Re-Emphasizing African Bioethics in Light of Potential CRISPR-Based Treatment for HIV and Sickle Cell Disease

ABSTRACT

Recent genetic studies indicate that CRISPR-Cas9, a biological gene-editing mechanism derived from bacteria, may be capable of curing HIV and Sickle Cell Disease. Clinical research for HIV and SCD is prevalent in African nations because of the high incidence of those diseases in all forms. Because past research studies in Africa demonstrate how Western companies can abuse lax ethics regulations in developing African nations, ethics systems must prevent this new, potentially far-reaching CRISPR technology from being prematurely and unethically used on African research participants. In updating current international bioethics frameworks, drafters should pay particular attention to its application in African nations. International bioethics agreements cannot fully protect African research participants, however, until developing countries accord those agreements the power of law. African nations should accelerate the development of unitary systems of ethics laws and education programs unique to the cultural underpinnings of each nation. Only with both the reappraisal of international frameworks to better incorporate traditional African ideals and the development of coherent regional bioethics systems will African research participants be adequately protected.

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I. INTRODUCTION

A 1996 Pfizer study of unapproved drugs in Nigeria resulted in the deaths of several children and injured many more.[1] In 1996, Nigeria was struggling with a severe outbreak of spinal meningitis.[2] Seizing this opportunity for clinical research, Pfizer began to test its experimental drug, Trovan, on Nigerian children.[3] The group exposed to the experimental drug was comprised of children between infancy and eleven years of age, a group that traditionally cannot give consent.[4] The parents of these children were largely illiterate and were only given incomplete oral translations of the consent documents.[5] By the end of the Trovan trial, eleven Nigerian children died and many more

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[1] David M. Carr, *Pfizer's Epidemic: A Need for International Regulation of Human Experimentation in Developing Countries*, 35 CASE W. RES. J. INT'L. L. 15, 30 (2003).

[2] *Id.* at 28.

[3] *Id.* at 29.

[4] *Id.*

[5] *Id.* at 30.

suffered brain damage and paralysis.[6] The Pfizer trial illustrated the evasion of ethical ideals that is acute in Africa's developing countries, where researchers can avoid stringent ethics regulations due to lagging bioethics regulations and education.[7] The 1996 Pfizer trials tragedy, coupled with the incredibly high incidence of Human Immunodeficiency Virus (HIV) and Sickle Cell Disease (SCD) in African nations, suggests that African research participants could be vulnerable to premature or unethical use of technology to treat HIV and SCD.[8]

The global regulatory scheme of bioethics, which was born out of international human rights law, has attempted to keep pace with increasingly complicated biotechnology.[9] Currently, drafters of international bioethics frameworks have been struggling to address the use of CRISPR-Cas9 (CRISPR) as a potential treatment for some of the world's most prevalent diseases.[10] Ethically contentious experiments, like the 2018 "designer baby" experiment in China, prove that the world needs cognizable and culturally-applicable regulations regarding both somatic and germline use of CRISPR.[11] When adjusting the current ethics frameworks to address this challenge, global bodies should reassess the underlying assumptions of "global" ideas of ethics to ensure easy applicability throughout the world. In this reassessment, the countries that are at the forefront of ethics

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[6] *Id.*

[7] *See* Olukunle Cornelius Ewuoso, *Bioethics Education in Nigeria and West Africa: Historical Beginnings and Impacts*, 27 GLOB. BIOETHICS 50, 52 (2016). Although the phrase "developing nation" is generally regarded as an improvement over "third world country," I acknowledge that there are still issues with this phrase. "Developing nation" can imply a superiority of "developed" countries. *See* Marc Silver, *If You Shouldn't Call It The Third World, What Should You Call It?*, NPR (Jan. 4, 2015, 5:30 AM), https://www.npr.org/sections/goatsandsoda/2015/01/04/372684438/if-you-shouldnt-call-it-the-third-world-what-should-you-call-it [https://perma.cc/35KY-FWE6] (archived Jan. 26, 2021). I will continue to employ this phrase throughout my Note because it is the widely used term for this group of nations and can aid in clarity of understanding. *See id.*

[8] *See* World Health Organization [WHO], *HIV/AIDS Fact Sheet*, WHO (Nov. 30, 2020), https://www.who.int/news-room/fact-sheets/detail/hiv-aids [https://perma.cc/VF55-LFWF] (archived Jan. 26, 2021) [hereinafter WHO, *HIV Fact Sheet*] (stating that 25.7 million people infected with HIV are in African nations); *see also* Scott D. Grosse, Isaac Odame, Hani K. Atrash, Djesika D. Amendah, Frederic B. Piel & Thomas N. Williams, *Sickle Cell Disease in Africa: A Neglected Cause of Early Childhood Mortality*, 41 AM. J. PREVENTATIVE MED. S398, S398 (2011).

[9] Jennifer Gunning, *Bioethics and Human Rights*, 27 MED. & L. iii, iii (2008).

[10] Carolyn Brokowski & Mazhar Adli, *CRISPR Ethics: Moral Considerations for Applications of a Powerful Tool*, 431 J. MOLECULAR BIOLOGY 88, 88 (2019) ("[E]thical (moral) and safety concerns about certain areas of CRISPR applications, such as germline editing, are apparent around the world.").

[11] *See* Jing-ru Li, Simon Walker, Jing-bao Nie & Xin-qing Zhang, *Experiments That Led to the First Gene-Edited Babies: The Ethical Failings and the Urgent Need for Better Governance*, 20 J. ZHEJIANG U.-SCI. B 32, 33 (2019) (explaining the negative reaction to the gene-edited babies' experiment).

discussions (Western countries, generally) should listen to and incorporate non-Western ethics.

CRISPR-based treatment for HIV and SCD must be regulated at a global level that incorporates African ethics because this ethically sensitive topic will strongly affect Africa. Although it is difficult to develop a distinctly African view of ethics, as African nations contain many different cultures, some generalized concepts can be drawn from traditional African cultures.[12] One central concept is communitarianism, which is much more prevalent in African cultures than in Western countries.[13] Rather than focusing solely on individual rights, communitarianism emphasizes the role and responsibilities of the individual as a member of many different communities.[14] Most international bioethics agreements foundationally prioritize individualism.[15] However, it is imperative that drafters of future international bioethics agreements thoroughly consider African ideas, such as communitarianism, if CRISPR treatments will be used to treat HIV and SCD.[16] Complicating this view, however, is intense disagreement about African bioethics itself.

Global outsourcing—choosing to organize clinical trials in developing nations to both take advantage of lax ethics systems and evade the stricter ethics laws and regulations of developed nations—is of both historical and contemporary concern.[17] To ensure the safety of non-Western research participants, drafters must take care to incorporate African ethics and account for application in developing nations. Additionally, with the constant advancements of CRISPR technology, African nations should accelerate the passage of laws regulating the use of germline editing.[18] In conjunction with legal systems, African medical professionals should be increasingly aware of international frameworks and engage frequently in normative assessments of the nation's bioethical models.[19]

Following this brief introduction, this Note proceeds in four parts. First, this Note analyzes the development of international bioethics

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[12] Godfrey B. Tangwa, *Bioethics: An African Perspective*, 10 BIOETHICS 183, 186 (1996) [hereinafter Tangwa, *Bioethics*] ("It is, however, no secret that Africans, in spite of remarkable diversities, do have a common outlook on life, a common world-view and similar philosophies and practices.").

[13] *Id.* at 192.

[14] Adrien Katherine Wing, *Communitarianism vs. Individualism: Constitutionalism in Namibia and South Africa*, 11 WIS. INT'L L.J. 295, 299 (1992).

[15] *See* Sana Loue, David Okello & Medi Kawuma, *Research Bioethics in the Ugandan Context: A Program Summary*, 24 J.L. MED. & ETHICS 47, 49 (1996).

[16] *See* Tangwa, *Bioethics*, *supra* note 12 (describing the Nso' world view as communitarian).

[17] *See* Ewuoso, *supra* note 7.

[18] *See* Cletus T. Andoh, *Bioethics and the Challenges to Its Growth in Africa*, 1 OPEN J. PHILOSOPHY 67, 74 (2011) [hereinafter Andoh, *Bioethics*].

[19] *See id.* at 73–74.

from its human rights origins, the HIV and SCD crises in Africa and the application of CRISPR to these diseases, and how international bioethics bodies have addressed CRISPR so far. The foundational tenets of international bioethics agreements are not particularly inclusive of traditional African beliefs, as evidenced by problems with bioethical research in Nigeria, Cameroon, and Tanzania. The proposed solution is multifaceted: a global reexamination and reclassification of the tenets of bioethics to better incorporate non-Western cultural ideas in conjunction with the accelerated establishment of domestic legal frameworks and education in developing African nations.

II. BACKGROUND

One of many recent challenges facing bioethicists is the advent of CRISPR, a mechanism for cutting-and-pasting DNA that offers promise in curing many devastating diseases.[20] For example, CRISPR mechanisms offer a potential cure for the HIV/AIDS epidemic and SCD.[21] HIV and SCD are particularly prevalent in African nations, therefore, many future clinical trials will likely happen in Africa.[22]

A. *International Human Rights Develops into Bioethics of Genetic Modifications*

Bioethics explores the ethical concerns of medicine, biotechnology, and life sciences as applied to human beings.[23] Bioethical questions are inherently international questions because of the multidimensional and cross-cultural nature of the field.[24] Bioethics is closely intertwined with human rights and draws much of its strength from generally recognized human rights principles.[25] In the wake of the atrocities of World War II, the United Nations passed the Universal Declaration of

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[20] Patrick D. Hsu, Eric S. Lander & Feng Zhang, *Development and Applications of CRISPR-Cas9 for Genome Engineering*, 157 CELL 1262, 1262 (2014).

[21] *See* Qiaoqiao Xiao, Deyin Guo & Shuliang Chen, *Application of CRISPR/Cas9-Based Gene Editing in HIV-1/AIDS Therapy*, 9 FRONTIERS IN CELLULAR & INFECTION MICROBIOLOGY 1, 10–11 (2019); *see also* Cletus Tandoh Andoh, *Genome Editing Technologies: Ethical and Regulation Challenges for Africa*, 2 INT'L J. HEALTH ECON. & POL'Y 30, 33 (2017) [hereinafter Andoh, *Genome*] ("There is currently no uniform, African approach to ensuring that novel clinical approaches using genome technologies are scientifically, medically and ethically sound.").

[22] *See* WHO, *HIV Fact Sheet*, *supra* note 8.

[23] WENDY ZELDIN, BIOETHICS LEGISLATION IN SELECTED COUNTRIES: BIOETHICS IN INTERNATIONAL LAW 1 (Law Library of Congress 2012).

[24] UNESCO, *Brochure of the Declaration: Universal Declaration on Bioethics and Human Rights*, United Nations Educational, Scientific, and Cultural Organization [UNESCO], http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html [https://perma.cc/9UM4-2HPH] (archived Jan. 26, 2021) (adopted on Oct. 19, 2005).

[25] Gunning, *supra* note 9.

Human Rights.[26] This Declaration included the "right to a standard of living adequate for the health and well-being of himself and his family."[27] As the international assurances of fundamental human rights were strengthened over time, international bodies were created to oversee specialized human rights concerns.[28] These organizations included the United Nations Educational, Scientific, and Cultural Organization (UNESCO) and the World Health Organization (WHO).[29]

Contemporaneously with the development of human rights frameworks, the world sought to directly condemn the eugenic experiments performed on unwilling participants during the Holocaust.[30] A group of American judges overseeing the trials of Nazi doctors developed the Nuremberg Code, a set of ten principles designed to guide ethical research.[31] These ten principles essentially promote four values: autonomy, beneficence, nonmaleficence, and justice.[32] The conception of autonomy put forth in the Nuremberg Code has generally survived in subsequent agreements—primarily through the emphasis of the choice of the participant to end the experiment at his own will.[33] Beneficence and nonmaleficence, together, can be summarized as doing good and not causing harm.[34] The central contribution of the Nuremberg Code was to join medical views of ethics with the emerging realm of human rights law.[35]

In 1964, the World Medical Association adopted the Declaration of Helsinki.[36] Although not legally binding, this Declaration strongly impacted the ethics of practitioners and became the foundational

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[26] George P. Smith II, *Human Rights and Bioethics: Formulating a Universal Right to Health, Health Care, or Health Protection?*, 38 VAND. J. TRANSNAT'L L. 1295, 1299 (2005).

[27] G.A. Res. 217 (III) A, Universal Declaration of Human Rights (Dec. 10, 1948).

[28] Smith, *supra* note 26, at 1305.

[29] *Id.*

[30] *See* Evelyne Shuster, *Fifty Years Later: The Significance of the Nuremberg Code*, 337 NEW ENGLAND J. MED. 1436, 1436 (1997).

[31] *Id.*

[32] *See* Loue, Okello & Kawuma, *supra* note 15.

[33] NATIONAL INSTITUTE OF HEALTH (NIH), TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10 (1949), https://history.nih.gov/display/history/Nuremberg+Code [https://perma.cc/74A3-783D] (archived Feb. 8, 2021); *see also* Loue, Okello & Kawuma, *supra* note 15, at 50.

[34] Loue, Okello & Kawuma, *supra* note 15, at 50–51.

[35] Shuster, *supra* note 30, at 1439.

[36] World Medical Association [WMA], *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, 189 JAMA 33–34 (1964), https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ [https://perma.cc/URJ6-39NL] (archived Jan. 26, 2021) [hereinafter Declaration of Helsinki] (amended in 1975, 1983, 1989, 1996, 2000, 2002, 2004, 2008, and 2013).

bioethics document.[37] This document established ethical standards for medical professionals and largely reiterated and expounded upon the same underlying tenants of the Nuremberg Code.[38] Specifically, the Declaration of Helsinki reinforced the researcher's responsibility to obtain informed consent from participants.[39] More broadly, the Declaration clarified that the ultimate responsibility is always on the researching physician, providing that "[t]he responsibility for clinical research always remains with the research worker; it never falls on the subject even after consent is obtained."[40]

Several years and universal agreements later, the Council of Europe addressed human rights concerns as applied to increasingly sophisticated biotechnology.[41] In the Convention for the Protection of Human Rights and the Dignity of the Human Being with Regard to the Applications of Biology and Medicine: Convention on Human Rights and Biomedicine, the Council of Europe emphasized individualism.[42] In Article 2, member states agreed that "the interests and welfare of the human being shall prevail over the sole interests of society and science."[43] The Convention on Human Rights and Biomedicine was an important step toward governing biotechnology by relying on accepted human rights ideas.[44]

Since the Council of Europe intertwined bioethics with human rights, framers of other international bioethics agreements often rely on universally recognized human rights to garner agreement on foundational principles.[45] Recent global bioethics agreements are rooted in recognized human rights, such as the right to "equitable access to health care of appropriate quality."[46] By focusing on long-standing and widely recognized human rights, drafters of global bioethics agreements attempt to create a generalized framework

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[37] *See* Robert V. Carlson, Kenneth M. Boyd & David J. Webb, *The Revision of the Declaration of Helsinki: Past, Present and Future,* 57 BRIT. J. CLINICAL PHARMACOLOGY 695, 696 (2004) (describing the impact of the Declaration of Helsinki).

[38] John R. Williams, *The Declaration of Helsinki and Public Health*, BULL. WORLD HEALTH ORG., https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2649471/ (last visited Jan. 26, 2021) [https://perma.cc/VTW9-B5U4] (archived Jan. 26, 2021).

[39] Declaration of Helsinki, *supra* note 36.

[40] *Id.*

[41] Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (1997), https://rm.coe.int/168007cf98 [https://perma.cc/Q3NE-CRRE] (archived Jan. 26, 2021) [hereinafter Convention on Human Rights and Biomedicine].

[42] *Id.*

[43] *Id.*

[44] *See* Smith, *supra* note 26, at 1309–10.

[45] Gunning, *supra* note 9 ("Bioethics, it is proposed, has taken on the language of human rights in setting out bioethical norms and principles.").

[46] *Id.* (specifically acknowledging the concerns of health care access in Sub-Saharan Africa).

within which individual countries can adjust cultural specifications.[47] In 2005, UNESCO adopted the Universal Declaration on Bioethics and Human Rights.[48] UNESCO represents 193 Member States and eleven associate Member States.[49] Like the previous bioethics agreements, one of the first principles established in the Declaration is prioritizing the interests of the individual over the advancement of science.[50] The Declaration also reemphasized the generally accepted principles of informed consent, nondiscrimination, and confidentiality.[51]

B. *The Severity of HIV and Sickle Cell Disease in Africa*

HIV and SCD are two prevalent and deadly diseases in Africa. HIV attacks the immune system and renders the infected unusually susceptible to infections and cancers.[52] HIV, if allowed to progress, can result in Acquired Immunodeficiency Syndrome (AIDS).[53] Once an individual has AIDS, their immune system is incapable of fighting infection, which can often lead to death from opportunistic infections.[54] Although current therapies have been relatively effective at curbing the development of AIDS, other opportunistic infections can cause death in individuals with HIV.[55] For example, tuberculosis is the most common cause of death resulting from HIV infection in Africa.[56] The HIV epidemic continues to be a serious health concern throughout the world. By the end of 2019, approximately 38 million people were living

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[47] *See id.*

[48] *UNESCO Adopts Universal Declaration on Bioethics and Human Rights*, UN NEWS (Oct. 20, 2005), https://news.un.org/en/story/2005/10/157362-unesco-adopts-universal-declaration-bioethics-and-human-rights [https://perma.cc/WH5S-3MMZ] (archived Jan. 26, 2021) [hereinafter UNESCO Universal Declaration].

[49] *See Countries*, UNESCO, https://en.unesco.org/countries (last visited Jan. 26, 2021) [https://perma.cc/REU8-RQE9] (archived Jan. 26, 2021).

[50] *See* UNESCO Universal Declaration, *supra* note 48.

[51] *See id.*

[52] *See HIV Basics: About HIV/AIDS*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/hiv/basics/whatishiv.html#what-is-hiv (last visited Jan. 26, 2021) [https://perma.cc/P5SM-96B9] (archived Jan. 26, 2021) [hereinafter CDC, *HIV Basics*].

[53] *Id.*

[54] *See What Are HIV and AIDS?*, AVERT, https://www.avert.org/about-hiv-aids/what-hiv-aids (last visited Jan. 26, 2021) [https://perma.cc/MBF8-JJUN] (archived Jan. 26, 2021). Opportunistic infections are diseases that occur more frequently and severely in individuals with HIV and AIDS, due to their compromised immune systems. Some examples of common opportunistic infections are tuberculosis, pneumonia, and herpes simplex virus. *See Living with HIV: AIDS and Opportunistic Infections*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/hiv/basics/livingwithhiv/opportunisticinfections.html (last visited Jan. 26, 2021) [https://perma.cc/2JRT-6YKK] (archived Jan. 26, 2021).

[55] *See HIV/AIDS*, WHO, https://www.who.int/features/qa/71/en/ (last visited Jan. 26, 2021) [https://perma.cc/3FVG-LNH7] (archived Jan. 26, 2021).

[56] *See id.*

with HIV.[57] Nearly two-thirds of those individuals resided in Africa.[58] There are two types of HIV: HIV-1 and HIV-2.[59] Although the two types share many commonalities, HIV-1 progresses much more quickly to immunodeficiency and is highly transmittable.[60] For these reasons, HIV-1 is the major cause of AIDS. [61]

Despite the severity of the HIV-1 epidemic, there remains no cure for the disease.[62] Currently, the most prevalent method of treatment is highly active retroviral therapy (HAART).[63] While HAART is effective in allowing those infected with HIV to live long, fruitful lives, HAART is unable to eradicate the disease in infected individuals.[64] Specifically, antiretroviral drugs are not effective in eliminating latent reservoirs of the virus.[65] These latent reservoirs, often located in the brains, gastrointestinal tracts, and lymphoid tissues of infected individuals, can be reactivated, and reestablish the virus in an infected individual.[66] Therefore, the world is desperately in need of an HIV-1 treatment that is able to eliminate latent reservoirs for a lasting cure.[67]

SCD is an umbrella term for a group of inheritable blood disorders.[68] Individuals with SCD have abnormal hemoglobin proteins in their red blood cells, caused by gene mutations.[69] The most common and severe type of SCD is sickle cell anemia, which results from two abnormal hemoglobin genes.[70] Hemoglobin is an integral part of the red blood cell and functions to help the cells carry oxygen throughout the body.[71] Red blood cells are typically soft and round and survive for about 120 days.[72] However, red blood cells in individuals with SCD are

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[57] WHO, *HIV Fact Sheet*, *supra* note 8.

[58] *See id.* (stating that 25.7 million people infected with HIV are in African nations).

[59] Samuel Nyamweya, Andrea Hegedus, Assan Jaye, Sarah Rowland-Jones, Katie L. Flanagan & Derek C. Macallan, *Comparing HIV-1 and HIV-2 Infection: Lessons for Viral Immunopathogenesis*, 23 REVS. MED. VIROLOGY 221, 221–22 (2013).

[60] *Id.*

[61] Xiao, Guo & Chen, *supra* note 21, at 2.

[62] *See* CDC, *HIV Basics*, *supra* note 52.

[63] *See* Xiao, Guo & Chen, *supra* note 21.

[64] *Id.* at 1 (explaining that HAART can eliminate suppress replication of the virus but cannot cure HIV).

[65] *Id.* at 2.

[66] *See id.*

[67] *See id.* at 1.

[68] *See Sickle Cell Disease*, NAT'L HEART, LUNG, & BLOOD INST., https://www.nhlbi.nih.gov/health-topics/sickle-cell-disease (last updated Mar. 01, 2020) [https://perma.cc/BZ5P-XF4T] (archived Jan. 26, 2021) [hereinafter NHLBI, *Sickle Cell Disease*].

[69] *See id.*

[70] *See id.*

[71] *What is Sickle Cell Disease (SCD)?*, SICKLE CELL DISEASE ASS'N. OF AM., INC., https://www.sicklecelldisease.org/sickle-cell-health-and-disease/types/ (last visited Jan. 26, 2021) [https://perma.cc/7T95-8CLY] (archived Jan. 26, 2021).

[72] *Id.*

stiff, sickle-shaped, and only survive for about sixteen days.[73] Because SCD affects the shape of red blood cells, it affects the transport of oxygen throughout the body.[74] Therefore, SCD complications often result in the areas of the body that have not gotten sufficient oxygen over time.[75] The complications of SCD include, but are not limited to, lung tissue damage, stroke, jaundice, and spleen damage that can leave patients vulnerable to bacterial infection.[76] Currently, the only cure for SCD is a bone marrow transplant.[77] Various treatment options, like blood transfusions and hydroxyurea transfusions, can increase the longevity and quality of life for individuals with SCD.[78]

SCD is prevalent in African nations, particularly among children under five years old.[79] Up to 3 percent of children born in sub-Saharan Africa are thought to have SCD.[80] Some studies estimate that the early-life mortality rate for children with SCD in Africa is between 50 percent and 90 percent.[81] In the United States and other more developed countries, child mortality from SCD is essentially nonexistent due to newborn screening and early treatment.[82] Despite the severity of SCD in Africa, the disease is understudied and remains a low priority for many African nations.[83] Instead, many nations focus on infectious diseases like HIV and malaria.[84]

C. *The Advent of CRISPR and Its Use in HIV and Sickle Cell Treatment*

A biotechnological surprise, CRISPR merely "exploits an existing genetic system that allows bacteria to acquire immunity from viruses."[85] The enzyme Cas-9 allows scientists to slice DNA at specific sequences and insert desired genetic material.[86] In laypeople's terms, the CRISPR-Cas9 system essentially works like a word processor,

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[73] *Id.*

[74] *See id.*

[75] *See id.*

[76] *Complications and Treatments*, SICKLE CELL DISEASE ASS'N. OF AM., INC., https://www.sicklecelldisease.org/sickle-cell-health-and-disease/treatments/ (last visited Jan. 26, 2021) [https://perma.cc/2TXY-KBNT] (archived Jan. 26, 2021) [hereinafter SCDA, *Complications & Treatments*].

[77] *See* NHLBI, *Sickle Cell Disease*, *supra* note 68.

[78] *See* SCDA, *Complications and Treatments*, *supra* note 76.

[79] *See* Grosse, Odame, Atrash, Amendah, Piel & Williams, *supra* note 8.

[80] *Id.*

[81] *Id.*

[82] *See id.*

[83] *See id.*

[84] *See id.*

[85] Amy Gutmann & Jonathan D. Moreno, *Keep CRISPR Safe: Regulating a Genetic Revolution*, 97 FOREIGN AFF. 171, 171 (2018).

[86] *Id.*

allowing scientists to edit and manipulate the mammalian genome.[87] First adapted to edit the genomes of mammalian cells in 2013, CRISPR is the future of genome editing.[88] CRISPR revolutionized biomedical science almost entirely, even changing how scientists conduct basic research.[89] Scientists have used CRISPR to "edit out Huntington's disease in mice, slow the growth of cancerous cells, and open the door to the eradication of mosquito-borne diseases."[90] CRISPR can be used in either somatic (body) cells or in the germline (cells that will be passed to offspring).[91]

Global researchers looking for a cure for HIV are in luck: the increasingly pervasive and exciting CRISPR technology could be a solution.[92] Although researchers have largely isolated the use of CRISPR to nonhuman testing, the scientific community acknowledges the incredible potential of CRISPR-based treatments for human diseases.[93] Recent experiments suggest that CRISPR can be successful in treating HIV somatically.[94] For example, a paper released in July 2019 announced the elimination of HIV-1 in infected, humanized mice using CRISPR.[95] In this study, scientists combined CRISPR with anti-

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[87] *See generally* Hsu, Lander & Zhang, *supra* note 20.

[88] *See id.* at 1267 (detailing the evolution of CRISPR/Cas9 technology from its primitive use to its application in mammalian cell research).

[89] *See* Sarah Ashley Barnett, Comment, *Regulating Human Germline Modification in Light of CRISPR*, 51 U. RICH. L. REV. 553, 559–60 (2017) (describing the various uses of CRISPR technology, including genetically modifying crops, curing mice of genetic disorders, and generally conducting biological research in cost-effective and simplistic ways).

[90] Tracey Tomlinson, *A Crispr Future for Gene-Editing Regulation: A Proposal for an Updated Biotechnology Regulatory System in an Era of Human Genomic Editing*, 87 FORDHAM L. REV. 437, 441 (2018).

[91] Gutmann & Moreno, *supra* note 85.

[92] *See id.* (This article tracks the development of HIV treatment and prevention through use of CRISPR-Cas9 technology. In addition to explaining the relevant biomechanisms, the article explores possible ethical issues with the use of this technology).

[93] *See* Hsu, Lander & Zhang, *supra* note 20, at 1274 ("Although Cas9 has already been widely used as a research tool, a particularly exciting future direction is the development of Cas9 as a therapeutic technology for treating genetic disorders.").

[94] *See* Prasanta K. Dash, Rafal Kaminski, Ramona Bella, Hang Su, Saumi Mathews, Taha M. Ahooyi, Chen Chen, Pietro Mancuso, Rahsan Sariyer, Pasquale Ferrante, Martina Donadoni, Jake A. Robinson, Brady Sillman, Zhiyi Lin, James R. Hilaire, Mary Banoub, Monalisha Elango, Nagsen Gautam, R. Lee Mosley, Larisa Y. Poluektova, JoEllyn McMillan, Aditya N. Bade, Santhi Gorantla, Ilker K. Sariyer, Tricia H. Burdo, Won-Bin Young, Shohreh Amini, Jennifer Gordon, Jeffrey M. Jacobson, Benson Edagwa, Kamel Khalili & Howard E. Gendelman, *Sequential LASER ART and CRISPR Treatments Eliminate HIV-1 in a Subset of Infected Humanized Mice,* 10 NATURE COMM. 1, 1 (2019) [hereinafter *Sequential LASER ART*]; *see also* Xiao, Guo & Chen, *supra* note 21.

[95] *See Sequential LASER ART*, *supra* note 94. Researchers "humanize" mice by engrafting them with "human DNA, human tissue, a human tumor, a humanized immune system, or parts of the human microbiome." Humanized mice are an extremely useful models for human genetic research. *See* The Jackson Laboratory, *Why Humanized*

retroviral therapy to eradicate the disease.[96] CRISPR treatment, in combination with antiretroviral therapy, is able to eliminate latent reservoirs by improving the typical "shock and kill" method of reactivating latent reservoirs.[97] This experiment is but one indication of the promise of CRISPR technology in eradicating HIV-1 in humans. CRISPR, unlike HAART, promises a true cure for HIV-1.[98]

CRISPR can also be used somatically to potentially cure SCD.[99] Because SCD is caused by genetic mutations, CRISPR can be a particularly useful tool.[100] Several methods, proposed by scientists, could use CRISPR to attain healthy hemoglobin production.[101] First, researchers could use CRISPR to correct the genetic mutation itself, and the edited cells will proliferate throughout the body with normal hemoglobin.[102] Scientists are not yet using this method clinically.[103] Second, by mutating a repressor of fetal hemoglobin, CRISPR can be used to indirectly increase production of fetal hemoglobin.[104] High amounts of fetal hemoglobin can prevent cells from sickling.[105] Researchers recently used this second method in a human for the first time.[106] Victoria Grey, a 34-year-old Mississippi woman, agreed to be the first patient to undergo this novel treatment.[107] One year after her treatment, Grey is doing exceptionally well.[108] According to her doctors, "[s]he is functioning as somebody who does not have sickle cell disease."[109] The doctors intend to expand the clinical trial to forty-five patients soon and hope the results are equally as optimistic.[110] They also intend to try to lower the age of patients who receive this

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Mice?, JACKSON LAB., (July 21, 2020), https://www.jax.org/news-and-insights/jax-blog/2020/july/why-humanized-mice [https://perma.cc/23UD-8AKP] (archived Jan. 26, 2021).

[96] *Sequential LASER ART*, *supra* note 94.

[97] *See* Xiao, Guo & Chen, *supra* note 21, at 7. Shock and kill involves eradicating latent HIV-1 reservoirs by reactivating "dormant virus in the host cells and" inducing "cell killing by HAART and activation of antiviral immune responses." *See id.*

[98] *See id.* at 2.

[99] *See Sickle Cell Gene Therapy Using CRISPR*, SYNTHEGO, https://www.synthego.com/crispr-sickle-cell-disease (last visited Jan. 26, 2021) [https://perma.cc/D4TU-HV4V] (archived Jan. 26, 2021).

[100] *See id.*

[101] *See id.*

[102] *See id.*

[103] *See id.*

[104] *See id.*

[105] Roz Plater, *First Person Treated for Sickle Cell Disease with CRISPR Is Doing Well*, HEALTHLINE (July 6, 2020), https://www.healthline.com/health-news/first-person-treated-for-sickle-cell-disease-with-crispr-is-doing-well [https://perma.cc/X286-W5ST] (archived Jan. 26, 2021).

[106] *See id.*

[107] *Id.*

[108] *Id.*

[109] *Id.*

[110] *Id.*

treatment, to try to prevent the complications of SCD at an earlier age.[111]

CRISPR-based treatments of HIV and SCD may soon be implemented in African nations.[112] In 2019, the U.S. National Institutes of Health (NIH) and the Gates Foundation announced plans to each devote $100 million over four years to bring gene-based treatments to Africa.[113] These organizations, working collaboratively, hope to make gene-based treatments affordable for the millions of sub-Saharan Africans struggling with HIV and SCD.[114] While this collaboration can change the lives of many Africans, some scientists note that gene-based treatments of SCD cannot solve the screening crisis for African children.[115] In addition to the introduction of gene-based treatments, the NIH and Gates Foundation say they plan to fund screening efforts for African children.[116] Increased screening efforts, combined with gene-based treatments like CRISPR, could enable many African children with SCD to live long, healthy lives.[117]

D. *The International Bioethics Community Responds to CRISPR*

With the incredible potential of CRISPR in treating HIV and SCD comes significant ethical concerns. Researchers can potentially use CRISPR both for treatment in somatic cells and germline cells.[118] Somatic mutations would ideally work to cure the patient of HIV-1/AIDS, but the mutations would not follow into the subsequent generations.[119] Germline modifications, however, affect reproductive cells and embryos and are heritable, meaning future generations would not have HIV or SCD.[120] Most resources have been expended in the development and application of somatic cell modifications.[121]

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[111] Plater, *supra* note 105.

[112] Jon Cohen & Jocelyn Kaiser, *NIH and Gates Foundation Lay Out Ambitious Plan to Bring Gene-Based Treatments for HIV and Sickle Cell Disease to Africa*, SCIENCE (Oct. 23, 2019, 5:00 PM), https://www.sciencemag.org/news/2019/10/nih-and-gates-foundation-lay-out-ambitious-plan-bring-gene-based-treatments-hiv-and [https://perma.cc/TC69-2UWL] (archived Jan. 26, 2021).

[113] *Id.*

[114] *Id.*

[115] *See id.*

[116] *Id.*

[117] *See id.*

[118] *See generally* Barnett, *supra* note 89 (comparing somatic and germline modifications generally).

[119] *See id.* at 556.

[120] *See id.* at 553–54 ("Genetic alterations in reproductive cells and embryos affect more than just an individual consenting patient—they become part of the resulting child's genetic make-up.").

[121] *See id.* at 556.

CRISPR can be ethically problematic due to unpredictable off-target mutations with potentially dangerous consequences.[122] Germline modifications are more ethically problematic than somatic modifications.[123] One reason for this contentiousness is that germline modifications reach beyond consenting patients to future generations, disrupting the conventional idea of informed consent to clinical trials.[124] The need for a global regulatory system is heightened by the powerful impact germline editing can have on the entire human race.[125]

The U.S. National Academies of Sciences, the U.S. National Academy of Medicine, the Royal Society, and the Chinese Academy of Sciences co-hosted the first International Summit on Human Gene Editing in 2015.[126] A major focal point of the Summit was the risks and benefits of CRISPR.[127] Some participants, like Jin-Soo Kim from Seoul National University, raised concerns about possible off-target mutations.[128] The participating scientists appeared to generally accept somatic use of CRISPR without raising too many ethical concerns.[129] In contrast, there was extensive discussion about how germline editing was too unsafe and could exacerbate socioeconomic inequities.[130]

In November 2018, Dr. Jiankui He claimed to have created the world's first two "designer babies."[131] In his experiment, Dr. He created HIV-resistant offspring from an HIV-positive parent using CRISPR gene-editing technology.[132] The results of his experiment sparked a firestorm of academic debate about the ethical boundaries of germline modifications.[133] Although Dr. He's experiment illustrated the potential of CRISPR-based treatment of HIV, bioethics scholars worldwide condemned this research as premature, demonstrating the

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[122] *See* Xiao, Guo & Chen, *supra* note 21.

[123] *See* Andoh, *Genome*, *supra* note 21, at 32 (describing reasons for a general consensus prohibiting germline modifications, including: "serious . . . safety concerns, . . . challenges to human dignity, and the potential for permanent negative impact on future generations); Gutmann & Moreno, *supra* note 85 (explaining that the current state of medical research regulations can sufficiently regulate CRISPR somatic mutations but are not prepared to address germline modifications).

[124] *See* Barnett, *supra* note 89, at 555 (commenting that germline modifications will affect every cell in the body and alter the genes of offspring).

[125] *See* Tomlinson, *supra* note 90, at 442.

[126] Comm. on Sci., Tech., and Law, *International Summit on Human Gene Editing: A Global Discussion*, NAT'L ACADS. OF SCIS., ENG'G & MED. 1, 1 (Dec. 1-3, 2015), https://www.nap.edu/catalog/21913/international-summit-on-human-gene-editing-a-global-discussion [https://perma.cc/8KC3-HUJ6] (archived Jan. 26, 2021).

[127] *See generally id.*

[128] *Id.*

[129] *See generally id.*

[130] *See id.* at 4.

[131] Li, Walker, Nie & Zhang, *supra* note 11.

[132] *Id.*

[133] *Id.* at 32.

failings of current attempts to regulate medical research.[134] The aftermath of this controversial experiment led many to reappraise the current state of bioethics.[135] Ethicists are primarily concerned with CRISPR's low efficiency rates and off-target mutations that can cause serious illness.[136] For example, one of He's experimental babies had an off-target mutation, but the side effects from this mutation are still to be determined.[137]

Two days after Dr. He released his announcement of genetically modified babies, the Second International Summit on Human Genome Editing convened.[138] The Second Summit reiterated the usefulness and relative ethical acceptability of somatic genome editing.[139] While the Second Summit once again concluded that germline editing is ethically concerning, Dr. He's experiment caused participants to recognize the inevitability of germline editing.[140] The Second Summit called for an international forum to continually discuss the ethics of germline genome editing.[141] In the wake of Dr. He's experiment, the World Health Organization has established an advisory committee to develop global governance recommendations regarding gene editing.[142] This committee includes African representation, in the form of long-standing South African constitutional judge, Edwin Cameron.[143]

III. ANALYSIS

CRISPR biotechnology offers a possible future cure for HIV and SCD, but with serious ethical risks.[144] Addressing these risks is imperative to protect research participants, particularly in non-

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[134] *See* Jon Cohen, *The Untold Story of the 'Circle of Trust' Behind the World's First Gene-Edited Babies*, SCIENCE, (Aug. 1, 2019), https://www.sciencemag.org/news/2019/08/untold-story-circle-trust-behind-world-s-first-gene-edited-babies [https://perma.cc/T6UF-WZ23] (archived Jan. 26, 2021).

[135] *See* Li, Walker, Nie & Zhang, *supra* note 11.

[136] *See* Xiao, Guo & Chen, *supra* note 21, at 10–11 (specifically discussing the concerns of CRISPR for human use).

[137] Li, Walker, Nie & Zhang, *supra* note 11, at 34 ("The off-target site was not identified by Sanger sequencing and deep sequencing in the baby's cord blood, but it as yet unknown what effects this once-detected off-target site will bring to the girl.").

[138] *Id.* at 33.

[139] *See generally Second International Summit on Human Genome Editing: Continuing the Global Discussion: Proceedings of a Workshop in Brief*, NAT'L ACADS. PRESS (Jan. 2019), https://www.nap.edu/read/25343/chapter/1#8 [https://perma.cc/8NUW-UMVA] (archived Jan. 26, 2021).

[140] *See id.*

[141] *See id.*

[142] Natalie Kofler, *Gene Editing Like Crispr Is Too Important to Be Left to Scientists Alone*, GUARDIAN (Oct. 22, 2019), https://www.theguardian.com/commentisfree/2019/oct/22/gene-editing-crispr-scientists [https://perma.cc/8XCQ-BWWH] (archived Jan. 29, 2021).

[143] *Id.*

[144] *See* Barnett, *supra* note 89.

Western countries where researchers have sometimes mistreated participants.[145] Taken together, the 1996 Pfizer scandal and the recent "designer babies" experiment in China illustrate the serious ethical concerns associated with the clinical application of CRISPR in Africa.[146] One central issue looming over current international bioethics is the colonization of African ethical thought and the difficulties in applying Western frameworks in some African cultures.[147] Many future clinical trials for CRISPR-based treatment of HIV and SCD in humans will likely take place in Africa, because of the high incidence of the diseases in many different forms.[148] This Part will document particular areas of bioethics that should be adjusted to better incorporate traditional African ideals, which will hopefully help ensure an easier application in African nations.

A. *Academic Debate about African Bioethics*

If CRISPR is the future of HIV-1/AIDS and SCD treatment, researchers and clinicians may find it necessary to incorporate more than just Western standards of ethics. Because HIV and SCD are extremely prevalent in African nations, African ideas of ethics may be significant in developing a coherent and inclusive global ethics regime.[149] As a threshold matter, before examining whether the current international ethics scheme sufficiently incorporates African ideas, ethics scholars' debate whether uniquely African bioethics even exist. Some argue for the existence of uniquely emphasized and coherent ethical concepts in African cultures that can be applied to modern-day bioethical concerns.[150] Other academics, however, argue that traditional African ideas are not yet able to properly deal with contemporary bioethical concerns and that many "African ideas" are already adopted in Western thought. [151]

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[145] *See* Carr, *supra* note 1; Godfrey B. Tangwa & Nchangwi Syntia Munung, *Sprinting Research and Spot Jogging Regulation: The State of Bioethics in Cameroon*, 20 CAMBRIDGE Q. HEALTHCARE ETHICS 356, 361 (2011) (detailing other major ethics scandals in Africa, including: a genetic study carried out in Kenyan AIDS orphans that was lacking proper approval, clinical testing of a drug on commercial sex workers in various African nations that lacked informed consent and approval).

[146] *See* Li, Walker, Nie & Zhang, *supra* note 11.

[147] *See* Wing, *supra* note 14, at 318.

[148] *See* Tangwa & Munung, *supra* note 145, at 356.

[149] *See* CDC, *HIV Basics*, *supra* note 52.

[150] *See* Tangwa, *Bioethics*, *supra* note 12, at 194 ("It should, however, be stated that *some* of the bioethical issues currently most discussed in western society, such as those which arise directly from very recent technological developments, would not make much sense to an average Nso' person, although that is not to say that a firm opinion on them, in line with overall Nso' metaphysical and ethical conceptions would be difficult to formulate.").

[151] *See* Ademola K. Fayemi, *African Bioethics vs. Healthcare Ethics in Africa: A Critique of Godfrey Tangwa*, 16 DEVELOPING WORLD BIOETHICS 98, 101 (2016) ("[T]he

Because most codified models of bioethics are relatively new, some African scholars argue that no African bioethics exist independent of Western thought.[152] Some scholars have recognized this Western prominence, leading them to envision the field of bioethics as colonized.[153] Some commentators describe the current Western bioethical regime as "an unintended imperialistic project."[154] Even African bioethics organizations, such as the Pan-African Bioethics Initiative (PABIN) and the West African Bioethics (WAB) are sponsored by Western agencies.[155]

Because of this Western influence, some African scholars believe that the development and application of a uniquely African system of bioethics is imperative to restore the dignity of Africans.[156] Although it is generally recognized that traditional African cultures emphasized communitarianism more so than Western cultures, some scholars even dispute how communitarian the cultures are. To some scholars, like Godfrey B. Tangwa, African bioethics should be an independent system from Western thought.[157] Tangwa takes the approach of constructing models of bioethics from traditional ideas of the Nso of the Bamenda Highlands of Cameroon.[158] Tangwa's work suggests that bioethics regulations may be more effectively implemented in African societies if the regulations accurately reflect the indigenous ideas of the communities.[159] Although Tangwa acknowledges that different African communities have unique values, he identifies certain underlying characteristics he believes are uniquely important to African identity generally.[160] Because bioethics has a strong cultural underpinning, its application should thus be unique to African culture.[161] Although Tangwa's work speaks to a specifically "African" form of bioethics, he seems to be advocating for a more regional system of bioethics, instead of the global incorporation of African bioethics.[162]

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implication is that the traditional worldviews may be unable to adequately respond to contemporary bioethical concerns and challenges.").

[152] *See id.* ("Ethics, just like logic, remains an undeveloped aspect of African philosophy 'at its infancy.'").

[153] *See generally* Ademola Kazeem Fayemi & O.C. Macaulay-Adeyelure, *Decolonizing Bioethics in Africa*, BEONLINE (Nov. 21, 2016), http://www.bioethicscenter.net/journal/index.php/journal1/article/view/No.%204 [https://perma.cc/2X63-E59W] (archived Feb. 10, 2021).

[154] *Id.* at 5.

[155] *Id.*

[156] *See* Tangwa, *Bioethics*, *supra* note 12, at 192.

[157] *See id.* at 183.

[158] *Id.* at 192.

[159] *See* Fayemi & Macaulay-Adeyelure, *supra* note 153, at 7.

[160] *See* Tangwa, *Bioethics*, *supra* note 12, at 192.

[161] *See* Fayemi & Macaulay-Adeyelure, *supra* note 153, at 7.

[162] *See infra* Part IV.B.

Tangwa summarizes the African ethical model as "eco-bio-communitarianism."[163] Communitarianism contrasts with the Western focus on individual autonomy.[164] The focus on community also reframes individual identities as interdependent.[165] The idea that relationships with others are necessary to achieve ideal personhood is sometimes referred to as *ubuntu*.[166] *Ubuntu* philosophy teaches communitarianism; the grounding principle is essentially "a person is a person through other persons."[167] Because individual autonomy underpins many regulations of human clinical trials, a bioethical framework based on communitarianism and *ubuntu* may differ from the current framework.[168] Specifically, *ubuntu* differs from the "common morality" underlying foundational bioethics guidelines like those elucidated in the Declaration of Helsinki.[169] These four central considerations, often referred to as "principilism" are problematic in that they place more emphasis on individual autonomy than many non-Western cultures would prefer.[170] Gerald Ssebunnya argues that, while bioethics should remain a universal field, the broad Westernized scheme of bioethics could be enriched by a closer examination of traditional African thought.[171]

Other scholars, like Ademola K. Fayemi, critique Tangwa's approach.[172] Fayemi particularly argues that traditional African thought is not adept to deal with current bioethical concerns and that African ideas are not so different from Western thought.[173] For example, he contests that communitarianism is not unique to Africa, but is instead a widely held ideal already encompassed into Western thought.[174] Fayemi argues that "the mere moral ethnographic presentation of a people's beliefs and attitudes to some bioethical

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[163] Tangwa, *Bioethics*, *supra* note 12, at 192.

[164] K. G. Behrens, *Towards an Indigenous African Bioethics*, 6 S. AFR. J. BIOETHICS & L. 32, 34 (2013) (arguing for a new standard of common morality that encompasses more than individual autonomy).

[165] *See id.* at 33 ("[A]uthentic personhood or true humanity require being in a relationship with others.").

[166] *Id.*

[167] Yaw A. Frimpong-Mansoh, *Bioethics: Traditional African Perspective*, *in* BIOETHICS IN AFRICA, THEORY AND PRAXIS 52 (Yaw A. Frimpong-Mansoh & Caesar A. Atuire eds., 2019).

[168] *See* Behrens, *supra* note 164 (proposing an African form of principalism that would more closely mirror *ubuntu* and communitarianism).

[169] *See* Loue, Okello & Kawuma, *supra* note 15, at 50–51.

[170] *See* Gerald M. Ssebunnya, *Beyond the Sterility of a Distinct African Bioethics: Addressing the Conceptual Bioethics Lag in Africa*, 17 DEVELOPING WORLD BIOETHICS 22, 26 (2017).

[171] *See id.*

[172] *See* Fayemi, *supra* note 151.

[173] *See id.* at 101.

[174] *See id.* at 103 ("[S]ince the last decade or so, there has been a drift toward solidarity, family centeredness, dignity, care, precaution, relationality, among others in European bioethics.").

issues cannot suffice for constructive and well-articulated African moral theories that can be justifiability applied to a given bioethical problem, whether at the local or global level." [175] Fayemi also argues that African bioethics should not be the forefront concern in a movement for indigenous African dignity because new biotechnologies are not heavily utilized in African nations.[176] Instead, he advocates for an immediate focus on the development of health care ethics, with the hope of eventually improving health care systems enough to have a need for bioethics.[177]

B. *International Frameworks Do Not Properly Account for African Context*

Regardless of the existence of uniquely African bioethics, there are many ways in which the current international framework is unsuited for proper application in African nations. Specifically, these frameworks fall short of ensuring the safety of research participants in developing nations. Autonomy and informed consent, two foundational tenets of international bioethics agreements, are difficult to comport with traditional African values and the realities of developing nations.[178] First, many African countries are traditionally communitarian, meaning that these countries focus on the collateral effects of individual actions on family and surrounding communities.[179] While this belief sounds incompatible with Western individualism, it is very possible (and in fact, preferable) for the two ideas to coexist.[180] Second, history indicates that foreign and domestic researchers may take advantage of research participants in developing nations, where the idea of informed consent must reflect the unique context of developing nations.[181] The disparity between international frameworks and African ideals/realities is compounded by Western-centric sources of funding for biotechnological research, rendering many developing nations unable to condition funding on ethical compliance.[182] The lack of long-standing domestic regulations in many African nations and the dispersed nature of ethical leadership within

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[175] *Id.*

[176] *Id.* at 101 ("A second fundamental factor, which Tangwa though mentioned in the passing, is the poor state of the use of state-of-the-art bio-technologies in Africa, which for the most part, generates many bioethical dilemmas.").

[177] *See id.* at 104.

[178] *See* Loue, Okello & Kawuma, *supra* note 15.

[179] *See* Andoh, *Bioethics*, *supra* note 18.

[180] *See* Wing, *supra* note 14.

[181] *See* Carr, *supra* note 1.

[182] *See* Cheluchir Onyemelukwe, *Research Involving Humans in African Countries: A Case for Domestic Legal Frameworks*, 16 AFR. J. INT'L & COMP. L. 152, 166–69 (2008).

many countries complicates implementing international agreements.[183]

1. Traditional Communitarianism and Accepted Individualism

In light of increasingly powerful germline editing technology, worldwide regulators are contemplating new regulations to more closely and specifically monitor CRISPR. Thus far, global bioethics has focused its efforts with a decidedly individualistic view.[184] Individualism stresses the importance of the individual over the state, society, or the community.[185] This individualism, though, is perhaps not as readily applicable in traditionally communitarian cultures.[186] Communitarianism instead focuses on responsibilities to family, religion, culture, and community over the interests of individuals.[187] Western cultures reflect individualist beliefs, while African cultures largely adopt communitarian values.[188] Because of this foundational difference, it is difficult to implement Westernized frameworks in African cultures.[189] Western cultures, however, have been more dominant in creating bioethical models.[190] This prevalence of individualism can subordinate African beliefs and create a disconnect between cultures, leading to issues with the successful implementation of bioethics in Africa.[191] That difference in fundamental beliefs could inhibit bioethical frameworks from working effectively in African nations.[192]

Although many African cultures are traditionally communitarian, the prevalence of Western thought has led to the incorporation of individualism in recent African agreements and constitutions. For example, the African Charter on Human and Peoples Rights ("Banjul Charter") is an agreement that entered into force in 1986 that has since been ratified by the majority of African nations.[193] This agreement was intended to ensure human rights and protections for citizens of African

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[183] *See* Andoh, *Bioethics*, *supra* note 18, at 68 ("[T]hough bioethics has come of age in the developed and some developing countries, it is still largely 'foreign' to most African countries."); Tangwa & Munung, *supra* note 145, at 356.

[184] *See, e.g.*, Convention on Human Rights and Biomedicine, *supra* note 41.

[185] Wing, *supra* note 14.

[186] *Id.*

[187] *Id.* at 296.

[188] *Id.* at 299–303.

[189] *Id.*

[190] *See id.*

[191] *See* Andoh, *Bioethics*, *supra* note 18, at 69 ("This attitude of assimilating Western values and ideologies into Africa can give rise to a situation of self-dehumanization and outright self-subversion both in terms of dignity and self-esteem.").

[192] Wing, *supra* note 14.

[193] Org. of Afr. Unity [OAU], *African (Banjul) Charter on Human and Peoples' Rights*, CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (June 27, 1981) [hereinafter Banjul Charter].

nations.[194] Predictably, this document incorporates many individualistic notions—such as the right to self-determination, freedom of association, and equality before the law.[195] Instead of merely parroting Westernized conceptions of individualism, this document crafts a vision of rights protections without rejecting traditionally communitarian values. Article 27 of the agreement states that "[e]very individual shall have duties toward his family and society" and "[t]he rights, and freedoms of each individual shall be exercised with due regard to the rights of others, collective security, morality and the common interest."[196] Similarly, Article 29 reemphasizes the duties of the individual toward his family, specifically his parents.[197]

The Banjul Charter emphasizes that communitarian visions are often not at odds with individualistic notions. On the surface, these concepts can appear strongly in tension. On the contrary, many scholars who espouse communitarian views believe they should exist in conjunction with individualism.[198] Communitarianism can be seen as informing individualist decisions—individuals should take others, such as family and the larger community, into account when making decisions. The Academy of Science of South Africa recently released a study on the implications of genetic research in South Africa.[199] The Academy described the traditional communitarian *ubuntu* philosophy of South Africa and its importance in South African constitutionalism.[200] The Academy expounded upon the implicit understanding in the Banjul Charter—the coexistence of individualism and communitarianism.[201] The Banjul Charter describes the importance of incorporating communitarian values into international frameworks.[202]

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[194] *See id.* art. 4 (reaffirming dedication to human rights as envisioned by the United Nations and by previous OAU instruments).

[195] *See id.*

[196] *Id.* art. 27.

[197] *Id.* art. 29. ("The individual shall also have the duty: 1. To preserve the harmonious development of the family and to work for the cohesion and respect of the family; to respect his parents at all times, to maintain them in case of need.").

[198] *See* Wing, *supra* note 14, at 300 ("Thus, the choice is not whether there should be individual rights or communitarian duties. For communitarian theorists, there must be both.").

[199] Michael Pepper, Collet Dandara, Jantina de Vries, Amaboo Dhai, Melodie Labuschaigne, Freddy Mnyongani, Keymanthri Moodley, Antonel Olckers, Anne Pope, Raj Ramesar, Michele Ramsey, Himla Soodyall & Wayne Towers, *ASSAf Consensus Study on the Ethical, Legal and Social Implications of Genetics and Genomics in South Africa*, 114 S. AFR. J. SCI., no. 11/12, 2018, at 10, 10.

[200] *Id.*

[201] *Id.*

[202] *Id.*

2. Informed Consent

The history of medical research in Africa illustrates how foreign companies sometimes conduct research in developing nations at the expense of African research participants.[203] Despite many international ethics agreements, including the foundational Declaration of Helsinki, that require researchers to obtain informed consent from research participants, these agreements tend to have less force in developing nations because some nations have not yet incorporated these agreements into their domestic law.[204] The incorporation of internationally accepted ideals into domestic legal frameworks is an important step in protecting African research participants.[205]

Legal guidelines are perhaps more integral in developing nations because, unlike Western nations with greater research funding, developing nations have more difficulty enforcing ethical ideals through funding choices.[206] Western nations can informally enforce international agreements by conditioning funding on compliance.[207] Even if foreign researchers' funding for clinical trials in African nations is tied to compliance, the African nations themselves have no say in which regulations are required for funding. Additionally, due to the lack of local funding, African nations are not as capable of assuring compliance with local cultural values.[208]

Because many African nations do not have longstanding ethical frameworks requiring informed consent, or have disparate sources of local oversight, companies generally have fewer laws and regulations to comply with when conducting research in developing nations.[209] One

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[203] *See* Ewuoso, *supra* note 7.

[204] *See* Ileana Dominguez-Urban, *Harmonization in the Regulation of Pharmaceutical Research and Human Rights: The Need to Think Globally*, 30 CORNELL INT'L L.J. 245, 268 (1997); Onyemelukwe, *supra* note 182.

[205] *See* Andoh, *Genome*, *supra* note 21, at 43 ("Informed consent must take local and regional values into account and enable true decision-making on particularly sensitive use of cells and DNA from certain sources. Africans need to assert their convictions about human beings, life, and dignity, and social, economical, and political order in the discourse of society."); *see also* Onyemelukwe, *supra* note 182.

[206] *See* Onyemelukwe, *supra* note 182 (discussing how the standards of Western funding agencies, such as the World Health Organization, can help protect research participants but are not as comprehensively protective as domestic legislation).

[207] *See id.*

[208] *See id.* (also elaborating on the often-differing priorities of foreign researchers and African communities).

[209] *Id.* at 153 (suggesting that developing countries are deterred from developing legal frameworks because of the risk of deterring foreign research trials). Parents of the children involved in this experiment brought suit, some in the Federal High Court in Nigeria and others in Federal District Court in the United States. The Nigerian suit was dismissed. Plaintiffs brought suit in the U.S. under the Aliens Tort Claims Act, specifically alleging violations of the Declaration of Helsinki and the Nuremberg Code. The District Court dismissed this case, finding the Nigerian courts to be the proper venue

memorable example of the failure to obtain consent, and the devastating consequences that can result from the disregard of ethical guidelines, is the 1996 Pfizer trials in Nigeria. In the midst of a deadly spinal meningitis outbreak, Pfizer included an experimental drug, Trovan, alongside its charitable medical assistance.[210] In addition to this inherent coercion, Pfizer tested Trovan on children who could not provide informed consent.[211] Their parents were unable to give sufficient consent because they were either illiterate or given incomplete translations of necessary documents.[212] As mentioned earlier, the Trovan trial resulted in paralysis, brain damage, and even the death of many Nigerian children. This experiment illustrates the historical tendency of foreign research organizations to take advantage of participants in developing nations. This failed experiment encouraged Nigeria to develop ethical guidelines to protect research participants, which will be further discussed in the next Part.

Research participants in developing nations are traditionally and currently at risk of coercive and dangerous biological research. The central bioethics tenant of informed consent foundationally emphasizes individualism, which may not be as salient in African nations without the inclusion of communitarian concerns.[213] A larger concern, though, appears to be the lag in developing comprehensive and consistently applied domestic legal frameworks.[214] The potential for future clinical trials using CRISPR to cure HIV and SCD raises similar concerns of opportunistic scientists taking advantage of countries with weak legal frameworks, coupled with the high risk of off-target mutations.[215]

C. *Examination of Bioethics in Three African Nations*

The colonization of international bioethics is not merely a theoretical discussion, but rather one that concretely impacts the success of bioethics implementation in African nations. A closer examination of the development of bioethics in Nigeria, Cameroon, and Tanzania provides different views of the state of bioethics in Africa and its ongoing struggles. Bioethics in these three nations demonstrate the

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for these suits. The Court of Appeals affirmed. Onyemelukwe, *supra* note 182, at 158. Despite the availability of the Nigerian venue, the victim's counsel sought review in the U.S. courts largely because of Pfizer's influence in Nigeria. *See* Carr, *supra* note 1, at 45.

[210] Carr, *supra* note 1.

[211] *See id.* at 29.

[212] *See id.* at 30.

[213] *See* Andoh, *Bioethics*, *supra* note 18, at 69 ("[E]thical principles grown from African soil is a necessity for Africa especially as people in life act in ways that are more consistent with the values they hold, rather than following any particular bioethical principles.").

[214] *See* Dominguez-Urban, *supra* note 204.

[215] *See* Xiao, Guo & Chen, *supra* note 21, at 10.

need for centralized ethics governance, increased focus on educational programs, and protection of economically and socially vulnerable groups from opportunistic research.[216]

1. Nigeria—Push for Ethical Infrastructure Following Pfizer

The ethical nightmares of the 1996 Pfizer trials provided the impetus for increased development of bioethics in Nigeria. International agreements, such as the Universal Declaration on Human Genome and Human Rights, did not sufficiently protect the research participants from global outsourcing, so the need for local enforcement became clear.[217] The concept of national ethics committees was not novel—in fact, Nigeria technically already had a national Ethics Research Committee, which was unhelpful in actually enforcing ethical clinical practices.[218] This nonfunctional system of ethical oversight, in addition to a generally weak health care system and the rule of a military dictatorship, resulted in Pfizer successfully taking advantage of Nigerian research participants.[219]

In the wake of the Pfizer trials, many Nigerian scholars recognized that the lack of ethics education and domestic frameworks had allowed foreign researchers to exploit research participants.[220] In response, many scholars traveled to foreign universities to receive bioethics training.[221] Over time, Nigeria developed a National Code for Research Ethics and a National Health Research Ethics Committee.[222] These developments coincided with an increased focus on ethics education, specifically the origination of the West African Bioethics (WAB) Training programs.[223] The WAB Training programs are an important step toward educating practitioners in West Africa, but are still foundationally Western, especially since these programs are sponsored by the United States National Institutes of Health.[224] Programs such as WAB Training have certainly increased awareness of bioethics in Nigeria, but there is still room for progress. A 2014 study

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[216] *See* Jerome Ateudjieu, Samia Hurst, Martin Ndinakie Yakum & Godfrey Tangwa, *Biomedical Research Ethics in Cameroon: A Survey to Assess Training Needs of Medical Residents and Students*, 19 BMC MED. ED., Jan. 2019, at 1, 6; Ewuoso, *supra* note 7; Sirkku K. Hellsten, *Bioethics in Tanzania: Legal and Ethical Concerns in Medical Care and Research in Relation to the HIV/AIDS Epidemic*, 14 CAMBRIDGE Q. HEALTHCARE ETHICS 256, 256 (2005); Tangwa & Munung, *supra* note 145, at 356.

[217] Ewuoso, *supra* note 7.

[218] Onyemelukwe, *supra* note 182, at 157. There is no evidence that any review committee approved of this trial despite Pfizer's insistence that it received approval.

[219] *Id.*

[220] *See id.* at 153.

[221] *See id.*

[222] *See id.* (Local ethics committees also emerged during this time).

[223] *See id.*

[224] *See id.* at 152.

indicated that many medical professionals still lack knowledge of good ethical practices, and many are also unaware of the governing ethical bodies in the area.[225] Additionally, there is a need for other West African countries to take more initiative in their involvement with WAB.[226]

2. Cameroon—Educational Lag and Dispersed Leadership

Because so many citizens of Cameroon suffer from all strains and subtypes of HIV, Cameroon has become a hotbed of HIV research.[227] While foreign researchers traditionally carried out most clinical trials, advances in Cameroon's education system have resulted in more local researchers.[228] Although these local studies are carried out by Cameroonian scientists, most of these studies are still funded by foreign organizations.[229] Despite the frequent research occurring in the country, and the concern of differing interests between nonnationals funding research and local Cameroonian researchers, Cameroon does not have a single governing regulation of research on humans.[230] Instead, participants must rely on international ethical guidelines and local laws that lack consistency.[231]

A recent survey of medical students at the University of Yaounde I, Cameroon, details how unfamiliar many future physicians are with the international bioethics documents that are supposedly governing their studies.[232] Only 12.6 percent of those surveyed were aware of the content of the Declaration of Helsinki—the foundational bioethics agreement—and only 10 percent of those surveyed were familiar with the content of the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects.[233] This failure in the teaching of international agreements can create a knowledge disparity that inhibits proper collaboration on cross-border research projects. While different ethics committees developed in Cameroon, the lack of a centralized national consensus on ethical principles and application is detrimental to the future of genetic research in the country.[234] Tangwa, in his close examination of bioethics in Cameroon, advocated for a singular, independent national ethics committee in conjunction

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[225] *See id.*

[226] *See id.*

[227] *See* Tangwa & Munung, *supra* note 145, at 356.

[228] *See id.*

[229] *See id.*

[230] Ateudjieu, Hurst, Yakum & Tangwa, *supra* note 216, at 1, 6.

[231] *See id.* at 6.

[232] *Id.* at 1–7. This survey examined fifth and sixth-year medical students, as well as medical residents. Overall, two-fifths of those surveyed stated that they had received ethics education. *See id.*

[233] *Id.* at 4.

[234] Tangwa & Munung, *supra* note 145, at 356.

with better bioethical education in the Cameroonian medical school curriculum.[235]

3. Tanzania—Economic Disparity and Concerning Views of Women

Tanzania is an East African nation with a growing economy largely dependent on tourism and agriculture.[236] The HIV/AIDS crisis seriously affected Tanzanian citizens, and the country ranks as one of the most affected by the disease.[237] In 2005, Sirkku Hellsten undertook an examination of health care ethics concerns in Tanzania.[238] While the country has since grown in both economy and governmental sophistication, many of the concerns Hellsten identified may still be barriers to the implementation of CRISPR in Tanzania. She identified the tendency for local medical professionals to ignore international bioethics in favor of efficiency as a central concern.[239] Additionally, Hellsten touched on the tension between traditional Tanzanian views and the use of modern medicine by foreign practitioners, referring to this as the "double standard in bioethics in Tanzania."[240] This double standard can lead to inequity of treatment—as wealthy citizens will seek treatment at internationally funded hospitals while poorer citizens are relegated to relying on pro bono work of doctors who may fail to uphold ethical ideals.[241] Hellsten also discussed the possible repercussion of disclosure of HIV-positive status, especially as it relates to Tanzanian women.[242] Because of the stigma of HIV and the often-patriarchal nature of Tanzanian society, diagnosed women can face "domestic violence and/or abandonment, unemployment, and social isolation" or be blamed by her HIV-positive husband for spreading the infection.[243] Despite these ethical difficulties, as of 2012,

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[235] *See id.* at 363.

[236] *The World Factbook: Tanzania*, CENTRAL INTELLIGENCE AGENCY, https://www.cia.gov/library/publications/the-world-factbook/geos/tz.html (last visited Jan. 13, 2021) [https://perma.cc/P9UU-TBF2] (archived Jan. 13, 2021).

[237] *Id.*

[238] *See generally* Hellsten, *supra* note 216.

[239] *Id.* at 257 ("[E]ven when there is awareness of the international codes of medical ethics, medical practitioners tend to apply them according to the local needs and values, in consideration of the resources available, to guarantee any efficiency in service delivery.").

[240] *Id.* at 259.

[241] *Id.*

[242] *Id.* at 261.

[243] *Id.*; *cf.* Lindsay Carniak McLaughlin, *The Price of Failure of Informed Consent Law: Coercive Sterilization of HIV-Positive Women in South Africa*, 32 LAW & INEQ. 69, 69 (2014) (detailing horrific accounts of forced sterilizations in South Africa that mirror some concerns of gender equity in medical treatment in African countries).

the coverage of antiretroviral therapy for those with HIV was at 61 percent.[244]

Taken together, the development of bioethics in Nigeria, Cameroon, and Tanzania can teach us important lessons about the central issues with the implementation of bioethics in African nations. The impact of the notorious Pfizer Trovan trial in Nigeria illustrates the impressive progress that can be made once a tragedy forces a nation to reexamine bioethics protections.[245] Simultaneously, Nigeria demonstrates that even African nations that have emphasized the development of bioethics can face educational lags.[246] Recent statistics out of Cameroon further emphasize the lack of ethics knowledge of future practitioners, which could inhibit the cross-cultural implementation of biotechnology.[247] The "double standard of bioethics" in Tanzania suggests that economically and socially vulnerable populations may be more susceptible to unsafe, unethical trials.[248] Many African nations have made commendable progress in developing systems of bioethics, but more needs to be done.

IV. SOLUTION

CRISPR could potentially cure HIV and SCD.[249] Before this technology is used in more human experiments, like Dr. He's "designer babies" experiment, global bioethics must provide cogent guidelines for ambitious researchers.[250] Since global cures for HIV and SCD would necessarily be implemented in African nations, bioethics regulators must adopt strategies to ensure efficient implementation in African cultures. As history has shown, some opportunistic researchers may circumvent the stricter regulations of Western nations by carrying out dangerous research in developing African nations.[251] This danger is amplified in the context of CRISPR-based clinical trials for HIV and SCD treatments. The prevalence of HIV and SCD in African nations

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[244] World Health Organization, *Global Health Observatory Country Views, United Republic of Tanzania Statistics Summary*, WHO, http://apps.who.int/gho/data/node.country.country-TZA (last updated Oct. 21, 2019) [https://perma.cc/JJ4A-ZJF5] (archived Jan. 13, 2021).

[245] Carr, *supra* note 1, at 30.

[246] Ewuoso, *supra* note 7.

[247] *See* Ateudjieu, Hurst, Yakum & Tangwa, *supra* note 216.

[248] Hellsten, *supra* note 216.

[249] Xiao, Guo & Chen, *supra* note 21, at 10.

[250] Andoh, *Genome*, *supra* note 21, at 38 ("Scientists are ignoring ongoing policy debates and conducting dangerous and socially fraught experiments on mothers and children. Although evidence of safety and efficacy of the technique has not been well quantified, many scientists are using Crispr Cas-9 technology to create embryos for reproduction or implantation into the womb, which is prohibited."); *see also* Li, Walker, Nie & Zhang, *supra* note 11, at 34.

[251] *See* Andoh, *Genome*, *supra* note 21, at 38; Carr, *supra* note 1, at 30.

creates a hotbed of research opportunities, with limitless possible participants and countless strains of the virus.[252]

The solution to this problem must be a dual one: (1) the incorporation of non-Western cultural ideals into newly updated international frameworks and (2) an increased focus on domestic laws and education. First, international bioethics agreements governing CRISPR experiments on humans should be cognizant of communitarian values and possible issues with implementation in non-Western cultures.[253] When drafting new declarations, particularly surrounding potentially lifesaving research in African nations, drafters should be particularly attuned to African perspectives on ethics and implementation of biotechnology. Second, African nations should focus on developing local laws to regulate genetic experiments.[254] Local regulations would better protect research participants and could ensure efficient implementation of culturally appropriate ethical ideals. While this system of local laws is being established, African medical schools should place more emphasis on teaching international bioethics frameworks.[255] Cross-cultural research projects could be more easily implemented if African practitioners were more familiar with international ethics ideals and had more opportunities to consider African perspectives on bioethics.

A. *Incorporating Communitarianism, Modifying Informed Consent, and Rejecting Global Outsourcing*

If CRISPR will be utilized world-wide, as the current trajectory suggests, the underlying assumptions of international bioethics should incorporate non-Western ideologies. This is even more imperative considering the recent developments in using CRISPR to treat HIV and SCD, diseases most prevalent in non-Western nations.[256] As previously mentioned, Western-born bioethics tends to emphasize individualism without due regard for countries with communitarian values.[257] The lack of inclusion of communitarian ideals, coupled with the strong focus on individualism and human rights, may lead to difficulties in applying these frameworks in non-Western countries.[258] Additionally, reliance on solely international agreements to govern research in Africa may be

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[252] Tangwa & Munung, *supra* note 145, at 356 (discussing the unique disease profile of Cameroon).

[253] Carr, *supra* note 1, at 30; Wing, *supra* note 14, at 300.

[254] Onyemelukwe, *supra* note 182.

[255] *See* Tangwa & Munung, *supra* note 145, at 358–60.

[256] Xiao, Guo & Chen, *supra* note 21, at 10.

[257] Declaration of Helsinki, *supra* note 36.

[258] *See* Wing, *supra* note 14, at 317–18 (describing the difficulties of the "copycat approach" of constitutionalism, in which the African populace could not fully comprehend the foreign constitutional ideals that were supposed to govern them).

ill-advised, since international regulations do not carry the force of law.[259] If international frameworks better incorporate non-Western ideals, local African researchers may be more likely to act in accord when pursuing research trials.[260]

Western cultures could benefit from including communitarian ideals in international ethics agreements.[261] Communitarianism can be particularly important when utilizing technology, like potential germline use of CRISPR, that can reach into future generations and impact the human race.[262] It does not denigrate individualistic ideas to incorporate broader considerations into individual decision-making.[263] Of course, human rights and individual choice should be upheld in international research projects. A total shift away from the human-rights-centered approach of bioethics would be too abrupt.[264] Instead of a rejection of individualism, this Note proposes the drafting of future documents to include communitarian ideals that would serve to broaden the implications of individual choices.

The express incorporation of communitarian ideals in future international bioethics frameworks would strike a harmony between the perspectives of both Tangwa and Fayemi in the scholarly debate about African bioethics. Tangwa insists that traditional communitarianism is essential to the successful implementation of bioethics in Africa.[265] Alternatively, Fayemi insists that communitarianism is not unique to Africa but is already encompassed in Western thought.[266] If this is true, Westernized frameworks should be able to more easily adapt to the express inclusion of communitarian ideals. Regardless of the scholarly debate about uniquely African forms of bioethics, ideas of communitarianism should be able to peacefully coexist in current international frameworks.

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[259] Onyemelukwe, *supra* note 182, at 161–62.

[260] *See* Ssebunnya, *supra* note 170, at 29 ("Overcoming the deeply entrenched colonial legacy is perhaps the most fundamental task . . . for conceptual bioethics in Africa."); *see also* Wing, *supra* note 14, at 318.

[261] *See* Wing, *supra* note 14, at 300 (explaining that individualists could gain broader societal understanding by inclusion of communitarian ideals, because of the constant grouping of humans in society).

[262] *See* Andrew Cunningham, *A Cleaner, CRISPR Constitution: Germline Editing and Fundamental Rights*, 27 WM. & MARY BILL RTS. J. 877, 883 (2019) (explaining the safety risks of side effects in subsequent generations through CRISPR and the need for clinical trials to span generations to ensure safety).

[263] Wing, *supra* note 14, at 300.

[264] *See* Smith, *supra* note 26, at 1308–09 (detailing the evolution of bioethics agreements created with due regard for human rights).

[265] *See* Tangwa, *Bioethics*, *supra* note 12, at 183.

[266] Fayemi, *supra* note 151, at 103 ("The Nso'-African account of bioethics explored by Tangwa is in no way unique to the Nso' in particular, nor the Africans in general, as such are views only contingently and historically associated. For instance, since the last decade or so, there has been a drift towards solidarity, family centeredness, dignity, care, precaution, relationality, among others in European bioethics.").

The incorporation of communitarian ideals is a particularly important step toward addressing future human CRISPR trials, as CRISPR technology may strongly impact families and communities.[267] This is especially true of germline mutations, as they will carry into subsequent generations and continue to affect the human race.[268] Thus, when engaging the use of this wide-reaching technology, researchers and participants should be careful to consider the implications on the various communities that will be affected.[269]

The pervasively incorporated concepts of beneficence and nonmaleficence could provide one nondisruptive avenue for incorporating communitarianism into future declarations.[270] The ideas of beneficence and nonmaleficence, which essentially provide researchers with a baseline rule of creating benefit and avoiding harm, could be expressly broadened for a more global understanding of decision-making.[271] An express guideline for researchers to analyze the potential benefits and harms on the community at large would be an important step toward easier incorporation in African nations. Therefore, there is no real need to deviate from the four tenets emphasized in the foundational Nuremberg Code and its progeny.[272]

International frameworks could also be adjusted to better account for problems of global outsourcing to developing nations.[273] Some of the most dramatic examples of opportunistic foreign researchers, such as the Pfizer trial in Nigeria, clearly involve researchers acting in contravention of internationally agreed-upon principles of informed consent.[274] Based on examples like the Pfizer trial, it could be argued that express acknowledgment and condemnation of opportunistic global outsourcing would not solve these problems. However, express condemnation could work in conjunction with increased local frameworks to protect research participants in developing nations. This could simply be in the form of a paragraph stating the international disapproval of conducting research in developing nations to circumvent the more established domestic ethics laws in developed nations.

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[267] Cunningham, *supra* note 262, at 883 (describing the uncertainty of resulting off-target mutations carrying into future generations).

[268] *Id.*

[269] *See id.*

[270] *See* Loue, Okello & Kawuma, *supra* note 15, at 50–51. Communitarianism and beneficence are not the same. As Loue points out, "[t]he assessment of risks and benefits of participation may differ significantly in Uganda as compared to a Western nation." While this observation is still true, the interests of African and Western nations may align more closely regarding CRISPR-based research, since CRISPR can affect the entire human race. *See id.*; *see also* Cunningham, *supra* note 262, at 883.

[271] *See* Loue, Okello & Kawuma, *supra* note 15, at 50–51.

[272] *See id.* at 50.

[273] *See* Ewuoso, *supra* note 7.

[274] *See id.*

This Note suggests amendments to the Declaration of Helsinki, both to expressly include communitarianism and to protect against global outsourcing.[275] Since its adoption in 1964, the World Medical Association (WMA) has amended the Declaration many times. In the twenty-first century alone, the WMA has amended the Declaration four times. Because the WMA frequently amends the Declaration, the proposed amendments, detailed below, should not be unduly burdensome. Amending the Declaration of Helsinki, a document generally regarded as the foundation of bioethics, could result in ease of understanding and familiarity.[276] The Cameroon study suggests that, while many African researchers are not familiar with many bioethics documents, they are most familiar with the Declaration of Helsinki.[277] One limitation of this solution is the Declaration of Helsinki's limited reach—it only applies to physicians under the umbrella of the World Medical Association.[278] However, this limitation does not eliminate the global importance of the Declaration.

Paragraph 25 of the most recent Declaration of Helsinki, amended in 2013, states, "[a]lthough it may be appropriate to consult family members or community leaders, no individual . . . may be enrolled in a research study unless he or she freely agrees."[279] International bioethics could benefit from a slight shift in the language of this provision to mirror the language of the Banjul Charter in Part III(B)(1).[280] This Note specifically advocates for an amendment to paragraph 25 of the Declaration of Helsinki to emphasize the necessity of exercising consent "with due regard to the rights of others, collective security, morality and the common interest."[281] Additionally, the Declaration should be amended to include a broader consideration of community-wide risks and benefits. Currently, paragraphs 16–18 discuss how researchers should consider the "risks and burdens to the individuals and groups involved in the research."[282] This Note advocates that this section of the Declaration be amended to include

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[275] *See* Declaration of Helsinki, *supra* note 36; *see also* Andoh, *Genome*, *supra* note 21, at 38.

[276] *See* Declaration of Helsinki, *supra* note 36.

[277] *See* Ateudjieu, Hurst, Yakum & Tangwa, *supra* note 216. As mentioned in Part III.C.2, the percentage of Cameroonian students familiar with this document was still very low. Only 12.6% of students were aware of the existence and content of the document. However, this number compares favorably to the awareness of other documents. Therefore, this Note suggests that amending the Declaration of Helsinki would be the most efficient way to affect the international bioethics scheme, especially as understood in African nations.

[278] Declaration of Helsinki, *supra* note 36. Therefore, the Declaration is does not apply to non-physician researchers. *See id.*

[279] *Id.*

[280] *See supra* Part III.B.1.

[281] Banjul Charter, *supra* note 193; see *supra* Part III.B.1.

[282] Declaration of Helsinki, *supra* note 36, at 16–18.

"risks and burdens to the individuals and groups involved in the research, the communities surrounding those research subjects, and the community in which the research occurs."

This Note also advocates express acknowledgment and condemnation of global outsourcing as a possible avenue for protecting the rights of vulnerable research participants in developing nations. Global outsourcing is already condemned as a practice and researchers who evade ethics laws can face recourse in their home countries, but an express condemnation in a foundational ethics agreement could further discourage the behavior. An express condemnation of global outsourcing could fit within the "vulnerable groups" section of the most recent Declaration.[283] This Amendment could state universal disapproval of researchers circumventing stricter Western bioethics by intentionally seeking research locations with lagging domestic ethics legislation and systemic inabilities to enforce international agreements. With both the express recognition of communitarianism and express condemnation of global outsourcing, international bioethics could be more finely tuned for application in developing African nations.

B. *Accelerating Domestic Bioethics Laws and Education*

Solely increasing inclusivity of international frameworks will not fully protect African research participants because they are often unenforceable unless similar legislation has been adopted into a nation's domestic legal framework.[284] In addition to the reformulation of international frameworks, African nations must continue to develop and emphasize the development of ethical frameworks, national oversight committees, and educational programs.[285] While many African nations have been slowly cultivating ethics laws, committees, and education, these nations must emphasize and accelerate this development before foreign researchers are able to take advantage of the lag.[286] This development can function more broadly than just the protection of research participants from nefarious researchers; if the technology advances to become safe for clinical research, updated

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[283] *Id.* at 19–20. Paragraph 19 provides a blanket protection for vulnerable groups. However, the paragraph does not specify which groups qualify as vulnerable and are thus entitled to protection. *See* Carr, *supra* note 1, at 42.

[284] Dominguez-Urban, *supra* note 204 ("[N]ational regulations have very little extra-territorial effect, and international guidelines have not been widely accepted and have no enforcement mechanisms.").

[285] *See* Ateudjieu, Hurst, Yakum & Tangwa, *supra* note 216; Onyemelukwe, *supra* note 182.

[286] Andoh, *Bioethics*, *supra* note 18, at 68 (explaining the lack of motivation of African decisionmakers in developing bioethical guidelines).

systems of ethics can enable positive research to help cure HIV and SCD in African nations.

The development of domestic legal frameworks can function most efficiently under an umbrella of African inclusion in international frameworks. Within a developed international framework that emphasizes both individualism and communitarianism, African nations could logically create their own unique sets of laws governing bioethics.[287] This Note does not advocate for any particular set of laws to be enacted but rather suggests that African nations accelerate the passage of legislation geared toward the unique cultures and beliefs of each nation, with special attention paid to centrality in oversight and advanced protection against opportunistic research. This solution may be beneficial for African nations because it provides a more navigable path out of Western colonization of African bioethics.[288]

However, this solution has its own set of issues. For example, a nonglobal system of ethics can lead countries to develop conflicting regulations.[289] This could be a problem as researchers will seek worldwide application of their medical advancements. To properly eradicate worldwide diseases like HIV and SCD, a regional system of bioethics may not be the most efficient option, even though it may do a better job at ensuring cultural respect.[290] The hope, though, is to develop international frameworks within which all of these differing national regulations could fit comfortably, with limited conflict. If Western nations better incorporate communitarianism into frameworks, it will hopefully be less difficult for African-Western collaboration to attack the HIV/AIDS epidemic. Efficient cross-border collaboration could still exist, however, if medical schools and higher education across the globe improve their curriculum on international bioethics. This could help avoid educational gaps, like those evidenced by the Cameroonian study suggesting that most medical students and residents are unaware of governing international agreements.[291]

One central problem with the regional approach is the difficulty of establishing a system of ethics in countries that do not yet have one.[292]

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[287] Currently, many African nations have lagged in developing coherent regulations on genome editing. This apathy of generating regulations is likely a result of the lack of inclusion of African beliefs in international agreements. The inclusion of African beliefs into important international agreements—like the Declaration of Helsinki—might prompt more local action on the subject. *See* Andoh, *Genome*, *supra* note 21.

[288] *See* Fayemi & Macaulay-Adeyelure, *supra* note 153.

[289] *See* Andoh, *Genome*, *supra* note 21, at 69.

[290] *See id.*

[291] *See* Ateudjieu, Hurst, Yakum & Tangwa, *supra* note 216, at 1–7.

[292] *See* Andoh, *supra* note 21, at 68 (explaining the difficulty of dispelling bioethics misconceptions and improving awareness among African nations); Onyemelukwe, *supra* note 182, at 154 (describing that many African nations have not yet created legislative frameworks regarding human research).

Without one national set of laws regarding bioethics, many African countries lack centrality in ethical oversight.[293] The lack of a central framework causes many ethics committees to develop, each claiming to have the authority to dictate proper ethics guidelines within the same country.[294] At times, these ethics committees disagree on what is acceptable within the culture of the nation.[295] This can understandably lead local researchers to be confused on the appropriate way forward regarding contentious experiments. This dispersion in oversight can also afford foreign researchers more opportunities to exploit developing nations.[296] To avoid global outsourcing and evasion of stricter regulations in other countries, nations with several different ethics committees must consolidate into one solid voice.[297]

Many African nations have been and are currently attempting to develop such national regulations and improve bioethics education within their universities.[298] For example, a group of African doctors, ethicists, and researchers came together to develop a guidebook for African research ethics committees.[299] This helpful guidance demonstrates that many African scholars understand the importance of clear national ethics regulations and are pushing for the advancement of ethics laws and education. Nigeria's quick development of ethics frameworks following the Pfizer trial illustrates the ability of African nations to develop such frameworks. Hopefully these nations can implement ethics protections before a tragedy occurs. This shift may not be getting the attention it desperately deserves, however, as technology is improving dramatically in short periods of time.[300] Because CRISPR is becoming cheaper and more accessible, and because many African nations are currently hotbeds for genetic research regarding HIV, nations such as Cameroon could significantly

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[293] *See* Tangwa & Munung, *supra* note 145, at 358–60.

[294] *See id.* Tangwa and Munung detailed the birth of many different ethics committees in Cameroon, caused by a lack of national funding and unclear national guidelines. It is unclear how much, if any, authority each of the different ethics review committees hold. Lack of clarity in the ethics review process can exacerbate unethical research in Cameroon, a hotbed country for HIV/AIDS research. *See id.*

[295] *Id.* at 358 (identifying the presence of up to 24 ethics review committees existing in Cameroon at one time).

[296] *See* Ewuoso, *supra* note 7.

[297] *See* Tangwa & Munung, *supra* note 145, at 364 (recommending that Cameroon adopt a centralized, uniform National Ethics Committee to avoid the problems of multiple voices speaking to the ethics of the nation).

[298] *See id.* at 357 (commending certain African nations, such as South Africa and Nigeria, for their encouraging bioethics developments, while commenting on the lack of such action in many developing nations).

[299] *See generally* MARIANA KRUGER, PAUL NDEBELE & LYN HORN, RESEARCH ETHICS IN AFRICA: A RESOURCE FOR RESEARCH ETHICS COMMITTEES (2014).

[300] *See* Andoh, *Bioethics*, *supra* note 18, at 74.

benefit from the improvement of national ethics on an accelerated timeline.[301]

The prior examination of Nigeria and Cameroon illustrates the educational lag for professionals in some African nations.[302] Ethics education can benefit the development and implementation of domestic legal frameworks. One important consideration is the development of education that emphasizes application in African cultures. As mentioned previously, Western-conceived notions of ethics may not be entirely applicable or preferable in African nations, mainly concerning the lack of communitarian thought and the contextual differences in obtaining informed consent.[303] While African medical students and philosophers should become highly familiar with internationally accepted frameworks, they should also engage in ongoing conversations about the ethical consequences of technological improvements.[304]

Increased educational awareness can help ensure equitable treatment for poorer citizens of countries with large economic disparities, like Tanzania.[305] A strong domestic legal framework coupled with programs in bioethics could prevent local researchers from forgoing ethics for the sake of efficiency.[306] Increased awareness of the international principles of bioethics could likewise help prevent paternalistic views of women resulting in dangerous and coercive procedures.[307] If local practitioners, especially in developing nations, are more often exposed to internationally accepted views of informed consent, they may be less likely to use coercive strategies to obtain consent.

V. CONCLUSION

As recent experiments have demonstrated, CRISPR affords scientists an unprecedented opportunity to cure SCD and HIV.[308] The incredible potential of this technology is accompanied by equally significant ethical concerns, especially with the probable influx of CRISPR clinical trials in African nations. Global bioethics agreements should attempt to ensure ease of application in non-Western nations. The inclusion of African cultural ideals and the application of ethics in

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[301] *See* Tangwa & Munung, *supra* note 145, at 357.

[302] *See* Ateudjieu, Hurst, Yakum & Tangwa, *supra* note 216, at 1–7; Ewuoso, *supra* note 7, at 53.

[303] *See supra* Part III.B.

[304] *See* Andoh, *Bioethics*, *supra* note 18, at 73–74.

[305] *See* Hellsten, *supra* note 216, at 257–61.

[306] *See id.*

[307] *See* McLaughlin, *supra* note 243, at 73.

[308] *See* Xiao, Guo & Chen, *supra* note 21.

developing nations are essential to protect research participants in this new era of HIV and SCD treatment.[309]

The express acknowledgment of bioethics in the African context can lead to a more globally inclusive conversation about CRISPR. Acknowledging communitarianism—its heritage in traditional African cultures and its benefits to Western nations—and accounting for cultural differences in regard to informed consent and confidentiality, can be important steps forward.[310] In addition to reforming international frameworks, many African nations themselves could benefit from prioritizing the development of centralized national regulations that further incorporate the cultural ideals of individual nations.[311] By creating local frameworks and prioritizing the bioethics education of local medical researchers, African nations that have thus far lagged behind in upholding standards of ethics can begin to keep pace with significant technological improvements.[312]

Taylor Daniel[*]

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[309] *See* Tangwa, *Bioethics*, *supra* note 12, at 198–99 (describing how Africans have enthusiastically adopted Western culture while Western culture has been generally unaccepting of adopting aspects of African tradition).

[310] *See* Wing, *supra* note 14.

[311] *See* Onyemelukwe, *supra* note 182.

[312] *See* Andoh, *Genome*, *supra* note 21, at 35 ("[T]here is the possibility that the technology might be used in the reproductive contexts of Africa long before there are sufficient data to support such use, and before the potential benefits and risks of harm are properly identified.").

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