2021 HOUSE HUMAN SERVICES

HB 1348

2021 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

HB 1348
1/26/2021

Relating to prohibiting the testing of wastewater for genetic material or evidence of disease; and to provide a penalty.

Chairman Weisz opened the hearing at 2:15 p.m.

Representatives	Attendance
Representative Robin Weisz	P
Representative Karen M. Rohr	P
Representative Mike Beltz	P
Representative Chuck Damschen	P
Representative Bill Devlin	P
Representative Gretchen Dobervich	P
Representative Clayton Fegley	P
Representative Dwight Kiefert	P
Representative Todd Porter	P
Representative Matthew Ruby	P
Representative Mary Schneider	P
Representative Kathy Skroch	P
Representative Bill Tveit	P
Representative Greg Westlind	P

Discussion Topics:

- Covid-19 in wastewater
- Surveillance of wastewater

Rep. Claire Cory, District 42 (2:16) introduced the bill, testified in favor, and submitted testimony #3533.

Margo Knorr, Coleharbor ND (2:24) testified in favor and submitted testimony #2339, #3569, #3571, #3572, #3573

Steve Knorr, Coleharbor ND (2:38) testified in favor.

David Glatt, Director North Dakota Department of Environmental Quality (2:41) testified in opposition and submitted testimony #3450.

Pete Hanebutt, Directory of Public Policy North Dakota Farm Bureau (2:59) testified in opposition.

Tracy Miller, North Dakota Department of Health (3:02) testified in opposition and submitted testimony #3423.

Additional written testimony: #2647, #3005, #3277, #3287, #3383

Chairman Weisz adjourned at 3:05 p.m.

Tamara Krause, Committee Clerk

Hello Mr. Chairman and members of the human services committee,

My name is Representative Claire Cory and I represent District 42 in Grand Forks. My district encompasses the University of North Dakota campus and a section of the north end of Grand Forks. I rise today to provide testimony in support of HB 1348.

I will start by telling you a little bit of background on the topic. In mid july of this year, the Department of Environmental Quality (DEQ) began a study to find COVID-19 in wastewater. The first couple cities tested were Grand Forks, Bismarck, and Fargo. In order to cover the costs of this study Cares Act Funds were used. (including a **$50,000** grant for NDSU.) Eventually the State of North Dakota began testing more and more cities (up to 21) in hopes of monitoring COVID 19 trends throughout communities.

HB 1348s goal is to regulate surveillance of wastewater.

The original purpose I wanted to introduce this bill was to protect the privacy of students at public universities and to create a conversation on the invasion of privacy and effects of having your wastewater tested for COVID 19.

- Are the rights of personal privacy more important than a government's right to violate that privacy under a guise of "public health"?
- In regards to testing on campuses, students at public universities should still have rights and protections.
- There are no "warrants" or any regulations of WHEN and WHERE your wastewater will be tested.
- There aren't any protections in place to keep data private (I.e. Public mandates to quarantine a dorm, city block, apartment complex)
- There is no plan in place to limit what the data is used for.

So at the very least I hope to raise conversation and awareness.

Please vote for a do pass.

Dear Chairman and House committee members,

It is an honor and privilege to write to you today knowing that we here in the United States and specifically the State of North Dakota consider all people equal, which allows for me to share with you, the research I have been doing for many months.

I would like to voice my support of HB 1348 . The only clarification to this bill that would be beneficial for all of us, would be differentiating between “testing” and “surveillance.” It is important to recognize the difference between testing and surveillance with regards to sewage maintenance and safety. Perhaps the wording can be amended to clarify

how this bill is an effort to protect North Dakotans from rather large corporations inside and outside of ND from using ND residents in a research experiment without their informed consent. Moving forward and after the pandemic it is important we are clear on what surveillance is.

Testing is good and useful and is not used to research on

the population experimentally. Surveillance signifies something quite different. The terminology of surveillance is being used to enter humans into a research experiment without informed consent. This act of surveillance crosses over into the area of using humans for experimental research. This is not only illegal, it is unethical, as established by the Nuremberg Code, Belmont

Report, and the legal requirements of ethical research outlined in the Research act of 1974.

Testing: researches water.

Surveillance: researches the Humans. It is an ongoing and repeated testing which is then

entered into an artificial intelligence software that uses humans beings for experimental research and behavior modification campaigns by targeting the humans who are experimentally being researched on. This data is then used to market to and or scrutinize the population being surveilled. Industry leaders are all ready gearing up to push forward with

surveillance of humans beings through their waste even still while in the throws of Covid 19. Surveillance can include, but is currently not limited to biological make up potentially including DNA, chemical composition, disease of all kinds, medications ..... just to mention a few things planned for the humans that have now been entered into this experimental research study.

Research experiments involving humans, even in the context of a population is federally restrained by mandatory informed consent of participating humans who are being targeted for research.

During a pandemic we recognize that sometimes laws get broken and federal offenses happen. But this practice of surveillance, clearly needs to be scrutinized and recognized for what it is. It is using humans within the towns being surveilled and automatically entering the humans into the research experimental study. Currently those humans are neither

informed nor consenting. The current population has NOT been fully educated on what waste surveillance really is and the plans that are in the works for the towns who volunteered and continue on in using surveillance for other matters.

If you have any questions regarding the history of waste

water surveillance or the industry leaders who are now backing this unethical use of humans for their own research agendas, I will be available for questions and would be thankful, that as our elected officials, you are caring enough about our future to ask how this will impact us if not restrained legally. HB 1348 is making a good faith effort to put legal protections in place for the

humans who have now become a part of experimental research with out their consent, until appropriate and legal informed consent of each individual is initiated, we need this Bill to protect us from rather large corporations who do not care about how the experimental research and outcomes can potentially affect those who have unwittingly been included in

their experimental research efforts.

Respectfully, Margo Knorr

COVID-19 Wastewater Surveillance
North Dakota 2020

The CDC and the US Department of Health and Human Services (HHS), in collaboration with agencies throughout the federal government, have initiated the National Wastewater Surveillance System (NWSS) in response to the COVID-19 pandemic. The data generated by NWSS will help public health officials to better understand the extent of COVID-19 infections in communities.

In an effort to eradicate polio in third world countries, the World Health Organization (WHO) and the Gates Foundation (PATH, GAVI) first led communities to monitor wastewater. These initial efforts in 2003 were well-meaning as they tracked and monitored a mass vaccination campaign in third world countries. However, the same practice and surveillance to monitor COVID-19 in 2020—in a free nation—has unintended consequences. And it had dire consequences in Pakistan as well.

COVID-19 wastewater surveillance was established in Fargo, ND at a North Dakota State University (NDSU) dormitory without consent of students in the fall of 2020. Collection of wastewater was tested and results were disclosed to the student residents of the dormitory. In this case, wastewater tests came back positive for SARS-CoV2. Asymptomatic (defined as having no symptoms of COVID-19) students were then sent out an email and told to “COVID-19 test tomorrow.”

In North Dakota, efforts to surveil wastewater for SARC-CoV2 without consent led to government overreach and unintended consequences, including students being forced to clinically test before resuming classes at NDSU, isolation, disruption of campus restart, and an ongoing disjointed methods of instruction for students. This form of surveillance—as well as any proof of its practice slowing the spread of the virus—has no evidence-based guidelines to prove it is warranted.

As the CDC continues to promote wastewater surveillance, targeting cities, workplaces, institutions, and facilities across the nation, the results at NDSU illuminate exceptionally poor outcomes of a human research experiment. Uninformed individuals used as a “research population,” or in the case of NDSU, uninformed students used as a “research population,” has yet to be addressed either legally or ethically.

Overreach and overreaction secondary to COVID-19 is at the forefront of law and bioscience; here is how the Journal of Law and Bioscience has weighed in thus far:

- "If wastewater-based surveillance can be applied at a community level, then ‘effective intervention can be taken as early as possible to restrict the movements of that local population.’"

- "Thus, developers see wastewater surveillance methods as potentially leading to testing (Compelled? Everyone in the sewage district? Answers to this are unstated.) and to restricting movement…"(of population)

The argument has been made that:

- "Efforts by state or local health officials to surveillance wastewater for SARS-CoV-2 would almost certainly come within the state's broadly recognized police powers, which generally permit state and local governments to have broad authority to act and regulate to protect the health and welfare of the population…" However, this police power is only so far and was never intended to be used to promote using humans as their research subject dismissing autonomy and beneficence to the test populations chosen to be researched on. And what ended up happening was inadvertently using human test populations as guinea pigs in a mass experimental science research program.*
- The Nuremberg Code, Belmont Report, and Research Act of 1974 have long been held as ethical parameters in guiding new scientific research; however, with wastewater surveillance, the primary goal appears to have been finding gaps in the law that preclude this form of researching on humans from adhering to such principles.
- The WHO has lower standards of human rights and autonomy because of the vast number of countries and varying governments involved in it. That afforded it to successfully establish wastewater surveillance in third world countries like Pakistan and other countries with the cooperation of governments that have vastly different standards of human rights than those of the United States of America. Wastewater surveillance in Pakistan produced mass paranoia and had deadly outcomes in one vaccination campaign initiated based on waste surveillance.

Headlines

Nearly 70 United States university systems monitored wastewater in the fall of 2020; here are some examples in the news.

- ***Denver Post***
  - "CSU quarantines 900 students after wastewater monitoring detects COVID-19 in two dorms"
- ***CNN***
  - "287 Utah State University students quarantined after Covid-19 found in wastewater from four dorms"
- ***Washington Post***
  - "When a wastewater sample from one dorm came back positive this week, the school quickly tested all 311 people who live and work there and found two asymptomatic students..."

Which North Dakota cities allow wastewater surveillance?

North Dakota leadership initiated community surveillance in conjunction with NDSU this fall. Federal and state dollars have been allotted to the Department of Environmental Quality (DEQ) in an effort to advance this form of surveillance in our state.

Listed below is an initial list of municipalities that volunteered to participate in wastewater sampling. *Note: this number has increased to 21 municipalities

1. Fargo
2. Bismarck
3. Grand Forks
4. Minot
5. West Fargo
6. Williston
7. Dickinson
8. Mandan
9. Jamestown
10. Watford City
11. Devils Lake
12. Wahpeton
13. Valley City
14. Rugby
15. Edgeley
16. Gwinner
17. Ellendale
18. Casselton
19. Glenn Ullin

If your city is listed, it is classified as having "volunteered," according to the DEQ.

How do North Dakota Cities volunteer?

The DEQ reached out to city water and sewage treatment plants and requested collection of samples on an ongoing basis. According to a DEQ engineer, a wastewater collector presented this research experiment for approval to every city council in which it collects. Many city councils petitioned did not approve. Some were not approached as suggested by the DEQ.

What happens when wastewater is tested?

Wastewater samples are collected and sent off to be tested and researched. A municipality's results are provided to the state's executive branch and the ND Department of Health. This data is used to justify executive orders, government overreach, and extensive mandates—essentially providing the fuel for heavy-handed governance.

What can I do about it?

If wastewater surveillance was never taken to your city council, you were never given an opportunity to say no. Now is your opportunity to speak out.

Be on the lookout for false arguments you may hear when you voice your concern:

- ***"This is nothing new."***
    - This is a lie. This is very different from wastewater testing that has gone on before. This is far more scientifically advanced and far more invasive, given what has already happened.
- ***"This is NOT the same research as what the CDC is doing."***
    - This is a lie. Officials are testing municipalities for COVID-19 in the RNA of your fecal material. The results of community biomaterial are then tabulated and reported back to state officials.
- ***"The law supports it."***
    - This is a lie. Wastewater testing involves research that is experimental in nature. It also involves human analysis that opens the door to discrimination against those being researched on.
- ***"This provides an early warning to the medical community and government so both know how to respond."***
    - This is a lie. As we've seen in 2020, this leads to lockdowns, arbitrary restrictions on schools, churches, and businesses, and extensive executive overreach.

The monitoring of wastewater may well implicate the Fourth Amendment. COVID-19 testing is different from testing for lead or E.coli in water in an effort to make the water safe for the residents. Testing water to keep it safe for residents is a good thing. Testing wastewater to find out if residents of a municipality are "safe" to freely move about society is something else entirely.

Conclusion

Imagine what America will look like for our children if we allow this type of surveillance to take hold of our municipalities—and to be expanded. It starts with the state collecting from main sewage water, but as the data gathering advances, it will become more and more desirable to be more aggressive toward human population. Wastewater collectors will be encouraged to begin collecting in a more targeted manner, exactly like what was done to students living in on-campus university housing. When the next novel disease comes around and this form of surveillance is in play, what will become of freedoms that have always involved the enjoyment of taking risks?

Wastewater surveillance will also logically increase the demand for vaccination laws and mandates. What happened at our nation's universities will become commonplace. Every time the CDC, Health Department, Governor, or President or World Organization deems a virus "novel" or a "public health threat," wastewater surveillance the state has quietly enacted will be called upon to monitor our communities.

Action Steps

- Contact your city to inquire about its involvement in wastewater management. Reach out to your city council leaders, mayor, city water plant manager, public works director, etc.
- Contact your district's senator and representatives (find your legislators here: www.legis.nd.gov)

Together we can dismantle the overreach and overreaction to COVID-19 wastewater surveillance and ensure our privacy and freedom.

Resources

https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/wastewater-surveillance/wastewater-workplaces.html

https://www.washingtonpost.com/nation/2020/08/28/arizona-coronavirus-wastewater-testing

https://www.denverpost.com/2020/09/25/csu-quarantine-covid-wastewater-testing

https://www.cnn.com/2020/09/01/health/us-coronavirus-tuesday/index.html

https://academic.oup.com/jlb/article/7/1/lsaa039/5861905

Dear Chairman and House committee members,

It is an honor and privilege to speak to you today knowing that we here in the United States and specifically the State of North Dakota consider all people equal, which allows for me to share with you, the research I have been doing for many months.

I would like to voice my support of HB 1259 . The only clarification to this bill that would be beneficial for all of us, would be differentiating between "testing" and "surveillance." It is important to recognize the difference between testing and surveillance with regards to sewage maintenance and safety. Perhaps the wording can be amended to clarify how this bill is an effort to protect North Dakotans from rather large corporations inside and outside of ND from using ND residents in a research experiment without their informed consent. Moving forward and after the pandemic it is important we all are clear on what surveillance is.

Testing is good and useful and is not used to research on the population experimentally. Surveillance signifies something quite different. The terminology of surveillance is being used to enter humans into a research experiment without informed consent. This act of surveillance crosses over into the area of using humans for experimental research. This is not only illegal, it is unethical, as established by the Nuremberg Code, Belmont Report, and the legal requirements of ethical research outlined in the Research act of 1974.

Testing: researches water.

Surveillance: researches experimentally with Humans. It is an ongoing and repeated testing which is then entered into an artificial intelligence software that uses human beings for experimental research and behavior modification campaigns by targeting the humans who are experimentally being researched on. This data is then used to market to and or scrutinize the population being surveilled. Industry leaders are already gearing up to push forward with surveillance of human beings through their waste even while we are all in the throws of Covid-19. Surveillance can include, but is currently not limited to: biological composition potentially including DNA, chemical composition, disease of all kinds, medications predominantly used by those in the research and test population . These are just a few planned repeated tests for the populations who have now been entered into this experimental research study with out their knowledge or consent.

Research experiments involving humans, even in the context of a population is federally restrained by mandatory informed consent of participating humans who are being targeted for research.

During a pandemic we recognize that sometimes laws get broken and federal offenses happen. But this practice of surveillance, clearly needs to be scrutinized and recognized for what it is. It is using humans within the towns being surveilled and automatically entering the humans into the research

experimental study. Currently those humans are neither informed nor consenting. The current population has NOT been fully educated on what waste surveillance really is and the plans that are in the works for the towns who volunteered their populations and continue on in using surveillance for other matters.

If you have any questions regarding the history of waste water surveillance or the industry leaders who are now backing this unethical use of humans for their own research agendas, I will be available for questions and would be thankful, that as our elected officials, you are caring enough about our future to ask how this will impact us if not restrained legally. I would also like to voice my support for HB 1348 because it is making a good faith effort to put legal protections in place for the humans who have now become a part of experimental research with out their consent, until appropriate and legal informed consent of each individual is initiated, we need this Bill to protect us from rather large corporations who do not care about how the experimental research and outcomes can potentially affect those who have unwittingly been included in their experimental research efforts.

Respectfully, Margo Knorr

Definition of surveillance:

Surveillance is the monitoring of behavior, activities, or information for the purpose of information gathering, influencing, managing, directing, or controlling

LeRoy Walters

#3572

The Belmont Report

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

The National Commission
for the Protection of Human Subjects
of Biomedical and Behavioral
Research

The Belmont Report

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National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

September 30, 1978

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

On behalf of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, I am pleased to transmit our "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research." The identification of basic ethical principles that should underlie the conduct of research involving human subjects, and the development of guidelines to assure that such principles are followed, were topics of studies set forth in the Commission's mandate under Public Law 93-348. This mandate also directs the Commission to submit its report to the President, the Congress, and the Secretary of Health, Education, and Welfare.

Unlike most of the previous reports of the Commission, the Belmont Report does not make specific recommendations for administrative actions by the Secretary of Health, Education, and Welfare. Instead, it is our recommendation that the Belmont Report be adopted in its entirety as a statement of departmental policy on the conduct of research involving human subjects. Publication and dissemination of this policy will provide federal employees, members of Institutional Review Boards and scientific investigators with common points of reference for the analysis of ethical issues in human experimentation. While the principles cannot always be applied so as to resolve beyond dispute particular ethical problems, they provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

The Belmont Report is the outgrowth of an intensive four-day period of discussions that were held in February 1976 at the Smithsonian Institution's Belmont Conference Center and the monthly Commission's deliberations that have been conducted over the nearly four years of our existence.

We appreciate the opportunity to have worked on this fundamental task in the protection of human research subjects.

Respectfully,

Kenneth J. Ryan, M.D.
Chairman

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

September 30, 1978

The Honorable Walter F. Mondale
President of the United States Senate
Washington, D.C. 20510

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September 30, 1978

The Honorable Thomas P. O Neill, Jr.
Speaker of the House of Representatives
Washington, D.C. 20515

Dear Mr. Speaker:

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Kenneth J. Ryan, M.D.
Chairman

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

September 30, 1978

Honorable Joseph A. Califano, Jr.
Secretary of Health, Education, and Welfare
Washington, D.C. 20201

Dear Mr. Secretary:

On behalf of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, I am pleased to transmit our "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research." The identification of basic ethical principles that should underlie the conduct of research involving human subjects, and the development of guidelines to assure that such principles are followed, were topics of studies set forth in the Commission's mandate under Public Law 93-348. This mandate also directs the Commission to submit its report to the President, the Congress, and the Secretary of Health, Education, and Welfare.

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Respectfully,

Kenneth J. Ryan, M.D.
Chairman

NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS
OF BIOMEDICAL AND BEHAVIORAL RESEARCH

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B E L M O N T R E P O R T

ETHICAL PRINCIPLES AND GUIDELINES FOR RESEARCH INVOLVING HUMAN SUBJECTS

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crimes Trials, the Nuremberg Code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype of many later codes* intended to assure that research involving human subjects would be carried out in an ethical manner.

The codes consist of rules, some general, others specific, that guide the investigators or the reviewers of research in their work. Such rules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized and interpreted.

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in this statement.

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* Since 1945, various codes for the proper and responsible conduct of human experimentation in medical research have been adopted by different organizations. The best known of these codes are the Nuremberg Code of 1947, the Helsinki Declaration of 1964 (revised in 1975), and the 1971 Guidelines (codified into Federal Regulations in 1974) issued by the U.S. Department of Health, Education, and Welfare. Codes for the conduct of social and behavioral research have also been adopted, the best known being that of the American Psychological Association, published in 1973.

Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

This statement consists of a distinction between research and practice, a discussion of the three basic ethical principles, and remarks about the application of these principles.

A. BOUNDARIES BETWEEN PRACTICE AND RESEARCH

It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research. The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called "experimental" when the terms "experimental" and "research" are not carefully defined.

For the most part, the term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular

individuals.* By contrast, the term "research" designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is "experimental," in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be

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* Although practice usually involves interventions designed solely to enhance the well-being of a particular individual, interventions are sometimes applied to one individual for the enhancement of the well-being of another (*e.g.,* blood donation, skin grafts, organ transplants) or an intervention may have the dual purpose of enhancing the well-being of a particular individual, and, at the same time, providing some benefit to others (*e.g.,* vaccination, which protects both the person who is vaccinated and society generally). The fact that some forms of practice have elements other than immediate benefit to the individual receiving an intervention, however, should not confuse the general distinction between research and practice. Even when a procedure applied in practice may benefit some other person, it remains an intervention designed to enhance the well-being of a particular individual or groups of individuals; thus, it is practice and need not be reviewed as research.

incorporated into a formal research project.*

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.

B. BASIC ETHICAL PRINCIPLES

The expression "basic ethical principles" refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect for persons, beneficence and justice.

1. Respect for Persons

Respect for persons incorporates at least two basic ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The

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* Because the problems related to social experimentation may differ substantially from those of biomedical and behavioral research, the Commission specifically declines to make any policy determination regarding such research at this time. Rather, the Commission believes that the problem ought to be addressed by one of its successor bodies.

principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show a lack of respect for an autonomous agent is to repudiate that person's considered judgments , to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequences. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to "volunteer" or to "protect" them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

2. Beneficence

Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.

The Hippocratic maxim "do no harm" has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm. Further, the Hippocratic Oath requires physicians to benefit their patients "according to their best judgment." Learning what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

The principle of beneficence often occupies a well-defined justifying role in many areas of research involving human subjects. An example is found in research involving children. Effective ways of treating childhood diseases and fostering healthy development are benefits that serve to

justify research involving children -- even when individual research subjects are not the direct beneficiaries. Research also makes it possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be dangerous. But the role of the principle of beneficence is not always so unambiguous. A difficult ethical problem remains, for example, about research that presents more than minimal risk withhout immediate prospect of direct benefit to the children involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out much research promising great benefit to children in the future. Here again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices.

3. Justice

Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated

equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit.

Questions of justice have long been associated with social practices such as punishment, taxation and political representation. Until recently these questions have not generally been associated with scientific research. However, they are foreshadowed even in the earliest reflections on the ethics of research involving human subjects. For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemmed as a particularly flagrant injustice. In this country, in the 1940s, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available.

Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (*e.g.*, welfare patients, particular racial and

ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

C. APPLICATIONS

Application of the general principles to the conduct of research leads to consideration of the following requirements: informed consent, risk/benefit assessment, and the selection of subjects of research.

1. Informed Consent

Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness.

Information. Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc.

However, a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information should be provided. One standard frequently invoked in medical practice, namely the information commonly provided by practitioners in the field or in the locale, is inadequate since research takes place precisely when a common understanding does not exist. Another standard, currently popular in malpractice law, requires the practitioner to reveal the information that reasonable persons would wish to know in order to make a decision regarding their care. This, too, seems insufficient since the research subject, being in essence a volunteer, may wish to know considerably more about risks gratuitously undertaken than do patients who deliver themselves into the hands of a clinician for needed care. It may be that a standard of "the reasonable volunteer" should be proposed: the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation.

A special problem of consent arises where informing subjects of some pertinent aspect of the research is likely to impair the validity of the research. In many cases, it is sufficient to indicate to subjects that they are being invited to participate in research of which some features will not be revealed until the research is concluded. In all cases of research involving incomplete disclosure, such research is justified only if it is clear that (1) incomplete disclosure is truly necessary to accomplish the goals of the research, (2) there are no undisclosed risks to subjects that are more than minimal, and (3) there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

Comprehension. The manner and context in which information is conveyed is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration or curtailing opportunities for questioning, all may adversely affect a subject's ability to make an informed choice.

Because the subject's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information.

While there is always an obligation to ascertain that the information about risk to subjects is complete and adequately comprehended, when the risks are more serious, that obligation increases. On occasion, it may be suitable to give some oral or written test of comprehension.

Special provision may need to be made when comprehension is severely limited - for example, by conditions of immaturity or mental disability. Each class of subjects that one might consider as incompetent (*e.g.,* infants and young children, mentally disabled patients, the terminally ill and the comatose) should be considered on its own terms. Even for these persons, however, respect requires giving them the opportunity to choose to the extent they are able, whether or not to participate in research. The objections of these subjects to involvement should be honored, unless the research entails providing them a therapy unavailable elsewhere. Respect for persons also requires seeking the permission of other parties in order to protect the subjects from harm. Such persons are thus respected both by acknowledging their own wishes and by the use of third parties to protect them from harm.

The third parties chosen should be those who are most likely to understand the incompetent subject's situation and to act in that person's best interest. The person authorized to act on behalf of the subject should be given an opportunity to observe the research as it proceeds in order to able to withdraw the subject from the research, if such action appears in the subject's best interest.

Voluntariness. An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occures through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.

Unjustifiable pressures usually occur when persons in positions of authority or commanding influence -- especially where possible sanctions are involved -- urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitled.

2. Assessment of Risks and Benefits

The assessment of risks and benefits requires a careful arrayal of relevent data, including, in some cases,alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about proposed research. For the investigator, it is

a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks that will be presented to subjects are justified. For prospective subjects, the assessment will assist the determination whether or not to participate.

The Nature and Scope of Risks and Benefits . The requirement that research be justified on the basis of a favorable risk/benefit assessment bears a close relation to the principle of beneficence, just as the moral requirement that informed consent be obtained is derived primarily from the principle of respect for persons. The term "risk" refers to a possibility that harm may occur. However, when expressions such as "small risk" or "high risk" are used, they usually refer (often ambiguously) both to the chance (probability) of experiencing a harm and the severity (magnitude) of the envisioned harm.

The term "benefit" is used in the research context to refer to something of positive value related to health or welfare. Unlike "risk," "benefit" is not a term that expresses probabilities. Risk is properly contrasted to probability of benefits, and benefits are properly contrasted with harms rather than risks of harm. Accordingly, so-called risk/benefit assessments are concerned with the probabilities and magnitudes of possible harms and anticipated benefits. Many kinds of possible harms and benefits need be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits. While the most likely types

of harms to research subjects are those of psychological or physical pain or injury, other possible kinds should not be overlooked.

Risks and benefits of research may affect the individual subjects, the families of the individual subjects, and society at large (or special groups of subjects in society). Previous codes and federal regulations have required that risks to subjects be outweighed by the sum of both the anticipated benefit to the subject, if any, and the anticipated benefit to society in the form of the knowledge to be gained from the research. In balancing these different elements, the risks and benefits affecting the immediate research subject will normally carry special weight. On the other hand, interests other than those of the subject may on some occasions be sufficient by themselves to justify the risks involved in the research, so long the subjects' rights have been protected. Beneficence thus requires that we protect against risk of harm to subjects and also that we be concerned about the loss of the substantial benefits that might be gained from research.

The Systematic Assessment of Risks and Benefits. It is commonly said that benefits and risks must be "balanced" and shown to be "in a favorable ratio." The metaphorical character of these terms draws attention to the difficulty of making precise judgments. Only on rare occasions will quantitative techniques be available for the scrutiny of research protocols. However, the idea of systematic, nonarbitrary analysis of risks and benefits should be emulated insofar as possible. This ideal requires those making decisions about the justifiability of research to be thorough in the accumulation and assessment of information about all aspects of the

research, and to consider alternatives systematically. This procedure renders the assessment of research more rigorous and precise, while making communication between review board members and investigators less subject to misinterpretation, misinformation and conflicting judgments. Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible. The method of ascertaining risks should be explicit, especially where there is no alternative to the use of such vague categories as small or slight risk. It should also be determined whether an investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.

Finally, assessment of the justifiability of research should reflect at least the following considerations: (i) Brutal or inhumane treatment of human subjects is never morally justified. (ii) Risks should be reduced to those necessary to achieve the research objective. It should be determined whether it is in fact necessary to use human subjects at all. Risk can perhaps never be entirely eliminated, but it can often be reduced by careful attention to alternative procedures. (iii) When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject - or, in some rare cases, to the manifest voluntariness of the participation). (iv) When vulnerable populations are involved in research, the appropriateness of involving them should itself be demonstrated. A number

of variables go into such judgments, including the nature and degree of risk, the condition of the particular population involved, and the nature and level of the anticipated benefits. (v) Relevant risks and benefits must be thoroughly arrayed in documents and procedures used in the informed consent process.

3. Selection of Subjects

Just as the principle of respect for persons finds expression in the requirements for consent, and the principle of beneficence in risk/benefit assessment, the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects.

Justice is relevant to the selection of subjects of research at two levels: the social and the individual. Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research on to some patients who are in their favor or select only "undesirable" persons for risky research. Social justice requires that a distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (*e.g.,* adults before children) and that some classes of potential subjects (*e.g.,* the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions.

Injustice may appear in the selection of subjects, even if individual subjects are selected fairly by investigators and treated fairly in the course of the research. This injustice arises from social, racial, sexual and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs are taking care to assure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. Although individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they can consider distributive justice in selecting research subjects.

Some populations, especially institutionalized ones, are already burdened in many ways by their infirmities and environments. When research is proposed that involves risks and does not include a therapeutic component, other less burdened classes of persons should be called upon first to accept these risks of research, except where the research is directly related to the specific conditions of the class involved. Also, even though public funds for research may often flow in the same directions as public funds for health care, it seems unfair that populations dependent on public health care constitute a pool of preferred research subjects if more advantaged populations are likely to be the recipients of the benefits.

One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized

may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.

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Accountability of International NGOs: Human Rights Violations in Healthcare Provision in Developing Countries and the Effectiveness of Current Measures

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ACCOUNTABILITY OF INTERNATIONAL NGOS: HUMAN RIGHTS VIOLATIONS IN HEALTHCARE PROVISION IN DEVELOPING COUNTRIES AND THE EFFECTIVENESS OF CURRENT MEASURES

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ABSTRACT

In recent years, the number of non-governmental organizations (NGOs) working in the international arena has vastly increased, generally making a positive impact. But, as this influence has deepened, governments in the developing world and scholars have scrutinized the work and accountability of NGOs given they are mostly independent and not subjected to international law. While NGOs must adhere to the domestic laws of the places within which they work, adherence is dependent upon the strength of enforcement of those laws. Proponents argue that this independence is essential for NGOs to effectively carry out their work. However, a review of healthcare programs funded by the Bill & Melinda Gates Foundation (Gates Foundation) calls into question current accountability measures of NGOs in the healthcare sector and can shine a light on weaknesses and potential areas of improvement in the current accountability regime for NGOs.

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The Gates Foundation focuses on world health and population and highlights its strategy of accelerating scientific discovery with reducing costs. Since the early 2000s, the Global Alliance for Vaccines and Immunizations (Gavi), Global Health Innovative Technology Fund and PATH, all heavily funded by the Gates Foundation, have been distributing vaccines and drugs to vulnerable populations in Africa and India. In 2010, the Gates Foundation funded experimental malaria and meningitis vaccine trials across Africa and HPV vaccine programs in India. All of these programs resulted in numerous deaths and injuries, with accounts of forced vaccinations and uninformed consent. Ultimately, these health campaigns, under the guise of saving lives, have relocated large scale clinical trials of untested or unapproved drugs to developing markets where administering drugs is less regulated and cheaper.

With the revelation of such abuses, the shortcomings of the current accountability regime for NGOs must be addressed in two critical areas: monitoring projects and monitoring potential influences and exploitation between donors and NGOs. Through the review of recent Gates-funded healthcare campaigns in Africa and India, this paper seeks to highlight and analyze these shortcomings by looking at the failures of the current accountability regime to prevent and resolve human rights abuses committed during these programs. This paper will offer recommendations to strengthen the accountability regime for NGOs through a more active role by the local governments and through community outreach and development. The findings in this paper will have implications for all NGOs working in the healthcare sector and potentially other sectors.

INTRODUCTION

"Who watches the watchmen?": a variant English translation of the Latin phrase "Quis custodiet ipsos custodies?" commonly used today to question how effectively those in positions of power are held accountable for their actions.[1] It is a fitting question for international non-governmental organizations (NGOs) today, considering their global role, expansive missions and unmonitored activities. With globalization and the increasing awareness of poverty, health, and governance issues in developing countries, the international community has seen a rise in international NGOs and similar organizations (foundations) pledging to save lives in poor countries.[2]

1. E.O. Winstedt, *A Bodleian MS of Juvenal*, 13 CLASSICAL REV. 201–05 (1899).

2. For mission statements of NGOs using the common phrases of 'save lives' and 'change the world', see *About*, PATH, http://www.path.org/about/index.php (last visited March 1, 2017); *About*

However, when NGOs make it their mission to change the world and save lives, do we, as citizens of the international community, really know who benefits most from these changes? For better or worse, when the call to action is to "save lives", a second thought is never given. Any goal to "save lives" is generally deemed important and honorable, leaving a long list of rarely answered questions: how will those lives be saved and from what, to what end, after that life is saved will they have a better quality of life or face the same fate under a different disguise, do these lives know they are in danger and need to be saved, do they want to be saved, and what does the savior receive in return.

The influence and reach of international NGOs and philanthropic organizations is quickly expanding.[3] The grant-making powers and personal networking is unmatchable and they are increasingly shaping the agenda of international organizations and governments. The active role of these organizations has been encouraged and highlighted by the United Nations agencies and some member states, stating in an event summary from 2013 that "[w]hile their contributions are difficult to fully quantify, philanthropic organizations are well-suited to play an ever-more important role in addressing sustainable development challenges . . . in implementing a post-2015 development agenda."[4] The concern, however, is that these foundations and international NGOs enable developed countries and corporations to achieve their own agenda in developing countries with activities ranging "from setting up public-private partnerships with pharmaceutical companies to promoting certain sorts of corporate farming and the use of biotechnology for health and agriculture."[5]

While NGOs have played a role in public healthcare for centuries, in recent decades, the scale of their work in healthcare projects has grown, especially in vaccine, immunization and drug development and delivery. The increasing activities of NGOs in vaccine, contraceptive and drug distributions in developing countries since the early 2000s must be understood in the context of costly drug trials for new drug development.

Gavi, the Vaccine Alliance, GAVI, http://www.gavi.org/about/ [hereinafter *About Gavi*] (last visited March 1, 2017).

3. United Nations Development Programme [UNDP], The Role of Philanthropic Organizations in the Post-2015 Development Agenda Setting, DCPB/OESC/UNDESA (Apr. 2013), http://www.un.org/en/ecosoc/newfunct/pdf13/dcf_philan_summary.pdf; John Vidal, *Are Gates and Rockefeller Using Their Influence to Set Agenda in Poor States?*, GUARDIAN, Jan. 15, 2016, http://www.theguardian.com/global-development/2016/jan/15/bill-gates-rockefeller-influence-agenda-poor-nations-big-pharma-gm-hunger. Note that this article is in the "Global Development" section of The Guardian, which is financially supported by the Bill & Melinda Gates Foundation.

4. UNDP, *supra* note 3.

5. Vidal, *supra* note 3.

The cost of new drug development in the U.S. is about $5.8 billion.[6] Ninety percent of the cost of new drug development is incurred in Phase III clinical trials required by the Food and Drug Administration (FDA) in the United States and similar agency in Europe.[7] In Phase III clinical trials, tests are administered to human subjects to monitor side effects and confirm treatment.[8] As a result of the regulatory requirements to conduct costly clinical trials in the United States and Europe, the relocation of these trials to developing countries with emerging markets where regulatory regimes for drug testing are more lax, and less costly.[9]

The Bill & Melinda Gates Foundation and its recent campaigns in the healthcare sector will serve as a case study in this paper to examine the weaknesses in the accountability regime for NGOs generally. The Gates Foundation is the largest philanthropic organization in the world, and is leading vaccine and immunization research and development. Since 1999, the foundation has invested $32.9 billion of its $43.5 billion endowment on health programs.[10][11] Although developed countries welcome this level of funding for research and many have praised the work of the Foundation,[12] others have questioned the Foundation's power to shift the agenda.[13] Recent reports of human rights abuses resulting from Gates Foundation funded vaccine trials in Africa and India have raised questions about their activities and agenda. Critics have shared concerns on the Gates Foundation and potential policies on population control.[14] This paper seeks to analyze the claims of human rights abuses committed during the course of these Gates Foundation funded healthcare campaigns. With the surfacing of human rights abuses, the shortcomings of

6. *Id.*

7. Avik S.A. Roy, *Stifling New Cures: The True Cost of Lengthy Clinical Drug Trials*, Manhattan Inst. (Apr. 2012), http://www.manhattan-institute.org/html/fda_05.htm.

8. *Id.*

9. Vivan Hunt et al., *A Wake-Up Call for Big Pharma*, McKinsey & Co. (Dec. 2011), http://www.mckinsey.com/insights/health_systems_and_services/a_wake-up_call_for_big_pharma; Michael Edwards, *R&D in Emerging Markets: A New Approach for a New Era*, McKinsey & Co. (Feb. 2012), http://www.mckinsey.com/insights/winning_in_emerging_markets/r_and_38d_in_emerging_markets_a_new_approach_for_a_new_era.

10. *Foundation Factsheet*, Bill & Melinda Gates Foundation, http://www.gatesfoundation.org/Who-We-Are/General-Information/Foundation-Factsheet.

11. *What is the Bill and Melinda Gates Foundation*, The Guardian, Mar. 16, 2015, https://www.theguardian.com/environment/2015/mar/16/what-is-the-bill-and-melinda-gates-foundation.

12. Devin Thorpe, *The Real Reason the World Will Remember Bill Gates*, Forbes (Sept. 5, 2012), https://www.forbes.com/sites/devinthorpe/2012/09/05/the-real-reason-bill-gates-the-world-will-remember-bill-gates-hint-its-not-windows-8/#42671a6e1a00.

13. Vidal, *supra* note 3.

14. *Bill Gates*, TED Talk (2010), https://www.ted.com/talks/bill_gates_unplugged; Matthew Harper, *With Vaccines, Bill Gates Changes the World Again*, Forbes (Nov. 2, 2011), https://www.forbes.com/sites/matthewherper/2011/11/02/the-second-coming-of-bill-gates/#75ceb5fb13fd.

the current accountability regime for NGOs must be addressed as it relates to monitoring NGO projects and donor-NGO relations. The conclusions drawn in this paper will have applicability to other NGOS working in the healthcare sector and other sectors.

This paper will first provide a case study analysis of the healthcare campaigns funded by the Gates Foundation that resulted in human rights claims. The case study analysis will first provide background information on the mission and key partnerships of the foundation and will then review methods and results for malaria and meningitis vaccine trials in Africa and the HPV vaccine trial in India, focusing on the latter campaign. Next, this paper will provide an overview and assessment of the current legal regime governing INGOs, including internal policies, rules for drug trials in the medical industry, the 2005 INGO Accountability Charter and international law and domestic laws of host countries. Lastly, this paper will offer recommendations to strengthen the accountability measures for INGOs and will conclude with remarks on future projects.

I. GATES FOUNDATION-FUNDED HEALTH CAMPAIGNS & RESULTING VIOLATIONS

A. Background of the Bill & Melinda Gates Foundation

1. Mission & Policies

The Bill & Melinda Gates Foundation, founded by Microsoft Corporation Chairman Bill Gates, and his wife, Melinda, focuses on the areas of global health and development, global policy and advocacy, and has a U.S. program specializing in education. The foundation bases itself on the principle that "every life has equal value" and in developing countries, focuses on improving health.[15] It is the largest foundation in the world, with an endowment of $43.5 billion.[16] The Gates Foundation is currently the second largest donor to the World Health Organization, with the U.S. as the largest donor. It is also one of the largest single investors in biotechnology for farming and pharmaceuticals in the world.[17] It is heavily invested in large pharmaceutical companies.[18] In 2002, the foundation purchased shares in nine big pharmaceutical com-

15. *Foundation Factsheet*, *supra* note 10.
16. *Id.*
17. Vidal, *supra* note 3.
18. David Bank & Rebecca Buckman, *Gates Foundation Buys Stakes in Drug Makers*, Wall Street J. (May 17, 2002), https://www.wsj.com/articles/SB1021577629748680000. In 2002, the

panies valued at nearly $205 million.[19] This level of investment and funding affords the Gates Foundation a high amount of influence over the global agenda.

Underpinning the work at the Gates Foundation is the hope of "helping every person lead a healthy and productive life"[20] by "focusing on a few big goals."[21] The Gates Foundation identifies one of these goals in the area of "Discovery and Translational Sciences" as follows: "to identify, support, and shape scientific research that can have the most impact and to accelerate the translation of scientific discoveries into solutions that improve people's health and save lives."[22] Within this goal, the Gates Foundation concentrates on issues related to "vaccines, drugs, diagnostics, maternal and child health, and control of disease-transmitting mosquitoes."[23] In doing so, the Foundation utilizes the following strategy:

> All of our investments advance the goal of creating solutions that can be deployed, accepted, and sustained in the developing world. To speed the translation of scientific discovery into implementable solutions, we seek better ways to evaluate and refine potential interventions—such as vaccine candidates—before they enter costly and time-consuming late-stage clinical trials.[24]

This strategy essentially tasks the Gates Foundation to fund and support easier and cheaper drug trials in developing countries.

The Gates Foundation also focuses on vaccine introduction and related market issues.[25] The foundation views partnerships as the best method to vaccinating those in need and partners with organizations that can help with the entire vaccine process "from discovery to development to delivery."[26] It invests in vaccine research and development, including

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Gates Foundation invested $205 million in pharmaceutical companies, including Merck & Co., Pfizer Inc., Johnson & Johnson, and GlaxoSmithKline.

19. *Id.*

20. http://www.gatesfoundation.org/Who-We-Are/General-Information/Letter-from-Bill-and-Melinda-Gates

21. *Id.*

22. *Discovery and Translational Sciences Strategy Overview*, BILL & MELINDA GATES FOUNDATION, http://www.gatesfoundation.org/What-We-Do/Global-Health/Discovery-and-Translational-Sciences (last visited Jan. 26, 2017).

23. *Id.*

24. *Id.*

25. *Vaccine Delivery*, BILL & MELINDA GATES FOUNDATION, http://www.gatesfoundation.org/What-We-Do/Global-Development/Vaccine-Delivery (last visited Jan. 26, 2017).

26. *Id.*

projects to lower costs of vaccines by strengthening the immune response which could reducing the amount of antigen needed per dose, also projects to reduce doses required and easier administration and storage of vaccines.[27] It also works on the price element of vaccines "by working with private industry on innovative, market-based financing mechanisms to ensure that vaccines are developed at the lowest possible cost" and incentivizing manufacturers with demand and delivery strategies for vaccines.[28]

2. Partners

The Gates Foundation emphasizes the importance of partnerships in its strategy. The foundation promoted the following: "Dramatic progress in global health and development can be made if research institutions, governments, foundations, nongovernmental organizations, and private industry join together to generate new discoveries and new technologies that could greatly improve outcomes for families and children."[29]

The Gates Foundation has made substantial financial commitments to partners in the health sector and pharmaceutical industry.[30] There is a concern that some of these organizations, although technically independent, are funded by the Gates Foundation so heavily that they should be considered as part of the Gates Foundation because of how much influence the Gates Foundation holds over the agenda of these organizations. In the early 2000s, these organizations, began to conduct large-scale clinical drug trials in South Asia and Africa.[31] The most prominent partnerships will be discussed: Global Alliance for Vaccines and Immunizations (Gavi), Program for Appropriate Technology in Health (PATH), and the World Health Organization (WHO).

a. *Global Alliance for Vaccines and Immunizations (Gavi)*

The Gates Foundation holds their partnership with Gavi to be "one of [its] most important collaborations" as Gavi helps to shape the vaccine

27. *Id.*
28. *Id.*
29. *Discovery and Translational Sciences Strategy Overview*, *supra* note 22.
30. *Vaccine Delivery*, *supra* note 25.
31. Gates-funded public-private affiliates typically subcontract with local Contract Research Organizations to conduct trials in the field. This global industry for Contract Research Organizations was over $32 billion in 2015. *See The Clinical Trials Industry in South Africa: Ethics, Rules and Realities*, WEMOS 11–13 (July 2012), *available at* http://www.wemos.nl/files/Documenten%20Informatief/Bestanden%20voor%20'Medicijnen'/Clinical_Trials_Industry_South_Africa_2013_v3.pdf.

market.[32] Gavi is described as "a global public-private partnership of scientists, health experts, government leaders, businesses, and philanthropic organizations whose goal is to save children's lives and improve health through increased access to immunization in 73 of the world's poorest countries."[33] Its mission aims to help children and adult health and save lives through providing immunizations to poor countries.

Gavi, the Vaccine Alliance is comprised of four key members: the Gates Foundation (founder), World Health Organization (WHO) (founder), UNICEF, and the World Bank Group. Additional members include civil society organizations, developing country governments, developing country pharmaceutical industry, industrialized country governments, industrialized country pharmaceutical industry, and research and technical health institutes.[34]

The Gates Foundation plays a financial and technical role in Gavi to help shape vaccine markets. It assists with data collection and encourages new products. It also provides extensive financial support to enable market investments.[35] The Gates Foundation was a co-founder of Gavi and pledged the initial $750 million to set up Gavi in 1999. Since the launch of Gavi in 1999, the Gates Foundation's additional grants to Gavi have amounted to over $4 billion.[36] The Foundation retains a permanent seat on the Gavi Board of Directors.

In partnership with the Gates Foundation, Gavi is enabled to participate in vaccine market shaping.[37] It states the by increasing demand in Gavi-funded vaccines, the cost is lower in developing countries.[38] Gavi funds the purchase of vaccines and technical support to administer the vaccines to the poorest developing countries. The organization works on a variety of vaccines, including those for diseases that are among the leading causes of death for women and children in developing countries, such as pneumococcal disease and rotavirus. After identifying cervical cancer as a leading cause of cancer-related deaths among women in developing

32. *Vaccine Delivery*, *supra* note 25.

33. *Id.*

34. *Partnership Model*, GAVI, http://www.gavi.org/about/gavis-partnership-model/ (last visited Mar. 1, 2017).

35. *Id.*

36. *Id.*

37. *Gavi*, BILL & MELINDA GATES FOUNDATION, http://www.gavi.org/about/partners/bmgf/ (last visited Mar. 1, 2017).

38. *About Gavi*, *supra* note 2.

countries, Gavi began supporting projects for administering the HPV vaccine.[39]

b. *Program for Appropriate Technology in Health (PATH)*

The Gates Foundation is also partnered with PATH, which is the arm it funds to develop and test vaccines. The Gates Foundation has granted PATH over $150 million since 1998.[40] PATH is an international nonprofit global health organization with a mission to save lives and improve the health of women and children through drug innovations.[41] It is a public-private partnerships originally founded in the 1970s to work on contraceptives in developing countries and later expanded to public health projects and works in over seventy countries.[42] PATH is one of the largest nonprofits in global health and considered the leading organization in global health innovations and focuses on five areas: vaccines, drugs, diagnostics, devices, system and service.[43] PATH specializes accelerating innovations in health in "overcoming the barriers . . . especially those that arise in the middle of the journey of innovation . . . during steps like testing and refining, gaining approvals, commercializing a product, and introducing new approaches."[44] PATH works on vaccine delivery through advancing devices and also works with pharmaceutical companies to develop vaccines.

c. *World Health Organization (WHO)*

Another key partnership of the Gates Foundation is with the World Health Organization. The Gates Foundation has donated $2.1 billion between 1998 and 2014.[45] The Gates Foundation is the largest non-state funder of the WHO and the second largest donor overall, with the United States as the largest donor. Aside from providing financial support, the Gates Foundation actively advises on projects. The Gates Foundation has a large amount of influence on the agenda of the WHO because each grant is predesignated with a specific purpose, limiting its use on specific

39. *Id.*; Vidal, *supra* note 3.

40. *Awarded Grants Database*, BILL & MELINDA GATES FOUNDATION, http://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database (last visited Mar. 1, 2017).

41. *Frequently Asked Questions*, PATH, http://www.path.org/about/faq.php (last visited Mar. 1, 2017).

42. *Id.*

43. *Id.*

44. *Id.*

45. *Awarded Grants Database*, *supra* note 40.

programs or project areas.[46] Most grants by the Gates Foundation have been dedicated to polio eradication ($1.16 billion), global policy and advocacy ($146 million) and maternal and child health ($132 million).[47] Thus, donor interests drive the budget and agenda. The WHO welcomes and is essentially dependent upon large grants from private organizations because many member countries default on their contributions.[48]

Overall, each strategic partnership enables the Gates Foundation to contribute to every aspect of the drug delivery process, from the development stage to the delivery stage, and affords it access to implement projects on a global scale without obstruction.

B. Vaccine Campaigns

In 2010, Bill and Melinda Gates called for a "Decade of Vaccines" and pledged $10 billion to increase access to vaccines.[49] Three of the vaccine campaigns that were underway following this announcement will be reviewed, the HPV vaccine trial in India and the MenAfriVac project and phase 3 Malaria vaccine trials in Africa. The analysis will focus on the trial in India because of availability of information as a result of government investigations.

1. Human Papilloma Virus (HPV) Vaccine Project in India

In 2009, the Bill & Melinda Gates Foundation funded a project in collaboration with PATH to administer the Human Papilloma Virus (HPV) vaccine. Gavi was initially considered to subsidize the project. PATH undertook a five-year project, from June 2006 to May 2011 "to generate and disseminate evidence for informed public-sector introduction of HPV vaccines" in the countries of India, Uganda, Peru and Vietnam, each with a different ethnic population. Each country has a state-funded national vaccine immunization program. This can ultimately be highly profitable for pharmaceutical manufacturers and a study of this kind can give important data for promotion of the vaccine globally.[50] The project

46. *Bill & Melinda Gates Foundation Member Profile*, World Health Organization [WHO], http://www.who.int/workforcealliance/members_partners/member_list/gates/en/.

47. Andy Beckett, *Inside the Bill and Melinda Gates Foundation*, Guardian, July 12, 2010, https://www.theguardian.com/world/2010/jul/12/bill-and-melinda-gates-foundation.

48. *Id.*

49. *Decade of Vaccines*, Bill & Melinda Gates Foundation, www.gatesfoundation.org/Media-Center/Press-Releases/2010/01/Bill-and-Melinda-Gates-Pledge-$10-Billion-in-Call-for-Decade-of-Vaccines.

50. Parliament of India, 72nd Report on Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine by PATH in India, at 16 (Aug. 2013),

was entitled "HPV Vaccine: Evidence for Impact." The case in India will be focused on in the following analysis as it drew investigation by the national government.

For India, it was to be applied in three phases, the second phase entitled "A Post-Licensure Observational Study of HPV Vaccination: Demonstration Project."[51] It was implemented to two states in India: Andhra Pradesh and Gujarat.[52] The purpose of the vaccine is to ultimately prevent cervical cancer, which is related to certain forms of the Human Papilloma Virus. Two types of vaccines from two different pharmaceutical companies were used in separate states, Gardasil by Merck and Cervarix by GlaxoSmithKline. These were the two brands available in the market and both manufacturers donated the vaccines. One year prior to this project, in 2008, both vaccines were given marketing approval in India. PATH carried out the trial jointly with the Indian Council of Medical Research (ICMR), which is the India's primary governmental agency tasked with conducting biomedical research. PATH implemented what the Department of Health Research described as "an operational research study."[53] ICMR provided technical support and consultation for development of protocol and plan of monitoring. The purpose of the trial was to generate data to support the inclusion of the HPV vaccine in India's Universal Immunization Program. The project recruited female children between the ages of ten and fourteen from low-income, rural, largely tribal households. Gardasil was injected into 13,000 girls in the Khammam district of Andhra Pradesh and Cervarix was injected into 10,000 girls in the Vadodra district of Gujarat.

a. *Investigation & violations*

The project received public attention when the deaths of seven girls from Andhra Pradesh were reported.[54] The ICMR suspended the project in

available at http://www.elsevierbi.com/~/media/Supporting%20Documents/Pharmasia%20News/2013/September/HPV%20Vaccines%20Parliameetnary%20Report%20%20Aug%2031%202013.pdf.

51. *Id.* at 7.

52. *Id.* at 8.

53. PARLIAMENT OF INDIA, *supra* note 50, at 3.

54. Sandhya Srinivasan, *A Vaccine for Every Ailment*, INFO CHANGE (Apr. 2010), http://infochangeindia.org/public-health/healthcare-markets-and-you/a-vaccine-for-every-ailment.html; Aarti Dhar, *It's a PATH of Violations, All The Way to Vaccine Trials: House Panel*, THE HINDU, Sept. 2, 2013, http://www.thehindu.com/news/national/its-a-path-of-violations-all-the-way-to-vaccine-trials-house-panel/article5083151.ece; Gethin Chamberlain, *Judge Demands Answers After Children Die in Controversial Cancer Vaccine Trials in India*, THE DAILY MAIL, Jan. 13, 2015, http://www.dailymail.co.uk/news/article-2908963/Judges-demand-answers-children-die-controversial-cancer-vaccine-trial-India.html#ixzz4YiEMw1yM; S. Kumar & D. Butler, *Calls in India For Legal Ac-*

April 2010.[55] The Indian Parliament's Standing Committee on Health began its investigation and made the overall conclusion that the "safety and rights of children were highly compromised and violated."[56] PATH and the Committee did not agree as to whether the seven deaths were connected to the vaccinations.[57] The Government of India persists that there is the possibility of a connection according to their own studies.[58] However, the Committee found certain violations related to registration and the approval status of PATH to operate and conduct trials in India, informed consent procedures, compensation and treatment in the event of injury or death and conflicts of interest.

The Committee found that PATH was not a registered legal entity when it began working with the ICMR. PATH is considered a foreign non-commercial organization under Indian laws, which requires it to obtain permissions from governmental agencies including the Ministry of External Affairs and Ministry of Home Affairs before an office can be set up locally, but PATH failed to do so and set it its office prior to receiving approval.[59] Documentation shows that it obtained proper permission on May 2009, ten years after originally setting up its office.[60] The Committee also found irregularities with the approval given for trial. The Secretary of the Department of Health Research admitted that the DCGI guidelines were not adhered to as trials cannot be conducted on children until conducted on adults first. But, the Secretary provided that the reasoning behind this was that vaccine must be given before puberty to protect against cancer.[61]

Research using human subjects must follow the Good Clinical Practice requirements. The gap in the law that was utilized by the study, was in the characterization of the clinical trial. The clinical trial was described as a "post-licensure observational study." Drugs Controller General of India said that it must follow clinical trial guidelines. PATH however said the project was an observational study and the ICMR supported PATH explaining that the nature of the project did not require them to

tion Against U.S. Charity, NATURE NEWS, Sept. 9, 2013; Dinesh C. Sharma, *Rights Violation Found in HPV Vaccine Studies in India*, 14 LANCET ONCOLOGY (2013).

55. PARLIAMENT OF INDIA, *supra* note 50, at 4.

56. *Id.* at 12.

57. *Id.*

58. *Id.*

59. *Id.* at 32.

60. *Id.* at 35.

61. PARLIAMENT OF INDIA, *supra* note 50, at 2.

follow clinical trial rules.[62] But the research included human participants so it had to follow related statutory requirements.

b. *Informed consent*

The investigation revealed violations related to informed consent procedures. According to laws, consent for minors had to be signed by parents or guardians and for those uneducated, there had to be an independent witness.[63] In the trials conducted in the state of Andhra Pradesh, 9,543 forms were signed and 1,948 had thumb impressions. The hostel warden had signed 2,763 forms. In the state of Gujarat, 6,217 forms were signed and 3,944 had thumb impressions, with 5,454 signed by given thumb impression by guardians. The report noted that its data shows that a large amount of the parents and guardians were illiterate and could not even sign in their local language.[64]

After a review of the consent forms, it was identified that 69 forms did not have signatures of witnesses. One signature appeared on the forms of many participants. The consent forms signed by school headmasters and wardens were directed to do so by the local government and did not have written permission by the parents or legal guardians to sign on behalf of the children. Many of the forms lacked witness signatures or investigator signatures. In some cases, parent and guardian signatures did not match their names. Many forms, the signatures of parents and guardians were obtained after the date of the vaccinations.[65]

c. *Compensation & conflicts of interest*

The trial did not provide for urgent expert medical attention in case of serious adverse events, which were anticipated to occur. There were no measures in place to compensate or provide medical treatment for the child in the event of injury or death.[66]

The Committee highlighted concerns of conflicts of interest related to the commercial interests of manufacturers influencing the government policy on vaccines.[67] The Ministry of Health and Family Welfare reported that no written conflicts of interest declarations were sought.[68] The report

62. *Id.* at 5–6.
63. *Id.* at 20.
64. *Id.*
65. *Id*. at 21.
66. *Id*. at 9.
67. *Id*. at 11.
68. *Id*. at 18.

noted that the ICMR representative acted to promote PATH and the interests of manufacturers of the HPV vaccine.[69] It also noted concern for the inaction by DCGI for the enforcement of the rules for clinical trials and the irregular marketing approvals from the DCGI.

d. *Actions after investigation*

In response to violations related to informed consent, monitoring procedures, registration, inclusion of vulnerable and tribal population groups, lack of compensation and treatment for injury or death, other conflict of interest irregularities, the Committee made several recommendations to hold PATH accountable by the Government of India as laws in place to ensure informed consent and proper medical treatment for human subjects were blatantly violated.[70] Overall, the Committee concluded that the project violated all laws and regulations laid down for clinical trials and deemed the violations in breach of human rights because of the treatment to the children used in the trial.[71] However, changes were only slowly implemented.

On July 3, 2010, the Government of India only issued a warning letter to PATH, requesting that it "be careful while conducting clinical trials so to ensure that discrepancies and violations are not repeated."[72] In 2012, the ICMR implemented provisions requiring that each approval of a clinical trial include a condition for medical treatment and compensation in the event of injury or death.[73] In 2017, the Government of India made steps to address concerns of foreign donors influencing policy making. It announced that it would stop receiving grants from the Gates Foundation for the Immunization Technical Support Unit, which provides immunization strategy advice for a large program covering 27 million infants annually. Instead, the government will partially fund the programs through the Ministry of Health.[74]

Based on this case, laws and regulations in India need to be strengthened. PATH was able to continue its operations under the radar without proper registration because of the wieldy registration process in India. Although

69. *Id*. at 12.

70. KP N. Kumar, *Controversial Vaccine Studies: Why is Bill & Melinda Gates Foundation Under Fire From Critics?*, Economic Times (Aug. 31, 2014), http://articles.economictimes.indiatimes.com/2014-08-31/news/53413161_1_hpv-vaccine-cervarix-human-papilloma-virus.

71. Parliament of India, *supra* note 50, at 36.

72. Dhar, *supra* note 54.

73. *Id.*

74. Aditya Kalra, *India cuts some funding ties with Gates Foundation on immunization*, Reuters (Feb. 10, 2017), http://www.reuters.com/article/us-india-health-bmgf-idUSKBN15N13K.

PATH should have followed laws for using human subjects in medical research, its characterization of the study as an "observational study" and its support from the ICMR relaxed the requirements for following set laws.[75] The process required approvals from various agencies and as a result, entities could not be tracked properly. The Report recommended a single point of registration, an umbrella agency, to increase efficiency.

Also, there were many deficiencies on the part of the governmental agencies and ethical committees that were put in place to approve research and ensure research is conducted according to set rules and guidelines. ICMR approved the trial in 2007 before the drug was even approved in the country in 2008. The Committee said that the ICMR should have undertaken an independent study before approving the drug trial and could not explain the actions of the ICMR. The fact that the Committee cannot understand the action of the ICMR shows disconnect within these governmental agencies. This could potentially be resolved with the implementation of a universal framework, to make policies uniform and give extra enforcement.

e. *Note on how Gardasil went overseas*

The HPV vaccine project essentially facilitated low-cost clinical trials and assisted in creating new markets for a drug that underperformed in the U.S. Gardasil was first introduced in the U.S. in 2006 and it had extremely high sales.[76] But, the vaccine received criticism from the Journal of the American Medical Association and others, who questioned the risks.[77] In 2010 Fortune Magazine described Gardasil as a "marketplace dud." Thereafter, sales fell for both Gardasil and Cervarix.[78] In 2010, the project by PATH was implemented in four developing countries. By FYE 2012, Merck was able to report an increase in Gardasil sales in Japan and developing markets.[79]

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75. D. Scott LaMontagne & Jacqueline D. Sherris, *Addressing Questions About the HPV Vaccine Project in India*, 12 Lancet Oncology 492 (2013); Amy MacIver, *Statement from PATH: Cervical Cancer Demonstration Project in India*, PATH (Sept. 3, 2013), http://www.path.org/news/press-room/642/.

76. Zosia Chustecka, *HPV Vaccine: Debate Over Benefits, Marketing, and New Adverse Event Data*, Medscape (Aug. 18, 2009), http://www.medscape.com/viewarticle/707634.

77. Charlotte Haug M.D., *The Risks and Benefits of HPV Vaccination*, J. Am. Med. Ass'n 795 (Aug. 19, 2009), *available at* http://jama.jamanetwork.com/article.aspx?articleid=184404.

78. Shelley DuBois, *What Went Wrong With Gardasil*, Fortune (Sept. 7, 2012), *available at* http://money.cnn.com/2010/09/06/news/companies/merck_Gardasill_problems.fortune/.

79. *Merck Announces Full-Year and Fourth-Quarter 2012 Financial Results*, Business Wire (Feb. 1, 2013), http://www.businesswire.com/news/home/20130201005282/en/Merck-Announces-Full-Year-Fourth-Quarter-2012-Financial-Results. For information on other drugs supported by the Gates Foundation and marketed first in the U.S. and afterwards in developing countries under a

The Indian Parliamentary Committee included the following remarks in their report on the potential financial benefit of the project:

> Had PATH been successful in getting the HPV vaccine included in the universal immunization programme of the concerned countries, this would have generated windfall profit for the manufacturer(s) by way of automatic sale, year after year, without any promotional or marketing expenses. It is well known that once introduced into the immunization programme it becomes politically impossible to stop any vaccination.[80]

2. Trials Across Africa

Africa has experienced a large increase in medical research using human participants.[81] While there are many untreated diseases in Africa, the continent is home to some of the most vulnerable groups and individuals in the world, suffering from poverty, lack of education, environmental issues, and other problems. As such, it is crucial to ensure the protection and safety of these groups when foreign entities engage with them. This is especially true for clinical drug trials, where the trial is invasive and dangerous for the participant and potentially profitable for the administrator. A news article in South Africa even recently declared "we are guinea pigs for the drug makers."[82] Two large scale clinical trials, funded by the Gates Foundation, took place across Africa, the 2010 phase III trial of malaria vaccine and the MenAfriVac Project.

The phase III Malaria vaccine trial was part of a larger project by PATH, the PATH Malaria Vaccine Initiative, which administered multiple malaria vaccines around the world. This specific project received $150 million in funding from the Gates Foundation.[83] The phase III Malaria trial took place in multiple testing sites across Kenya, Ghana, Tanzania, Ga-

different name, see David J. Morrow, *Maker of Norplant Offers a Settlement in Suit Over Effects*, N.Y. Times, Aug. 27, 1999, http://www.nytimes.com/1999/08/27/us/maker-of-norplant-offers-a-settlement-in-suit-over-effects.html; N. B. Sarojini & Laxmi Murthy, *Why Women's Groups Oppose Injectable Contraceptives*, 2 Indian J. Med. Ethics (2005), *available at* http://216.12.194.36/~ijmein/index.php/ijme/article/view/702/1715.

80. Parliament of India, *supra* note 50, at 6.

81. A. Nyika et al., *Composition, Training Needs and Independence of Ethics Review Committees Across Africa: Are the Gate-Keepers Rising to the Emerging Challenges?*, 35 J. Med. Ethics 189–93 (2009).

82. *We Are Guinea Pigs for the Drug Makers*, Times (July 25, 2013), http://www.timeslive.co.za/news/2013/07/25/we-are-guinea-pigs-for-the-drugmakers.

83. *Vaccine Delivery*, *supra* note 25.

bon, Malawi, Mozambique and Burkina Faso.[84] This trial utilized malaria vaccine version RTS,S, which was manufactured by GlaxoSmithKline.[85] The vaccines were administered to 20,000 across the sub-Saharan African countries and included children between ages 6 to 12 weeks and children between 5 to 17 months old.[86] The trials resulted in 151 deaths and caused serious adverse effects, including paralysis and seizure in 1048 of 5949 children aged 5-17 months.[87] However, medical researchers concluded that these were normal risks expected from the vaccinations.[88]

The MenAfriVac project was administered through a larger collaboration by PATH and WHO called the Meningitis Vaccine Project.[89] This project is funded by the Gates Foundation and focuses on development, testing licensing and introduction of affordable vaccines.[90] MenAfriVac is the trademark name of a vaccine developed through this program to prevent meningitis outbreaks specifically in Africa and provide an affordable vaccine. The MenAfriVac project started in 2010 across the twelve African countries of Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Côte-d'Ivoire, Ethiopia, Ghana, Mali, Niger, Nigeria, and Togo. By 2016, the vaccine was administered to over 270 million people in 26 different countries. While there were reports of informed consent violations, these were unsubstantiated.[91] Also, there were reports of adverse health effects in Burkina Faso, but these were deemed by medical researchers as normal and did not warrant safety concerns.[92]

Both the phase III malaria trial and the MenAfriVac project were considered successes by the pharmaceutical companies.[93] However, the reports of the research trials were published by the Foundation for the National

84. *First Results of Phase 3 Trial of RTS,S/AS01 Malaria Vaccine in African Children*, 365 N. ENGL. J. MED 1863 (Nov. 17, 2011).

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.*

89. *Vaccine Delivery*, *supra* note 25.

90. *Overview of MenAfriVac*, PATH, http://www.path.org/menafrivac/overview.php (last visited Apr. 15, 2017).

91. *Minimum of 40 Children Paralyzed after New Meningitis Vaccine*, VACTRUTH (Jan. 6, 2013), http://vactruth.com/2013/01/06/paralyzed-after-meningitis-vaccine/.

92. Ouandaogo et al., *Adverse events following immunization during mass vaccination campaigns at first introduction of a meningococcal A conjugate vaccine in Burkina Faso*, NATIONAL INSTITUTE OF HEALTH (Jan 9., 2012), https://www.ncbi.nlm.nih.gov/pubmed/22230584.

93. *Malaria Vaccine Could Save Millions of Children's Lives*, GUARDIAN, Oct. 18, 2011, http://www.theguardian.com/society/2011/oct/18/malaria-vaccine-save-millions-children.

Institutes of Health.[94] The Gates Foundation provides funding to this organization.[95] Thus, there is a conflict of interest.[96]

While these trials did not receive the same type of public recognition as the HPV trial discussed above in India and claims of abuses were not substantiated, they did share other characteristics with the trial in India. As with the trial in India, these were also vaccine programs funded by the Gates Foundation and executed by its partners. These trials took place in a significant amount of countries in Africa, all with similar non-binding guidelines to govern clinical trials with human participants. While claims of human rights abuses resulting from these trials across Africa may be unsupported, the trials had the same potential for abuse as in India because of the weak legal regime governing trials in these countries. In fact, an analysis of national laws across relevant African countries shows that they have a generally less developed legal system governing clinical trials than in India, so the potential for abuse is even greater. Thus, an analysis of the national laws across these African countries hosting the Gates Foundation funded trials is still necessary to illustrate the very weak laws and the ease through which potential abuse can happen, if they did not already.

II. CURRENT LEGAL REGIME GOVERNING INGOS IN CLINICAL DRUG TRIALS

While NGOs often have internal policies to ensure transparency and accountability, these policies are not enough.[97] With their influence, reach, and resources, NGOs have the potential to carry the same influential weight in the international arena as a state.[98] Just as there are laws to hold individuals accountable for their actions in each state and international laws to hold states accountable, NGOs need a similar legal regime

94. *Partners*, BILL & MELINDA GATES FOUNDATION, http://www.gatesfoundation.org/What-We-Do/Global-Health/Discovery-and-Translational-Sciences/Partners (last visited Mar. 1, 2017).

95. *See* Ouandaogo et al., *supra* note 92.

96. The Foundation for the National Institutes of Health (FNIH) is a nonprofit medical research agency and works to accelerate biomedical research and strategies. It raises funding from public and private institutions. *About*, FOUNDATION FOR THE NATIONAL INSTITUTE OF HEALTH, https://fnih.org/about. Corporations, individuals, or foundations can bring an idea to FNIH, which then works with donors to assess which of the extraordinary array of existing and prospective programs within NIH's priorities would be most relevant to their interest. https://ppp.od.nih.gov/pppinfo/foundation.asp (last visited Mar. 1, 2017).

97. *Ethical, Social, and Cultural Program*, BILL & MELINDA GATES FOUNDATION, http://www.gatesfoundation.org/Jobs/Ethical-Conduct-and-Governance (last visited Jan. 26, 2017).

98. Michael Szporluk, *A Framework for Understanding Accountability of International NGOs and Global Good Governance*, 16 IND. J. GLOBAL LEGAL STUD. (2009).

as well for guidance and accountability.[99] This section will review relevant institutional guidelines, national laws of host countries, international law, and the INGO Accountability Charter for binding provisions applicable to clinical drug trials using human participants. The analysis will focus on issues identified from the clinical trials discussed in the previous section: informed consent processes, generally and for children, compensation and medical treatment for harm resulting from participation in clinical trials, conflicts of interest disclosures and reporting for all organizations involved with the clinical trial or research on human participants, including sponsors, institutions and investigators, and mechanisms or committees for handling complaints and enforcing compliance with standards and laws.

A. Non-Binding Institutional Requirements: International Ethical Guidelines For Human Clinical Trials

There are often institutional guidelines governing the activity of which the organization is engaged.[100] For clinical trials on human participants, two international human research guidelines are recognized to form the foundation of an international ethical code of for these trials: The Declaration of Helsinki (Declaration) and the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guideline (ICH GCP Guideline).[101] These two instruments are often used by countries as a basis for non-binding guidelines and influence laws and regulations.[102] The Declaration of Helsinki is utilized by many African countries for guidance. The ICH GCP Guideline was noted to be used by the investigators during the Phase II Malaria trials and the MenAfriVac Project.[103]

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99. Anastasia Telesetsky, *Moving Beyond International Nongovernmental Organizations' Accountability: Promoting International Human Rights-Based Review of INGOs' Performance*, 19 Williamette J. Int'l L. & Dis. Res. 232 (2011).

100. Council for International Organizations of Medical Sciences [CIOMS], *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002), *available at* http://www.cioms.ch/guidelines_nov_2002_blurb.htm.

101. International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use [ICH], *Guideline for Good Clinical Practice* (1996), http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf [hereinafter ICH GCP].

102. *Id.*; CIOMS, *supra* note 100; World Medical Association [WMA], *Declaration of Helsinki* (2008), *available at* http://www.wma.net/e/policy/b3.htm.

103. *First Results of Phase 3 Trial of RTS,S/AS01 Malaria Vaccine in African Children*, 365 N. Engl. J. Med 1863 (Nov. 17, 2011).

1. Declaration of Helsinki

The Declaration of Helsinki was formulated by the international medical community and established by the World Medical Association in 1964, an international organization charged with ensuring the independence and ethical behavior of physicians.[104] The Declaration is addressed to physicians primarily, but encourages others involved in medical research on human subjects to follow the principles, including sponsors.[105] Most recently updated in 2013,[106] the Declaration provides many ethical considerations for medical research on human participants.[107]

The Declaration includes provisions related to the informed consent of human participants. For those capable of giving informed consent, the participant "must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study."[108] Consent is preferred in writing and if non-written consent is needed, it must be formally documented and witnessed."[109] For those incapable, consent must be sought by the physician from a legally authorized representative.[110] If the human subject that is incapable of giving informed consent can assent to participation in the research, then the assent must be sought by the physician in addition to the legally authorized representative.[111] This provision was expanded in 2012 to include the assent of a child as acceptable consent in cases where the risk is minimal in order to allow for more testing on pediatric drugs.[112]

The Declaration also includes various provisions related to compensation for harm, conflicts of interest, registries, considerations for vulnerable groups and enforcement. It requires appropriate compensation and treatment be given to any participating subjects harmed.[113] Each study must

104. WMA, *supra* note 102.
105. *Id*., pmbl. § 2.
106. 64th WMA General Assembly, WMA, https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.
107. WMA, *supra* note 102, ¶¶ 16–18.
108. *Id.* ¶ 26.
109. *Id.*
110. *Id.* ¶ 28.
111. *Id.* ¶ 29.
112. *11th World Congress of Bioethics WMA Satellite Meeting: The Future of the Declaration of Helsinki*, WMA (June 26, 2012), https://www.wma.net/events-post/wma-satellite-meeting-rotterdam/westra-2/.
113. WMA, *supra* note 102, ¶ 15.

be publicly registered.[114] For conflicts of interest, it requires a declaration of sources of funding, institutional affiliations and conflicts to be declared in writing.[115] The Declaration requires the inclusion of local communities in understanding the research conducted.[116] Finally, it provides for the creation of an independent ethics committee, which can review research proposals and monitor ongoing studies.[117]

While, the Declaration of Helsinki does provide exhaustive guidelines for clinical trials, there are many weaknesses related to its enforcement. Foremost, it is not a legally binding instrument under international law. Its authority comes from its ability to influence national legislation and regulations, local laws do prevail over the Declaration. As a tool of guidance, it does not provide structure on how the ethics committees should best operate and responsibilities.

2. ICH GCP Guideline

The second, and leading, international ethical guideline is the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) Guideline (ICH GCP Guideline).[118] It was published once in 1996 by the ICH, a partnership among the United States, Japan and the European Union to advance the global development of new medicines. The objective of the guideline is to provide a unified standard for the three countries to conduct clinical trials and share data. It is based on and makes references to the Declaration of Helsinki. The use of this guideline has a large impact on the globalization of industry sponsored clinical research because it enables clinical data collected from one country to be used to file new drug applications in another country. This set of guidelines also applies to sponsors, using a broad definition to include "an individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial."[119] The general principles are similar to those in the Declaration of Helsinki.

The ICH GCP Guideline includes provisions on informed consent and compensation in the event of injury, which are slightly more expansive

114. *Id.* ¶ 35.
115. *Id.* ¶¶ 13, 19, 20.
116. *Id.*
117. *Id.* at 23.
118. ICH GCP, *supra* note 101.
119. *Id.* § 1.53.

than the Declaration of Helsinki. Participants who are minors should still be informed about the trial to the extent compatible with their understanding.[120] It requires that the participant or their legally acceptable representative sign and personally date the written informed consent, if possible, and receive ample time and details to consider participation.[121] In the case where a participant or legally acceptable representative is unable to read, then "an impartial witness should be present during the entire informed consent discussion . . . the witness should sign and personally date the consent form" and attest to the consent.[122] It also provides for the protection of participants from undue influence, stating that "neither the investigator, nor the trial staff, should coerce or unduly influence a subject to participate or to continue to participate in a trial."[123] It also includes provision for compensation and medical treatment to be provided in the event of serious adverse effects.[124]

The ICH GCP Guideline contains reporting[125] and monitoring procedures similar to the Declaration of Helsinki, with some additions.[126] In the event of noncompliance with the guidelines or any regulations by an investigator, institution, or member of the sponsor's staff, the sponsor is recommended to take prompt action to secure compliance.[127] If monitoring or auditing uncovers serious or persistent noncompliance on the part of the investigator or institution, then the sponsor is required to terminate their participation and should notify regulatory authorities.[128]

Although the ICH GCP Guideline is the most prominent, it shares the same key problem with the Declaration of Helsinki. Both guidelines are non-binding and those engaged in medical research on human participants are only recommended to follow these principles. There is no true enforcement in the event of noncompliance. Also, rather than providing a uniform set of provisions to guide how the ethics committee should function, it leaves these details up to the implementing institution to figure out. This can cause inconsistencies.

120. *Id.* § 4.8.12.
121. *Id.* § 4.8.5.
122. *Id.* § 4.8.9.
123. *Id.* § 4.8.3.
124. *Id.* §§ 4.11.1, 5.8.2.
125. *Id.* § 5.17.
126. *Id.* § 5.18.1(c).
127. *Id.* § 5.20.1.
128. ICH GCP, *supra* note 101, § 5.20.2.

B. National Laws of Host Countries

Unlike institutional requirements that serve as mere guidelines, NGOs are bound to follow national laws of the host countries within which they work, including any laws of local communities. This section will highlight and offer an analysis of national laws of the host countries within which the Phase III Malaria Trial, the MenAfriVac Project, and the HPV Vaccine Trial took place that govern the health sector and apply to human subject research or clinical drug trials. Host countries will include India and the following countries from the two African trials, selected based on the availability of information and English documents: Ghana, Cameroon, Ethiopia, Nigeria, Kenya, Tanzania, Malawi, and Mozambique.[129] Specifically, this analysis will look for provisions related to informed consent, both generally and for minors, compensation and treatment in the event of injury from the trial, conflicts of interest, complaint mechanisms and enforcement mechanisms.

1. African Continent

Across Africa, there is no unified law governing clinical drug trials. Regional guidelines exist related to clinical research on human participants and ethics, but these are non-binding principles. Individual states have their own national laws, regulations and non-binding guidelines covering the health sector and clinical research on human participants, but these laws and guidelines vary across states. This analysis will evaluate national laws for legally binding principles related to the areas of informed consent, generally and for minors, compensation and treatment for participants who sustained injuries related to the clinical trials, conflicts of interest and mechanisms for complaint and enforcement.

Regarding the provision of informed consent, the following countries have a legally binding obligation requiring written informed consent: Cameroon[130], Ethiopia[131], Ghana[132], Mozambique[133], Nigeria[134] and

129. Of the host countries not covered in this analysis, Benin, Burkina Faso and Côte-d'Ivoire did not have documents available in English and for Niger, Togo, Mali, Chad, Gabon, Central African Republic, documents were difficult to obtain. For legislation in Benin, see Law No. 2010-40 (Dec. 8, 2010) and the Ethical Code and Duties in Health Research in the Republic of Benin, *available at* http://ethique-sante.org/pdf/loi-portant-code-ethique.pdf. For Burkina Faso, see Order No. 2010-292 / MS / CAB (Oct. 1, 2010) on the Conditions for Granting Authorizations for Clinical Trials. For Côte-d'Ivoire, see Decree No 317 / SP / DSPH on the Regulation of Drugs (July 14, 1987).

130. Law No. 96-06 (Jan. 18, 1996) to amend the Constitution of June 2, 1972, pmbl.; Civil Code, art. 1108 (Cameroon).

131. Drug Administration and Control Proclamation No. 176/1999, art. 21(1) (Ethiopia), *available at* www.fmhaca.gov.et.

Tanzania[135]. From these countries with binding informed consent, there are additional provisions in order to obtain the informed consent of minors or children. Both Cameroon and Ghana have specific provisions mentioning the requirement of written consent from a parent or guardian for children under 18 years.[136] Ethiopia has a unique clause prohibiting clinical trials on children under the age of 18.[137] In Nigeria, the informed consent of participant or their legally authorized representative is also orally permissible.[138] For the participation of minors in Nigeria, the informed consent of parents or a legal representative is required and the minor is required to have received and understood information regarding the trial.[139] Kenya and Malawi[140] have non-binding guidelines on the issue of informed consent. In Kenya, while there are provisions for the informed consent of minors and for the special consent and consideration for underdeveloped communities, these are non-binding guidelines.[141]

Overall, a majority of the surveyed countries do have a legally binding provision for informed consent of participants. However, informed consent is a key aspect of ensuring the rights of and respect for human participants in clinical drug trials and as such, it should be a legally binding requirement for all African countries.

Concerning the provision of compensation and treatment for any injury or loss sustained as a result of participating in clinical trials, a legally binding obligation exists in the laws of the following surveyed countries: Mozambique,[142] Nigeria,[143] and Tanzania[144]. The remaining countries

132. Ghana Public Health Act 851, 2012, GPC/A753/ 350/11/2012, *available at* http://www.moh.gov.gh/wp-content/uploads/2016/02/Public-Health-Act-851.pdf.

133. Constitution of the Republic of Mozambique, art. 48 no. 1; Science and Technology Ethics Code, Decree no. 71/2007, (Dec. 24 2007), art. 7 no. 2; Civil Code, arts. 132-137; Family Law, arts. 283, 284, 287, 337–341; Law n°7/2008 of 9 July, Promotion and Protection of Children's Rights, Law no. 7, art. 36 no. 1(July 9, 2008) (Mozambique).

134. Good Clinical Practice Regulations (2009), § 4 (Nigeria), *available at* http://apps.who.int/medicinedocs/documents/s17103e/s17103e.pdf.

135. Constitution of the United Republic of Tanzania of 1977, arts. 18, 21(2); Food Drug Cosmetics Act, § 66 (Tanzania).

136. Ghana Public Health Act 851, 2012, GPC/A753/ 350/11/2012, § 159.

137. Drug Administration and Control Proclamation No. 176/1999, art. 21(2) (Ethiopia).

138. Good Clinical Practice Regulations (2009), § 9(a) (Nigeria), *available at* http://apps.who.int/medicinedocs/documents/s17103e/s17103e.pdf.

139. *Id*.

140. General Guidelines on Health Research (2014) (Malawi), *available at* http://www.medcol.mw/comrec/wp-content/uploads/2014/07/comrec_guidelines.pdf.

141. National Guidelines for Ethical Conduct of Research Involving Human Subjects (2008) (Kenya), *available at* https://healthresearchweb.org/?action=download&file=final%20national%20ethical%20guidelines-last%20draft.pdf.

142. Order of Ministry of Health 2002, Normative Procedures, § 6 (Mozambique); Civ. Code art. 493(2), as referred by arts. 499, 562, 563; Pen. Code arts. 368, 369 (Mozambique).

include the provision in non-binding guidelines only: Ethiopia[145], Ghana[146], Cameroon[147], Kenya[148] and Malawi[149]. It is surprising that only three countries have a binding provision for compensation in the event of injury or loss for participants. The inclusion of this provision is a key remedy for harm suffered during clinical trials and is a key aspect of enforcing proper treatment of human participants. Thus, it should be legally required for all clinical trials.

Regarding the legally binding laws or regulations related to declaring and reporting conflicts of interest within the clinical trial among sponsors, institutions, investigators, physicians and ethics committees, there were no legally binding provisions included in any of the national laws of countries reviewed. Non-binding guidelines existed regarding conflicts of interests among these groups in the following countries: Ethiopia[150], Ghana[151], Mozambique[152], Cameroon[153] and Nigeria[154]. In Cameroon and Tanzania, provisions existed related to conflicts of interests, but were limited to internal conflicts of interest connected to the research and ethics committees.[155]

143. Good Clinical Practice Regulations (2009), § 9 (Nigeria), *available at* http://apps.who.int/medicinedocs/documents/s17103e/s17103e.pdf.

144. Law Reform (Fatal Accidents and Miscellaneous Provisions) Act, Cap. 310, §§ 2, 3 (Tanzania); Insurance Act, Cap. 394, § 110; Constitution of the United Republic of Tanzania of 1977, art. 13(3); Food, Drugs, and Cosmetics Act, (2003) § 67 (Tanzania).

145. National Health Research Ethics Review Guideline (4th ed. 2014) (Ethiopia), *available at* http://www.ccghr.ca/wp-content/uploads/2013/11/national-research-ethics-review-guidline.pdf.

146. Conduct of Clinical Trials, Doc. No. FDA/SMC/CTD/GL-CCT/2013/0, Version No. 2; Good Clinical Practice, Doc. No. FDA/SMC/CTD/GL-GCP/2013/02, Version No. 1 (Ghana).

147. ICH GCP is followed in Cameroon.

148. National Guidelines for Ethical Conduct of Research Involving Human Subjects (Kenya), *supra* note 141.

149. National Policy Requirements and Guidance for the Provision of Insurance Cover for Research Participants in Clinical Trials in Malawi (2012) (Malawi).

150. National Health Research Ethics Review Guideline, (2014) (Ethiopia), *available at* http://www.ccghr.ca/wp-content/uploads/2013/11/national-research-ethics-review-guidline.pdf.

151. Conduct of Clinical Trials, Doc. No. FDA/SMC/CTD/GL-CCT/2013/0, Version No. 02; Good Clinical Practice Doc. No. FDA/SMC/CTD/GL-GCP/2013/02, Version No. 1 (Ghana).

152. Sci. & Tech. Ethics Code, Decree No. 71/2007, art. 6(b) (Dec. 24, 2007); Code Prof'l Conduct Med. Doctors art. 66 (Mozambique).

153. Ministerial Order No. 079/A/MSP/DS of MINSANTE, art. 8, (Oct. 22, 1987) (Cameroon); Code Med. Ethics art. 13 (Cameroon).

154. Good Clinical Practice Regulations (2009), § 6(a) (Nigeria), *available at* http://apps.who.int/medicinedocs/documents/s17103e/s17103e.pdf. Clinical trials must be conducted in accordance with the Declaration of Helsinki. For non-binding guidelines, see Nigerian Code of Health Research Ethics (2007), *available at* http://www.nhrec.net/nhrec/NCHRE_10.pdf.

155. Guidelines on Ethics for Health Research in Tanzania (2009) (Tanzania), *available at* https://clinregs.niaid.nih.gov/documents/tanzania/G-EthicsHR.pdf.

On the topic of enforcement mechanisms and penalties for violations of any laws or regulations governing human participants in research and drug trials, related legally binding laws were found in the laws of Ghana, Nigeria, Kenya, Malawi and Tanzania, but varied by country. In Ghana, a penalty is enforced under law and violators will be held "liable on summary conviction to a fine not less than 15,000 penalty units or a term of imprisonment of not less than 25 years or both."[156] The Ghana Health Service Ethical Review Committee (GHSERC) was also established for enforcement and conducts regular monitoring visits to ongoing trial sites in order to ensure that projects are conducted according to approved protocols. In Nigeria, the legally binding National Health Act (2014) bestows upon its research and ethics committee to set norms and standards for clinical trials and to recommend disciplinary action for non-compliance. In Kenya, the Pharmacy and Poison Board is the regulatory authority responsible for clinical trial approvals, oversight and inspection. In accordance with Pharmacy, Medicines, and Poisons Act, Act 15 of 1988, the Board can impose penalties.[157] In Tanzania, the law imposes a penalty in the form of a fine, imprisonment for up to five years, or both for any violations.[158] Cameroon, Mozambique and Ethiopia did not have legally binding penalties or enforcement related to violations of provisions governing clinical trials or research with human participants.

Overall, legally binding provisions for penalties and enforcement either do not exist or vary when they do exist. It is important that countries hosting clinical drug trials or medical research on human participants have legally binding penalties and enforcement for violations. Moreover, it is essential that countries in Africa have uniform penalties for violations because as seen with the MenAfriVac Project and Phase III Malaria Trials, clinical drug trials in Africa are undertaken across many countries at one time. Penalties imposed will be more effective if they are uniform so that potential violators who may be participating in many countries at one time can expect the same penalty and not abuse one country in a multi-country trial that may be more legally relaxed.

Finally, a requirement to register clinical trials before they are conducted is important to monitor and ensure the safety of human participants. This requirement varies across African countries. For example, it is required

156. Ghana Public Health Act 851, 2012, GPC/A753/ 350/11/2012.
157. Pharmacy, Medicines, and Poisons Act, Act 15 (1988), § 51 (Kenya).
158. Food, Drugs, and Cosmetics Act, (2003) § 71 (Tanzania).

in Nigeria, Kenya, Tunisia and South Africa, but not Malawi.[159] It is essential for all African countries to implement a requirement to register clinical trials. A region wide clinical registry was established in 2012. The Pan African Clinical Trials Registry is a voluntary international registry for all clinical trials in Africa.[160] It provides a potential means of regulation for clinical trials conducted in Africa, as those conducting trials are encouraged to register in order to promote greater trust and public confidence and to standardize reporting of research for efficiency and collaboration. However, it is non-binding and under its definition of clinical trials, it excludes "observational studies which are studies in which individuals are observed and their outcomes are measured by the investigators,"[161] which is the very loophole used by PATH to avoid registering in India before conducting the HPV Vaccine trials. Thus, it is important for countries to have a requirement to register all clinical trials, both regionally and locally since many clinical trials in Africa can be conducted across many countries simultaneously. Additionally, it is important that the definition of clinical trials is expanded so that potentially harmful loopholes can be closed.

2. India

In India, legally binding regulations regarding the treatment of human participants in medical research and clinical drug trials have been implemented at different times.[162] In 2005, the government implemented legally binding provisions requiring the written informed consent of human participants in clinical drug trials.[163] Under the Appendix V to Schedule Y of the Drugs and Cosmetics Act (2005), where the details of

159. *Clinical Trial Registries National Health Research Ethics Committee*, NAT'L HEALTH RES. ETHICS COMMITTEE, http://nhrec.net; *Frequently Asked Questions*, NAT'L HEALTH RES. ETHICS COMMITTEE, http://nhrec.net/nctr/FAQ.php.

160. *About*, PAN AFRICAN CLINICAL TRIAL REGISTRY, http://www.pactr.org.

161. PAN AFRICAN CLINICAL TRIAL REGISTRY, http://www.pactr.org/ATMWeb/appmanager/atm/atmregistry?_nfpb=true&_pageLabel=atmportal_page_FAQ.

162. Central Drugs Standard Control Org., Office of Drugs Controller General of India [DCGI], *available at* http://cdsco.nic.in; Indian Council of Medical Research [ICMR], Ethics Committee Registration: General Statutory Rules 72(E), *available at* http://www.icmr.nic.in/human_ethics.htm; DCGI, GOOD CLINICAL PRACTICES FOR CLINICAL RESEARCH IN INDIA (2001), *available at* http://rgcb.res.in/wp-content/uploads/2014/07/Good-Clinical-Practice-Guideline.pdf.

163. Drugs and Cosmetics (IInd Amd.) Rules, 2005, Schedule Y–Requirements and Guidelines for Permission to Import and/or Manufacture of New Drugs for Sale or to Undertake Clinical Trials (Amended Version) (Schedule Y) (Jan. 20, 2005), § 2(4), Appendix V (India); ICMR, *available at* http://www.icmr.nic.in/human_ethics.htm; Drugs and Cosmetics Act, 2005, Schedule Y (India), *available at* http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf.

informed consent are listed, it is permissible to obtain either the signature or the thumb impression of the participant or legal representative.[164]

For the informed consent of children, under the law, pediatric participants are legally unable to provide written informed consent.[165] Their parent or legal guardian is able to provide consent on their behalf. The term 'legal guardian' is defined by the Guardians and Wards Act, 1890 as a "person having the care of the person of a minor or of his property or of both his person and property."[166]

However, all pediatric participants are required to be informed to the fullest extent possible. It requires that any refusal on the part of the pediatric participant must be respected unless the child's welfare is in danger and there is no alternative treatment. If the pediatric participant is able to assent, then their assent is additionally required to participate. However, mature minors and adolescents, those from age seven to eighteen must personally sign and date a separately designed written assent form.[167]

Also, India implemented a clinical trials registry, requiring the registration of all clinical trials in the ICMR Clinical Trial Registry.[168] This has been in place since 2009. Its definition of clinical trials excludes observational studies. This created the problem highlighted in the parliamentary investigation of the HPV Vaccine. It enabled a loophole whereby PATH was not required to register. After the violations in the HPV Vaccine trials came to light, the government expanded legislation in 2012 to require the compensation and treatment for human participants that have sustained injury or loss from the clinical drug trials or medical research.[169]

There were many weaknesses in the law in India at the time of the HPV Vaccine trials. While some beneficial changes have been made, it is im-

164. Drugs and Cosmetics Act, 2005, Schedule Y, Appendix V (India).

165. Drugs and Cosmetics (IInd Amd.) Rules, 2005, Schedule Y, §§ 1–3 (India).

166. Rep. No. 257 on Law Commission of India, Guardian and Wards Act, 1890, § 4(b), *available at* lawcommissionofindia.nic.in/reports/Report%20No.257%20Custody%20Laws.pdf.

167. ICMR, Ethical Guidelines for Biomedical Research on Human Participants, Ch. IV (2006) (India), *available at* http://icmr.nic.in/ethical_guidelines.pdf

168. Clinical Trials Registry India, *available at* http://ctri.nic.in/; *Registration of Clinical Trial in ICMR Clinical Trial Registry*, *available at* http://www.cdsco.nic.in/writereaddata/CTRegistration.doc. Central Drugs Standard Control Org., Office of Drugs Controller General of India [DCGI], *available at* http://cdsco.nic.in; Permission for Clinical Trials, General Statutory Rules 63(E) (India).

169. Drugs and Cosmetics (IInd Amd.) Rules, 2005, amds. 1–2; Order: Clinical Trial – Compensation in Case of Injury or Death Discerned at a Later Stage – Regarding (Order CT Compensation) (July 3, 2014); Order: Providing Ancillary Care to the Clinical Trial Subjects – Regarding (Order Ancillary Care) (July 3, 2014) (India).

portant that mechanisms in place to ensure ethical conduct are coordinated in their efforts. The case in India highlighted a lot of disconnect among agencies in charge of the health sector and clinical trials. The Indian legislation needs to ensure that there are uniform policies for its enforcement mechanism. Additionally, informed consent procedures in India should to be more restrictive to prevent abuse of human participants. Informed consent processes that permit a thumbprint for someone who is illiterate does not show true understanding of the choice to participate in a medical research or clinical trial. By thumbprint and witness, it is not guaranteed that informed consent would be met either. This is especially true of vulnerable populations like those used in the HPV Vaccine trial, low-income, tribal participants.

C. International Law

International law is often criticized for its lack of enforcement ability and in the case of laws concerning the treatment of human participants in clinical trials, this criticism stands true to an extent. While there are many non-binding international guidelines addressing medical research using human participants, such as those guidelines provided by the Council for International Organizations of Medical Sciences (CIOMS)[170], the World Medical Association, the World Health Organization[171], United Nations Educational, Scientific, and Cultural Organization[172] and UNAIDS[173], there are no legally binding instruments that specifically govern the conduct of medical research using human participants in clinical drug trials. The closest legal instruments would be treaties recognizing the right to health.

The right to health is the right to the highest attainable standard of physical and mental health and this right contains freedoms, including the right to be free from non-consensual medical treatment, such as medical

170. CIOMS, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002), *available at* http://www.cioms.ch/publications/layout_guide2002.pdf;

171. WHO, *Operational Guidelines for Ethics Committees that Review Biomedical Research* (2000), *available at* http://whqlibdoc.who.int/hq/2000/TDR_PRD_ETHICS_2000.1.pdf; WHO, *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants* (2011), *available at* http://whqlibdoc.who.int/publications/2011/9789241502948_eng.pdf; WHO, *Ethical Issues in Patient Safety Research: Interpreting Existing Guidance* (2013), *available at* http://apps.who.int/iris/bitstream/10665/85371/1/9789241505475_eng.pdf.

172. U.N. Educ., Sci. & Cult. Org. [UNESCO], Universal Declaration on Bioethics and Human Rights (2005), *available at* http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html.

173. UNAIDS, Ethical Considerations in Biomedical HIV Prevention Trials (2012), *available at* http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/jc1399_ethical_considerations_en.pdf.

experiments and research or forced sterilization.[174] It also includes the right to access healthcare and treatment, participation of the population in health-related decision making at the national and community level. For children, under the Convention on the Rights of the Child (CRC), the right to health includes diminishing infant and child mortality and ensuring that all segments of society, including parents and children, are informed and have access to child health education.[175]

The right to health is recognized in the following international treaties: Universal Declaration of Human Rights (1948) (UDHR)[176], International Convention on the Elimination of All Forms of Racial Discrimination (1965) (ICERD)[177], International Covenant on Economic, Social, Cultural Rights (1966) (ICESCR)[178], Convention on the Elimination of All Forms of Discrimination Against Women (1979) (CEDAW)[179], Convention on Rights of the Child (1989) (CRC)[180], International Convention on the Protection of the Rights of all Migrant Workers and Members of Their Families (1990) (CPRMW)[181], and Convention on the Rights of Persons with Disabilities (2006) (CRPD)[182]. It is also recognized in the regional treaty of the African Charter on Human and Peoples' Rights (1981) (ACHPR).

Individual complaints processes solidify the importance human rights, giving victims or their advocates the ability to seek justice at an international level. Currently, each treaty has a related committee where it may consider communications by individuals alleging violations of the respective treaty. Each individual complaint mechanism has been entered into force for all treaties above except for the Committee on Migrant Workers related to the CPRMW. For the African Charter, individuals and NGOs are able to file complaints against a state, when that state has

174. See general comment 14 (2000) on the right to health, adopted by the Committee on Economic, Social and Cultural Rights. International Covenant on Economic, Social and Cultural Rights, art. 12, Dec. 16, 1966, 993 U.N.T.S. 3.

175. Convention on the Rights of the Child, art. 24, Nov. 20, 1989, 1577 U.N.T.S. 3.

176. Universal Declaration of Human Rights, G.A. Res. 217 (III) A, U.N. Doc. A/RES/217(III), art. 25 (Dec. 10, 1948).

177. International Convention on the Elimination of All Forms of Racial Discrimination, art. 5(e)(iv), Dec. 21, 1965, 660 U.N.T.S. 195.

178. International Covenant on Economic, Social and Cultural Rights, art. 12, Dec. 16, 1966, 993 U.N.T.S. 3.

179. Convention on the Elimination of All Forms of Discrimination against Women, arts. 11(1)(f), 12, 14(2)(b), Dec. 18, 1979, 1249 U.N.T.S. 13.

180. Convention on the Rights of the Child, *supra* note 175.

181. International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families, arts. 28, 43(e), 45(c), Dec. 18, 1990, 2220 U.N.T.S. 93.

182. Convention on the Rights of Persons with Disabilities, G.A. Res. 61/106, Annex I, U.N. GAOR, 61st Sess., Supp. No. 49, U.N. Doc. A/61/49, art. 25 (Dec. 13, 2006).

declared its acceptance of the court. Only Ghana, Tanzania, Mali, Malawi and Burkina Faso have made the declaration to date.[183]

While these individual complaint mechanisms exist, for each treaty, complaints can only be brought against states parties who have made the necessary declarations recognizing the treaty and the competence of the respective monitoring committee and only after exhausting all domestic remedies. The weakness with these procedures is that complaints can only be brought against a state, not against an organization or NGO operating in the state. Thus, for violations of the right to health committed by external organizations, victims cannot directly bring a claim against that party. Rather, they would have to bring a claim against the state for failure to ensure that a non-state party did not infringe upon human rights.[184] The issue with this is that the state, especially in the case of a developing state, is not always intentionally complicit when it comes to violations that arise out of clinical trials and holding them accountable does not adequately address the true perpetrators of the abuses, the sponsors, investigators and non-state institutions responsible for the clinical trial. There must be a method to hold these non-state, private actors accountable as well.

D. INGO Accountability Charter

The INGO Accountability Charter (Charter) is the first ever set of international and cross-sector guidelines for the NGO sector and first global accountability charter for the non-profit sector. While it is a non-binding instrument, its content and procedures demonstrates the development of accountability measures for INGOs and have implications for a future legally binding instrument. This section will review the Charter, focusing on key provisions and enforcement mechanisms, and analyze its weaknesses.

1. Background

The INGO Accountability Charter is a voluntary code of conduct. It was initiated by eleven leading international NGOs in the areas of human rights, environment, and social development.[185] The Charter was adopted

183. *About*, African Charter on Human and People's Rights, http://www.achpr.org/about/afchpr/.

184. These and other important characteristics of the right to health are clarified in general comment no. 14 (2000) on the right to health, adopted by the Committee on Economic, Social and Cultural Rights.

185. These eleven founding NGOs include: ActionAid International, Amnesty International, CIVICUS, World Alliance for Citizen Participation, Consumers International, Greenpeace Interna-

in 2006 and fully revised in 2014. Membership is open to civil society and non-profit organizations and there are currently 27 members.[186] Each principle is intended to supplement any existing national or international laws. The Charter is not exclusive and Members of the Charter are able to use additional tools to promote transparency and accountability.

2. Key Provisions

The ten provisions or "10 Accountability Commitments" that make up the INGO Accountability Charter include: respect for human rights, independence, transparency, good governance, responsible advocacy, participation, diversity or inclusion, environmental responsibility, ethical fundraising, and professional management.[187] The principle to have 'respect for human rights' is the only provision that relates to an external commitment, meaning an obligation outside of internal accountability and institutional procedures.[188] The Charter states, "We seek to advance international and national laws that promote human rights . . . Where such laws do not exist, are not fully implemented, or are being abused, we will highlight these issues for public debate and advocate for appropriate remedial action."[189] This provision is the most significant as it bestows upon member organizations a responsibility to look outward and actively seek and resolve abuses or gaps in the law and advocate action. Thereby enabling member organizations to potentially investigate and take action against concerns of human rights abuses committed by non-member organizations.

3. Enforcement Mechanisms & Oversight

In 2008, the founding signatories to the Charter established Accountable Now as an independent organization to execute the reporting and vetting process of the member organizations against Charter commitments. A Board, consisting of representatives from member organizations and independent trustees, oversees actions of Accountable Now. The organization has a conflict of interest policy, including a policy against a trustee that "holds a senior level position in the government in which he or she

tional, Oxfam International, International Save the Children Alliance (partner of Gates Foundation), Survival International, International Federation Terre de Hommes, Transparency International, World YWCA.

186. *Members*, ACCOUNTABLE NOW, http://accountablenow.org/about-accountable-now/members/ (last visited Apr. 10, 2017).

187. *Accountability Commitments*, ACCOUNTABLE NOW, http://accountablenow.org/accountability-in-practice/our-accountability-commitments/ (last visited Apr. 10, 2017).

188. *Id*.

189. *Id.*

can make or significantly influence policy decisions which could affect Accountable Now's ministry."[190]

The organization implemented a two-tier complaints process.[191] In the first stage, the complaint is dealt with by the Accountable Now Secretariat. A complaint is only escalated for review by the Board if the complainant is unsatisfied or if the issue in the complaint has far reaching consequences calling for immediate action.[192] An anonymous version of the complaint is posted on the organization's website.[193]

Accountable Now established an independent review panel. The purpose of this committee is to ensure that members comply with Charter principles. The committee consists of internationally recognized experts in development, human rights, and business. It reviews all annual reports on member compliance and has the final say for handling complaints filed against members.[194] It reviews complaints made by any person, Accountable Now, and members against members or Accountable Now.[195]

4. Criticisms of the INGO Accountability Charter

While the INGO Accountability Charter does offer an accountability instrument for NGOs, the first of its kind, the Charter has many weaknesses. It is definitely a good start to developing a binding instrument to ensure the accountability of NGOs. But, this instrument in its current form cannot ensure accountability. It needs stronger enforcement mechanisms to hold both member NGOs accountable for non-compliance and a way to investigate and shed light on the potential violations by non-members. It needs stronger reporting mechanisms to ensure that long term goals are being achieved. Finally, it needs a way to incentivize more NGOs to become members and adopt the standards since only sixteen organizations have joined since 2006.[196] Without these improvements, it remains to be a good skeleton structure for a future document.

190. *Conflict of Interest Policy*, ACCOUNTABLE NOW, http://accountablenow.org/wp-content/uploads/2016/11/P09a_Conflict-of-Interest-Policy.pdf (last visited Apr. 10, 2017).

191. *Complaints Procedure*, ACCOUNTABLE NOW, http://accountablenow.org/accountability-in-practice/feedback-complaints-members/ (last visited Apr. 10, 2017).

192. *Id.*

193. *Id.*

194. Independent Review Panel Terms of Reference, ACCOUNTABLE NOW, http://accountablenow.org/wp-content/uploads/2017/03/P03a_Independent-Review-Panel-Terms-of-Reference.pdf (last visited Apr. 10, 2017).

195. Independent Review Panel, ACCOUNTABLE NOW, http://accountablenow.org/accountability-in-practice/independent-review-panel/ (last visited Apr. 10, 2017).

196. *Report on INGO Accountability Charter*, DIRECT IMPACT GROUP, http://direct-impact-group.com.

III. RECOMMENDATIONS

The previous case study and analysis identified key areas of concern. First, adherence and enforcement issues because international frameworks are non-binding and national laws do not include key provisions to be effective. Second, there are gaps in legal instruments concerning informed consent procedures for adults and children, compensation and treatment in the event of injury or death, conflicts of interest in the trial and enforcement and complaint mechanisms. Lastly, there is a concern regarding the influence of NGOs on the global agenda at the expense of national sovereignty and local community interest. Therefore, two general recommendations are offered to address these deficiencies. The first is a stronger and binding accountability framework to fill in gaps, make standards uniform and strengthen enforcement. The second recommendation is more community based efforts to prevent abuses, ensure all interests are protected, effectively monitor and sustainably help.

A. Stronger Accountability Framework

In order to address issues of non-compliance and gaps in the law, a stronger accountability framework is needed to govern NGOs, both in the health sector and generally. Instruments covering clinical drug trials using human participants must be legally binding under the national laws of host countries, whether through a standardized international legal instrument that states adopt and implement into their national legislation or through individual legislation adopted by each country. Since trials can be conducted across different regions concurrently, it would be most beneficial to have uniform policies.

Regardless, any legally binding instruments governing clinical drug trials using human participants need to include the following recommended provisions to fill in gaps and ensure protection for participants. First, legal instruments must properly define clinical trials. The definition of clinical trials should be expanded to include observational studies to avoid loopholes that could be taken advantage of like in India. Any definition of a clinical trial must be properly broad to encompass projects using a significant number of human participants. A registration process should be required, but made easy for researchers so as not to deter research or cause undue delay. National laws of host countries should require mandatory registration of all trials using human participants before the project begins. Additionally, a binding requirement to register with a regional, but preferably international registry should be in place. This would ensure proper conduct for those trials that occur across multiple

countries or regions at once. While the Pan African Registry would be useful if it was mandatory, some trials occur in Africa and Asia concurrently. Thus, an international registry would be able to make these connections and ensure uniform registration.

Additionally, informed consent procedures need to be more restrictive in the case of those who may be illiterate among vulnerable populations. Procedures must ensure that each person fully understands their participation and possible consequences. Procedures permitting a thumbprint for those who are illiterate may not be enough and requirements for independent witnesses should be included in legislation on informed consent. A provision checking for and declaring conflicts of interest needs to be included. Further, conflict of interest reviews need to include an external review for conflicts among sponsors, institutions, investigators, and governments. There should also be an individual complaint mechanism with the ability to hold all actors in the trial responsible, including sponsors. Uniform penalties, including fines and sanctions, need to be included in legislation and enforced by local authorities.[197] It is best if these penalties were uniformly implemented across different countries so as to prevent researchers from abusing one country's system that may have lower penalties. Finally, a local oversight committee should be required to monitor and ensure compliance with legal obligations and should be afforded the resources it needs to operate effectively.

Beyond implementing binding laws to hold NGOs accountable for their conduct during clinical drug trials, there should be a binding legal instrument to hold NGOs generally accountable.[198] The INGO Accountability Charter could serve as a preliminary framework. One path to implement a binding framework is through an international organization, such as the United Nations or one of its tasked agencies. Using an international organization would provide independent oversight. In this case, an oversight committee should be established to monitor compliance and ensure enforcement. Registration should be required of all types of international projects regardless of impact level so as to cover more invasive projects like clinical drug trials. States could be given uniform policies to imple-

197. *Africa Urged to Increase Monitoring of Drug Trials*, VOICE OF AFR. NEWS (Mar. 22, 2016), http://www.voanews.com/a/africa-urged-to-increase-monitoring-of-drug-trials—127945633/160322.html.

198. Jeremy Perelman, *Transnational Human Rights Advocacy, Clinical Collaborations, and the Political Economies of Accountability: Mapping the Middle*, 16 YALE HUM. RTS. & DEV. L. J. 89 (2013); Didier Pacquge & Stefaan Smis, *2008 Conference Report: International Conference on the Accountability for Human Rights Violations by International Organizations*, 12 INT'L PEACEKEEPING 175 (2008).

ment in their domestic legislation for monitoring, complaint and penalties.

As of now, peer accountability is the only mechanism in use by the INGO Accountability Charter to encourage organizations to become members. The concept relies on the NGOs community to encourage each other to adopt the policies and to not work with those organizations that have made violations. But, relying on peer accountability alone is not enough. The private sector is considered to have responsibilities with respect to human rights, but these responsibilities are unclear in legal instruments. Many initiatives, even by the United Nations,[199] have been undertaken to discuss the role of the private sector in relation to access to medication and their conduct in other countries, but such work is ongoing and these initiatives are non-binding.[200] No legally binding instrument exists yet, but one is needed.

B. Community Based Efforts & Development

The second concern is the growing influence of NGOs in agenda shaping at the expense of local community and government interests, especially those of developing countries. For example, large foundations like the Gates Foundation are increasingly applying business and market-based approaches to global development. While the approach does focus on results, it favors projects that have short term goals. The Gates Foundation invests most heavily in vaccine development, which provides quick results. At the same time, the priorities of the Gates Foundation neglect other issues related to systematic problems, such as weak infrastructure and health systems. This trend is seen across many organizations. For example, in 2012, the largest 1,000 U.S. based foundations spent 37% of international grant money on health sector projects and only 11% on the environment and 4% on human rights issues.[201] This approach is criticized often for "managing rather than empowering" the impoverished.[202]

199. See e.g., the United Nations Global Compact, a non-binding agreement defining principles of human rights and anti-corruption for companies. United Nations Global Compact, www.unglobalcompact.com.

200. For norms on the responsibilities of transnational corporations and other business enterprises related to human rights, see Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, E/CN.4/Sub.2/2003/12/Rev.2, Addendum: State Responsibilities (A/HRC/4/35/Add.1).

201. *Key Facts on U.S. Foundations*, Foundation Ctr. (2014), http://foundationcenter.org/gainknowledge/research/keyfacts2014/.

202. People's Health Movement/Medact/Global Equity Gauge Alliance (2008), Global Health Watch 2: An Alternative World Health Report, (Zed Books 2008), *available at* www.ghwatch.org/sites/www.ghwatch.org/files/ghw2.pdf.

As mentioned previously, the Government of India is now making efforts to fund key programs internally and turn down Gates Foundation grants in order to curb concerns about foreign donors influencing local policy and conflicts of interest within the Gates Foundation.[203]

While many provisions exist in non-binding guidelines covering medical research and NGOs for the protection of vulnerable groups and individuals, there are no binding provisions. Vulnerable groups and individuals, like low-income families in rural developing countries, have the potential to be abused more.[204] Even in 1964, provisions, albeit voluntary, in the Declaration on Helsinki protected this group, stating that it "should stand to benefit from the knowledge, practices or interventions that result from the research."[205] Community engagement and development would address concerns about NGOs agenda setting and using their influence against the interests of the national governments and local communities. Involving the local community would ensure that their interests and needs are being represented and addressed.[206] Community efforts would also help to have a local monitoring system in place to ensure conduct of the trial and treatment of the human participants.

One type of effort needed is a capacity building initiative for drug trials in developing countries. The implementation of capacity building initiatives ensures that the presence of a NGO in a host country is ethical and does not result in negative impacts. Developing countries lack capacity to effectively implement research ethics committees. When foreign entities conduct trials on human participants in developing countries, they should also be implementing capacity building initiatives to train the local scientific community, implement programs and share knowledge, technical equipment and other resources.[207] This ensures that the local community is not just being taken advantage of because it is not enough just that the local community received vaccinations in exchange for the important data and potential financial benefit that would be gained by the foreign entity. In this way, it is unethical to utilize such a vulnerable population as participants and not add more to the knowledge base of the local community. The hosting country, through one of its overseeing governmental agencies, should require capacity building initiatives to be included in research proposals using human participants. This could be

203. Kalra, *supra* note 74.
204. WMA, *supra* note 102, ¶ 19.
205. *Id.* ¶ 20.
206. J. Fadare & O. Ademowo, Ethical Issues in Malaria Vaccine Clinical Trials: A Principle-Based Approach, 3 Annals Tropical Med. & Pub. Health 35–38 (2010).
207. *Id.*

verified at the time of registration in the host country and throughout the ongoing monitoring process.[208]

Another form of community engagement is through implementation of a local monitoring agency or committee to ensure that all laws are adhered to during the clinical trials. A local monitoring agency will be the most effective to oversee compliance ongoing. Monitoring by a foreign agency will not be as effective and could be viewed as infringing upon national sovereignty.

These measures are also beneficial for projects undertaken in other sectors, such as environmental or civil society, not just for the health sector.

IV. CONCLUSION

The preceding analysis identified two key issues of NGOs in the health sector conducting trials on human participants improperly and their influence in agenda shaping at the expense of developing governments and communities. Through the recommendations provided, including filling in gaps in existing laws governing clinical trials with human participants, stronger and binding accountability framework for NGOs, community engagement and development, these concerns can be diminished.

There may be a concern that stricter review and monitoring of clinical trials using human participants may chill medical research. However, when the process and monitoring of clinical trials using human participants is more uniform, trusted and ensures protection of the human participants, host countries will be more inclined to cooperate with researchers and people will be more inclined to participate. More trust and monitoring is especially needed for trials using children because this will not only protect the interests and safety of vulnerable children, but will lead to more needed drug development for diseases plaguing children. A binding framework governing NGOs generally will also help develop trust in this sector.

The Bill & Melinda Gates Foundation touches two key aspects of human life: medicine and food. The Gates Foundation not only is connected every aspect of vaccine development and delivery in the health sector, but is increasing their efforts in agricultural development across Africa and Asia.[209] The Gates Foundation exemplifies the expanding reach and

208. *Id.*

209. *Agricultural Development*, BILL & MELINDA GATES FOUNDATION, http://www.gatesfoundation.org/What-We-Do/Global-Development/Agricultural-Development/Agriculture-Partners.

potential influence of large NGOs and the need for stronger and more uniform accountability measures. The need for uniform measures is even more important in the international sphere. As demonstrated by the cases used in the analysis, a clinical trial can be very expansive and cover a variety of countries at one. The best way then to hold the sponsors, institutions or investigators accountable for such a wide-reaching project is to have uniform accountability and enforcement practices. This will diminish abuse on the part of institutions looking for locations with more relaxed rules. This will not negatively affect state sovereignty, but will rather protect and strengthen it because it only requires implementation on the part of national laws and allows for national governments to hold NGOs accountable in necessary, but limited circumstances.

Strengthening existing laws in the health sector, both internationally and nationally, will resolve the addressed weaknesses related to clinical trials. The gaps found in the laws governing clinical trials and resulting in human rights violations illustrates the need for NGOs, international organizations, state governments and citizens to review the laws governing other sectors, such as in the environmental sector. Beyond that, strengthening the accountability framework for NGOs, across all sectors, will provide a uniform enforcement and accountability measures so that transnational projects can be monitored and citizens of the international community can hold NGOs responsible for their actions.

It is essential that any kind of assistance, whether for health, the environment or civil society work, given to vulnerable communities and individuals in developing countries is sustainable and empowering. At the end of day, NGOs are still comprised of human beings, susceptible to acting out of human nature and self-interest. While the work of NGOs may need to the freedom to circumvent the politics of an oppressive state government, for example, it should never need to circumvent international law. Without a uniform binding framework to guide and hold these organizations accountable for their actions, they will be free to continue operate without limits. A uniform binding framework is the only way to ensure protection of vulnerable citizens of the international community, as the international community knows too well that "power tends to corrupt and absolute power corrupts absolutely."[210]

210. Lord John Acton, ACTON INST., https://acton.org/research/lord-acton-quote-archive (last visited Apr. 30, 2017).

Testimony
House Bill 1348
House Human Services Committee
January 26, 2021; 2:00 p.m.
North Dakota Department of Environmental Quality

Good afternoon Chairman Weisz and members of the House Human Services Committee. My name is David Glatt, Director of the Department of Environmental Quality (DEQ). The DEQ is responsible for implementing the primary environmental protection programs in the state of North Dakota. I am here today to provide testimony in opposition to HB 1348.

HB 1348 aims to restrict the collection of public health and environmental data relating to the current pandemic but also can act to restrict data collection required under other state and federal laws. The DEQ has historically collected environmental data testing our air, water and waste streams through the authority of federal and state laws such as the Clean Water Act and the Safe Drinking Water Act. Additional monitoring has also been conducted to determine emerging contaminants, such as Perfluorooctanoic Acid (PFOA), Perfluorooctanoic Sulfonate (PFOS) or the presence of potentially hazardous environments. Data collected by the DEQ provides the necessary information used to protect public and environmental health throughout the state.

There are several important points that we would like to note relating to HB 1348.

- HB 1348 conflicts with long-established monitoring requirements, mandatory under the Clean Water Act. This federal and state program requires the monitoring of wastewater by using indicators such as coliform bacteria to determine the potential presence of disease-causing organisms. Prohibiting this required monitoring would; 1) put communities in violation of the federal/state monitoring requirement resulting in potential enforcement action; 2) put the State/US EPA primacy agreement in jeopardy, resulting in a potential takeover of the programs by the federal government, and 3) most importantly, place the public at increased risk to exposure to disease.

- The concern that individuals could be identified as COVID carriers as part of this testing is not accurate. To put this into perspective, the study requires that a 250 milli-liter composite sample (0.066 gallons) be collected over a 24-hour period. One to four daily composite samples can be collected from a municipal wastewater collection system each week, depending on the system's size. Each sample is collected from a wastewater stream that can total 1,000's to millions of gallons per day. Sample collection sites are typically located near lift stations or central collection points. The bottom line is this testing program cannot identify single persons with COVID; rather it provides information on what is happening at the community level.

- Several municipalities have expressed their support for this monitoring program as it assists them in their goal to protect public health by giving them timely COVID data at the community level. It is important to note that the state has initiated COVID sampling programs only after each municipality provided prior authorization. All data generated is shared with each municipality and can help determine upward or downward trends of the virus in the community.

Wastewater testing continues to be an emerging science that can provide early warning of disease outbreaks. As a state, we have proven that by following sound science utilizing expertise at the municipal, local public health, university and state level, we can lead the dialogue in public and environmental health protection to the benefit of our state's citizens.

This concludes my testimony. I now stand for questions from the committee.

NORTH Dakota | Health
Be Legendary.™

House Bill 1348
Human Services Committee
January 26, 2021, 2:00 p.m.

Good afternoon, Chairman Weisz and members of the Human Services Committee. My name is Tracy Miller, PhD, and I am the State Epidemiologist at the North Dakota Department of Health (NDDoH). I am here today to testify in opposition of House Bill 1348.

In July, the North Dakota Department of Health (NDDoH) collaborated on a wastewater sampling project with the Department of Environmental Quality and North Dakota State University. The purpose behind this project was to conduct additional COVID-19 surveillance during a time of limited human testing options and then identify areas in the state that may benefit from additional community-wide testing events.

Regardless of the disease, the benefits to wastewater testing include:

- Providing a pooled community sample to help identify illness in areas where testing is limited or mass testing is not an option.
- Nearly 80% of United States households are served by municipal sewage collection systems.
- Detection in sewage serves as an indicator that is independent of health care-seeking behaviors and access to clinical testing.

The following link provides additional information specific to the Centers for Disease Control and Prevention's COVID-19 wastewater project: www.cdc.gov/coronavirus/2019-ncov/cases-updates/wastewater-surveillance.html

Although this type of testing is new for COVID-19, wastewater testing has been successfully used as a method for early detection of other diseases, such as polio, cryptosporidium and giardia. It can also be used to test for heavy metals such as arsenic, mercury, and lead.

Data collected in wastewater does not identify individual cases, nor should it be the sole source in determining an increase or decrease of mitigation measures. For example, wastewater data alone would not be used to determine travel restrictions, closing of businesses, or implementing/removing measures

such as mask mandates. It is one tool that provides information to help monitor illness in a community, track trends in a community, and help determine if additional measures may be needed.

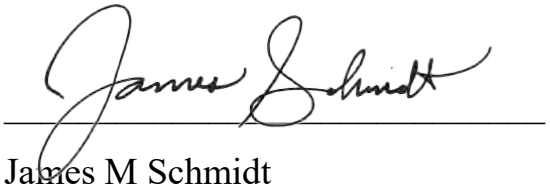
For these reasons, we ask you to oppose the passage of House Bill 1348. This concludes my testimony. I am happy to answer any questions you may have.

January 24, 2020
Attn: House Human Service Committee Members
Subject: HB 1348 & HB 1249

Dear Members of the Committee,

I would urge you to vote in favor of HB 1348 or HB 1249. As a result of the COVID-19 pandemic, citizens across the country have experienced gross governmental overreach and a further encroachment on our personal freedoms. A health crisis does NOT mean that the United States Constitution and our guaranteed right to privacy is suspended. I would urge you to vote in favor of these bills to protect North Dakota from a Federal Government implementing laws that target and restricted US Citizens based on their waste water. Such actions, I believe, are a direct threat to our Republic and a violation of the United States Bill of Rights, Right to Privacy. Thank you in advance and I look forward to the vote on these measures.

Best regards,



James M Schmidt
CEO Red Baron Enterprises
Watford City, ND
James@RedBaronCorp.com

*Please vote in favor of HB 1348 or HB 1249

Dear Committee Members,

I would like to voice my concern regarding the use of wastewater surveillance of COVID-19 to inform public health guidelines and restrictions. There is a big difference between TESTING wastewater in order to protect citizens from contamination and SURVEILLING wastewater in order to protect citizens from each other. Until reliability and efficacy of this new public health tool are demonstrated, implementing wastewater screening for COVID-19 to target public health resources, to require testing, to impose restrictions on movement, or to remove restrictions based on an absence of virus in the wastewater is premature at best. Even if reliability and efficacy are established, the legal and moral ramifications must be strongly and thoroughly considered before implementation.
Please render a “DO PASS” out of committee for HB 1348 or HB 1249.

Thank you for your leadership and service to our state.

https://academic.oup.com/jlb/article/7/1/lsaa039/5861905

Sixty-seventh Legislative Assembly of North Dakota

Re: Testimony in favor HB 1348

Attn: Committee Members,

I, Todd Kjelland am writing in favor of HB 1348 because I believe by passing this bill infringes upon privacy rights of individual persons.

Testing for DNA or genetic material needs a notice (Warrant) of search and seizure. I believe this would circumvent those rights.

Thank you for your consideration to PASS HB 1348

Todd Kjelland

emocoach@live.com

701-331-2956

I respectfully submit the following testimony regarding HB 1348, relating to prohibiting the testing of wastewater for genetic material or evidence of disease.

I am a professor in the department of Microbiological Sciences at NDSU. Over the past 7 months, my lab has been testing wastewater from cities across North Dakota for the COVID virus. We test a half-cup sample, representing just a drop in the ocean of wastewater that flows through a facility in a day (5-15 million gallons for larger cities), yet this has proven remarkably informative about the amount of virus circulating in a community. Testing a single sample of wastewater is considerably more cost effective than mass testing of individuals and data can be produced in within hours. From a privacy standpoint, an important limitation of wastewater monitoring is that it does not, nor cannot reveal personal information about individuals contributing to that watershed. Wastewater monitoring is intended to be a tool to help municipalities make decisions about how best to use their limited resources in the fight against the COVID virus.

Testimony Presented on HB 1348

House Legislative Assembly

Representatives Cory, Becker, D. Ruby, M. Ruby, Skroch, Tveit
Senator O. Larson

James Hausauer, Water Reclamation Utility Director
City of Fargo
January 25, 2021

Mr. Chairman and Members of the Committee,

The City of Fargo OPPOSES House Bill 1348.

Testing of wastewater – Limitation.
Water or other material in any wastewater disposal system may not be tested for genetic material or evidence of disease.

I do not understand the intent behind this proposed bill; however, I can imagine a number of concerns if this bill were enacted. This bill would contradict goals and requirements of the North Dakota Department of Health and the Environmental Protection Agency (EPA). The requirements of the North Dakota Pollution Discharge Elimination System (NDPDES), which is in compliance with Chapter 33-16-01 of the North Dakota Department of Health rules as promulgated under Chapter 61-28 (North Dakota Water Pollution Control Act) of the North Dakota Century Code. Publicly Owned Treatment Works (POTW's) are authorized to discharge treated wastewater to receiving streams, provided the conditions of the permit are met. Those conditions include routine testing of parameters to protect ground water/surface water from pollution and sources of disease. Without establishing and enforcing wastewater discharge standards, upstream dischargers (polluters) can damage and alter downstream drinking water sources, making treatment more expensive, thus potentially leading to illness.

CONCLUSION. The Water Reclamation Utility Director of the City of Fargo OPPOSES House Bill 1348.

2021 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee
Pioneer Room, State Capitol

HB 1348
2/2/2021

Relating to prohibiting the testing of wastewater for genetic material or evidence of disease; and to provide a penalty.

Chairman Weisz opened the committee meeting at 11:24 a.m.

Representatives	Attendance
Representative Robin Weisz	P
Representative Karen M. Rohr	A
Representative Mike Beltz	P
Representative Chuck Damschen	P
Representative Bill Devlin	P
Representative Gretchen Dobervich	P
Representative Clayton Fegley	P
Representative Dwight Kiefert	P
Representative Todd Porter	P
Representative Matthew Ruby	A
Representative Mary Schneider	A
Representative Kathy Skroch	P
Representative Bill Tveit	P
Representative Greg Westlind	P

Discussion Topics:

- HB 1348 Committee Action

Rep. Gretchen Dobervich (11:25) moved Do Not Pass.

Rep. Mike Beltz (11:25) second.

Representatives	Vote
Representative Robin Weisz	Y
Representative Karen M. Rohr	A
Representative Mike Beltz	Y
Representative Chuck Damschen	Y
Representative Bill Devlin	Y
Representative Gretchen Dobervich	Y
Representative Clayton Fegley	Y
Representative Dwight Kiefert	Y
Representative Todd Porter	Y
Representative Matthew Ruby	A
Representative Mary Schneider	A
Representative Kathy Skroch	N
Representative Bill Tveit	N

Representative Greg Westlind	Y

Motion Carried Do Not Pass 9-2-3

Bill Carrier: Rep. Mike Beltz

Chairman Weisz adjourned at 11:27 a.m.

Tamara Krause, Committee Clerk

REPORT OF STANDING COMMITTEE

HB 1348: Human Services Committee (Rep. Weisz, Chairman) recommends **DO NOT PASS** (9 YEAS, 2 NAYS, 3 ABSENT AND NOT VOTING). HB 1348 was placed on the Eleventh order on the calendar.