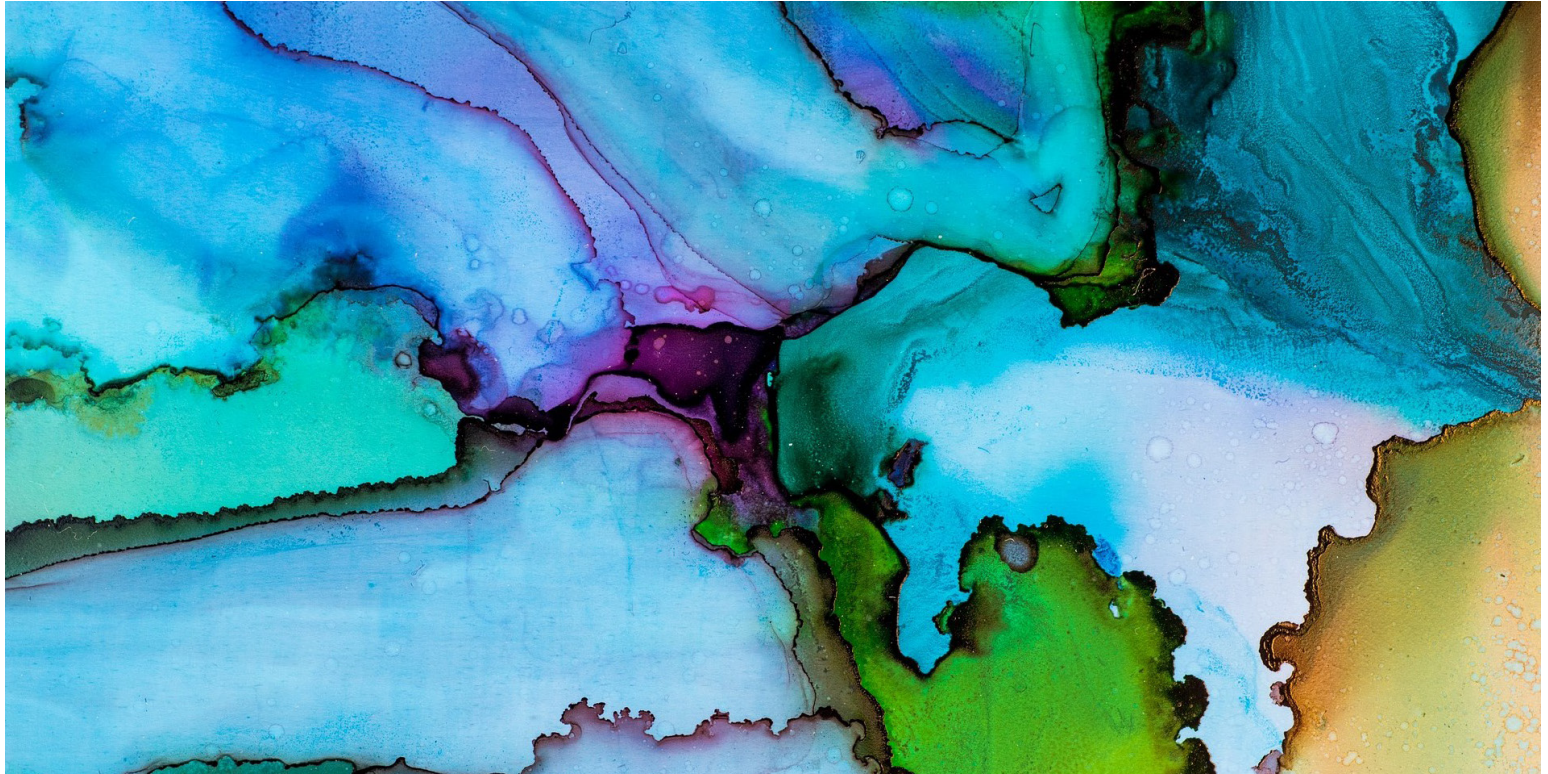


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Michael H. Campbell, PhD Faculty of Medical Sciences University of the West Indies-Cave Hill Barbados



“Engage members and friends of the Caribbean research community in ethics developments and discourse on ethics.”

Welcome to the inaugural issue of the CANREC Bulletin! The Bulletin is a publication of the Caribbean Network of Research Ethics Committees, established by the Caribbean Public Health Agency to promote cooperation and collaboration among the growing number of national and institutional research ethics committees in CARICOM.

The Bulletin aspires to engage members and friends of the Caribbean research community in ethics developments and discourse on ethics through news updates and thought-provoking original contributions. In this first issue, you'll find Dr. Derrick Aarons' thorough coverage of the historical development of research ethics training and practice in the Caribbean. See also timely and thoughtful contributions on issues of particular relevance to our region: "Research tourism" (a new manifestation of medical tourism) and the ethical dimensions of disaster management response to hurricanes. We've also included an opinion piece on challenges to implementation of the Health Research Policy for the Caribbean based on experiences in St. Vincent and the Grenadines.

The opinions expressed by contributors do not necessarily reflect those of CANREC or CARPHA. If they do or don't reflect yours, please consider writing a response for our next issue. Our aim is to promote fresh and constructive discussion on important topics and challenges in research ethics.

We hope you find something valuable in this issue. Please let us hear from you with contributions or suggestions for future volumes of the Bulletin.

The historical development of research ethics in the English-speaking Caribbean

By Derrick Aarons, MBBS(UWI), MSc(Bioethics), PhD(McGill)
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“Research ethics involves the application of fundamental ethical principles and rules to the process of research, with the main aim of protecting the participants in the research endeavour.”

Introduction

The history of research ethics in the western world began as a result of the inhumane research conducted by Nazi researchers during World War II, with the subsequent Nuremberg Code providing the first legal document on research ethics (European Commission Directorate-General for Research, 2010). Research ethics involves the application of fundamental ethical principles and rules to the process of research, with the main aim of protecting the participants in the research endeavour (Aarons, 1995). Research Ethics Committees (RECs) have the responsibility for ensuring that all proposed research with human participants meet the required ethical standards that are acclaimed internationally (Aarons, 2017a). Institutional Review Board (IRB) is the name given to a research ethics committee that is located within an institution, and is the nomenclature most commonly used in the United States of America (USA), as well as in countries that have established IRBs based on the need for collaborative research with institutions, organizations, and researchers from the USA.

History in the Caribbean

The history of research ethics with human participants in the English-speaking Caribbean perhaps began with the formation of ethics committees at the Faculties of Medical Sciences at the UWI Campuses in Mona, Jamaica and Cave Hill, Barbados in the early 1990s (some informal review processes had existed earlier). That was followed in 1995 by the formation of an Institutional Review Board (IRB) at the Windward Islands Research and Education Foundation (WINDREF), located on the campus of the St. George's University School of Medicine in Grenada.

The 1st academic publication on the subject in the region occurred in December, 1995, when the West Indian Medical Journal (WIMJ) published the manuscript, “Research Ethics” (Aarons, 1995). Dr. Derrick Aarons was at the time graduating from McGill University in Montreal, Canada, with a master's degree in bioethics.

Subsequently, in March, 1997, the Ethics Committee at the UWI in Jamaica, which had become dormant in 1994, was resuscitated to review research proposals from local researchers as well as collaborative research from overseas. This came about as the UWI applications for research grants and collaborative research from North America had increasingly required that research proposals be first reviewed and approved by a local research ethics committee within the host country. Dr. Aarons was invited to serve as the bioethicist on that UWI committee and served in that position until he demitted office in November, 2004. The committee met on the last Friday of every month to review all submitted research protocols.

The next publication in the subject area of research ethics was “Research Ethics Committees: A Regional Approach” by C.C. Macpherson (1999) in Theoretical Medicine and Bioethics. Cheryl Macpherson was appointed professor and subsequently became the chair of the Bioethics Department at St. George's University School of Medicine in Grenada in 2003. Prof. Macpherson also served on the IRB of the Windward Islands Research and Education Foundation (WINDREF), which became the official IRB of St. George's University during that year.

In October 1999, Dr. Aarons made an oral presentation entitled “The Current Status of Research Ethics Review in Jamaica” to the Joint United Nations Programme on HIV/AIDS (UNAIDS) meeting in Rio de Janeiro, Brazil. In March 2000, Dr. Aarons addressed the faculty and post-graduate students at the Tropical Metabolic Research Institute, UWI, Jamaica, on “Research Ethics and Research in Children.” The next month, working with the Ethics Committee of the UWI, Jamaica, Dr. Aarons authored the Guidelines for the Conduct of Research for the Faculty of Medical Sciences and the University Hospital of the West Indies.

The decade of growth for research ethics

In October 2000, the Ministry of Health in Jamaica formed the Panel on Ethics & Medico-Legal Affairs and invited Dr. Aarons to serve as its first Chairman. Then, in November 2001, Dr. Aarons authored A System for the Ethical Review of Research Protocols across Jamaica, which outlined the process for review of research proposals in the 14 parishes of that country; review at the regional health authority level; and review at the national level by the Ethics Panel in the Ministry of Health. He also wrote the template for The Ministry of Health Guidelines for the Conduct of Research on Human Subjects.

In 2000 and again in 2001, Prof. David Picou, then Director of the Caribbean Health Research Council (CHRC), who had developed a keen interest in research ethics, hosted two conferences in Trinidad: Ethics in health care and research in the Caribbean (2000), and Ethics in Human Subjects Research in the Caribbean (2001). Prof. Picou invited several persons from around the Caribbean to present topics in these subject areas. Discussions regarding the possibility of establishing a Caribbean Ethics Network that would provide a forum for ethics discussion in Caribbean countries were among several issues mooted at these conferences.

In 2001, Prof. Cheryl Macpherson published “Research Ethics Committees: Getting Started” in WIMJ, as well as “Research Ethics in Grenada: Beyond the Guidelines” in Developing World Bioethics (Macpherson, 2001a, 2001b). Then, Macpherson and Connolly published “Enough is Enough: Disclosure in Cross Cultural Research” (2002).



Dr. Aarons delivered several oral presentations on research ethics during 2001: “Constituting an Ethical Review Committee” and “Confidentiality in Research” at the Ethics in Human Subjects Research in the Caribbean conference in Trinidad; “Ascertaining the Attitudes and Levels of Communication of Health Professionals in Government Hospitals in Jamaica” at the annual conference of the Caribbean Health Research Council (CHRC); and “Issues of Consent” at the 10th Annual Research Day of the Faculty of the Faculty of Medical Sciences, UWI, Jamaica. Subsequently, Aarons (2003a) published “Issues in Bioethics: Teaching Research Ethics” in WIMJ. Dr. Aarons also authored a chapter, “Research Ethics” in the CHRC Research Skills Workshop Manual, which was edited and published by the then-newly installed Director of the CHRC, Dr. Donald Simeon (Aarons, 2003b). The manual was used by the CHRC to provide training for researchers across the Caribbean in subsequent years.

In May 2003, another workshop, Ethics in Research with Human Subjects, was hosted in Trinidad, and, in September 2003, a training workshop for medical officers on health research proposals was hosted at the Ministry of Health in Jamaica. Presentations included “Research Ethics, Evaluation of Risks & Benefits” and “Constituting a Research Ethics Committee.”

In November 2003, the University of Technology in Jamaica hosted its 1st Research Ethics Seminar, on the Kingston Campus. Dr. Aarons presented “International Guidelines for Biomedical Research” and “Ensuring Confidentiality and Protection of Privacy.”

In April 2005, the 1st Caribbean Ethics Conference was hosted by Dr. Anthony Mullings at the UWI, Mona, Jamaica, with topic presentations by Dr. Aarons such as “Vulnerable Populations – Who and Why?” and “Research Ethics–Nuts & Bolts: Exclusion.” In November 2005, a research ethics workshop was conducted in Belize City, with presentations by Dr. Aarons on topics such as: “Making Risk-Benefit Assessments,” “Vulnerable Populations – Children & mentally impaired persons,” “Special Populations - Women & minorities,” and “Overview of Ethics in International Research.”

At the 2nd Caribbean Research Ethics Conference held on May 19, 2006, at the UWI, Jamaica, the Bioethics Society of the English-speaking Caribbean (BSEC) was launched, spearheaded by Dr. Derrick Aarons and Prof. Cheryl Macpherson, who served as founding president and vice-president, respectively. The president of BSEC charged his newly elected Executive to aim to achieve: 1) A facilitating function that would encourage dialogue about bioethical issues and the setting up of research ethics committees to serve the Caribbean territories; and 2) An advocacy function that would strive for the formulating of ethical policies in health care and research.

In 2007, Dr. Aarons wrote a template manual for developing research ethics committees in Caribbean countries, which included guidelines for the contents of research proposals, was sent by BSEC to all Chief Medical Officers in the English-speaking Caribbean. Entitled *The Ethical*

Requirements for Research with Human Participants in the Caribbean, the template was ratified by the Executive of BSEC and posted on its website for use by persons across the Caribbean. This proved invaluable to many persons and committees in subsequent years and was utilized by the Caribbean Public Health Agency (CARPHA) when compiling the Standard Operating Procedures in preparation for instituting a research ethics committee at CARPHA in 2014 to serve the Caribbean region.

Further, in May, 2007, the 1st Bioethics Forum in the English-speaking Caribbean was held by BSEC and hosted on the final day of the annual conference of the Caribbean Health Research Council (CHRC), which was being held that year in Montego Bay, Jamaica. Research ethics was one of the primary topic areas.

In the later 2000s, there was growing awareness of the importance of research ethics beyond medical sciences, most particularly in psychology and social sciences, in tandem with the University of the West Indies developing a multidisciplinary and multi-campus research ethics policy, which was last updated in 2011. Regional conference presentations promoted research ethics in these broader areas (Campbell & Emmanuel, 2016; Campbell, 2014, 2015).

During this developmental period for research ethics during the 2000s, collaborative research projects were being proposed in several Caribbean countries. This was the same impetus during the early 1990s that had caused the Ethics Committee at the UWI, Jamaica and that at WINDREF in Grenada to be formed (i.e., the international requirement for a local committee to evaluate research proposals coming from outside the countries), and so led to the formation of other RECs/IRBs across the region.

The growth of RECs/IRBs

Being integrated into long-standing academic institutions, the Research Ethics Committees at the UWI in Barbados and in Trinidad had been formed and functioning for some time prior to 2004. The Barbados Research Ethics Committee, which had been championed by Prof. Errol Walrond for more than a decade, became more formalized in the early 2000s and implemented a memorandum of understanding expanding its remit to include projects under the jurisdiction of the Barbados Ministry of Health as well as the Cave Hill Campus. Then, the research ethics committee in Suriname began its work in 2004. After that, the REC for the Turks & Caicos Islands commenced its work in July 2008, and that for the North-West Regional Health Authority in Trinidad had its 1st meeting in January 2009. In 2010, the IRB in Anguilla began functioning. The REC in St. Lucia began its work in 2011, as did that at the University of Technology in Jamaica and that at the University of the Southern Caribbean in Trinidad. Then the research ethics committee at the Eastern Regional Health Authority in Trinidad started its work in 2012, and that at the Ministry of National Security in Jamaica commenced functioning in the latter part of 2012.

Further, in 2012, D.E. Aarons wrote a book chapter, “Bioethics Education in the English-speaking Caribbean,” for a book published by UNESCO,

in which he detailed the education landscape at the time with regard to medical ethics, research ethics, and ethics of the life sciences (Aarons, 2012).

Publications in the subject area of research ethics continued with ‘Ethical Issues Surrounding Body Integrity and Research’ in the WIMJ in 2014, and “Research: An Ethical Answer in Addressing our People’s Health Problems and Inequities” in the WIMJ in 2015 (Aarons, 2014, 2015). Further, Dr. Aarons was appointed Ethicist for the Caribbean Public Health Agency (CARPHA) in 2014 (the first such ‘ethics’ position in the English-speaking Caribbean).

With the plan by CARPHA to institute a regional research ethics committee, a training workshop for the proposed committee was conducted in November 2014, with topics by Dr. D.E. Aarons such as “Ethical Principles in Research with Human Participants”, “International Guidelines for Biomedical Research”, and “International Collaborative Research & Research Ethics committees.” That committee was officially appointed by the Executive Director of CARPHA on December 1, 2014.

Subsequently, a presentation, “Ethics in Research, Medicine, Medical Product Testing, and Beyond” was delivered by Dr. Aarons in a Professional Development Series at CARPHA during February, 2015. Also, during February - April 2015, the 1st Webinar series in research ethics in the Caribbean was conducted through the combined efforts of PAHO, CARPHA, and BSEC, with topics such as “Research Ethics: Importance and History” and “What makes research with human subjects ethical” by Dr. Carla Saenz of PAHO, “What is Research?” and “Harms & Benefits in Research” being delivered by Dr. Aarons of CARPHA, “Problems in Research Design” by Prof. C. Macpherson from BSEC, and “Voluntary Informed Consent” by Dr. Grace Sirju-Charran from BSEC.

Also in 2015, in keeping with the charge of the first BSEC Executive to the incoming 2nd Executive (made in 2010) to develop a certificate course in ethics, Past BSEC Presidents Prof. Cheryl Macpherson and Dr. Derrick Aarons, along with BSEC Executives Dr. Grace Sirju-Charran and Prof. Donald Simeon were a part of the preparation team (in November 2014) who met at St. George’s University in Grenada for the launch of the Caribbean Research Ethics Education Initiative (CREEI), which occurred in May 2015. The CREEI is funded by a 5- year Fogarty Grant that supports a collaborative effort between St. George’s University in Grenada and Clarkson University in the USA to provide an online graduate certificate course in research ethics fully financed for 12 candidates from the low and middle-income Caribbean countries each year.

After the initial 6 months for the graduate certificate, candidates then go on for a further 6 months to complete a post-graduate diploma in research ethics. Two members of each cohort are then given a scholarship to complete a Masters in Bioethics at Clarkson University in the USA. The CREEI programme delivered its first cohort of graduates in May 2016, with 11 persons receiving diplomas in research ethics. Three of those graduates were given full scholarships, and a 4th received 50% discounted tuition fees into the Clarkson Master in Bioethics Programme, which students completed in 2017.

In 2018, three graduates of the CREEI post-graduate diploma in Research Ethics were likewise given scholarships to do the Masters in Bioethics at Clarkson University, and are scheduled to complete same in May 2019. However, having completed the initial 5 years of the Fogarty grant funding, the CREEI programme has taken a hiatus during 2019 while applying for renewal of grant funding for another 5 years. Initial informal

feedback at the time of updating this article is that the grant has been renewed.

Graduates of the Caribbean Research Ethics Education Initiative

Many graduates of the CREEI programme have been making significant contributions to the field of research ethics through the high quality of their improved work on research ethics committees; sharing their expertise; publications in the field; oral presentations on various aspects of research ethics; implementing the policies they developed while doing the CREEI programme; as well as the teaching by those who work in universities.

Some (e.g., Dr. Rosmond Adams and Ms. Tashoya Streete) have reported career-related accomplishments attributable to the training received in the research ethics post-graduate course, while others (e.g., Ms. Karen Wilson and Dr. Copeland Stuart) have described how they have used their training to refine the research activities in their departments, or in more effectively reviewing research proposals submitted by students, staff, and others affiliated with their universities (e.g., the UWI in Trinidad and the University of Technology in Jamaica).

One graduate (Dr. Andrea Kanneh) described how her research ethics training provided the opportunity to teach research ethics to ICT students as well as to others doing Management in Health Administration (64 students so far). Along with colleagues serving on the research ethics committee of the University of Trinidad & Tobago (UTT), she was also able to guide the review and revision of UTT’s Research Ethics Policy, which is used by all researchers at that university. Another (Dr. Allana Roach) published in the Journal of Applied and Translational Genomics (Roach, 2016) and delivered oral presentations at the International Association of Bioethics (IAB) Conference in Edinburgh (2016) and the Global Health and Bioethics International Conference at Oxford University (2017).

Another CREEI graduate, Dr. Cynthia Onyefulu, has lauded her new knowledge gained, especially in medical/health research, on ethics policies and guidelines for evaluating submitted research protocols. She facilitated the formation of a research ethics committee within her faculty at the University of Technology (UTech) in Jamaica and trained 12 post-graduate students in research ethics during 2017. She also established a unit of research ethics education within the research syllabus of her university. This graduate has also delivered seminar and conference presentations in the subject area of her CREEI training.

One of the CREEI graduates (Ms. Janice Gaspard) was a research officer tasked with managing research projects, but is now employed as a monitoring and evaluation officer with the Caribbean Public Health Agency (CARPHA); she benefitted from the CREEI programme in preparing her projects for ethics approval, and the training also gave her the “extra edge” to become a Monitoring & Evaluation Officer with CARPHA. Her CREEI training also assisted in the development of policy for a database. She was able to provide pertinent advice for the requisite data elements to be included in a repository for various countries to report on the status of confidential patient information during 2017.

Another graduate, Dr. Sherry Ephraim Le Compte, is relied upon by the Ministry of Health in St. Lucia for guidance on the research ethics processes when the Ministry is approached by local and foreign entities wishing to do research in the health sector. The CREEI training has facilitated her speaking and advising with authority from the wealth of knowledge acquired, and also in becoming a member of the executive committee for

the Caribbean Network of Research Ethics Committees (CANREC). She is now able to give support to RECs who do not have research ethicists on their committees, or who require assistance and guidance. So far, she has taught 5 research ethics committee members.

An executive member of CANREC, Dr. Sharmella Roopchand Martin, attributes her knowledge in research ethics and her confidence level to competently lead and chair the regional REC of the Caribbean Public Health Agency (CARPHA) to her work in the CREEI programme. Her CREEI training also assisted her in obtaining a research ethics internship at the National Institutes of Health (NIH) in the USA in 2016 (the first such placement for a person from the Caribbean); in her developing policy and assisting in revising the standard operating procedures for the REC at CARPHA, and in formulating guidelines for CANREC. Further, in her academic institution (the UWI in Jamaica), she was able to tutor over 60 undergraduate and 20 graduate students in research and research ethics. Dr. Roopchand Martin now heads the Academy of Sports at the Mona campus of the University of the West Indies.

Research ethics committee training

Other research ethics training opportunities have supported RECs in the region. In August 2015, the Caribbean Public Health Agency (CARPHA) hosted its 1st research ethics training workshop for a Caribbean country, with the support of PAHO. The 3-day training workshop in St. Lucia included topics such as “Achieving Informed Consent,” “Research Ethics Committees,” “Vulnerable Populations: Children & Mentally Impaired Persons,” “Clinical Trials,” and “Human Research Regulation.” A similar training workshop was conducted by CARPHA in collaboration with the Regional Bioethics Programme of UNESCO, in Antigua and Barbuda in October 2015.

Out of a concern for the absence of any regulation to protect research participants in the Caribbean, to reduce the risk of exploitation, and to prevent unapproved research from proceeding, Dr. Aarons wrote a green paper, “Regulation of Research Involving Human Participants in Caribbean Countries” for the CARICOM Ministers of Health (COHSOD) meeting at the PAHO headquarters in Washington DC, in September 2015. The policy proposal was approved unanimously by the Health Ministers for drafting into model legislation for CARICOM countries. The final draft of the regulations is currently being worked on by IMPACT Justice at the Cave Hill Law School in Barbados, for subsequent dissemination to countries across the Caribbean.

In October 2015, the 9th Annual Bioethics Forum of BSEC was held in Trinidad & Tobago, in conjunction with the Trinidad & Tobago Anaesthetists’ Association, and was hosted at the St. Augustine Campus of the UWI. Interactive workshops were conducted by BSEC members, including “Clinical Research & Research Ethics Committees,” which was conducted by a past secretary of BSEC, Dr. Sharmella Roopchand Martin.

In November 2015, the University of Trinidad & Tobago hosted a seminar on research ethics, with topics such as “How Research Ethics Affects Many Areas of Research” presented by Dr. Aarons. In December 2015, CARPHA sponsored another 3-day research ethics training workshop for the four main RECs in Jamaica. CARPHA then conducted a similar training workshop for the five main Trinidadian RECs/IRBs in January 2016.

In March 2016, CARPHA established a regional network of research ethics committees (CANREC), comprising 21 RECs from across the Caribbean region. At the launch, which was hosted in Barbados through

a 3-day workshop for the Chairs of all the RECs, a 5-member Executive was elected to steer the work of CANREC over the first 3-year period.

Also in 2016, in furthering knowledge in research and research ethics, Aarons published “Family Health, Public Health, and Vulnerability in Research: A Caribbean Perspective” in *Redbioetica/UNESCO* (Aarons, 2016). Subsequently, Aarons published “Research Ethics Committees are Crucial for Health Research” in the *Caribbean Medical Journal*, and “Research in Epidemic and Emergency Situations: A Model for Collaboration and Expediting Ethics Review in Two Caribbean Countries” in *Developing World Bioethics* (Aarons, 2017a, 2017b). In 2018, Aarons published “Addressing the challenge for expedient ethical review of research in disasters and disease outbreaks” in the *Journal Bioethics*. All these Caribbean articles in research ethics can be read online under “Publications” at the CANREC website: <http://carpha.org/What-We-Do/Research-Training-and-Policy-Development/Research-Ethics/CANREC>

Additional research ethics training

Research ethics training has been increasingly integrated into the curriculum on all University of the West Indies. The University’s early partnership with the Collaborative Institutional Training Initiative (CITI) Programme provides free-of-charge training to staff and student researchers on all campuses and is required for persons submitting research protocols at Cave Hill. Further, research ethics is taught in a number of undergraduate and post-graduate courses, particularly in the medical and social sciences.

In addition to the aforementioned post-graduate training available to persons from the low and middle-income countries of the English-speaking Caribbean that is provided by the CREEI programme, the UNESCO Bioethics Regional Programme customarily offers 2 online graduate courses in Latin America annually: “Clinical & Social Ethics” and “Research Ethics.” As of 2017, this offer has been extended to candidates from the English-speaking Caribbean. Candidates would have their full tuition expenses covered by UNESCO. However, the documents used in the courses are in Spanish, and applicants should therefore have sufficient reading knowledge of Spanish. Interested persons may contact the BSEC Secretariat at kwilliams@sgu.edu.

In November, 2016, the Caribbean Public Health Agency conducted another 3-day research ethics training seminar for RECs/IRBs, this time for the RECs of Guyana and Suriname. Topics such as ‘Standards for Ethical Review: The assessment of Risks and Benefits’, ‘RECs/IRBs – Their roles and authority’, ‘Human vulnerability and research ethics’, and ‘Overview of research and the human research protection framework – the Caribbean context’ – were all presented at the workshop.

In March 2017, the University of Trinidad & Tobago hosted another research ethics seminar, where the CARPHA Ethicist was invited to provide a presentation on CANREC. The CARPHA Ethicist was subsequently invited in July 2017 to provide 3 days of research ethics training for the newly installed Research Ethics Committee of the Tobago House of Assembly. Dr. Aarons presented on topics including ethical requirements for research; the composition roles and authority of research ethics committees; achieving informed consent; international research ethics guidelines; assessment of risks and benefits; oversight and monitoring of research; and responsibilities of sponsors and researchers.

In July 2017, chairs of RECs/IRBs contributed to model legislation governing human participant research for CARICOM at a workshop hosted in Barbados by IMPACT Justice, which is based at the Cave Hill Law School.

The resulting model legislation should be ready for circulation to all CARICOM countries some time in the future.

In October 2017, Dr. Aarons presented “Ethical Concerns for Global Cancer Research” at the 6th International African-Caribbean Cancer Consortium Conference, Miami, Florida, and in November 2017, he gave a presentation on the new developing international frontier of alternative research designs, delivering his paper “Current International Ethics Guidance on Use of Alternative Research Designs: A Caribbean Perspective” to the Global Forum for Bioethics in Research International Conference in Bangkok, Thailand.

Further, in 2018 Dr. Aarons developed his oral presentation delivered at the Cancer Consortium Conference on “Ethical Concerns for Global Cancer Research” into a manuscript that was accepted by the West Indian Medical Journal (WIMJ) for publication. He was also appointed in 2018 by the Director-General of UNESCO to serve for 4 years on the International Bioethics Committee (IBC) of UNESCO, the only advisory body within the United Nations system that debates and forms policies on the ethical issues of advances of the life sciences worldwide.

Closing comment

The spirit embodied by research ethics has come a far way in the English-speaking Caribbean over the past two decades, and a growing level of expertise in the subject area has been developed by several persons. The philosophy, teachings, and rationale for research ethics now need to be firmly inculcated in the minds of all researchers across the Caribbean, so that all research participants will be respected and their welfare be placed paramount over all considerations in the research endeavour.

Further, research ethics involving prior assessment by a recognized research ethics committee should be “codified” into regulations that govern research with human participants in every country of the Caribbean!

References

- Aarons, D.E. (1995). Research ethics. *West Indian Medical Journal*, 44(4), 115-8.
- Aarons, D.E. (2003a). Issues in bioethics: Teaching research ethics. *West Indian Medical Journal*, 52(2), 145-50.
- Aarons, D.E. (2003b). Research ethics. In D. Simeon. (Ed.), *CHRC research skills workshop manual* (pp. 103-122). Trinidad: The Caribbean Health Research Council.
- Aarons, D.E. (2012). Bioethics education in the Anglophone Caribbean. In S. Vidal (ed), *La Educación en bioética en América Latina y el Caribe: Experiencias realizadas y desafíos futuros* (pp. 141-152). UNESCO. Retrieved from: <http://www.unesco.org.uy/shs/fileadmin/shs/2012/EducacionBioeticaALC-web.pdf>
- Aarons, D.E. (2014). Ethical issues surrounding body integrity and research. *West Indian Medical Journal*, 63(5), 399-401.
- Aarons, D.E. (2015). Research: An ethical answer in addressing our people's health problems and inequities. *West Indian Medical Journal*, 64 (Suppl 2), 97-100.
- Aarons, D.E. (2016). Family health, public health, and vulnerability in research: A Caribbean perspective. *Redbioetica/UNESCO Journal*, 2(14), 12-18.
- Aarons D.E. (2017a). Research ethics committees are crucial for health research. [Editorial]. *Caribbean Medical Journal*, 78(2), 3.

Aarons D.E. (2017b). Research in epidemic and emergency situations: A model for collaboration and expediting ethics review in two Caribbean countries. *Developing World Bioethics Journal*, 00, 1-10. DOI: 10.1111/dewb.12157

Aarons D.E. (2018). Addressing the challenge for expedient ethical review of research in disasters and disease outbreaks. *Bioethics*, 00:1-4. DOI: 10.1111/bioe.12543

Campbell, M.H. (2015, March). And you think you have problems? Research ethics in small societies. *Dialogue* 158. Paper presented at the University of Miami Research Programs Dialogues in Research Ethics, Miami, Florida.

Campbell, M.H. (2014, November). Core issues in the development of an ethical code. 2nd Caribbean Regional Conference of Psychology, Paramaribo, Suriname.

Campbell, M.H. & Emmanuel, M.K. (2016, November). Research ethics in small island states: The development of ethics review in Barbados. Paper presented at 3rd Caribbean Regional Conference of Psychology, Port-Au-Prince, Haiti.

European Commission Directorate-General for Research. (2010). *European textbook on ethics in research*. Luxembourg: Publications Office of the European Union.

Macpherson, C.C. (1999). Research ethics committees: a regional approach. *Theoretical Medicine and Bioethics*, 20, 161- 179.

Macpherson, C.C. (2001a). Research ethics committees: Getting started. *West Indian Medical Journal*, 50 (3), 186-188.

Macpherson, C.C. (2001b). Research ethics in Grenada: Beyond the guidelines. *Developing World Bioethics*, 1(1), 57-68.

Macpherson, C.C & Connolly, R.L. (2002). Enough is enough: Disclosure in cross cultural research. *IRB*, 24 (3), 7-9.

Roach, A., Braithwaite, T., Carrington, C., Marcellin, E., Sharma, S., Hingorani, A., Casas, J.P., Hause, M.A., Allingham, R.R., Ramsewak, S.S., & Bourne, R. (2016). Addressing ethical challenges in the Genetics Substudy of the National Eye Survey of Trinidad and Tobago (GSNESTT). *Journal of Applied and Translational Genomics*, 9, 6-14.

Ethics and emergency management: Lessons from Hurricane Irma

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“In the core discipline of emergency management, ethics is generally an elusive topic. Little consideration is given to ethical issues, and the subject does not occupy a prominent position in planning or responding.”

Hurricane Irma was an extremely powerful and catastrophic storm: the strongest observed in the Atlantic Region since Hurricane Wilma (2005) in terms of maximum sustained winds. Irma was the first Saffir-Simpson Category 5 hurricane on record to strike the Leeward Islands of the Caribbean.

Hurricane Irma caused widespread and severe damage throughout its long lifetime, particularly in parts of the north-eastern Caribbean. The storm caused catastrophic damage to many Caribbean countries, with the death toll reaching approximately 135. The British Virgin Islands, Barbuda, Cuba, Saint Martin, Sint Maarten, and the U.S. Virgin Islands were all affected.

While national and regional efforts focused on emergency response and recovery activities to rapidly access the damage and bring aid to the affected areas, there was hardly any mention of the ethical considerations that should accompany emergency management.

In the core discipline of emergency management, ethics is generally an elusive topic. Little consideration is given to ethical issues, and the subject does not occupy a prominent position in planning or responding. However, all phases of emergency management (preparedness, response, recovery, and mitigation) bring with them certain ethical dilemmas that should not be ignored. This article seeks to examine briefly the four phases of emergency management and to explore the key ethical issues for consideration in each phase using the recent impact of Hurricane Irma on the Caribbean as an example.

The first and very important phase of emergency management is preparedness. Preparedness takes the form of plans or procedures designed to save lives and to minimize damage when an emergency occurs. The Leeward Islands had never seen a storm of such great magnitude, and so assessing their levels of preparedness for a category five hurricane presented difficulty. In preparedness phase, a key principle is that of joint responsibility of all agencies. The national emergency management organizations do not have sole responsibility. Everyone should be part of preparedness plans. This include not only government entities but also the private sector, non-governmental and faith-based organizations. Responsibility should also shift to other competent agencies. Even if organizations/groups may not be mentioned, they should step in to assist. This solidarity is very important, as entire islands are affected, and no one is immune from the impact. During Hurricane Irma, the national emergency organizations in many of the affected countries had overall coordination and took on most of the tasks. This caused them to become overwhelmed quickly and thus compromised their ability to deliver.

The response phase includes the mobilization of the necessary emergency services and first responders in the disaster area. It is in this phase that

the acuity of impact on affected individuals is most prominent. This is the phase when lives lost and damage to property is recorded. People become displaced and are forced to move into shelters. It is the most uncomfortable period. In this phase, the principle of justice is very important. Women, men and children are all displaced and deserve to be treated fairly. Assistance should be distributed in a fair and transparent manner and should be based on properly assessed needs. Urban areas should not be priority while rural areas are ignored. Areas where politicians are most vocal should not get most resources leaving others with little or no resources.

In terms of shelter, adequate provision must be put in place to protect vulnerable persons. Women, children, and the elderly should be protected and cared for. Persons with disabilities require special attention, because they may be less able compete for scarce resources, like water, medication and food. A shelter manager who understands these peculiarities is essential to ensure that the interests of these individuals are protected. Any practice with respect to the response phase should be non-discriminatory.

The recovery phase is defined as the actions taken to return the community to a state of normalcy following the disaster. Repairing, replacing, or rebuilding property and putting infrastructure in place are examples of recovery. Recovery efforts should be based on the principle of solidarity, in which there is an a whole-community approach, and communities do not depend on government alone to rebuild.

The final phase is mitigation. This is the cornerstone of emergency management—the continuing effort to lessen the impact that disasters have on people and property. Mitigation is defined as the sustained actions that reduce or eliminate long-term risk to people and property from natural hazards and their effects. Mitigation efforts should be a joint responsibility of government and the people. The focus should not be about who is running the show but about working together in harmony to be resilient.

Emergency management, therefore, has an ethical responsibility to prepare and respond to emergencies in ways that protect the poor, the disadvantaged and the vulnerable. Principles of justice and respect for persons are essential to protect everyone. in an ethical manner.

“Research Tourism” in the Caribbean

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“A nontrivial and well-studied feature of international research ethics addresses the tradition of high-income countries doing research in low income countries, where many or most subjects were themselves vulnerable by virtue of lower socio-economic status and low literacy and education levels.”

Medical tourism has been known for centuries. The Greeks and Romans, among others, developed facilities that were magnets for travelers looking for therapeutic and relaxing properties of hot springs, baths, stones and volcanic mud.

More recently, entrepreneurs in some high-income countries have targeted the affluent population of lower-income countries, promoting state-of-the-art healthcare facilities and offering treatment for life-threatening conditions such as cancer and cardiovascular disease. In the opposite direction, many Latin American and Caribbean countries market cosmetic procedures, in vitro fertilization and dental treatments that are less expensive than in the higher-income countries.

The economic benefits of this trade seem evident, and particularly relevant for small Caribbean countries. St Lucia, Barbados, Jamaica and the Cayman Islands are among the countries in which hospitals and governments identified medical tourism as a strategy for economic development. (Connell, 2013).

Indeed, a nontrivial and well-studied feature of international research ethics addresses the tradition of high-income countries doing research in low income countries, where many or most subjects were themselves vulnerable by virtue of lower socio-economic status and low literacy and education levels.

Now there is a new ingredient in the international research ethics stew: overseas studies conducted by investigators from high-income countries who recruit their compatriots to travel to participate in clinical trials. We here coin the term “research tourism” to label this.

Paradise, experiments, and ethics

In August 2016, William Halford, a researcher from Southern Illinois University School of Medicine, working for “Rational Vaccines,” a company based in the United States, conducted a vaccine trial in St. Kitts using live herpes viruses. The trial had not been reviewed by a research ethics committee or institutional review board in the United States; and St. Kitts health authorities were not informed about the clinical trial.

Three years earlier, the same investigator performed another experiment, this time in the United States. In that study, according to one of the participants, the investigator vaccinated the subjects in a hotel room. (Taylor, Kaiser Health News, 2017).

Thereafter, he submitted an enthusiastic manuscript, which included the description of a self-inoculation, to *Future Virology*, a peer-review journal. Reviewers rejected it due to lack of scientific and methodological consistency.

For the St. Kitts study, he invited subjects with a history of herpes in whom other herpes treatment had failed. Participants came from the United States and the United Kingdom. They traveled to St. Kitts convinced they would be cured. (Taylor, Daily Beast, 2017).

For some of the subjects, Halford was “someone who finally cared about an illness that is painful, debilitating and affects almost all aspects of the daily life.”

According to some of the subjects’ testimonies, Rational Vaccines covered all their travel and lodging expenses. If the subjects stayed for the whole duration of the trial, they were offered a payment of \$500. It is not surprising that the subjects/patients described the experience as like “being in paradise, combining therapy with a vacation in a beautiful spot.”

The inoculations started in April 2016, and ended in August the same year. Each participant received 3 shots over the study period.

However, any comfort fostered among individuals sharing an unexpected brotherhood while sharing the same sorrows caused by their illness and while seeking succor in paradise, gave way to disturbing sensations: After the subjects were inoculated, some reported dizziness, flu-like aches, numbness, slurred speech, dizziness, and, in one case, an outbreak of herpes.


The investigator dismissed the symptoms, suggesting they were caused by “some kind of mosquito-borne virus infection” (Caribbean Health News, 2017). The trial was carried out in a house and not in a health facility; there were no records or any kind of documentation of adverse events, or, indeed, any significant occurrence during the study.

Halford, who was suffering a nasal cancer, died in June 2017.

Politics and ideology were apparently not far from the decision to ignore the standard regulatory and ethical framework for experiments with humans. Peter Thiel, a billionaire co-founder of PayPal who invested a large sum in Rational Vaccines, said in a 2015 interview with *The Economist* that FDA regulatory burdens impede drug discovery: “You would not be able to invent the polio vaccine today,” he said (Geier, 2015).

Once the trials became public, the Government of Saint Christopher and Nevis released a statement denying any previous knowledge of the situation, affirming “no government agency approved such a venture.” A new trend?

Although medical tourism is an established trend in which individuals cross borders searching for opportunities ranging from state-of-the-art treatments,



quality of care, affordability, wellbeing, cosmetic and aesthetic procedures, research tourism might represent a new trend for researchers trying to overcome regulatory burdens. What makes the vaccine research carried out in St. Kitts particularly chilling is that subjects were individuals travelling from industrialized countries, eager to find “regulatory havens” that would provide them with therapeutic hope that was not authorized in their homelands.

In a world in which “alternative truths” are replacing facts, and where many perceive regulatory bodies as incompetent bureaucracies, the St. Kitts experience could be the tip of a new iceberg in which scientific reasoning and charlatanism are indistinguishable.

References

- Caribbean Health News. (2017, October 24). Retrieved December 6, 2017, from Caribbean Health News: <http://wp.caribbeannewsnow.com/2017/10/24/no-word-investigation-st-kitts-nevis-government-rogue-herpes-vaccine-trial/>
- Connell, J. (2013). Medical Tourism in the Caribbean Islands: A Cure for Economies in Crisis? *Islands Studies Journal*, 8(1), 115-130.
- Geier, B. (2015, February 11). (Fortune, Editor) Retrieved December 8, 2017, from Peter Thiel never met a regulation he didnt hate: <http://fortune.com/2015/02/10/peter-thiel-regulation/>
- PBS. (2017, August 28). Peter Thiel sponsors offshore testing of herpes vaccine sidestepping U.S. safety rules. Retrieved November 15, 2017, from <https://www.pbs.org/newshour/health/peter-thiel-sponsors-offshore-testing-herpes-vaccine-sidestepping-u-s-safety-rules>
- Taylor, M. (2017, November 21). Retrieved December 11, 2017, from Kaiser Health News: <https://khn.org/news/years-before-heading-offshore-herpes-researcher-experimented-on-people-in-u-s/>
- Taylor, M. (2017, August 8). Retrieved November 16, 2017, from Daily Beast: <https://www.thedailybeast.com/authorities-launch-investigation-of-une-thical-offshore-herpes-trial-backed-by-peter-thiel>

Promulgating the Health Research Policy for the Caribbean in the institutional context

By Shakel Henson, MD, MPH
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“The extent of research conduct differs among Caribbean countries, and so the governing body also varies. Nonetheless, stakeholders remain vital components of the organizational chart, and they include funders and producers of research, as well as the users of evidence collected from research studies.”

Introduction

The efforts of civil society, regional institutions, researchers, and Ministries of Health (MOHs) throughout the Caribbean have established the Health Research Policy for the Caribbean (HRPC) articulated by the Caribbean Health Research Council (CHRC). The policy aims to strengthen health research systems (HRS) in the Caribbean at both the national and regional levels; improve the conduct and execution of quality and effectively monitored research; protect research participants; promote health development with the aid of research; and make health decisions that are evidence-based (CHRC, 2009). Promulgation of this policy is strongly dependent on the MOH. However, it has also been proposed that national and regional health research agendas and communication networks, including a virtual platform and research registers, be established and subsequently implemented, with the support of all stakeholders (CHRC, 2009). Despite the goals and objectives of the aforementioned policy, culture and politics have strongly influenced its successful promulgation.

Standards/Regulations of accrediting body

The HRPC has been designed for the Caribbean, a region comprised of various small islands. Although no specific regulations or standards apply to all Caribbean countries, the CHRC has recommended that the MOH establish the necessary regulations to guide the appropriate and ethical conduct of research in each country (CHRC, 2009). This HRPC uses the previously established research policy by Trinidad and Tobago as a guide. However, even the Trinidad and Tobago policy lacks detailed regulations, but it too suggests that the responsibility of establishing guidelines for the ethical conduct of research lies with the MOH (CHRC, 2009).

Promulgation of policy

With the goal of the HRPC being to strengthen the respective HRS in each country, assistance was sought from the various MOHs plus organizations, such as the Caribbean Health Research Council (CHRC) to facilitate promulgation of the policy (CHRC, 2009). Other stakeholders, including representatives from the health, education, technology and economics sectors contributed to the implementation of this policy, which involved working collaboratively to increase awareness of the policy's objectives (CHRC, 2009). These stakeholders further promulgated the policy by engaging the national research ethics committees (RECs) in discussions about strengthening the Caribbean's HRS; promoting the ethical conduct of research; protecting human subjects in research; emphasizing the need to build capacity in research; and reiterating the

role of RECs (CHRC, 2009). The key functions of research systems are stewardship; financing; the creation and maintenance of resources; and the production and use of research. (Hyder et al., 2009). These essential elements were also adopted as the main strategies to help strengthen the various HRS throughout the Caribbean (CHRC, 2009). The author's home country, St. Vincent and the Grenadines (SVG), uses this HRPC (HRWeb, n.d.), but there are still some uncertainties regarding how well it is implemented in the country. The lack of a transparent and easily accessible reporting system by the local MOH and the limited number of research studies that are conducted in SVG make it difficult to conclude that this policy established by the CHRC is properly promulgated.

The extent of research conduct differs among Caribbean countries, and so the governing body also varies. Nonetheless, stakeholders remain vital components of the organizational chart, and they include funders and producers of research, as well as the users of evidence collected from research studies (CHRC, 2009). Effective HRS include decision makers, communities and civil society, researchers, and development agencies so that they collectively form the organizational structure of each Caribbean country's research system (CHRC, 2009). The MOH is the leader of the hierarchical organization. If the country is actively involved in research then an Essential National Health Research (ENHR) Council should be present. If, however, the country is not actively involved in research, there may not be an ENHR Council (CHRC, 2009). The Chief Medical Officer (CMO) comes next in the hierarchy, followed by an individual designated to liaise with the MOH subunits that govern research, as well as non-MOH departments that are also involved in research. Further down the hierarchy exist the RECs, researchers, decision makers, civil society and development agencies (CHRC, 2009). Despite the theoretical existence of this hierarchical structure, some Caribbean countries, like SVG, lack the financial and human resources needed to effectively promulgate the policy (CHRC, 2000). Hence, as Longest (2001) warned, with regard to the policy implementation phase, a policy that is not properly implemented will have a negative impact, thus causing it to fail. Unfortunately, in SVG the goals and objectives of the HRPC have still not yet been realized.

Role of politics in policy formulation and implementation

Policy formulation and implementation are different phases in the public policymaking process (Longest, 2002). Political circumstances fall under the agenda setting category of the policy formulation phase and thus influence this phase as well as other aspects of the policymaking process including the implementation phase (Longest, 2002). For the

HRPC, hierarchical authority is a source of power, but politics also play a vital role in the formulation and implementation of this policy. Politics have played both a constructive and destructive role in this policy and the budgeting game appears to have a strong influence (CHRC, 2009; Philpott-Jones, 2015).

The System of Authority, as described by Mintzberg (1983), describes the source of power of the HRPC. It is the local MOH for each of these Caribbean countries that represents top management and is thus responsible for ensuring that the goals are operationalized (Mintzberg, 1983; CHRC, 2009). However, the System of Politics is also influential and the game that appears to be most applicable to this HRPC is that which relates to building power bases (Mintzberg, 1983). Hence, the budgeting game seems most appropriate to describe the political situation. Although monies may be obtained through funders such as the Pan American Health Organization (PAHO), there is nonetheless relatively little research conducted in some countries (Mintzberg, 1983; CHRC, 2009). A number of funder-specific factors can effect funding. For example, a rheumatic fever study (with which the author was involved) in SVG received US \$75,000 from PAHO and other organizations. The PAHO representative was supportive of the project and mentioned that, if monies were not used up for that year, SVG would receive the same amount of funds the following year. This sentiment was also expressed by the German embassy and an American organization supporting the project.

Monitoring and updating policy

To facilitate effective monitoring of the HRPC, performance standards, which were regionally agreed upon, were developed to determine if the policies' goals and objectives are being met (CHRC, 2009). Hence, these standards serve as guidelines and checklists for countries to verify what elements of the policy are achieved; what further actions are needed; as well as the extent to which the previously implemented parameters are effective (CHRC, 2009). CHRC proposed that the HRPC would benefit from the establishment of an Essential Regional Health Research (ERHR) strategy, as this approach would help to identify any further health research needs; recognize areas for capacity building; and identify the research areas that will be of most benefit to Caribbean countries (CHRC, 2009). A multi-country HRS assessment was conducted to help with the development of the HRPC, focusing on governance and capacity for the different HRSs, as well as the use, demand, and access to health research results (CHRC, 2009).

Consequences of non-compliance

There are no laws governing this policy and, although regulations are drafted by the MOH for each Caribbean country, the consequences for non-compliance are not specifically articulated. Nonetheless, given the fact that a national research policy does not exist for every English-speaking Caribbean country, failure to comply with this HRPC would mean that countries would be less likely achieve the goals of a strengthened health research system; protected research participants; and the ability to make health decisions that are evidence-based.

Conclusion

The HRPC has commendable goals and objectives, including strengthening HRSs in Caribbean countries and using research to make more effective and evidence-based healthcare decisions. However, there have been challenges in the promulgation of this policy due to poor communication. Hence, improved communication is essential for dissemination of information, especially through the media. Additionally, limited finances for research; lack of a research culture; insufficient

capacity to effectively execute research; poor health research efforts; and lack of designated research units within the MOHs make it very difficult to promulgate the policy; achieve its goals and objectives; strengthen HRS in the Caribbean; and effectively manage health-related issues using evidence from research.

The HRPC may be plausible and precise, but existing limitations have affected the success of the Policy in all of the English-speaking Caribbean countries. Acknowledging the existence of these limitations and recognizing the influence of culture and politics are vital, because knowledge of these factors can help to improve the content and implementation of the HRPC for benefit of the Caribbean people.

References

- CHRC - Caribbean Health Research Council (2009). Health Research Policy for the Caribbean. Retrieved from <https://www.healthresearchweb.org/files/CaribbeanHealthResearchPolicy1.pdf>
- HRWeb – Health Research Web (n.d.) St. Vincent and the Grenadines. Retrieved from <https://healthresearchweb.org/en/st.+vincent+and+the+grenadines/policies>
- Hyder, A.A., Dawson, L., Bachani, A.M., & Lavery, J.V. (2009). Moving from research ethics review to research ethics systems in low-income and middle-income countries. *Lancet*, 373, 862-865.
- Longest, B.B. (2002). A Model of the Public Policymaking Process in the United States. *Health Policymaking in the United States*, Chicago, Health Administration Press, 115. Retrieved from <http://online.uniongraduatecollege.edu/mod/page/view.php?id=65672>
- Longest, B.B. (2001). Influencing Public Policy Environments. *Back to Basics: Foundations of Healthcare Management*, Chicago, Health Administration Press, 211-238. Retrieved from <http://online.uniongraduatecollege.edu/mod/page/view.php?id=65672>
- Mintzberg, H. (1983). *The System of Politics in Power in and Around Organizations*. Englewood Cliffs, NJ, Prentice Hall, pp. 171-217. Retrieved from <http://online.uniongraduatecollege.edu/mod/page/view.php?id=65672>
- Philpott-Jones, S. (2015.) Audio-Enabled Lecture: Power and Politics in the Professional Organization. Retrieved from <http://online.uniongraduatecollege.edu/mod/page/view.php?id=65672>

Observations from The Caribbean Public Health Agency's Research Ethics Committee

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Research ethics is in its infancy in the Caribbean region, and this is clearly reflected in the issues encountered in protocols reviewed by the CARPHA REC over the past 4 years. A brief review of commonly observed areas of deficit follows:

Informed consent

Some researchers appeared to view informed consent as simply the signing of a form rather than a process. Protocols often lacked information regarding who would obtain consent; the relationship of the person obtaining consent to the participants; and when and under what circumstances consent would be obtained. In many proposals, once the form was signed, there was no provision for reaffirming of consent during the research process. Some proposals called for treating physicians to consent their patients for research or for persons in senior position to consent subordinates. These trends signalled lack of understanding of issues like coercion, therapeutic misconception, and conflict of interest in research.

Justice and fair selection of participants

Protocols frequently lacked justification for the sample, and sample size calculations were either not presented or not properly done. Researchers listed inclusion and exclusion criteria with no justification provided, and some described sampling methodology without reference to representation by race, gender, and other relevant sociodemographic characteristics. Some researchers did not attempt to show that the persons recruited were, in fact, representative of populations who would benefit from the research. In several cases, researchers proposed to select convenience samples to meet an academic requirement in a timely manner.

Risk benefit analysis

Very few protocols presented a proper risk benefit analysis, and, in many cases, researchers provided very general information related to possible benefit to the wider society as opposed to weighing the risk and benefit to the individual participant. Protocols often overlooked or underestimated the potential for psychological harm.

Data analysis

In many protocols, researchers simply listed a range of tests but did not link measures to the objectives. Ethical review requires an assessment of soundness in scientific approach, which depends on adequate research design and analytic strategies.

Conclusion

Research ethics committees can contribute to research ethics education by using their reviews as teaching moments. Though these efforts may be more time consuming, providing a brief explanation of why issues raised present ethical concerns and directing researchers to relevant

international guidelines facilitates understanding and practice of ethical research. Researchers should also be invited to contact the committee if they desire further clarification of points, and, in some cases, committees may need to take the initiative to meet with researchers to discuss ethical concerns. These efforts should facilitate more timely resubmission of revised protocols and should reduce the number of resubmissions required prior to obtaining approval. More importantly, research ethics education promotes improvement in the quality of both submitted protocols and real-world research practice.

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INSTRUCTION TO AUTHORS

We invite submissions to future issues of the CANREC Bulletin, published online twice yearly by the Caribbean Public Health Agency.

The Caribbean Network of Research Ethics Committees (CANREC) is a network established by the Caribbean Public Health Agency (CARPHA) with the cooperation of Research Ethics Committees (RECs/IRBs) across the CARPHA member states. CANREC promotes a sustainable infrastructure, intraregional cooperation, harmonized review processes, information sharing, and capacity development for research ethics in the Caribbean. For more information, visit <http://carpha.org/What-We-Do/Research-Training-and-Policy-Development/Research-Ethics/CANREC>.

The CANREC Bulletin solicits contributions on research and research ethics, as well as news and updates from member states and organizations working in the region. We invite short reviews of books that would interest our readers. Please email the editor in advance with suggestions for reviews.

We encourage a broad range of submissions from an equally broad range of contributors. Submissions from academics, researchers, ethicists, policy makers, and others are welcome. We will consider contributions from authors at all levels, from students to senior colleagues.

Articles should be about 1500 words in length; please limit news and update items to 500 words. Book reviews should be 500-700 words. All citations and references should follow APA format. Please prepare manuscripts in Microsoft Word and direct submissions via email to: canrecbulletin@carpha.org.

CONFERENCES

Regional

64th Annual CAPRHA Research Conference, 20-22 June 2019, Trinidad & Tobago: <http://conference.carpha.org/>

International

Ethics and Humanitarian Research: Generating Evidence Ethically, 25-26 March, 2019, Columbus, OH USA: <http://www.preaportal.org/conference/>

2019 PRIM&R Institutional Animal Care and Use Committee (IACUC) Conference, 2-3 April 2019, Bellevue, WA USA: <https://www.primr.org/iacuc19/>

6th World Conference on Research Integrity, 2-5 June 2019, Hong Kong: <http://wcri2019.org/index>

7th International Conference on Ethics Education, 22-24 July 2019, Porto, Portugal: <https://www.ethicsassociation.org/>

2019 PRIM&R Advancing Ethical Research (AER) Conference, 18-20 November 2019, Boston, MA USA : <https://www.primr.org/aer19/>