A REGULATORY FRAMEWORK FOR A-I HEALTH RESEARCH IN THE CARIBBEAN

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PROPOSAL TO REGULATE HUMAN SUBJECTS RESEARCH IN THE CARIBBEAN

- The Caribbean Public Health Agency (CARPHA) proposed model legislation for research with human participants in all Caribbean countries in 2015
- The Ministers of Health for the various countries unanimously approved the 'green paper' proposal
- To date, some 7 years later, nothing further has been heard

UPDATE TRAINING FOR REC/IRB MEMBERS:

- A-I currently being used in processing health data for research
- A number of ethical issues arise
- Members of Research Ethics Committees/IRBs will need update training

UPDATE TRAINING FOR REC/IRB MEMBERS:

- 23 RECS/IRBS currently exist across the Caribbean
- Most do not have A-I expertise or experience to assess A-I related research
- Ethical assessment of risk/benefit ratio, and the model of consent proposed by A-I researchers
- Assess any complex algorithms to be used in the research

MANDATORY UPDATE TRAINING:

- REC/IRB members should be mandated to undergo update training in A-I use in research
- Update the draft research legislation and regulations approved in 2015 for implementation

INCLUDE IN THE UPDATE TRAINING SESSIONS:

- REC/IRB Members to discuss possible challenges to local implementation of A-I in research
- Inadequate access to internet service
- Unreliable electricity power supply in some communities

INCLUDE IN THE UPDATE TRAINING SESSIONS:

- Discuss the inadequate human resources
- Insufficient skills among the local population
- Inadequate local investments
- Risk of job losses due to A-I automation

UPDATE THE PROPOSED LEGISLATION:

- To address specific challenges for consent in Caribbean A-I health research
- Issues of privacy and security in A-I health research within the Caribbean
- Address the power imbalances between A-I research data collectors and research participants

UPDATE THE PROPOSED LEGISLATION:

- Stipulate the need for public engagement in A-I health research
- Include community representatives from the conceptual stages

THE AID OF COMMUNITY REPRESENTATIVES:

- Participate in discussions about the design of A-I health research
- Assist in identifying possible local risks
- Assist in identifying possible benefits

ROBUST RESEARCH REGULATORY FRAMEWORK:

- Achieved through the expansion of the scope of the draft Legislation & Regulations

- Include risks of A-I health research as well as potential benefits

RECOMMENDATIONS FOR CARIBBEAN COUNTRIES:

- A comprehensive research regulatory framework entrenched in legislation
- Address the new realities and challenges of A-I health research

UPDATE THE DRAFT LEGISLATION:

- Update the draft legislation to address all the ethical issues raised by A-I health research
- All Caribbean countries to enact the approved model legislation for research with human participants after its updating

CARPHA'S SUBMISSION IN 2015:

- CARPHA's Research Ethics Secretariat hereby recommends the following to CARICOM Ministers of Health:
- 1. The establishment of a Regulatory Framework for the conduct of research with human participants based on the principles and standards outlined above and including the following requirements:-
  - i) All researchers must apply for approval from an appropriately designated national or regional research ethics committee before embarking on research
  - ii) An appropriately constituted research ethics committee with the required legal authority shall review all research proposals that involve human participants
  - iii) All approved research should be monitored for the well-being of research participants by the research ethics committee
- 2. **The preparation of a model legislation for CARICOM countries to regulate research with human participants.** The legislation should contain the provision of appropriate sanctions for non-compliance.
- 3. That CARICOM Ministers of Health approve the Proposals for implementation of a regulatory framework in principle, and agree to their adoption as Policy.
- 4.This Policy will have immediate effect, pending the implementation of the process for enactment of legislation.
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REFERENCES:

- International Bioethics Committee (IBC). Report of the International Bioethics Committee of UNESCO (IBC) on the Ethical Issues of Neurotechnology. Paris; December 2021: SHS/BIO/IBC-28/2021/3 Rev.

- Social and Human Sciences Commission (SHS) of UNESCO. Recommendation on the Ethics of Artificial Intelligence. Report of the SHS, 41st UNESCO General Conference, 2021: pp. 14-39.

- Aarons D. The historical development of research ethics in the English-speaking Caribbean. CANREC Bull.2019; 1(1): 3-7.

- Aarons D.E. Research in epidemic and emergency situations: A model for collaboration and expediting ethics review in two Caribbean countries. Developing World Bioethics Journal Jul.2017; 00:1-10. https://doi.org/10.1111/dewb.12157.