourge will linger on for about two more decades before its eradication in SSA is nightmarish. Considering the complex epidemiology of malaria, Bill Gates further remarks that "eradication is the only sustainable solution to malaria. The alternative would be endless investment in the development of new drugs and insecticides just to stay one step ahead of resistance. The world can't afford that approach" (Gates & Chambers, 2015). Gates' advice underscores the need to adopt a massive and concerted attack strategy for swift malaria eradication in SSA, of which my present study proposal is a pragmatic paradigm.

To speed up the delivery of this crucial public health research for the benefit of the people of SSA, I propose waiving the informed consent requirement in its Euro-American tradition. This proposal aligns with international ethical standards and demonstrates a dedicated effort to urgently address the critical health needs of the SSA region.

Considering the above perspectives, I contend that the proposal for mandated participation in research can be ethically justified, even in the face of forgoing the informed consent requirement, if the research is entirely safeguarded against exploiting research participants and host communities. In the ensuing section, I shall highlight specific oversight mechanisms inherent in the traditions and values of SSA societies. These mechanisms serve as an additional layer of protection for individuals and communities from potential research-related abuse and exploitation. In the section after, I elucidate further external oversight mechanisms to protect against research abuse and participant exploitation in a more inclusive socio-cultural global research landscape.

3.2 SSA Cultural Norms and Ethos as Protective Mechanisms for Research Participants

A further consideration supporting the ethical justification of this proposal is that it is consistent with the moral and cultural values of SSA societies where respect for personal autonomy is not considered a priority (Akpa-Inyang & Chima, 2021). At the same time, these indigenous customs and values have built-in safeguards to avoid harming individuals in their communities, while promoting fairness, equal respect, and minimizing suffering (Nuffield Council on Bioethics, 2020).

There is a rich literature discussing African perspectives on prevailing bioethics principles and guidelines. Some African bioethics scholars (Appiah et al., 2024; Ssebunnya, 2016; Tangwa, 1996) argue that the prevailing Western bioethics principles, as outlined by Beauchamp and Childress (2019), are too narrow and insensitive to the diverse socio-cultural contexts that have their own moral values and ethos. These values and ethos are consistent with common morality but differ from Western paradigms. This bioethical dissonance is typically exemplified in the principle of respect for personal autonomy, a foundational concept in Euro-American bioethics. Behrens (2018) argues that the term 'respect for autonomy' is inappropriate for describing the inalienable right of individuals as moral agents to make informed decisions about their health and well-being. He believes that 'respect for autonomy' is too individualistic and fails to account for an individual's essential relational connections with their immediate and wider community. Instead, Behrens (2018) prefers the term 'respect for persons,' which acknowledges both an individual's right to decision-making and their integral bonds with, and responsibililty to, others, promoting community harmony and well-being.

African traditional societies and their lifestyles are characteristically oriented toward communalism, egalitarianism, a shared sense of interdependence, solidarity, collective decision-making, and compassion (Ujewe, 2023; Metz, 2021; Ikuenobe, 2018). Much of African literature, such as Chinua Achebe's iconic works, *Things Fall Apart* (1958) and *Arrow of God* (1964) explore traditional Igbo society in Nigeria before and during colonialism, respectively. These accounts are full of narratives and scenarios depicting the various ways in which African institutions and traditions shape and sustain indigenous African values and ethos (embedded in safeguards against injustice, abuse and exploitation of individuals) from past generations to the present. Several indigenous African works illustrate the resilience and ingenuity of African communities in protecting their members from internal and external harm. Here, I discuss some of the traditional African institutions, ethical values and norms that support and strengthen the protection of individuals from injustice, abuse and exploitation.

Extended family practices and virtue ethics are two African cultural practices that dominate the indigenous education curricula and serve as the moral compass for child socialization and education in African societies (Mafumbate, 2019; Adeyinka & Ndwapi, 2002). From an early stage of development, African children are taught to internalize the fundamental cultural and ethical principles of honesty, kindness, solidarity, resourcefulness, respect for elders and authority, and compassion (Eze, 2011; Oguejiofor, 2007). This is intended to shape and influence the children’s character and adult preferences for responsible citizenship, promote community bonds and solidarity, and serve as a means of protecting the citizens from abuse, harm, and exploitation in any form.

The ‘age grade’ institution is another African cultural practice that strengthens the practice of solidarity and brotherhood. It accomplishes this by establishing a lifelong platform for people within the same age bracket who are bonded together under the same ‘age grade’ through a formal traditional rite of initiation. For instance, in the Igbo society, this network promotes their collective interests and those of their community at large (Achebe, 1958). Protecting the interests of their community includes respecting and protecting the rights of community members as well as supporting the less privileged in their midst (Ujewe, 2023; Mafumbate, 2019).

Oral traditions and narrative practices in SSA societies are the traditional equivalent of social media platforms that promote the exchange of individual experiences in the everyday lives of children and young people. They are also mechanisms for mentoring and socialization and serve as an uncomplicated way to monitor people's behavior for their moral conformity to societal norms and expectations (Anike Foundation, n.d.). They ensure that violations of moral norms and community ethos are appropriately punished, including through public confessions and apologies, shaming, exclusion, and return of embezzled or extorted assets (Tabalia & Simwa, 2023; Berry, 2018). They are highly effective mechanisms to checkmate injustice, abuse and exploitation of all forms in SSA societies and would serve as one safeguard for citizen’s protection while participating in health research in SSA (Barker & Sinclair, 2016).

The Council of Elders is a respected governance institution in traditional African communities (Busia, 2018). Elders are the guardians of the community's customs and traditions, acting as advisors to the king and usually assisting him in resolving serious disputes in the community (Admethics, 2021; Achebe, 1958). Their core duties include assisting the king and the democratic institutions in maintaining law and order in the community and ensuring that no community member is subjected to any form of injustice, abuse, or exploitation either from within or outside the community.

Customary laws exist in every indigenous African community and serve as a guide or code for acceptable behavior in all aspects of community life (Bwire, 2019). Community customs and laws are usually enshrined in child-rearing curricula to facilitate their learning and impact community members' character (Bwire, 2019). Severe sanctions are imposed for violation of customary laws, ranging from verbal reprimands, or fines, to ostracism for serious offences such as exploiting community members and embezzling community funds.

Women's groups and associations are another mechanism that allows people in the community, especially women, children and the vulnerable, to always be treated with respect and dignity. Women are active promoters of solidarity between families and the extended family system, which serves as a network of care for individuals and their families for social protection (Lebaka-Ketshabile, 1999). The women's groups' activities and programs also help to motivate children and young people to develop good character and resourcefulness.

Community solidarity in SSA is characterized by community mutual aid and support. In times of crisis, such as illness, death, or natural disasters, community members come together to provide support and assistance to those affected (Gyekye, 2011; Gyekye & Wiredu, 1992). This can include financial contributions, labor, or emotional support and is an indication of the community's abhorrence of injustice and exploitation in the community. It reflects the idea that community members should function as an extended family, genuinely caring for each other's well-being and progress, reflecting the *Ubuntu* philosophy in many African societies, “I am because we are” (Eze, 2011).

Contemporary Civil Societies Organizations (CSOs) and other human rights groups are actively involved in ethical oversight in modern SSA societies. The functions of the above-mentioned traditional institutions are now being expanded by CSOs and interest groups advocating for various human rights, such as the girl-child’s protection from early (forced) marriage and other abuses (Girls Not Brides, 2020). These provide additional support for protecting people from harm, abuse, and exploitation when participating in people-centered research and health interventions in SSA.

In the paragraphs above, I have argued to demonstrate the mechanisms inherent in the cultural and traditional practices of SSA societies to protect people from injustice, abuse and exploitation. However, because the proposed research requires mandatory citizen participation for optimal outcomes, it is critical to adapt research oversight and additional external mechanisms to align with local ethical and cultural norms, to further protect participants from potential risks, and as alternatives to the formal protocol of informed consent. Here are some specific mechanisms that are considered appropriate and would be in place for protecting research participants in the proposed SSA research context with mandatory citizen participation.

3.3 Specific External Mechanisms to Further Protect Research Participants from Harm

Community engagement and consultation with local communities and leaders are critical for the proposed research. Researchers and other implementation partners for the proposed interventions must invest time in building relationships, discussing research goals, and seeking broad input and buy-in from community representatives. This can promote trust and ensure that a given research protocol is culturally sensitive, inclusive, and respectful of local norms (TCPS 2, 2022).

Research participants and host communities potentially face several risks, including those of economic exploitation stemming from proprietary rights to research assets, secondary data usage, and violations of their privacy protection (Emanuel et al., 2004). Ethics Review Boards (Ethics Committees) are essential for evaluating the ethical aspects of the protocols for the proposed research (Pan American Health Organization, 2020). These boards are to be established at regional, national and sub-national levels and are to include members who understand the local culture and can adapt the research objectives and implementation protocols to align with community values while ensuring that participants and host communities are protected from harm and exploitation. This is achieved by implementing steady oversight during and after research to ensure that the interests and rights of participants are continually protected.

Maintaining bi-directional communications through regular meetings of community representatives with ethics review committees can facilitate this process. The board also ensures that appropriate compensations are made to participants for research injuries where they occur (CIOMS, 2016). The board’s functions may also include facilitating knowledge generation and dissemination, especially in emergencies, to promote surveillance and future studies (Neil & Saenz, 2020; WHO, 2016).

Data Safety and Monitoring Boards (DSMBs) are essential in this proposal and need to be established at regional, national and subnational levels with qualified data scientists and local representatives trained in ethics with expertise in the relevant field and an understanding of local cultural sensitivities and preferences, as members.

These panels are expected to play a critical role in ensuring the security of participants' health records during and after the intervention (NIH, 2018).

Community Advisory Boards (CABs) are another important mechanism that should be composed of knowledgeable community members to provide an additional layer of oversight for the research in every implementation site. These community-based panels can help researchers and other implementing partners understand and respond to community concerns and needs and ensure that the research remains consistent with cultural values and expectations (Pancras et al., 2022), while facilitating the research's core goal of malaria eradication and minimization of T2DM prevalence in the SSA region.

Benefit sharing is a key mechanism for the success of this proposal and takes into account stakeholders' considerations and agreements to share the benefits of the research with research participants and the host communities (TCPS 2, 2022). This includes providing access to medical treatments as part of the research and health literacy programs, which improve well-being and awareness of endemic diseases. This and other post-research benefits will help build and sustain trust and ensure that the communities perceive the research as non-exploitative and mutually beneficial (CIOMS, 2016; Emanuel et al., 2004).

Community feedback mechanisms are an important part of research monitoring mechanisms, requiring community members to provide ongoing feedback and raise concerns about the research when necessary (UNDP, 2013). This is particularly important considering that the proposed research requires mandatory citizen participation and participants deserve clear channels to express individual concerns and receive feedback. This may include hotlines, community meetings, designated community contacts and social media platforms, such as WhatsApp.

3.4 Conclusion

In summary, the above mechanisms collectively serve to protect participants and host communities in the proposed research against malaria and T2DM in the SSA region, where personal autonomy is typically not a priority, but the values and norms of the community, consistent with common morality, guarantee protection from injustice and harm for every individual in the community. It is important to involve local communities in the decision-making process regarding research implementation and adapt research practices to their expectations and concerns (Emanuel et al., 2004). Additionally, a collaborative approach with community leaders, researchers, ethics review boards and other stakeholders is critical to ensure the ethical, culturally sensitive, and successful implementation of the proposed research, devoid of abuses and exploitation, to combat the scourge of endemic malaria and T2DM in the SSA region, even without formal informed consent protocol as a pre-requisite.

Chapter 4

4.0: Managing Big Pharma in Health Research for Ethical Participant Protection and Community Benefit

4.1: The Problem - Big Pharma in Mandated Research Participation

The engagement of big pharmaceutical companies in health research has been a subject of extensive criticism due to their profit-centric behaviors, particularly in developing environments (Lexchin, 2018; Henry & Lexchin, 2002). In the context of mandated research participation, the involvement of pharmaceutical companies could create a scenario where these companies reap undue benefits, while the research participants who contributed to these outcomes are unfairly excluded from equitable benefit sharing (Miller et al., 2021). This issue raises concerns about the potential exploitation of human subjects and the host communities involved in such studies.

According to Nuffield Council on Bioethics, exploitation of research participants or host communities occurs when any or all of the following principles are violated, “the duty to alleviate suffering; the duty to show respect for persons; the duty to be sensitive to cultural differences; and the duty not to exploit the vulnerable” (2002, p. xv). Evidence abounds about the negligence and exploitation of research human subjects and host communities in health-related research in the past, especially in fragile and developing countries (Samman et al., 2018). For instance, there was a protracted legal battle between Pfizer and the Kano State government of Nigeria on the harm suffered by children in Kano State from the *Pfizer Meningitis Study in Kano-Nigeria* (Ezeome & Simon, 2010). Although the case was eventually settled out of court with Pfizer paying monetary compensation to the victims of their failed meningitis study, it has however created fear and suspicion about similar studies or research in the public psyche in SSA. As Montgomery (2017) observed, such unfortunate incidents pose a danger to the advancement of health research and to the well-being of participants.

It is no longer doubtful that many pharma companies, who are big players in the global and regional health-research industries, have historically prioritized their profit interests over equity and fairness in sharing research benefits with other stakeholders (Lewis et al., 2001). Their research practices have often compromised strict scientific and ethical rigor, especially in the Third World (Angell, 1997). This has earned the big pharma industry a characterization in the literature as "leopards in the temple" (Lemmens, 2004). For this reason too, university scholars partnering with big pharma in research are cautioned against its potential ethical risks to medical science (Sismondo, 2021) and to their academic integrity for "dancing with the porcupine" (Lewis et al., 2001, p. 783). The fundamental question arises: Why is it necessary to involve big pharma in health research at all - particularly in the research discussed in this thesis, which includes mandatory participation?

4.2: The Necessity of Big Pharma Involvement

The inclusion of big pharma in health research is often deemed a 'necessary evil' due to their unparalleled research expertise and financial strength (Lexchin, 2018). The public sector, burdened with constrained research and development provisions, finds itself reliant on the resources and capabilities that big pharma can provide. Accordingly, my position is that the pharmaceutical industry as a for-profit enterprise has come to stay as a crucial stakeholder in global biomedical research. Regardless of their several embarrassing episodes of compromise in the safety and efficacy of clinical trials on drug research and development (Morreim, 2021; Ezeome

& Simon, 2010; Spurgeon, 2001), their research expertise and enormous funding capacity for drug development remain invaluable assets to the global biomedical and behavioral research community (DuVal, 2021). As early as 2001, the big pharma industry contributed about 70% of the financing for clinical trials on drug development (DuVal, 2021) .

By and large, the advancement in medical science today owes much to various contributors, including the pharmaceutical industry's role in biomedical research and drug development, as evident in the timely development of COVID-19 vaccines (The Association of British Pharmaceutical Industry, 2024; WHO, 2021a). However, it is essential to recognize that fundamental research, which serves as the foundation for many novel drugs, is primarily financed by government bodies and public institutions. Pharmaceutical companies typically become involved at later stages, particularly when a potential therapeutic entity demonstrates promising results, often funding Phase 2 and Phase 3 clinical trials.

Critics, including Joel Lexchin (2024; 2018), have highlighted that while big pharma has made significant contributions, its priorities can sometimes skew towards the development of “me-too” or “follow-on” drugs - variations of existing therapies - rather than investing in groundbreaking treatments that address critical public health needs (DiMasi & Faden, 2010). This focus on profit-driven motives often overshadows the community's and patients’ broader health interests (Lexchin, 2017). Nevertheless, Lexchin (2018) does not dismiss the role of the pharmaceutical industry altogether; instead, he advocates for frameworks that foster ethical, accountable, and socially responsible behavior.

In light of these insights, my proposed research interventions targeting endemic malaria and T2DM in SSA, would welcome pharmaceutical companies as partners. However, such collaboration must operate under robust frameworks of engagement. These frameworks should clearly define research objectives, protocols, and the roles of all stakeholders. They must also ensure fair and equitable sharing of research benefits and proprietary rights, particularly with the host communities and research participants in developing settings. By prioritizing ethical principles and accountability, it is possible to align the capabilities of big pharma with the broader goals of global health equity and innovation.

4.3: Addressing Exploitation and Privacy Breaches

To mitigate the potential for exploitation and privacy breaches in health research involving big pharma, a comprehensive solution is required. Existing evidence suggests that with a well-crafted research framework and robust terms of engagement, big pharma can operate with greater transparency and efficiency, ensuring equitable sharing of research benefits among all stakeholders, including human research participants and host communities (Danescu & Popa, 2020; Strand et al., 2020).

Moreover, international not-for-profit organizations with expertise in health research are already contributing significantly to anti-malaria efforts in developing countries. For example, the European & Developing Countries Clinical Trials Partnership (EDCTP) is actively engaged in malaria research in SSA and is committed to eradicating infectious diseases in the region (EDCTP, 2018). EDCTP's strategy focuses on developing alternative chemotherapies to address increasing malaria resistance to standard treatments. Such organizations could be vital partners in implementing the comprehensive approach to malaria eradication proposed in this thesis. Their not-for-profit model and commitment to equitable practices minimize concerns about exploitation and ensure fair sharing of research benefits with research subjects and host communities, thus fostering trust and collaboration.

While collaborations with large pharmaceutical companies may not always be essential for malaria research outcomes, they can still play a critical role when innovative solutions, such as advanced drug development or large-scale production, are required (Remedial Health, 2024). For instance, in response to UNICEF/WHO call for the development of child-friendly medicines, Novartis went into partnership with Medicines for Malaria Venture to develop *Coartem Dispersible, "*the first paediatric dispersible ACT, developed especially for children with malaria, delivered to more than 50 malaria-endemic countries since launch in 2009" (Medicines for Malaria Venture, 2024). However, such partnerships must be carefully managed within robust frameworks to safeguard research participants and host communities from exploitation.

Mandated participation in research for treatment protocols could address several critical facets of combating endemic malaria in SSA. By instituting mandatory and ethically governed inclusion of relevant stakeholders - governmental health agencies, academic researchers, not-for-profit organizations, and, when necessary, pharmaceutical companies - the research process would ensure the following: comprehensive data collection, integrated treatment frameworks, inclusive stakeholder engagement, and accountability and trust-building.

This approach ensures that all facets - scientific innovation, ethical considerations, and community trust - are addressed, leading to sustainable progress in malaria eradication.

4.4: Evidential Support for Ethical Management

Several instances in the literature showcase successful collaborations where big pharma has adhered to ethical standards, ensuring participant protection and community benefit. Case studies, such as Merck & Co. Inc. (Hermsen, Sibbel & Holland, 2020), demonstrate that with proper oversight and adherence to established ethical principles and guidelines (GDPR, CIOMS, TCPS2, etc.), big pharma's involvement can be transformed into a force for good. Merck & Co. Inc., based in the US (also known as MSD outside Canada and the United States), operates patient-centered antimicrobial stewardship (AMS) programs across 28 countries. These programs focus on raising awareness about AMS, conducting research and surveillance, implementing AMS strategies, and advocating against antimicrobial resistance and infectious diseases (Hermsen, Sibbel & Holland, 2020). Merck follows a One Health approach to research, encompassing human, veterinary, and environmental health, while emphasizing transparency in drug research, production, and administration (MSD Animal Health, 2018; Feinstein et al., 2017).

Increasingly, the One Health approach is recognized as crucial for combating public health issues that arise at the human-animal-environment interface, such as zoonotic diseases (CDC, 2024). The CDC employs this strategy by involving experts from various fields, including professionals in human health, animal health, and environmental health, as well as other relevant sectors. Successful public health interventions require cooperation and coordination among these diverse professionals. For example, addressing diseases like malaria, Ebola, and T2DM in SSA benefits from the One Health approach. For malaria, its effective control involves human health experts to treat and prevent the disease, animal health professionals to manage vector populations (such as mosquitoes), and environmental specialists to address habitat conditions that facilitate mosquito breeding. Managing T2DM requires a comprehensive approach that includes human health professionals for medical treatment and lifestyle interventions, environmental health experts to address factors like urban planning and access to healthy food, and policymakers to create supportive public health policies.

The One Health approach emphasizes the need for multidisciplinary communication, collaboration, and coordination, recognizing that no single entity can address these complex health issues alone (Viegas, 2022). This integrated strategy is essential for effective intervention and control of endemic diseases in SSA and beyond. Interestingly, many traditional approaches to health in SSA societies align with the One Health approach. This alignment is evident in how healing in traditional SSA societies often involves a multi-disciplinary, comprehensive process that addresses physical, mental, emotional, and spiritual well-being (Moreira-Almeida, 2021). These healing practices typically require the collaborative efforts of various community members, including herbalists, hunters, guardians of deities, or healers with multidisciplinary expertise (Moreira-Almeida, 2021; Iddrisu, 2017; Mokgobi, 2015). This intricate process typically deprioritizes individual self-sovereignty in favor of relational autonomy, which recognizes shared physical and moral spaces and well-being with other individuals, organisms, and entities in the community. It also aligns with Brunger’s (2016) argument that biomedicine and bioethics are inherently cultural constructs.

Another example comes from the COVID-19 pandemic. While big pharma faced criticism for resisting calls to waive their intellectual property (IP) rights for COVID-19 vaccines to enhance access in developing countries (Okereke, 2021), their dedication to scientific rigor and their enormous resources led to the rapid development of vaccines and therapies. This commitment significantly contributed to mitigating the pandemic's impact, ultimately saving millions of lives globally (The Association of British Pharmaceutical Industry, 2024; Armstrong, 2020).

4.5: Strategies for Transparent and Equitable Benefit-Sharing

Effective strategies for managing big pharma's involvement include stringent adherence to ethical guidelines, transparent communication, and equitable benefit-sharing mechanisms (Emanuel et al., 2022; Nuffield Council on Bioethics, 2020). These requirements are like the stringent mechanisms identified in the preceding chapter for strengthening surveillance against harm and exploitation of research subjects and host communities. Establishing clear protocols for informed consent, data privacy protection, and compensation for participants are crucial steps. Moreover, a commitment to open data sharing and community engagement can contribute to building trust and ensuring that the benefits of research are distributed fairly among all stakeholders.

Fair sharing of the ownership of the research process and assets is an important part of community-based research benefits-sharing. The literature on ownership and governance of patient- and community-based research highlights several models, which include the collective ownership model or what Ballantyne (2018, pp. 33 & 38) described as a “co-governance” and “stewardship” model. My preference is for the co-governance and stewardship model over other prominent candidates.

The co-governance model recognizes that health research data is a complex product of multiple relationships and interests amongst stakeholders. These stakeholders include patients, families, communities, health professionals, research teams, financiers, and the government. The model envisions the co-creation or co-

construction, processing and safeguarding of the outcomes of health research (Ballantyne, 2018). In the co-governance and stewardship model of patient- and community-based research, ownership of research results is shared among various stakeholders. This model emphasizes collaborative decision-making and acknowledges the diverse interests and relationships involved in health research. Co-governance is managed through processes that facilitate collective decision-making, such as establishing advisory boards or committees where representatives from different stakeholder groups have a voice in shaping research priorities, methodologies, and outcomes. Stewardship involves the responsible management and oversight of research data and assets (including safe storage of health data or specimen in blood bank) to ensure that they are used ethically and for the benefit of all stakeholders involved (Wendelborn, Anger, & Schickhardt, 2023). Other models of the ownership and governance of patient- and community-based research favor either the patient or the government as exclusive owners of research data.

The present study aligns with the collective ownership and stewardship perspective of health data, given that mandated citizen participation in research on malaria and T2DM, as proposed, is a population-wide and complex public health initiative, which requires concerted effort and commitment from all sectors, to succeed. Its shared responsibility and benefits for all remains a major appeal for its envisaged sustainability. To ensure adequate protection for SSA citizens from financial benefit exploitation by the research team and their financiers, the strategic frameworks for the proposal’s policy design, implementation, and monitoring should be comprehensive and robust to address all areas of conflict and misrepresentation.

There are several similar community-based health research initiatives involving the community, the research team, and the government, which this study can learn from (Brunger et al., 2024; Corso et al., 2022; Berg et al., 2019). Several SSA countries are making significant strides in vaccine development and production to combat diseases endemic to the region. For example, in December 2021, Merck partnered with Nigeria’s Innovative Biotech to establish the country's first vaccine development and production facility. Similarly, in March 2023, Moderna concluded an agreement with the Kenyan government to build an mRNA production facility. Additionally, in September 2023, USAID awarded a contract to the South Africa Medical Research Council to support HIV vaccine research and development (Asoko Insight, 2023). These events serve as evidence of emerging trend of collaboration between SSA-based pharma companies and their global counterparts in addressing SSA health challenges.

The existing literature on community-based health partnerships (and the resulting community-based research protocols) of the Indigenous populations of Australia, New Zealand, and Canada provides helpful blueprints on major areas of tension and how to address them (Boot & Lowell, 2019). The central objective of these community-based health partnerships is to minimize abuse and exploitation in the research process and outcomes on Indigenous communities as well as to involve the communities in shaping their health destiny (Hayward et al., 2021; Schnarch, 2004).

The global recognition of the authority of Indigenous communities in shaping the objectives and process of research involving their constituency has grown significantly. Consequently, even if an ethics committee or Institutional Review Board approves the ethical validity of a research project, the Indigenous authority's non-approval can override such consent (Brunger et al., 2024). Following this and similar community-based research arrangements and the backing of the Canadian government, for instance, would position Canada’s Indigenous groups to reap the benefits of all studies conducted on their people and communities in recognition of their indigenous research data sovereignty in terms of research “ownership, control, access, and possession” (Schnarch, 2004, p. 80).

4.6: Ethical Justification of the Proposed Solution

The proposal to mandate citizen participation in research aimed at combating malaria and T2DM, underpinned by a robust research framework and strict adherence to ethical principles, is well-justified for several reasons. First, it aligns with the core ethical principles of respect for persons, beneficence, and justice, as established in widely recognized ethical codes and guidelines. Second, it demonstrates a strong commitment to protecting the well-being and rights of research participants, upholding the foundational principles of human research ethics.

The extensive literature on policies and guidelines on research in various indigenous and other marginalized societies (Brunger et al., 2024; Barugahare, 2018; Drawson et al., 2017) provides a rich resource for articulating a robust framework for the mandated research initiative on malaria and T2DM for citizens of SSA as canvassed in this thesis. Taken together, highlights of areas of interest from the literature to this thesis include the establishment of statutory structures, namely the health research council, national health research ethics board, and various implementation committees to superintend over the entire mandated health research project. The membership of the council and committees should include people from the stakeholders of the project namely, the government (Ministry of Health), the researchers and their financiers, and the citizens (represented by their various community leaders or their representatives).

Most importantly, to support mandated citizen research participation in combating malaria and T2DM, enabling national or regional laws should emerge from extensive consultations with the diverse constituent groups of participating SSA countries. This ensures that the cultural and socioeconomic contexts within and between partner countries are considered from the outset, reducing potential tensions and fostering collective ownership of the initiative. Such laws must explicitly outline the project's aims and objectives, policies, and guidelines for the safety and protection of citizens during and after their involvement in the research (CIOMS, 2016). They should also define the anticipated benefits to participants and their communities, ensuring alignment with ethical standards and the SSA-contextualized model of informed consent, which emphasizes relational and community-centered decision-making over individualistic approaches.

The anticipated benefits extend beyond addressing malaria and T2DM. They include enhancements to healthcare infrastructure, diagnostic capabilities, health education, and socioeconomic gains such as job creation, capacity-building for community-based research, and long-term improvements to health outcomes. However, these benefits must not be viewed merely as secondary outcomes but rather as integral to the planning and execution of the research, ensuring a robust health infrastructure from the onset.

A clear and equitable partnership framework is essential, defining the roles of governments (acting on behalf of their citizens) and researchers. This framework should include agreements on the financial benefits of research outcomes, long-term stewardship and ownership of research assets, and the distribution of responsibilities for sustaining improvements to the health landscape (Hudson, 2016). By embedding these elements into the process, the approach avoids exploitation and mitigates research-related harms, while fostering ethical and culturally sensitive practices tailored to SSA contexts.

4.7: Balancing Ethical Imperatives and Research Objectives

Balancing the imperative to protect research participants and communities with the need to advance scientific knowledge is a delicate task. Ethical research practices, particularly in SSA, require careful alignment with both local contexts and global standards. Big pharma plays a pivotal role in this process, not only through the provision of essential medicines but also by collaborating with SSA pharmaceutical companies to enhance local capacities in drug development and research (Medicines for Malaria Venture, 2024; Asoko Insight, 2023). Such partnerships strengthen ethical oversight and contribute to addressing endemic diseases like malaria and T2DM, ensuring that the advancement of scientific knowledge translates into tangible health benefits for SSA communities.

The growing SSA pharmaceutical industry complements these efforts by providing a foundation for local research and production. Companies like Aspen Pharmacare and Adcock Ingram (South Africa), Neimeth and Fidson Healthcare (Nigeria), Novartis GH and Sanofi GH (Ghana), and Universal Corporation Ltd (Kenya) are increasingly involved in partnerships with big pharma to address regional health challenges (Africa Logistics, 2024). These collaborations not only expand access to affordable medicines but also drive innovative research tailored to the unique epidemiological needs of SSA. Integrating ethical considerations into these partnerships enhances the credibility and societal value of research outcomes while fostering sustainable health improvements in the region.

Part of the credibility credentials of scientific research is its amenability to independent review as a validation and monitoring tool. Independent review is an essential tool in the proposed intervention against endemic malaria and T2DM in SSA. As a settled scientific research requirement, independent review enables other professionals unaffiliated with the research to review its processes for scientific and ethical rigor compliance before, during, and after implementation (Emanuel et al., 2000). The robust implementation framework for the proposed intervention covers the protocol for its independent review, which should incorporate mechanisms for sustainable data generation and safety monitoring and for timely updating in response to future developments (Moreno et al., 1998).

The proposed therapy-oriented research tackling endemic diseases in SSA provides a unique opportunity for poor citizens to access free diagnostic services, which can positively impact citizen well-being and productivity. The increasing importance of diagnostics and biotechnology in modern healthcare systems cannot be overemphasized. It makes clinical care more economical and facilitates the achievement of proper diagnosis for effective and quicker therapy (Mesko, 2020; Henriksen & Brady, 2013). Incidentally, big pharma has in recent time accelerated its investment in diagnostics as an essential complement of drug development in the treatment of diseases (Roche, 2024; Health Quad, 2024; Tan et al., 2020).

In resource-constrained regions like SSA, the proposed research provides a practical and efficient approach to addressing endemic diseases. By focusing on cost-effective strategies, it not only contributes to controlling diseases like malaria and T2DM but also fosters economic and social development. Furthermore, the research framework is designed to protect participants and host communities from abuse and exploitation, ensuring ethical conduct and equitable benefits for all involved.

In conclusion, this chapter discussed how to manage big pharma as research sponsors and partners, with a focus on ethical participant protection and community benefit. By emphasizing evidence-backed strategies and ethical justifications, this chapter aimed to contribute to a paradigm shift in the perception and practice of big pharma's role in ethical health research for improved global healthcare.

Chapter 5

Conclusion

In this thesis, I have investigated the prevalence of malaria and T2DM in SSA and explored how these diseases can be effectively controlled by requiring citizens to participate in health research. The severe consequences of neglecting these diseases, particularly T2DM and its complications - such as kidney and liver diseases, eye and nerve damage, cardiovascular disease, and comorbidities with other endemic diseases like HIV/AIDS and tuberculosis - underscore the need to prioritize them in any meaningful long-term healthcare plans in SSA (Ekoru et al., 2019).

To address the significant threat that malaria and T2DM pose to healthcare systems in SSA, I have argued for the necessity of increased and continuous original research involving human subjects. The compelling reasons for mandatory citizen participation in this research are threefold: first, the devastating and unchecked health impacts of malaria and T2DM; second, the inability to address these impacts without original research involving human subjects; and third, the historical reluctance of residents in SSA to voluntarily participate in clinical research due to low health literacy, poverty, and cultural barriers. Recruiting sufficient human subjects for research on these diseases has been a persistent challenge (Oladipo et al., 2022). Mandatory participation in health research would optimize outcomes, ensuring prompt translation into policy and practice frameworks to address the massive threats these diseases pose to the health and well-being of SSA populations. There is a compelling moral obligation to prevent avoidable deaths and suffering, particularly among vulnerable groups in SSA.

To enhance the real-world relevance of this study and to better illustrate the burden of endemic diseases in the region, I introduced two case studies - one on malaria and the other on T2DM - which were discussed separately. Given the region's unique socioeconomic challenges, such as low health literacy, pervasive poverty, limited national health budgets, and inadequate healthcare system capacities, the path to achieving a malaria-free SSA must be context-based (Ifeagwu et al., 2021; Degarege et al., 2019). The disproportionately high global burden of endemic malaria in SSA means that measures successful in WHO-certified malaria-free nations cannot be directly applied, as socioeconomic conditions, mosquito species, and other factors differ significantly. Therefore, SSA's malaria situation requires indigenous approaches tailored to the region's distinct epidemiology and virulence of malaria infection, which must be developed through research.

Similarly, to develop effective anti-T2DM therapies in SSA that can compete with or enhance current treatments, it is critical to conduct sustainable original research involving human subjects. This research should focus on investigating the region's indigenous functional foods - such as fruits, nuts, herbs, and other edible items - as cost-effective dietary inputs for improved blood glucose regulation (Malongane, Phoswa & Berejena, 2024). Additionally, governments and charitable organizations could support the construction of parks, pedestrian walkways, and other infrastructure to promote lifestyle interventions to combat T2DM in SSA populations.

I have also addressed two major objections to my argument for mandated citizen participation in health research in SSA. The first objection concerns the ethics of mandatory participation, which could be seen as a violation of the principle of respect for autonomy. To address this concern, I argued that respect for autonomy should not be an insurmountable barrier to achieving greater societal health and well-being. No single ethical principle is sufficient to determine the validity of a research program when tensions exist between relevant ethical principles (Emanuel et al., 2000). Mandated, population-wide, health research for the common good is supported by the communitarian values prevalent in SSA societies, such as the concept of 'Ubuntu' (Metz, 2019; Oguejiofor, 2007). Furthermore, the ethical rationale developed by the global healthcare community to combat the COVID-19 pandemic is comparable to this proposed intervention (Emanuel, Upshur & Smith, 2022). I have also proposed social and institutional oversight mechanisms to mitigate any risks associated with forgoing the informed consent protocol for research participation.

The second objection relates to the potential for exploitation of mandated research participants and host countries by the pharmaceutical industry. The industry has been criticized for exploiting human subjects in biomedical research, particularly in low- and middle-income countries (Samman et al., 2018). However, I have argued that with appropriate planning and efficient oversight, large pharmaceutical companies can be prevented from exploiting human subjects in health research (Danescu & Popa, 2020; Strand et al., 2020). Towards this, I have highlighted specific planning and oversight structures aimed at ensuring their transparency and accountability in research. These structures, when combined with existing prominent guidelines, such as the European Union’s General Data Protection Regulation (2016) and the CIOMS guidelines (2016), provide a robust protective framework for human subjects and host communities involved in biomedical and behavioral research.

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