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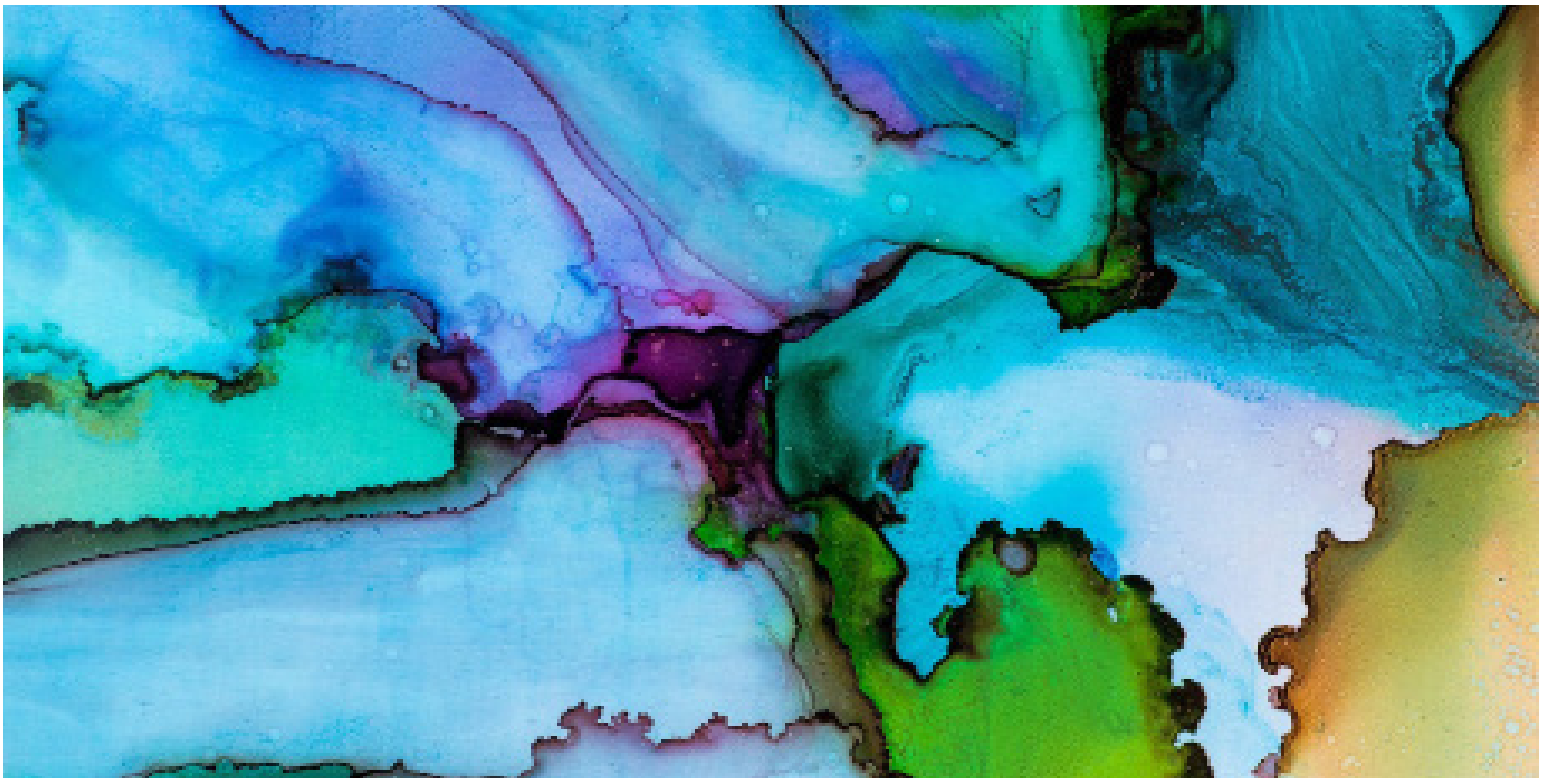

In this issue:

Letter from the Editor

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

CARPHA Awardees who were honored at the 64th Annual Health Research Confernce for their influential and exemplary contributions in improving the health of the Caribbean people and their communities.
Left to right: Professor T. Alafia Samuels, Professor Upton Allen and Dr Allison Kuipers accepting the award on behalf of Professor Clareann H. Bunker

"This issue, in particular, has articles the authors hope will be helpful tools for teaching."

Dear Friends of CANREC

We received quite a bit of positive feedback on our first issue, and I hope that our second is even more engaging. This issue, in particular, has articles the authors hope will be helpful tools for teaching. Prof. Ian Hambleton and colleagues have put together a readable, broadly accessible, guide to data security that provides links to a number of useful resources. Dr. Thea Scantlebury-Manning provides an introduction to guidelines for ethical care and use of animals in research, an emerging (or emerged) need for Caribbean researchers in the biological, medical, and behavioural sciences. Dr. Hetta Gouse and her collaborators offer a thoughtful analysis of the ethics of research with neurologically impaired persons whose occupational activities may present a threat to public safety based on work with drivers in South Africa.

See also important news from Dr. Shakel Henson, who reports on the most recent cohort of graduates from the Caribbean Research Ethics Education Initiative (CREEi). Congratulations to the five Caribbean graduates who earned their MS in Bioethics from Clarkson University in 2019!

The content of the Bulletin evidences the continuing development of research ethics capacity and expertise in the Caribbean, and the publication itself aspires to not only reflect but to actively build regional development in research ethics. In that light, please remember that the Bulletin is an open-access publication, and the contributors and I hope that you will share this issue widely. Feel free to reproduce content for teaching. We would appreciate the appropriate citation, and please provide a link to our website for access to future issues.

Enjoy reading, and please consider contributing to the Bulletin. Instruction to authors is included on page 17. Know that your work will benefit from increased visibility now that we have acquired both ISSN and doi designations. Please contact me directly if you would like to discuss a potential contribution.

A Case Study of the Ethics of HIV-Related Neurocognitive Impairment Research in Employed Populations

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"As the remarkable effectiveness of modern medicine allows increasing numbers of people living with HIV (PLWH) to return to or remain in the workplace, it is becoming paramount to effectively manage HIV-associated neurocognitive disorders (HAND) in high risk workplace settings, such as driving."

Certain chronic conditions like HIV, diabetes and hypertension may lead to neurocognitive impairment (NCI) (Heaton et al., 2010; Iadecola et al., 2016; Zilliox, Chadrasekaran, Kwan, & Russell, 2016). These frequently co-occurring conditions can, by implication, affect vocational functioning. There is a need to understand how such impairment may affect society vis-à-vis the work place, particularly as the relationship between neurocognitive performance and real-world vocational functioning is a determinant of employability and job placement, and it affects safety and medical treatment options. As the remarkable effectiveness of modern medicine allows increasing numbers of people living with HIV (PLWH) to return to or remain in the workplace, it is becoming paramount to effectively manage HIV-associated neurocognitive disorders (HAND) in high risk workplace settings, such as driving. Studies are needed to develop ways to identify impaired drivers while at the same time protecting the public and the individual. Working within existing research ethics frameworks (Belmont Report (Office for Human Research Protections, 2016) and Declaration of Helsinki (World Health Organization, 2001) we use our project as a case study to discuss ethical challenges associated with conducting research in professional drivers living with HIV in South Africa.

BACKGROUND

HAND can cause mild to severe NCI (Antinori et al., 2007). HAND is highly prevalent, with approximately 50% of PLWH presenting with it (Sacktor et al., 2016). It can significantly impact many aspects of everyday functioning, including work performance (Gorman, Foley, Ettenhofer, Hinkin, & van Gorp, 2009) (Heaton et al., 1996) and health outcomes. Driving constitutes a complex task that requires intact cognition and is thus a fitting entry point for assessing the effects of HAND on vocational functioning. Moreover, driving is an area where reduced cognitive functioning can have significant public health implications. The dearth of research on the effects of HAND on vocational functioning has left occupational health professionals with the challenge of providing services to PLWH without research informed treatment models that include HAND; resulting in a lack of screening for and treatment of HAND. Our study focusing on the impact of HAND on driving ability will inform occupational health screening and treatment models of people with chronic conditions (HIV, diabetes and hypertension), which will in turn support improved public health and road safety.

ETHICAL CONSIDERATIONS

We have identified several ethically relevant factors that must be considered before embarking upon research into the effects of NCI on vocational functioning, specifically driving: 1) Justification of research; 2) Minimizing risk within the study; 3) Benefits for participants; 4) Confidentiality; 5) Public road safety concerns; and 6) Policy formation.

1. JUSTIFICATION OF RESEARCH

A thorough risk/benefit analysis is needed to ensure that the research is justified. The potential short- and long-term risks of the project should be balanced against anticipated real-world societal benefits, as well as the possible risks of not performing the research. The research question must be informed by gaps in existing knowledge, practice and theory, and must have real world applicability. For example, there is growing consensus in the literature that routine screening for neurocognitive impairment among PLWH constitutes good clinical practice (Saylor et al., 2016; The Mind Exchange Working Group et al., 2013). There is, however, little understanding of the implications of screening for HAND in vocational settings; and, in the case of professional drivers, no guidance to determine at what point an individual should be considered a safety risk on the road. In addition, if HAND increases on-road risk behaviour, we need to understand the nature of the risk in order to address it without stigmatising HIV-positive drivers, as HIV itself is not a risk factor for driving (Marcotte et al., 1999).

2. MINIMIZING RISK WITHIN THE STUDY

The major ethical dilemma posed by this research lies in navigating the implications of the immediate assessment outcome of participants. The question is: Should a research participant's driver's license be revoked if their performance on research measures (neuropsychological testing and/or driving simulator performance) falls below expected standards? This

may be a moot point, however, as drivers would not agree to participate in this research if they are at risk of losing their driver's licenses, and by association their livelihoods. At the same time, if a driver presents with NCI on testing, this places researchers in the uncomfortable situation of knowing that a driver who may pose a risk to himself and other road users is continuing to drive. The above concerns may be mitigated to a certain extent by addressing the following important questions:

2.1. Is the research introducing risk? In our study's context participants must meet the legal requirements for professional drivers as stipulated by the South African National Road Traffic Act (NRTA) (South African Government, 1996). This act compels drivers to hold a professional driver's license permit (PrDP). PrDP licences are renewed by the Department of Transport every two years (more frequently if deemed necessary) and it requires the driver to pass a medical examination. By requiring participants to have a PrDP licence the participants are legally certified to be on the road. It is reasonable to assume that we are not introducing risk by simply assessing neurocognitive and driving simulator performance in this population. Having said this, ethical concerns will arise if attempts are not made to create awareness of the implications of potential impairment in participants who perform poorly on simulator driver testing and/or neuropsychological testing. In light of this, counselling interventions must form part of the research protocol for drivers whose performance on research measures are suggestive of increased driving risk.

2.2. Can a determination of driving ability be made? First, because of the lack of literature on HAND and its relation to professional driving, we do not currently have the knowledge base to make a definitive recommendation on a driver's ability with regard to remaining on the road. Second, current research tools (driving simulator and scenarios) are experimental (Aksan et al., 2016) and have not been validated on-road or in this South African population. Third, we do not yet have neuropsychological normative data for this population (Ferrett et al., 2014). By implication we cannot report on real world driving performance as related to simulator performance and cognitive status. It would be ethically dubious, therefore, to suggest revoking study participants' drivers' licenses on the basis of this information.

2.3. Can risk be mitigated? While we are currently only able to determine tentative relationships (correlation not causation) between HAND and risks associated with driving ability, we can mitigate perceived potential risk in drivers who perform poorly on simulator testing and/or neuropsychological testing. Here, there is an obligation to report back to participants on their driving style and neuropsychological assessment. The precedent for this has been set by HIV driving studies from the United States (Marcotte et al., 2006). In these studies, after consultation with institutional review boards and State driving entities, the decision was made to not report to authorities. Rather, drivers, and with their consent health care providers, are given feedback on test results. Reporting back to participants includes providing information that will support safer driving practices; informing them about any potential cognitive symptoms; advising them to seek treatment; giving referrals; and providing relevant medical information and counselling related to their condition.

3. BENEFITS FOR PARTICIPANTS

There is an ethical obligation that research should aim to benefit participants where possible (National Institutes of Health, 2016). In the context of our study, core benefits for participants are receiving feedback on the research medical, neuropsychological testing and driving performance, and having the option to have feedback provided to their own healthcare provider. Early diagnosis of cognitive symptoms results in recommendation for early treatment that may arrest or reverse cognitive symptoms, and result in better health outcomes and longer employability. Moreover, feedback on risky driving behaviour may result in participants taking cognisance of their driving style and adjusting their driving behaviour. Participants also benefit from receiving education on their current conditions that they may not previously have been aware of, for example, HIV-positive participants are educated on HAND. This increases their awareness of symptoms which may result in them seeking treatment early. In terms of wider societal benefits, this research allows us to start developing a treatment model and culturally appropriate rehabilitation programme for professional drivers who present with NCI.

4. CONFIDENTIALITY

Over and above protecting the confidentiality of study findings, participants' HIV status must be protected. Employees are generally not legally required to divulge their HIV status to employers. Moreover, due to high-levels of stigma associated with HIV many employees choose not to declare their HIV status to employers. This poses challenges for recruitment and research practice. For example, employers must be locked out of the research project to ensure confidentiality. Recruiting through occupational health clinics is not viable because drivers are reluctant to divulge their HIV status in that setting. In order to maintain confidentiality, prospective participants should be given the option to be the only participant on any given day.

5. PUBLIC ROAD SAFETY CONCERNS

The global rates of road traffic deaths range from 9.3 to 26.6 per 100 000 (Global status report on road safety 2018: summary, 2018). Most countries, including South Africa, hold the Department of Transport responsible for traffic injuries rather than the Department of Health, with the result that health care professionals are responsible for the consequences of traffic injuries, but not for ensuring their prevention. Given that, worldwide, health care professionals have had success in mitigating social health issues such as smoking and obesity, they could also play an important role in road safety by providing adequate guidelines for medical assessments and education regarding cognition and driving ability, especially considering that the advice of a medical specialist carries significant weight for most people (Oberg & Frank, 2009). In this regard, researchers arguably have a responsibility to provide health carers with adequate information and tools to be able to perform their duties to the best of their ability.

6. POLICY

Most countries have an act that provides the legal framework within

which professional drivers operate. The South African NRTA highlights certain medical issues (epilepsy) to be excluded in the course of the certification assessment but does not prescribe any minimum medical standards other than for visual acuity and visual fields. The most widely accepted minimum standards of fitness for drivers are guidelines published by the South African Society for Occupational Medicine (SASOM) (SASOM, 2017). While the standards acknowledge that HIV and other chronic conditions may cause NCI, no guidance regarding acceptable tests or thresholds for safe driving is provided due to absence of adequate information. Current practice is to conduct driver fitness medicals focussing on traditional biomedical problems that may lead to driver impairment. Any neuropsychological problems would have to progress to clinical disease before identification, even though it is widely recognised that a proportion of drivers may have subclinical but relevant NCI. The problem here is that there are no existing standards by which this standard of care may be improved.

CONCLUDING REMARKS

Research that can assist in more effectively managing the impact of HAND in high risk workplace settings is urgently required. While this research is justified on the grounds of beneficence, it elicits ethical challenges. We have used our project as a case study to indicate the main ethical considerations. While this research does not create further risk, the dilemma lies in the possibility that it potentially exposes existing risk. Insofar as research exposes potential risk, and no effective attempt is made to mitigate this, such research would be ethically problematic. We have discussed various ways in which we have responded to this dilemma in the context of our study. Our discussion aims to build an ethical foundation for further research.

REFERENCES

Aksan, N., Hacker, S. D., Sager, L., Dawson, J., Anderson, S., & Rizzo, M. (2016). Correspondence between Simulator and On-Road Drive Performance: Implications for Assessment of Driving Safety. Geriatrics (Basel, Switzerland), 1(1), 8. doi:10.3390/geriatrics1010008

Antinori, A., Arendt, G., Becker, J. T., Brew, B. J., Byrd, D. A., Cherner, M., . . . Wojna, V. E. (2007). Updated research nosology for HIV-associated neurocognitive disorders. Neurology, 69(18), 1789-1799. doi:10.1212/01.WNL.0000287431.88658.8b

Ferrett, H. L., Thomas, K. G., Tapert, S. F., Carey, P. D., Conradie, S., Cuzen, N. L., . . . Fein, G. (2014). The cross-cultural utility of foreign- and locally-derived normative data for three WHO-endorsed neuropsychological tests for South African adolescents. Metabolic Brain Disease, 29(2), 395-408. doi:10.1007/s11011-014-9495-6

Global status report on road safety 2018: summary. (2018). Retrieved from Geneva: World Health Organization:

Gorman, A. A., Foley, J. M., Ettenhofer, M. L., Hinkin, C. H., & van Gorp, W. G. (2009). Functional consequences of HIV-associated neuropsychological impairment. Neuropsychology Review, 19(2), 186-203. doi:10.1007/s11065-009-9095-0

Heaton, R. K., Clifford, D. B., Franklin, D. R., Jr., Woods, S. P., Ake, C., Vaida, F., . . . Group, C. (2010). HIV-associated neurocognitive disorders persist in the era of potent antiretroviral therapy: CHARTER Study. Neurology, 75(23), 2087-2096. doi:10.1212/WNL.0b013e318200d727

Heaton, R. K., Marcotte, T. D., White, D. A., Ross, D., Meredith, K., Taylot, M. J., . . . Grant, I. (1996). Nature and vocational significance of neuropsychological impairment associated with HIV infection. The Clinical Neuropsychologist, 10(1), 1-14.

Iadecola, C., Yaffe, K., Biller, J., Bratzke, L. C., Faraci, F. M., Gorelick, P. B., . . . Stroke, C. (2016). Impact of Hypertension on Cognitive Function: A Scientific Statement From the American Heart Association. Hypertension (Dallas, Tex. : 1979), 68(6), e67-e94. doi:10.1161/HYP.0000000000000053

Marcotte, T. D., Heaton, R. K., Wolfson, T., Taylor, M. J., Alhassoon, O., Arfaa, K., . . . Grant, I. (1999). The impact of HIV-related neuropsychological dysfunction on driving behavior. The HNRC Group. Journal of the International Neuropsychological Society, 5(7), 579-592.

Marcotte, T. D., Lazzaretto, D., Scott, J. C., Roberts, E., Woods, S. P., Letendre, S., & Group, H. (2006). Visual attention deficits are associated with driving accidents in cognitively-impaired HIV-infected individuals. Journal of Clinical and Experimental Neuropsychology, 28(1), 13-28. doi:10.1080/13803390490918048

National Institutes of Health. (2016). Guiding principles for ethical research. NIH clinical research trials and you. Retrieved from https://www.nih.gov/health-information/nih-clinical-research-trials-you/guiding-principles-ethical-research

Oberg, E. B., & Frank, E. (2009). Physicians' health practices strongly influence patient health practices. The journal of the Royal College of Physicians of Edinburgh, 39(4), 290-291. doi:10.4997/JRCPE.2009.422

Office for Human Research Protections. (2016, 15 March 2016). The Belmont Report. Ethical principles and guidelines for the protection of human subjects of research. Retrieved from https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

Sacktor, N., Skolasky, R. L., Seaberg, E., Munro, C., Becker, J. T., Martin, E., . . . Miller, E. (2016). Prevalence of HIV-associated neurocognitive disorders in the Multicenter AIDS Cohort Study. Neurology, 86(4), 334-340. doi:10.1212/WNL.0000000000002277

SASOM. (2017). Medical requirements for fitness to drive. (SASOM Guideline NO 6). Retrieved from

Saylor, D., Dickens, A. M., Sacktor, N., Haughey, N., Slusher, B., Pletnikov, M., . . . McArthur, J. C. (2016). HIV-associated neurocognitive disorder--pathogenesis and prospects for treatment. Nature Reviews: Neurology, 12(4), 234-248. doi:10.1038/nrneurol.2016.27

National Road Traffic Act, 1996, Republic of South Africa Government Gazette, 17603 Stat. (1996).

The Mind Exchange Working Group, Antinori, A., Arendt, G., Grant, I., Letendre, S., & Munoz-Moreno, J. A. (2013). Assessment, Diagnosis, and Treatment of HIV-Associated Neurocognitive Disorder: A Consensus Report of the Mind Exchange Program. Clinical Infectious Diseases, 56(7), 1004-1017. doi:10.1093/cid/cis975

World Health Organization. (2001). Declaration of Helsinki. Ethical Principles for medical research involving human subjects. Bulletin of the World Health Organization, 79(4), 373-374.

Zilliox, L. A., Chadrasekaran, K., Kwan, J. Y., & Russell, J. W. (2016). Diabetes and Cognitive Impairment. Current Diabetes Reports, 16(9), 87-87. doi:10.1007/s11892-016-0775-x

A Practical Guide to Protecting your Research Data (with Limited Resources)

By Ian Hambleton, PhD, Selvi Jeyaseelan, PhD [1], Brigitte Collins , MSc [2], Patrick Anglin, MBA, DBA [2], Kai-Saran Davis, LLB, LLM [3], Sasekea Harris , MLIS, MSc, EdD [4] and Curtis Gittens, PhD[5]

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"Do these six things well to secure your research data: use strong passwords, encrypt sensitive data, limit access to your computer, back-up data, send data securely, and dispose of data securely. Simple techniques and free software are available to enable each of these data protection considerations."

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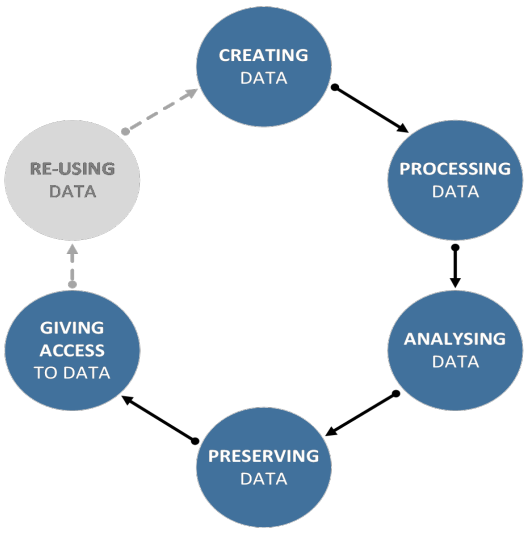
KEY POINTS

•When our research involves human participants, it is our ethical obligation to protect them from any harm that might result from unintended disclosure or inappropriate use of their personal data.
•Personal data are any information that can identify a living person.
•Some of the personal data you process are more sensitive in nature and therefore requires a higher level of protection.
•The country in which you operate may have data protection legislation that governs the protection of research data and could have accompanying penalties .for data breaches.
•Your organization may identify additional sensitive data items that should not be revealed, and this raises the important question of data ownership, especially for multi-institution data collection efforts.
•Practically, we can classify research data into 1 of 3 categories based on the perceived impact of a data security breach: low impact (protection level 1), moderate or high impact (protection level 2), and extremely high impact (protection level 3). This categorization can guide our approach to data security.
•Advice is offered in 6 areas of data security: password good practice for data files, encryption for data files, securing your physical space and computer, secure data backups, secure data transmission, secure data disposal.

RESEARCH DATA AND THE DATA LIFE CYCLE

Best practice research data handling is becoming more important for research success. The preparation of a Data Management Plan - a description of how you will manage your research data – is now a pre-requisite for an increasing number of funding agencies (Digital Curation Center, 2019; Univeristy of California, 2019). A useful concept that helps us think about the stages of data handling is the data life cycle (DLC) (Figure 1) (National Network of Libraries of Medicine, 2019). The DLC takes us through the stages of our research project, from data collection, processing, and analysis, to data preservation, sharing and reuse. Throughout this life cycle, a critical aspect is how to securely store the data, and if our research involves humans, how to protect the personal data we have collected from these individuals. It is our ethical obligation to protect these participants from any harm that might result from unintended disclosure or inappropriate use of their data.

Figure 1. The Research Data Life Cycle (National Network of Libraries of Medicine, 2019)



This article presents some simple advice on protecting the personal research data we have collected. Before we think about these data protection techniques, we should determine whether we are collecting personal research data, and, if so, also decide how sensitive the data are that we are collecting.

WHAT ARE PERSONAL DATA?

Using recent European data protection rules (known as the EU General Data Protection Regulation or GDPR), personal data are any information that can identify, or is capable of identifying a living person (known as a 'data subject') (Donnelly & McDonagh, 2019; European Commission, 2019).

WHAT DOES IDENTIFIABLE MEAN?

The word identifiable is used in relation to information that may be capable of identifying a living person.[1] In the US, the Health Insurance Portability and Accountability Act (HIPAA) lists 18 data items[2] (known as Personal Health Information or PHI), and these items are a useful summary of the more obvious personal identifiers (U.S. Department of Health and Human Services, 2019). The GDPR definition of "identifiable" is broader than the US HIPAA rules. It covers the same direct identifiers such as name and address and also includes indirect identifiers like online tracking data, as well as health and healthcare usage data. It includes the idea that many data items in isolation may not lead to identification, but can identify an individual when combined with other information. Therefore, a data item that potentially identifies an individual is personal data. Deciding on "potential identifiability" can be difficult, and there will be times when it remains uncertain whether a particular data item is personal data. If this is the case, as a matter of good practice, you should treat the information collected as though it is personal data.

WHAT IS SENSITIVE PERSONAL DATA?

Some of the personal data you process can be more sensitive in nature and therefore requires a higher level of protection. The GDPR calls this "special category" personal data, which more usefully might be termed "sensitive" personal data. Sensitive data include things like: racial or ethnic origin, political opinions, religious beliefs, genetic and biometric data, and health data (European Commission, 2019). In addition to international regulations, your particular setting may have additional data sensitivity considerations raised by your legal and/or organizational contexts.

Legal Context. Many countries have a legal definition for personal data and sensitive personal data. In the Caribbean, not all countries have data-related legislation, although the regional adoption of legal data standards is gathering pace.[3] These regulations set in law that data collected for research purposes must not identify data subjects, and may have accompanying penalties.

Organizational Context. As well as legal regulation, your organization may identify additional sensitive data items, such as, in the case of educational institutions, student information or university financial information. This raises the important question of data ownership, especially for multi-institution data collection efforts, with your data protection processes needing to follow the regulations of one or more institutions. Therefore, it is imperative that you clearly understand who owns the data you collect as part of your work.

HOW TO DETERMINE THE SENSITIVITY OF YOUR RESEARCH DATA

Whatever your context, you should consider data as "sensitive" wherever its loss could cause damage or distress to people. To guide your approach to data security, it is worth classifying your research data into 1 of 3 categories. Table 1 presents these categories based on the perceived impact of a data security breach: low impact (protection level 1), moderate or high impact (protection level 2), and extremely high impact (protection level 3). You can use the examples in Table 1 and in Box 1 to help you think about the protection level you should apply to your research data. Many individual universities, for example, use this type of classification to advise researchers on the data security level they should consider adopting (Carnegie Mellon University, 2019; Princeton University, 2019; The University of Manchester, 2019). Although your local ethics committee will make a formal determination on the sensitivity of your proposed research data, researchers should initially use their own judgement to determine their data sensitivity level, erring on the side of caution if uncertainty remains.

[1] In the Australian Privacy Amendment (Enhancing Privacy Protection Act) for example an "identifier of an individual" means "a number, letter or symbol, or a combination of any or all of those things, that is used to identify the individual or to verify the identity of the individual."

[2] The HIPAA identifiers are: Name, Address (any address element lower than State or equivalent), Dates relating to an individual, Telephone/Fax numbers, Email address, Administrative numbers (such as Social Security number, Medical record number, Health plan numbers, Account numbers, License numbers and so on), Vehicle identifiers, Device identifiers, Web URL, Internet Protocol (IP) Address, Biometric identifiers (such as finger or voice print), Facial photographic images, Any other characteristic that could uniquely identify the individual

[3] Active Laws: Antigua and Barbuda (Data Protection Act, 2013), Aruba (The Personal Data Protection Ordinance, 2011), Bahamas (Data Protection (Privacy of Personal Information) Act, 2003), Bermuda (The Personal Information Protection Act, 2016), Curacao (The Personal Data Protection Act, 2013), St. Maarten (The Personal Data Protection National Ordinance, 2010), St Kitts and Nevis (Data Protection Bill, 2018), St Lucia (Data Protection Act, 2011), St Vincent and the Grenadines (Privacy Act, 2003), Trinidad and Tobago (Data Protection Act, 2011). Draft Laws: Barbados (2019), Dominica (2007), Dominican Republic (2013), Jamaica (2017).

Table 1.
Classification of Personal Research Data into Three Categories of Data Sensitivity, Based on the Risk of Harm to Participants from a Data Breach

Sensitivity Level	Protection Level 1	Protection Level 2	Protection Level 3
Impact	Low	Moderate or High	Extremely High
Description	Non-sensitive individually identifiable or public information	Sensitive personal data	Highly sensitive personal data
Effect of Data Disclosure	Accidental or unintended disclosure is unlikely to result in harm to the study subjects.	Personal data which if disclosed might increase the risk of social, psychological, reputational, financial, legal or other harm to an individual or group	Personal data which if disclosed will increase the risk of criminal liability, loss of insurability or employability, or severe social, psychological, reputational, financial or other harm to an individual or group.
Examples	• Fully anonymised research information. • De-identified research information that is not PHI† related (caution required as full de-identification is very difficult). • Identifiable information which the subject has consented to make publicly available. • Information intended for public access, e.g., public directory information	• De-identified research information about people that is PHI† related (caution required as full de-identification is very difficult). • Datasets containing personal data that can overtly or potentially identify individuals.	•Datasets containing "special category" personal data. So, data resources that contain one or more data items linked to: -Racial or ethnic origin -Political opinions or political group membership (e.g., trade unions) -Religious or Philosophical beliefs -Genetic or biometric data -Sexual history / sexual orientation -Criminal offences -Health information

† PHI = Personal Health Information
Adapted from: Harvard University. Information Security Policy – Data Security Levels (https://policy.security.harvard.edu/view-data-security-level).

SEVEN EXAMPLES OF CLASSIFYING RESEARCH PROJECTS INTO THREE LEVELS OF DATA PROTECTION (PROTECTION LEVELS 1, 2, AND 3), BASED ON DATA SENSITIVITY.

Example 1.

A national STEPS survey has collected data on chronic disease risk factors among 1,800 adult participants. A de-identified dataset has been made available online for researcher use. A research team from The University of the West Indies will use the data to investigate determinants of high blood pressure.

Determination: Protection Level 2.
Reason: This analysis will use de-identified data. The dataset includes health data and a combination of data items could lead to potential identification of participants. So, although data are de-identified, the researchers must be careful to present only aggregated statistical summaries, and recognize the possibility of identification, especially if tabulated data includes small numbers of participants.

Example 2.

The monitoring of dengue incidence in Barbados. Data on laboratory-confirmed dengue cases are transmitted to a Ministry of Health and Wellness surveillance team and do not include any Personal Health Information (PHI).

Determination: Protection Level 1.
Reason: This surveillance project collects only anonymized laboratory-confirmed results, without any means of linking these laboratory results to individuals.

Example 3.
A follow-up study of dengue incidence in Barbados, which also collects participant name and healthcare identifier in order to follow their healthcare treatment and disease outcome using hospital records. Data are de-identified before analysis.
Determination: Protection Level 2.
Reason: The study collects PHI in order to track participants through the healthcare system. The subject matter is not taboo in the given setting, and, with immediate de-identification, the potential for harm from a data breach is moderate.

Example 4.
A second follow-up study of dengue incidence in Barbados now collects blood samples for genetic analysis, investigating the susceptibility of individuals to severe dengue infection.
Determination: Protection Level 3.
Reason: Although the subject matter is not particularly taboo in Barbados, the collected genetic materials could be used to reveal a wealth of personal health information about the individuals (and their families), and are therefore highly sensitive.

Example 5.
A study of HIV prevalence and sexual practices among sex workers.
Determination: Protection Level 3.
Reason: Prostitution is illegal in the territory concerned, and HIV/AIDS remains a highly taboo subject area for many. For both these reasons, the impact of a data security breach for the study participants could be catastrophic. The study contains highly sensitive data.

Example 6.
In this qualitative study, participants are asked to take photographs of their neighborhoods to highlight features that either encourage or deter physical activity.
Determination: Protection Level 3.
Reason: The project is rather low risk. However, there is the real chance that photographs will include images of passers-by who have not consented to become part of the study data. The researchers are encouraged to apply the highest data security standards and to permanently remove identifiable features from their imagery.[1]

Example 7.
A series of focus groups are planned to collect audio information on barriers to healthy eating in Jamaica. The researchers transcribe audio-recorded conversations mostly verbatim, but apply de-identification as appropriate (names if spoken would not be transcribed, for example).
Determination: Protection Level 2.
Reason: Again, this qualitative study does not concern a particularly taboo subject area. Although the researchers make all reasonable efforts to protect the identity of the study participants, it is difficult to maintain absolute anonymity during conversational interviews. For this reason, PHI may exist on the audio recordings, and they must be kept securely and deleted permanently at the earliest opportunity, usually after transcription. There may be instances in which a participant allows identification (for example in print, film, or audio recording). Examples might be a narrative history or a study of performance art. These will be exceptional cases for which additional elements of consent would be required.

[4] If this study is publically funded and addresses a public policy issue, images of people in public spaces may legally be captured in many countries. Nevertheless, this introduces ethical concerns related to civil liberty, and an ethics committee may request facial anonymization if (like this study) the individual is not the focus of the research.

THE PRACTICALITIES OF DATA PROTECTION
In this section we focus on the fundamentals of controlling access to your data, describing simple methods that can go a long way to ensuring the security and confidentiality of your research data. The extent to which these controls are applied are related to the protection level required for your data (Protection Level 1, Protection Level 2, or Protection Level 3 – See Table 1). We describe the basic elements of each data access control, noting the additional security needed for higher Protection Levels. Advice is offered in 6 areas: password good practice for data files (Table 2), encryption for data files (Table 3), securing your physical space and computer (Table 4), secure data backups (Table 5), secure data transmission (Table 6), and secure data disposal (Table 7).

Table 2. Secure Data Storage – Password Protection

Applies to	Protection Levels 1, 2, 3
Background	Hackers are very good at finding out passwords. They don't try to guess them, they get very fast computer programs to try out millions of possible passwords, very quickly. We advise that you memorize a few strong passwords for the systems you use to access your research data.
Advice	Your passwords should be long - we recommend 15 characters or more. A very useful way to choose (and remember) long and strong passwords is to make them up of three or four randomly chosen words, e.g. "promotion price papers consume" or to make it compatible with a service that insists on punctuation marks and capitals "Pr.motionPr!cePapersConsum3". Besides choosing strong passwords, store and transmit passwords securely to prevent theft: **Do** use secure password management software to securely store your passwords. **Do** store passwords in a sealed envelope in a secure place (e.g. a safe); **Don't** write passwords down, then leave the paper lying around. **Don't**use passwords in untrusted environments such as open Wi-Fi or coffee shops. **Don't** let your internet browser store your password
Additional Measures for PL3	Passwords are your first line of defense. Additionally, data you have classified at Protection Level 3 should always be stored as an encrypted file on your computer. See "Data Encryption" below.
Further Information	University of Edinburgh https://www.ed.ac.uk/infosec/how-to-protect/lock-your-devices/passwords
Useful (and Mostly Free) Software	Software for secure password management: **KeePass**(https://keepass.info/) **LastPass** (https://www.lastpass.com/)

Table 3. Secure Data Storage – Data Encryption

Applies to	Protection Levels 1, 2, 3
Background	Encryption is the process of encoding digital information in such a way that only authorized parties can view it. It is the main tool for securing sensitive personal data. When you encrypt a file, the information it contains is "translated" to meaningless code. To translate this code back into meaningful information a password or key is required. Recovering information from encrypted files without the key is almost impossible. It is therefore extremely important that you do not lose the key to decrypt your files.
Advice	**Do** encrypt data before transmitting it online, **Do** encrypt data before uploading it to the cloud **Do** encrypt data before transferring it to a portable storage device **Do** make sure that the key can be accessed by everyone who needs to access it (but only those people). **Do** ensure that you do not lose the key to decrypt your files.
Additional Measures for PL3	Additionally, data you have classified at Protection Level 3 should be encrypted "at rest" on your computer. This might mean encrypting individual files or folders on your computer, or it might mean encrypting your entire computer hard drive. See Useful Software below for more details.
Further Information	The UK Data Service has compiled information on encryption and offers short video tutorials demonstrating the use of different software tools to encrypt data (https://www.ukdataservice.ac.uk/manage-data/store/encryption).
Useful (and Mostly Free) Software	Commonly used encryption software includes **Bitlocker**. Available with selected editions of Windows. Full disk encryption and portable storage encryption (https://docs.microsoft.com/en-gb/windows/security/information-protection/bitlocker/bitlocker-overview) **FileVault**. The standard on MacOS. Full disk encryption (https://support.apple.com/en-gb/HT204837) **Veracrypt**. Open-source software for Windows, MacOS and Linux. Full disk and portable storage encryption (https://www.veracrypt.fr/en/Home.html). **Axcrypt**. Free or commercial software for Windows and MacOS. File and folder encryption. (https://www.axcrypt.net/) **SafeHouse**. Free or commercial software for Windows. File, folder, portable storage encryption (http://www.safehousesoftware.com/). **BoxCryptor**. Free or commercial software for Windows, MacOS, **Android**, IoS. File and folder encryption for cloud storage (https://www.boxcryptor.com/).

Table 4. Secure Data Storage - Physical, Network, and Computer Security

Applies to	Protection Levels 1, 2, 3
Background	To prevent your data from being manipulated or stolen, sufficient security measures to block any unwanted access to computers and networks and to rooms and buildings where they are held should be in place.
Advice	**Do** log and/or control access to physical sites where sensitive information is stored, e.g. with the help of key cards. **Do** use strong passwords and encryption. **Do**use up-to-date anti-malware scanners and firewalls. **Do** ensure that systems used to access data are continually updated (e.g. security updates for the operating system).
Additional Measures for PL2 and PL3	**Do** separate personal data identifiers from research datasets, e.g. store participant names and addresses separately from survey data files **Do** implement controlled access to electronic data, such as "no access", "read only", read and write" and so on. **Don't** transmit unencrypted data files by (e.g.) email **Don't** transfer unencrypted data files to portable storage devices **Don't** store unencrypted data files in cloud storage, such as Google Drive, DropBox, OneDrive, iCloud and so on.
Additional Measures for PL3	**Do** insist on non-disclosure agreements (sometimes termed confidentiality agreements or confidential disclosure agreements) for managers or users of sensitive personal data **Don't** store unencrypted data files on your computer
Further Information	The UK Data Service has a list of further important security measures (https://www.ukdataservice.ac.uk/manage-data/store/security).

Table 5. Secure Data Backups

Applies to	Protection Levels 1, 2, 3
Background	You will want a backup strategy for your research data. It will involve multiple data copies on different storage media, kept in different locations with at least one copy offsite. The strategy will call for regular checks that the storage devices work and that the research data can be restored. Remember the 3-2-1 backup rule: keep at least 3 copies of your data, on 2 different storage media, with 1 of them located offsite.
Advice	You must make sure that backups of data containing sensitive information are protected against unauthorized access in the same manner as the original files.
Additional Measures for PL2 and PL3	**Do** encrypt data before transferring it to a portable storage backup device
Further Information	The Consortium of European Social Science Data Archives (CESSDA) training site offers a nice resource for thinking about a backup strategy (https://www.cessda.eu/Training/Training-Resources/Library/Data-Management-Expert-Guide/4.-Store/Backup).
Useful (and Mostly Free) Software	**EaseUS ToDo Backup**. Free or commercial software for automated backups (https://www.easeus.com/backup-software/tb-free.html). **Paragon Backup**. Free and simple backup software (https://www.paragon-software.com/free/br-free/#downloads).

Table 6. Secure Data Transmission

Applies to	Protection Levels 2, 3
Background	There are many occasions when you need to share electronic research data with remote colleagues. For personal data classified at protection levels 2 or 3, you should always encrypt your data file before transmission. This can be done by encrypting the file before sending by email. Alternatively, software now exists specifically to share files in an encrypted cloud environment. Informally, we often suggest encrypting anything you would not write on a postcard!
Advice	**Do** encrypt your data file before transmission by email or other transmission method **Do**apply strong password rules to your encryption password. **Do** consider carefully how you will transmit the encryption password to the file recipient. You should not (for example) send the password in an unencrypted email. **Do** consider using an encrypted email service or cloud environment for transferring files (see software below).
Additional Measures for PL3	**Do** use a personal encryption key in preference to an encryption password.
Useful (and Mostly Free) Software	**Sync.com**. "Zero-knowledge" cloud provider for storing and sharing encrypted files. Free entry level account available. Zero-knowledge means that files are encrypted before transmission to the cloud (https://www.sync.com/your-privacy/). **Firefox Send**. Online software for sharing of encrypted files. Can set time or download limits (https://send.firefox.com/). **BoxCryptor**. Software for encrypting files before transmission to a cloud provider. Free entry level account available. Has functionality for direct sharing of encrypted files (https://www.boxcryptor.com/en/for-individuals/). **Mega.nz**. "Zero-knowledge" cloud provider with free entry-level account. Enables encrypted file transmission (https://mega.nz/). **ProtonMail**. Free email service with end-to-end encryption (https://protonmail.com/).

Table 7. Secure Data Disposal

Applies to	Protection Levels 2, 3
Background	Researchers are commonly encouraged to keep their research data for a minimum of 5 years or longer, and once de-identified or anonymized, researchers should be considering depositing their research data into long-term data-sharing repositories. Nevertheless, there are occasions when managing your data also means thinking about how to securely dispose of confidential information. This might be deletion of materials from a temporary computer location, or the deletion of sensitive and identifiable information in preparation for data sharing. Just hitting the "delete" button on your computer or mobile device is not enough.
Advice	There are two options for secure disposal of confidential data: (1) The physical destruction of the storage medium (e.g. shredding of discs) (2) The use of software for secure erasing
Additional Measures for PL3	At the end of your study, you should create an archived (and backup-up) copy of your sensitive personal data files. All additional data file copies should then be securely erased.
Further Information	The University of Western Australia is one of many with sensible guidelines on data retention and data disposal (http://guides.library.uwa.edu.au/c.php?g=325196&p=2177532).
Useful (and Mostly Free) Software	Three useful free software packages for secure file deletion are listed below. **Axcrypt**. (https://www.axcrypt.net/) **Eraser**. (https://eraser.heidi.ie/) **WiperFile**. (https://www.gaijin.at/en/softwarewipefile)

CONCLUSION

Researchers should make every effort to protect and properly store personal research data, whether it directly identifies, or has the potential to identify, individuals. In this article, we have suggested a simple classification of data protection levels, based on the perceived harm of a data breach on participants. In making determinations about the level of risk to participants, researchers should, when uncertain, opt for the highest level of data protection. Considering six areas of data protection can go a long way to ensuring research data security: using strong passwords, encrypting sensitive data, securing computers and networks, data backups, secure data transmission, and secure data disposal. Simple techniques and free software are available to enable each of these data protection considerations.

REFERENCES

Carnegie Mellon University. (2019). Information Security Office: Guidelines for Data Classification. Retrieved from https://www.cmu.edu/iso/governance/guidelines/data-classification.html

Digital Curation Center. (2019). DMPOnline. Retrieved from https://dmponline.dcc.ac.uk/

Donnelly, M., & McDonagh, M. (2019). Health Research, Consent and the GDPR Exemption. Eur J Health Law, 26(2), 97-119. doi:10.1163/15718093-12262427

European Commission. (2019). Data protection: Rules for the protection of personal data inside and outside the EU. Retrieved from https://ec.europa.eu/info/law/law-topic/data-protection_en

National Network of Libraries of Medicine. (2019). Data Life Cycles: Research Data Lifecycle Models and Guides. Retrieved from https://nnlm.gov/data/data-life-cycles

Princeton University. (2019). Research Integrity and Assurance: What kind of data protection do I need? Retrieved from https://ria.princeton.edu/human-research-protection/data/what-kind-of-data-protect

U.S. Department of Health and Human Services. (2019). Health Information Privacy. Retrieved from https://www.hhs.gov/hipaa/index.html

University of California. (2019). Curation Center of the California Digital Library: DMPTool - create data management plans that meet institutional and funder requirements. Retrieved from https://dmptool.org/

The University of Manchester. (2019). Data Protection: Information Security Classification Examples. Retrieved from http://documents.manchester.ac.uk/display.aspx?DocID=15677%20

International Ethical Guidelines for Animal Research

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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."

INTRODUCTION

The use of animals in research and teaching has been common over many years. Research using animals in experimentation, observation and biological exploration has afforded the scientific community with major discoveries and advances in applications. One such example was the award of the Noble Prize in Biology, in 1912, to Alexis Carrell, recognising his work with animals that pioneered the development of methods in surgery. After World War II, ethical guidelines for the use of subjects in research were established to prevent deliberate cruelty to humans. Subsequently, the use of animals in research increased extensively, and, thus, occasioned the need for guidelines on the ethical treatment and care of experimental animals. Principles of Humane Experimental Technique, by WMS Russell and RL Burch (1959), provided a seminal common standard for researchers. This served to ensure that the most humane treatment and care for animals was an essential criterion for all research including animals. Currently, there are stringent ethical guidelines for use of animals in research and teaching throughout the developed world.

The purpose of this article is to summarise the basic ethical principles and standards that should be implemented and to provide an update of animal categories and types of animal research now considered under the umbrella with which these principles and standards should be applied. Further, this article raises awareness of other alternative animal protection models.

GENERAL ETHICAL PRINCIPLES AND STANDARDS

In the early nineteenth century, mice and rats were the primary animals used in research. The definition of animals included in the category of vertebrates was vague and excluded humans. Currently, the widely accepted definition of animal is "any live vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or related purposes" (olaw.nih.gov), which is now inclusive of humans.

The principles outlined by Russell and Burch (1959) are also referred to as the 3Rs – Replacement, Reduction, and Refinement. Many developed countries (e.g., Canada, UK, and USA) have used the 3Rs in the development of their policy and regulation of the use of animals in research. The 3Rs include the principles of using in vitro models where possible to replace animals; designing experiments to reduce the number of animals in experiments to the minimum possible; and refining the experimental procedures to minimise the stress/pain experienced by the animal.

Over the last forty years, most industrialized countries have developed boards/committees that drafted guidelines with respect to the use of animals in experimentation. One such example, the Canadian Council on Animal Care (CACC) was mandated to advise and monitor experimentation and animal care in Canadian universities, private and government run laboratories in 1980 (Roswell, 1986; Cheluvappa, 2017). This further lead to the establishment of guidelines for ethical review of experimental protocols with animals. In the USA, the counterpart committee published the Guide for the Care and Use of Laboratory Animals (1963), which became the principle doctrine with respect to acceptable animal experimentation practices for all American public and private institutions; the regulations have been recently undated (NRC 2011)). The European Union, inclusive of the United Kingdom, established the Federation of European Laboratory Animal Science Associations under the Council of Europe to promote and guide ethical adherence in animal research (Council of Europe, 1986; Cheluvappa, 2017).

ETHICAL GUIDELINES

Ethical guidelines have been established acknowledging that the use of animals is wide-ranging. Commonly it is thought that experiments with animals have the main objective to create advancements that would be beneficial to humans, animals, and/or the environment. The following views have informed ethical consideration of treatment of animals.

1. Animals must be treated with respect due to their inherent worth.
2. Most animals (mainly vertebrates) are sentient and have the ability to feel and respond to pain.
3. The treatment of animals varies widely and tends to be directly dependant on the attitudes, influences, and morals of individuals.

The ten main guidelines operationalise the above points in an effort to reduce the harm versus benefit ratio in animal research. The following simplified guidelines were adapted from the Norwegian National Research Ethics Committees (2018):

1. Respect the dignity of animals

The researcher should respect the intrinsic value of each animal subject. The selection of experimental animals should be carefully considered. Researchers must adapt care and maintenance to the needs of each specific animal.

2. Responsibility for considering alternatives (Replace)
The researcher should determine whether that are considerable and acceptable alternative options to the experimentation on animals. If the alternative options can garner the same knowledge as the animal model, they should be ranked and employed. The researcher should rationalise the crucial need to use animals considering the lack of acceptable alternative options.

3. Responsibility for balancing harm versus benefit
The researcher must consider all potential risks of animal suffering and determine the relative value of the benefit to advance knowledge. Should suffering be unavoidable, the researcher must employ the scenario with the least pain/harm, and must justify the use of this experimentation to achieve significant contribution to science. The potential benefits should be substantiated and categorised based on relative terms (short vs. long). Researchers should be knowledgeable of institutionally accepted methods to analyse harm and benefit, which must be taken into account during the experiment planning process.

4. Responsibility for reducing the number of animals (Reduce)
During the planning process, extensive attention should be applied to determining the minimum number of animals needed to achieve the research goals, while satisfying the scientific quality of the research. All potential protocols should be assessed to meet this responsibility using appropriate statistical calculations.

5. Responsibility for minimizing the risk of harm and, where possible, improving animal wellbeing (Refine)
Understanding the suffering an experimental protocol could cause, researchers should consider all alternative protocols with the potential to achieve the research objectives with the least harm. If specific protocol is necessary and justified, the researcher should make all possible adjustments to the chosen experimental protocols to reduce suffering and possibly enhance good animal welfare. Animal suffering is defined as a state inclusive of pain, hunger, thirst, malnutrition, stress, injury, fear, extreme temperatures, illness, or restrictions that prevent normal and natural behaviour. The scale of suffering should be established with respect to the animals used. The researcher should be aware that scales must be customized to the specific type of animal since not all animals can display a varying range of reactions to degrees of discomfort/suffering. All effort must be made to limit the pain and suffering experienced by the animals. Researchers must also consider the periods 'pre' and 'post' experimentation, and an adaptation/transition period is recommended to minimize the suffering potentially endured, including trapping, labelling , anaesthetising, breeding, transportation, stabling and euthanizing.

6. Responsibility for sustaining biological diversity
The maintenance of the ecosystems and consequences of the stock of laboratory animals affecting the biological diversity of the ecosystem must be considered. Researchers should ensure that the laboratory animals chosen should exclude where possible endangered and/or vulnerable species. All precautionary protocols should be implemented to preserve biological diversity

7. Responsibility when intervening in the habitat of animals
A wide-range of environmental research can affect the state of the natural habitat and potentially disturb the normal behaviour of the animals in their surroundings. The researcher should make all attempts to reduce the possible negative impact of the animal population in their natural surroundings.

8. Responsibility for upholding transparency and dissemination of research findings
It is the responsibility of the researcher to share research data and methods with the scientific community. This helps to ensure that animals are not unnecessarily used due to experimental duplication unknowingly by other researchers. In addition, both positive and negative research findings can help guide the research community in future animal experimentation.

9. Requirement of animal training for all handlers
All animal researchers and handlers must have documented their level of training. It is required that all researchers and handlers obtain basic training on how to handle the animals, which includes general animal care and fundamental knowledge of the animal (e.g., anatomy and behaviour)..

10. Requirement of basic animal care
In addition to comprehensive national regulations, there are international conventions and standards with respect to animals in research. These constitute another level of compliance for research institutions necessary for international collaborations and funding. The researcher is responsible for understanding all applicable regulatory structures and ensuring that basic animal care is provided to animals used in experimentation.

The table below contains an updated list of animals for which researchers must obtain ethical approval before research (experimental or ecological) can be conducted. Please note that the list is not exhaustive.

Table 1: Vertebrates Used in Research that will Require Ethical Approval

Names of Vertebrates	
Amphibians	Guinea pigs
Bats	Humans
Birds	Mice
Cats	Non-human primates
Cows	Pigs
Dogs	Rabbits
Ferrets	Rats
Fish	**Reptiles**
Goats	Sheep

The bolded animals have been added in the last 10 years.

FIELD RESEARCH
Typically, biomedical research employs a broad scope of animal experimentation using ethically approved procedures performed in a laboratory facility. The main objectives of utilising animal models in biomedical research are to investigate diseases and drugs, as well as to explore physiological processes.

Selection of specific species as animal models is based on the similarity to humans, thus allowing appropriate extrapolation of results to humans. Inbred strains of domesticated rodents, specifically mice and rats, represent over 95% of all animals used in biomedical experimentation (Trull &Rich, 1999). Moreover, some rodent strains are deliberately engineered to display specific genetic traits to better refine the model, thus facilitating disease research.
In ecological research, organisms are studied in relationship to each

other and their surroundings (Oxford Dictionary, 2018). Generally this discipline requires the study of animals in the wild. Field studies facilitate the investigation of habitat, wildlife management strategies, and conservation biology. Although there are guidelines that regulate laboratory animal experimentation (NIH, 2002; Council of Europe, 1986; CACC, 1980), the study of animals in the wild has previously been guided by moral discretion of the researcher, which could be haphazard at best (Wallace & Curzer, 2015). Considering that protocols of capture, handling, marking, transport, and subsequent release are employed in field research, it became necessary to establish standards and practices to guide researchers. Moreover, animals can be removed from the wild for a period of time before release, which raises ethical considerations with respect to treatment and care during captivity. Over the last 10 years, various regulatory boards and committees have considered ethical concerns that may arise in field studies and have attempted to develop guidelines and, by extension, provide a systematic consensus of acceptable protocols for researchers. The recently developed guidelines (Table 2) address field research involving, amphibians, birds, fish, reptiles, and farm animals.

Table 2: International Guidelines for Animal Research

Title of Document	Agency Responsible and Website
Guide for the care and use of Laboratory Animals 8th Ed	National Research Council (NRC) (USA) www.nap.edu
CCAC guidelines on: the care and use of farm animals in research, teaching and testing	Canadian Council on Animal Care (CACC) www.cacc.ca
CCAC guidelines on: the care and use of fish in research, teaching and testing	Canadian Council on Animal Care (CACC) www.cacc.ca
CCAC species-specific recommendations on: BATS	Canadian Council on Animal Care (CACC) www.cacc.ca
CCAC species-specific recommendations on: AMPHIBIANS AND REPTILES	Canadian Council on Animal Care (CACC) www.cacc.ca
NC3Rs Guidelines: Non-human primate accommodation, care and use	PHS Policy on Humane Care and Use of Laboratory Animals National Institute of Health (NIH) (USA) www.olaw.nih.gov
Ethical Guidelines for the Use of Animals in Research	The Norwegian National Research Ethics Committees www.etikkom.no
The Arrive Guidelines	National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3R's) (UK) www.nc3rs.org.uk

In summary, developed countries have established various regulatory authorities responsible for the development of guidelines that direct acceptable treatment and care for animals involved in research. Researchers are required to be trained in the basic handling and experimental techniques of animals. In addition, researchers must be aware of the local and international guidelines that regulate ethical experimental conduct with animals, and, whenever possible, the application of the principle of the 3R's. Advances in the science have resulted in the creation of several in vitro models (e.g., micro-chips with organs, 3D tissue models, blood derivatives, computer modelling) (Huh et al., 2013; Sheasgreen et al 2009; Sladowski et al., 2001; Martonen et al., 2003; Aguda et al., 2011) potentially replacing and reducing animal experimentation. Researchers are encouraged to incorporate alternative models when experimentally feasible.

International boards and committees have used the basis of the 3R's in the development of their guidelines. These guidelines mandate that extensive thought and planning of experiments is performed, thus promoting the most humane treatment of animals. More importantly, no animal should be subjected to experimentation without justification of the harm to benefit relationship. Although the first established guidelines covered only a subset of laboratory animals, newly emerged guidelines address field studies and include a wider range of vertebrates, thus systematizing ethical standards for a wider range of studies with animals and reducing the inconsistent application of idiosyncratic ethical practice by individual researchers.

REFERENCES

Aguda, B.D., Marsh, C.B., Thacker, M., & Crouser, E.D. (2011). An in silico modeling approach to understanding the dynamics of sarcoidosis. PLoS ONE, 6, e19544.

Canadian Council on Animal Care (CCAC) (1980). Guide to the care and use of experimental animals. In Guide to the care and use of experimental animals, Vol. 1. Canadian Council on Animal Care, Ottawa, Ontario.

Cheluvappa, R, Scowen, P., & Eri, R. (2017). Ethic of animal research in human disease remediation, its institutional teaching; and alternatives to animal experimentation. Pharmacology Research & Perspectives 5(4). doi:10.1002/prp2.332

Council of Europe (1986). European convention for the protection of vertebrate animals used for experimental and other scientific purposes. European Treaty Series - No. 123.

Huh, D., Kim, H.J., Fraser, J.P., Shea, D.E., Khan, M., Bahinski, A, Hamilton G.A, & Ingber, D.E. (2013). Microfabrication of human organs-on-chips. Nature Protocols, 11, 2135-57. doi: 10.1038/nprot.2013.137.

National Institutes of Health, Office of Laboratory Animal Welfare. (2002). Public health service policy on humane care and use of laboratory animals. Retrieved July 10 2019 from: http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf

National Institute of Health (2015). PHS Policy on humane care and use of laboratory animals. Retrieved from: https://olaw.nih.gov/policies-laws/phs-policy.htm#Definitions

National Research Council. (2011). Guide for the care and use of laboratory animals. (8th Ed).. Washington,DC: National Academies Press (US).

Norwegian National Research Ethics Committees (2018). Ethical guidelines for the use of animals in research. Retrieved from: https://www.etikkom.no/globalassets/documents/publikasjoner-som-pdf/etiske-retningslinjer-for-bruk-av-dyr-i-forskning/ethical-guidelines-for-the-use-of-animals-in-research.pdf

Martonen T, Fleming J, Schroeter J, Conway J, & Hwang D. (2003). In silico modeling of asthma. Advanced Drug Delivery Reviews, 55,829–849 Oxford Dictionary. (n.d) Retrieved July 10, from: https://www.lexico.com/en/definition/vertebrate

Rowsell, H.C. (1986). Regulation of animal experimentation: Canada's program of voluntary control. Acta Physiologica Scandinavica. Supplementum 554, 95–105.

Russell WM &Burch, R.L. (1959). The principles of humane experimental technique. London, UK: Universities Federation for Animal Welfare. (Originally: Methuen & Co. Ltd).

Sheasgreen, J., Klausner, M., Kandarova, H., & Ingalls, D. (2009). The MatTek story - how the three Rs principles led to 3-D tissue success! Alternatives to Laboratory Animals, 37, 611–622.

Sladowski, D., Kinsner, A., Langezaal, I., Kay, S., & Coecke, S. (2001). Activation of the complement system as an indicator of pyrogenic reaction to lipopolysaccharide (LPS). Toxicology In Vitro, 15, 339–342.
Trull, F.L. & Rich, B.A. (1999). More regulation of rodents. Science. 284(5419),1463.

Wallace, M.C. & Curzer, H.J. (2015). Moral problems and perspectives for ecological field research. Institute of Laboratory Animal Resources Journal, 54(1), 3-4 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

Caribbean Students Graduate with Master of Science in Bioethics Degree from Clarkson University

By Dr. Shakel Henson, BSc, MD, MPH, MSc, MSc, MSBioethics, FRSPH, FRSTMH.

On the 14th June, 2019, several Caribbean professionals graduated from Clarkson University, Potsdam, New York, with a Master of Science degree in Bioethics. This was a great achievement for these individuals, who completed the Research Ethics track as part of the Caribbean Research Ethics Education Initiative (CREEi) Programme.

The CREEi Programme was initially offered by Union Graduate College's Center for Bioethics and Clinical Leadership, Schenectady, New York, in partnership with the Department of Bioethics and The Windward Islands Research and Education Foundation of St. George's University, Grenada. Activities were supported by the National Institutes of Health Research Grant # R25 TW009731, funded by the Fogarty International Center, the National Institute of Environmental Health Sciences, the U.S. National Heart Lung and Blood Institute, and the U.S. National Institute on Drug Abuse. Professor Sean Philpott-Jones and Ms. Ann Nolte, of Union Graduate College at the inception of CREEi, in collaboration with Caribbean ethicist, Dr. Derrick Aarons, and Professor and Chair of the Bioethics Department at St. George's University, Dr. Cheryl Cox Macpherson, were instrumental in recruiting, encouraging, and mentoring regional colleagues engaging in research ethics training.

The first cohort of the CREEi Programme, comprising twelve professionals, started training in 2015. Financial sponsorship has funded members of all three cohorts of the programme. This most recent commencement exercise conferred the Master of Science in Bioethics degree on four students from the English-speaking Caribbean. The current graduates have backgrounds in medicine, genetics, information technology, and physical therapy. Graduates are now expected to contribute to the enhanced protection of human subjects and the education of others in the field of bioethics in their home countries of St. Vincent and the Grenadines, Trinidad and Tobago, and Jamaica. An attorney from Suriname is expected to graduate from the programme later this year. The English-speaking Caribbean is expected to welcome more graduates currently enrolled in the programme next year.

Being a citizen and keen observer of the operations of the National Research Ethics Committee (NREC) of St. Vincent and the Grenadines, the author has noted that this committee is often understaffed. It lacks the resources to effectively monitor all research studies that are conducted in the country. Having trained professionals in the field of research ethics, however, will contribute to the effective functioning of the NREC. Trained ethics committee members will be better able to recognize obvious and subtle ethical issues and to optimally protect human research participants.

Strengthening research ethics systems is key to better protection of human subjects. Capacity building through educating leaders in the field of bioethics is a significant step in strengthening research ethics systems in the region.

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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, references, figures, and tables should follow APA format. Please prepare manuscripts in Microsoft Word and direct submissions via email to canrec bulletin@carpha.org.

CONFERENCES

October 27, 2019 Barbados
11th Annual Bioethics Forum
Bioethics Society of the English-Speaking Caribbean
www.bioethicscaribe.org getdrkandy@yahoo.com

March 9-10, 2020 Boston, MA
Annual Bioethics Conference
Harvard Center for Bioethics
https://bioethics.hms.harvard.edu/annual-bioethics-conference

May 11-14, 2020 Porto, Portugal
14th World Conference on Bioethics, Medical Ethics, & Health Law
UNESCO Chair in Bioethics
http://bioethics-porto2020.com/

June 25-27, 2020 Jamaica
65th Annual Health Research Conference
Caribbean Public Health Agency
http://conference.carpha.org/

July 3-5, 2020 Zagreb, Croatia
8th International Conference on Ethics Education
International Association for Education in Ethics
https://www.ethicsassociation.org/events/28/2020-eighth-international-conference-on-ethics-ed.html

November 7-10, 2020 Seattle, WA
2020 Advancing Ethical Research (AER) Conference
Public Responsibility in Medicine & Research
https://www.primr.org/aer20/