

## Ethical Challenges of Executing the Informed Consent Process in Caribbean Small Island Developing States

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Small Island Developing States (SIDS) in the Caribbean Sea have small population sizes, a quality that may mean that adherence to the requirement of written informed consent places research participants at higher risk than is necessary for the ethical conduct of research. The relatively small populations of SIDS contribute to concerns about privacy and confidentiality in a setting where ‘everybody knows everybody.’<sup>1</sup> As a result, there is reluctance from some research participants to sign a written informed consent document because of the fear that one’s signature may expose research participation, particularly in cases where the research participation reveals membership in a stigmatized group or stigmatized behaviors. This paper considers whether respect for participants’ privacy justifies waivers of written informed consent. I argue that obtaining verbal consent is sufficient in most cases when signing or writing one’s name raises concerns about privacy, anonymity, and confidentiality.

### Research & Privacy

Privacy concerns limiting access of research participants’ personal information to others whereas confidentiality is the protection of the subjects’ privacy by people to whom private information is disclosed.<sup>2</sup> Anonymity relates to both the identification of human subjects and the linkage of their data. When anonymity is preserved, it should not be possible to identify or link these human subjects to the study data.<sup>3</sup> Confidentiality entails the maintenance of sensitive data, which ought to be stored safely.<sup>4</sup> As such, a research participant’s concern about their privacy is directly related to researchers’ ability to anonymize data and/or maintain confidentiality. A participant’s desire to keep information about a stigmatizing condition, say past drug use or HIV status, private places an obligation on researchers not to disclose this information. Privacy concerns may be greater in Caribbean SIDS than in more populous contexts given the likelihood that researchers will know research participants or that research participants will be easily recognizable by

researchers and others. This does not amount to a waiver of informed consent but is rather a waiver of documentation of informed consent.

In Caribbean SIDS, privacy and confidentiality concerns related to a small population size are further compounded by factors such as limited resources, inadequate training of both researchers and members of research ethics committees (RECs), breaches of trust in clinical care, and inadequate public information about research studies. These issues may make confidentiality breaches more likely, potentially making privacy a bigger concern among research participants. Understanding these issues, and how they exacerbate privacy concerns, is vital.

Limited resources result in the conduct of fewer research studies and less support for researchers undertaking studies. The 58 United Nations (UN) Member and Non-UN Member States that constitute SIDS, represent less than 1% of the global population.<sup>5</sup> According to the UN, there are 16 Caribbean SIDS. Cuba, with 11 million people, is the most populous both in the Caribbean and among all SIDS.<sup>6</sup> St. Kitts and Nevis is the least populated Caribbean SIDS with a population of approximately 52,000.<sup>7</sup> There is unequal distribution among the low-, middle- and high-income groups with most SIDS being middle-income countries while very few are high-income.<sup>8</sup> With limited financial and human resources overall, it is challenging for Caribbean SIDS to contribute significantly to research and research ethics. As a result, there is often inadequate training of researchers and members of RECs; reduced research capacity; and weaker governance of research.<sup>9</sup>

Inadequate training of researchers may create trust issues and contribute to the reluctance of some research participants to participate in research studies done in Caribbean SIDS. Due to limited human resources, a small number of researchers are expected to work in varied capacities. Some consult the government, which may raise concerns among would-be research participants about leaking their names

and stigmatized conditions to government officials. Moreover, some researchers may propose work in areas where they are not sufficiently trained. According to the Pan American Health Organization (PAHO), the international health agency for a large region that includes Caribbean countries, there was an uptick in research proposals during the Covid-19 pandemic from researchers with limited research experience. For the year 2022, PAHO's REC received an unusually high number of 102 research protocols.<sup>10</sup> This required 14 meetings, 10 regular and 4 auxiliary.<sup>11</sup> It is concerning that many of the researchers had no prior experience conducting research in human subjects.<sup>12</sup>

Although a breach of confidentiality should not exist in clinical care, the following event, and others like it may undermine trust in health researchers. In March 2020, the Trinidad and Tobago Medical Association (T&TMA) publicly condemned the actions of a healthcare professional who posted a patient's referral letter on social media. This letter included the patient's full name, travel history as well as other pertinent and personal details. The T&TMA used the opportunity to educate healthcare professionals and the public on the importance of maintaining patients' privacy and confidentiality. It emphasized that a failure to do so is unethical and may result in serious consequences, such as suspension or revocation of one's license to practice medicine for healthcare professionals.<sup>13</sup> Nonetheless, the damage to the reputation and public trust in healthcare professionals' institutions may have a spillover effect on health research.

Finally, poor data reporting about studies happening in the Caribbean make it difficult to quantify the amount of research happening and monitor adverse events that occur within research studies, like breaches of confidentiality. The Caribbean Public Health Agency (CARPHA) addresses health issues that are related to the countries of this part of the Americas. This organization established the CARPHA Caribbean Network of Research Ethics Committee in 2014 and the Caribbean Network of Research Ethics Committee (CANREC) in 2016. After a period of being inactive, a new CARPHA REC was formed, and it had its first meeting in 2020.<sup>14</sup> Currently, there are no statistics available on the number of research protocols that were reviewed and/or approved by the CARPHA REC. There are individual RECs in various Caribbean countries. However, public data on the number of research protocols that were received by these RECs are not available.

### **Written versus Verbal Consent to Participate in Research**

Given the small population size of most Caribbean SIDS and compounding factors described above, it is reasonable to worry that concerns about privacy and confidentiality may contribute to resistance or reluctance to participate in research among people in these countries, a noted problem.<sup>15</sup> It's important to consider ways to counter research resistance and reluctance. One way is waiving the require-

ment to provide written informed consent to participate in research, substituting this with verbal consent that does not require a signature, especially for sensitive research that requires disclosure of sensitive or stigmatizing information. Not being made to sign an informed consent document may be reassuring to participants as there would be no physical evidence, as in the form of a signature, that links the participant to the research study.

The compromise of research participant's privacy and confidentiality is concerning particularly when it relates to sensitive research. In Caribbean SIDS, this may result in the identification of research participants who consequently may face social stigmatization or retaliation. Fear of being recognized, especially when participating in studies that involve a stigmatized condition, like human immunodeficiency virus (HIV), may serve as a deterrent to the signing of a written informed consent documents—and to research participants generally. Additionally, there is the probability that if leaked, a record of research participation would attract negative government attention to people who are “outed” putting them at risk of harm, such as losing their job. A possible solution to this problem is to waive the requirement of written informed consent and ask research participants to provide explicit verbal consent instead. In this way, names of research participants are not recorded.

From the public good perspective, conducting sensitive research may help to identify problematic areas and subsequently prompt stakeholders, such as healthcare professionals, hospital administrators and the Government, to implement measures that will benefit citizens who utilize the healthcare services. In general, health research is justified by the potential benefits to be gained, such as increased knowledge and skills.<sup>16</sup> Impediments to research participants should be mitigated as much as possible to reap the benefits of health research.

True informed consent requires competence, voluntariness, and receipt of adequate information.<sup>17</sup> These can be accomplished regardless of whether consent is documented in writing or obtained verbally. In Caribbean SIDS, to adequately protect the research participants' privacy and maintain confidentiality, the provision of verbal consent may be more appropriate. This is likely to reduce the risk of confidentiality breaches and privacy invasion, in a setting where ‘everybody knows everybody’.<sup>18</sup> Substituting verbal for written consent does not mean, however, that the informed consent process should be conducted in a substandard manner.<sup>19</sup> According to Tekola et al., the informed consent process is influenced by multiple factors, such as culture, language, personal preferences of verbal over written informed consent, community leaders, and educational background.<sup>20</sup> Since we already accommodate some variation on how informed consent is obtained, RECs should accommodate some variation in how informed consent is documented, too.

## Limits to Verbal Consent

Despite the justification given for the use of oral consent instead of written consent in Caribbean SIDS, there are times when written consent must be provided. Hence, irrespective of the geographical and cultural considerations that warrant a waiver of written informed consent to avoid a compromise of privacy, anonymity, and confidentiality, there are some noteworthy exceptions. These include research done on patients with sexually transmitted diseases (STDs), such as HIV, that threaten the lives and/or health of others and diseases that lead to epidemics or pandemics where it may be required to report incidence of the infectious disease.<sup>21</sup> For example, if the study involves HIV testing and the participant tested positive then it is necessary to notify that participant as well as their partner to minimize the spread and risk of harm of this infectious disease.

In St. Vincent and the Grenadines, the explosive eruption of the country's La Soufriere Volcano in 2021 occurred during the height of the Covid-19 pandemic. This was at a time when social distancing was recommended. However, the evacuation of approximately 20,000 people who then had to be placed in close quarters in shelters posed an increased risk of spread of Covid-19. There were also concerns of the spread of sexually transmitted infection due to sexual practices among individuals who were placed in these respective shelters.<sup>22</sup> The situation created an ethical dilemma of respecting individual autonomy versus the public good that the Government of St. Vincent and the Grenadines had to weigh. Various research studies were conducted during this period of the Covid-19 pandemic and the explosive eruption of La Soufriere Volcano. Research during this very sensitive era warranted written consent to participate in research, when it involved testing for infectious disease, because of the major risk of harm that testing positive for Covid-19 and/or sexually transmitted infection would have posed to other individuals. This way, participants who tested positive could be recontacted and appropriately counseled.

This scenario serves as a reminder that a change from the norm can create ethical challenges for which one must be prepared. It therefore means that in developing policies to support this use of oral consent in lieu of written consent in Caribbean SIDS, situations that warrant the use of written consent must be considered.

## Conclusions

Given the unique ethical challenges that researchers and research participants from Caribbean SIDS experience during the conduct of research in such countries, verbal instead of written informed consent should become a common practice. This, however, must be done in a manner that is ethical and reduces the risk of loss of privacy and compromise of confidentiality.

Additionally, measures, like the implementation of ethics training policies and the establishment of ethics oversight

boards, should be executed to ensure that ethical standards are applied and maintained during the conduct of research in these Caribbean SIDS. PAHO is continually working to strengthen research ethics systems throughout the Caribbean.<sup>23</sup> They should consider placing greater emphasis on verbal consent, especially when there is a high risk of the participants' being negatively affected by breaches of confidentiality. This, however, would require full support and approval from RECs and researchers in such countries. Verbal consent is likely to be preferred by the research participants when it would reduce the risk of them being recognized and eliminate harms that may result from recognition.

## References

- <sup>1</sup> M. Everest-Phillips, "Small, So Simple? Complexity in Small Island Developing States," UNDP Global Centre for Public Service Excellence, 2014. [https://www.undp.org/sites/g/files/zskgke326/files/publications/GPCSE\\_Complexity%20in%20Small%20Island.pdf](https://www.undp.org/sites/g/files/zskgke326/files/publications/GPCSE_Complexity%20in%20Small%20Island.pdf).
- <sup>2</sup> National Archives and Records Administration, "Code of Federal Regulations: Part 46 – Protection of Human Subjects," (Washington, D.C.: National Archives and Records Administration, 2017). <https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46>.
- <sup>3</sup> The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Office for Human Research, *The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research* (Bethesda, MD: U.S. Department of Health and Human Services, 1979). <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html>.
- <sup>4</sup> National Archives and Records Administration, "Code of Federal Regulations: Part 46 – Protection of Human Subjects," (Washington, D.C.: National Archives and Records Administration, 2017). <https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46>.
- <sup>5</sup> United Nations, Office of the High Representative for the Least Developed Countries, Landlocked Developing Countries and Small Island Developing States, *Small Island Developing States in Numbers* (New York, NY: United Nations OHRLLS, 2013). [https://wedocs.unep.org/bitstream/handle/20.500.11822/9279/-SIDS%20in%20numbers-2013SIDS\\_IN\\_NUMBERS\\_121813\\_FA\\_WEB.pdf](https://wedocs.unep.org/bitstream/handle/20.500.11822/9279/-SIDS%20in%20numbers-2013SIDS_IN_NUMBERS_121813_FA_WEB.pdf).
- <sup>6</sup> United Nations, Office of the High Representative for the Least Developed Countries, Landlocked Developing Countries and Small Island Developing States, *Small Island Developing States in Numbers* (New York, NY: United Nations OHRLLS, 2013). [https://wedocs.unep.org/bitstream/handle/20.500.11822/9279/-SIDS%20in%20numbers-2013SIDS\\_IN\\_NUMBERS\\_121813\\_FA\\_WEB.pdf](https://wedocs.unep.org/bitstream/handle/20.500.11822/9279/-SIDS%20in%20numbers-2013SIDS_IN_NUMBERS_121813_FA_WEB.pdf).
- <sup>7</sup> U.P. Barzey, "Caribbean?" *Caribbean & Co* (blog), August 2021. <https://www.caribbeanandco.com/what-is-the-most-populous-country-in-the-caribbean/#:~:>

text=Saint%20Kitts%20and%20Nevis%20comprise,independent%20country%20in%20the%20Caribbean.

<sup>8</sup> United Nations, Office of the High Representative for the Least Developed Countries, Landlocked Developing Countries and Small Island Developing States, *Small Island Developing States in Numbers* (New York, NY: United Nations OHRLLS, 2013). [https://wedocs.unep.org/bitstream/handle/20.500.11822/9279/-SIDS%20in%20numbers-2013SIDS\\_IN\\_NUMBERS\\_121813\\_FA\\_WEB.pdf](https://wedocs.unep.org/bitstream/handle/20.500.11822/9279/-SIDS%20in%20numbers-2013SIDS_IN_NUMBERS_121813_FA_WEB.pdf).

<sup>9</sup> B. Aguilera, et al., “Research ethics systems in Latin America and the Caribbean: a systematic assessment using indicators,” *The Lancet Global Health* 10, no. 8 (2022): 1204-08.

<sup>10</sup> Pan American Health Organization, *Pan American Health Organization Ethics Review Committee 2022 Annual Report* (Washington, D.C.: PAHO, 2023).

<sup>11</sup> Pan American Health Organization, *Pan American Health Organization Ethics Review Committee 2022 Annual Report* (Washington, D.C.: PAHO, 2023).

<sup>12</sup> Pan American Health Organization, *Pan American Health Organization Ethics Review Committee 2022 Annual Report* (Washington, D.C.: PAHO, 2023).

<sup>13</sup> “Respect patient privacy and confidentiality – Medical Association,” *Trinidad & Tobago Guardian* (blog). <https://www.guardian.co.tt/news/respect-patient-privacy-and-confidentialitymedical-association-6.2.1070498.d97a03580a>.

<sup>14</sup> J. St. John, “Resuscitation of the CARPHA REC, the Need for Such, and Future Plans,” *CANREC Bulletin* 3, no. 1,2 (2021): 3-4.

<sup>15</sup> K. Matheson, et al., “Anonymity versus advocacy: challenges and pitfalls of ethical island research,” *The Commonwealth Journal of International Affairs* 109, no. 6 (2020): 720-729.

<sup>16</sup> R. Zitoun, et al., “Review of the Scientific and Institutional Capacity of Small Island Developing States in Support of a Bottom-up Approach to Achieve Sustainable Development Goal 14 Targets,” *Oceans* 1, no. 3 (2020): 109-132.

<sup>17</sup> National Archives and Records Administration, “Code of Federal Regulations: Part 46 – Protection of Human Subjects,” (Washington, D.C.: National Archives and Records Administration, 2017). <https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46>.

<sup>18</sup> United Nations World Tourism Organization, *Small Islands Developing States (SIDS)* (New York, NY: UNWTO, n.d.). <https://www.unwto.org/sustainable-development/small-islands-developing-states>; H. Schembri and C. Sciberas, “Ethical considerations and limitations when researching education in small island states,” *Sentio Journal* (2020).

<sup>19</sup> Council for International Organizations of Medical Sciences and World Health Organization, *International ethical guidelines for health-related research involving humans*. (Geneva, CIOMS, 2017); National Archives and Records Administration, “Code of Federal Regulations: Part 46 – Protection of Human Subjects,” (Washington, D.C.: National Archives and Records Administration, 2017). <https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46>.

<sup>20</sup> F. Tekola, et al., “Tailoring Consent to Context: Designing an Appropriate Consent Process for a Biomedical Study in a Low Income Setting,” *PLOS Neglected Tropical Diseases* 3, no. 7 (2009): 482.

<sup>21</sup> B. Varkey, “Principles of Clinical Ethics and Their Application to Practice,” *Med Princ Pract* 30, no. 1 (2021): 17-28.

<sup>22</sup> United Nations, Office for the Coordination of Humanitarian Affairs, *St. Vincent & the Grenadines: La Soufriere Volcano Report No. 03* (New York, NY: United Nations OCHA, 2021). <https://www.unocha.org/publications/report/saint-vincent-and-grenadines/st-vincent-grenadines-la-soufriere-volcano-report-no-03-17>.

<sup>23</sup> B. Aguilera, et al., “Research ethics systems in Latin America and the Caribbean: a systematic assessment using indicators,” *The Lancet Global Health* 10, no. 8 (2022): 1204-08.

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