Health Research Ethics Workshop Report

Research Ethics Training Workshop
22nd – 26th July, 2013
Lugogo Sun, Ezwilini, Swaziland

PEPFAR

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ACKNOWLEDGEMENTS

COHRED extends appreciation to MOH especially the research unit for this capacity building initiative.

The Council on Health Research for Development (COHRED; www.cohred.org) through the MARC (Mapping African Research Ethics Review and Medicines Regulatory Capacity: (www.researchethicsweb.org) project is indebted to the President's Emergency Plan for AIDS Relief (PEPFAR) with USAID and CDC funding) through PSI Swaziland and University Research Cooperation (URC) for funding and according COHRED the opportunity to facilitate the first ever Health Research Ethics training workshop in Swaziland.

Sincere appreciation is extended to all SEC members for their participation and for being an absolutely wonderful audience who greatly enriched the workshop with their enthusiastic participation.

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Acronyms

CDC	Centre for Disease Control
COHRED	Council on Health Research for Development
EDCTP	European and Developing Countries Clinical Trials Partnership
GCP	Good Clinical Practice
IC	Informed Consent
IMS	Information Management System
ICH	International Conference on Harmonization
IRB	Institutional Review Boards
LMIC	Low and Middle Income Countries
MARC	Mapping African Research Ethics Review and Medicines Regulatory Capacity
MoH	Ministry of Health
MTA	Material Transfer Agreement
NHREC	National Health Research Ethics committee
NRC	National Research Committee
NREC	National Research Ethics Committee
PEPFAR	President's Emergency Plan for AIDS Relief
RECs	Research Ethics Committees
PSI	Population Services International
RHInnO	Research for Health and Innovation Organizer
SEC	Scientific Ethics Committee
SOP	Standard Operational Procedures
USAID	United States Agency for International Development
URC	University Research Cooperation

Executive Summary

Research ethics is a cornerstone for human subjects research and research ethics committees (RECs) have a key responsibility of protecting the rights and welfare of human subjects in research. Therefore, RECs must be competent and well resourced in order to optimally fulfil this role. This requires basic and continuous research ethics training and an understanding of the research process and governance. Although many programs have recently been designed to facilitate this need and strengthen RECs in Africa, much more needs to be accomplished before RECs can function optimally.

The Swaziland Ministry of Health (MoH) established the Science and Ethics committee (SEC) with the mandate of reviewing and approving research protocols under the MoH. Since its inception, SEC has done tremendous work in providing research oversight in Swaziland. With advent in health research, there is a constant need to update and equip the committee on emerging issues and appropriate skills required in protocol reviews. SEC has never had any formal training hence the MoH research unit advocated for this capacity building initiative.

The five day research ethics workshop, held in Swaziland, Ezulweni at the Lugogo Sun Hotel on 22-26 July, 2013, marks the Council on Health Research for Development (COHRED) comprehensive approach of developing and strengthening the research for health governance systems in low and middle income countries (LMICs). COHRED partners with governments, institutions and civil society organizations in their efforts to use research, innovation, science and technology to achieve equity and national development. COHRED's Africa office's team executed this training.

The workshop aimed to contribute to the development and strengthening of ethical-legal framework for protection of human subjects in research in Swaziland, by ensuring that those responsible for the research ethics oversight; administration of RECs and medicines regulation demonstrate an advanced level of knowledge, understanding, and experience of the ethics review process and REC functionality. The workshop provided basic training on research ethics, identified research ethical dilemmas and provided practical interactive exercises to solve such dilemmas. Additionally, the workshop aimed to empower participants in ways that can strengthen their REC, improve quality and reduce the turnaround times. Specific scenarios were shared highlighting the settings in other LMICs, as a way for Swaziland to benchmark. The MARC Project (www.researchethicsweb) was introduced as a platform for networking, increasing REC visibility, and a capacitating tool, while the Research for Health Innovation Organizer (RHInnO) (www.rhinno.net) was shared as an information management solution for the current complex manual paper based system widely used by RECs in Africa.

Key words: Research Ethics Committee, Ethical Review, Ethics, Capacity Building, Governance Framework, Science.

Introduction

Health research initiatives worldwide are growing in scope and complexity, particularly as they move into the developing world[1]. The ever increasing activity in health research involving human participants in low and middle income countries (LMICs) has resulted in a greatly increased and increasing need for sound ethical review structures and functions within these countries, and for greatly increased efficiencies in ethical review processes if the full potential benefits of health research are to be realized. Yet both expertise and efficiency are lagging behind as a result of the enormous challenges facing these countries, including poor resource availability, lack of expert capacity and user-friendly information management systems to support the flow of research proposals through the ethics review process. The complexities of research are increasing, hence the capacity to ethically review research protocols and provide ethical oversight of clinical trials including genetic/genomic studies is a core component of responsible and responsive research systems, and are key topics of the many international guidelines on research with human participants[2]. Each country and major institutions involved in the conduct of research, clinical trials and other research involving human subjects should have adequate capacity to conduct expert and efficient ethical review of such research, as this will promote better health, equity and development outcomes[3].

The purpose of health and health related research is to generate and contribute to generalizable knowledge that could benefit the present and future generations. In order to achieve these purposes, some people and communities have to bear the burden of research. It is therefore, important that the research participants' safety, rights and welfare must not be compromised during the research. To ensure this protection, all human subjects research is subjected to independent ethics review. Hence, governments and research institutions must establish an appropriate governance structure for research ethics review to ensure that RECs operate with a clear mandate, authority, accountability and autonomy.

Currently, over 173 RECs are known to be operating in 37 African countries with great variability in skills, membership, resources and capacity (www.researchethicsweb.org)[4]. Presently, the Swaziland Scientific and Ethics Committee (SEC) is faced with lack of capacity, which is characterised by undefined structures, limited research ethics knowledge, skills as well as resources. The situation is worsened by the increasing concerns about the self-instituted SEC's inadequacy in the health research regulatory framework, and its capacity to handle the ever-increasing volume and complexity of the national and international research conducted in Swaziland. Therefore, there is an urgent need to collaboratively build and strengthen the capacity of the research oversight framework in Swaziland to promote and improve the ethical review

quality and throughput systems. This requires continued training to avoid potential violation of the rights of research participant's particularly vulnerable populations.

Although there is research recognition in Swaziland, there is still a lack of research culture, limited coordination, governance, management and funding. Currently, there is no research agenda and research guidelines for the conduct of human research although the SEC has drafted a guiding document. At present, there is no budgetary allocation for research governance and at a very low scale, SEC manages and conducts ethics reviews although Swaziland has been trying to establish a research coordinating body for quite some time.

Objectives

- To conduct basic research ethics training.
- To identify and discuss practical ethical challenges and dilemmas encountered in the conduct of human subjects research in Swaziland.
- To assist participants strengthen their research ethics committee and improve the quality of the research ethics oversight in Swaziland.
- To guide the Swaziland SEC on the next steps for improving research ethics capacity in Swaziland.
- To establish country level partnership with Swaziland.

Expected Outcomes of the Workshop

The training of SEC members is expected to result into:

- Strengthening of legal framework for the National Research Ethics Committee (NHREC).
- Guidance on the role of the research unit on SEC operation.
- Capacity building to inform review and finalization of the national research governance documents currently in draft form (research agenda, research policy, standard operational procedures, research guidelines, human research bill and application documents).
- Continued training in research ethics at both basic and advanced level.
- Developing strategic and action plans for obtaining on-going financial and other resources support from the government, internal and external donors for sustainability of established RECs.
- Collaboration of the Ministry of Health and Ministry of science and technology to set up a national research coordinating body and finalize the national research bill that will encompass the human research.

Proceedings of the workshop

The workshop commenced on the most memorable day in Swaziland; 'the late kings birthday who is the father to the current reigning king'. There was 80% attendance, which was pretty good for a public holiday.

Following comprehensive participants' introductions, a pre test was administered to evaluate levels of research ethics knowledge; (see Figure 1 for results). The training combined mixed interactive approaches: from formal presentation 'lecture like' sessions to open discussions and group work. Both theoretical and practical aspects of basic research ethics and good practices were incorporated. There were a number of group discussion using case studies, exercises and REC simulation to allow participant to have practical experience about good practices and be able to identify ethical and practical issues encountered during the ethics review process. Sixteen (16) REC members out of the expected 25 participated in the five-day workshop. Participants were very enthusiastic and interactive during the discussions and made very good presentations and feedback at the end of each exercise. They also took very keen interest in the REC simulation exercise and used real protocols to work with. Participants appreciated the review guide as a good tool to guide the review process. Very interesting discussions took place during the workshop supported by life experiences from real situations.

Fundamental softcopy reading materials were provided ahead of the workshop, this included: international research ethics codes and regulations such as the Nuremberg Code (1947), the World Medical Assembly of the Declaration Of Helsinki (1964-2013), the Belmont Report (1974), the 2002 Council for International Organizations of Medical Sciences (CIOMS)/WHO) and ICH/GCP-International Conference Tripartite on Harmonization-Good Clinical Practice. The pre-test results reflected that most participants actually read the above highlighted documents. All the training materials were shared with participants in a USB for easy readability and future use. The movie "Constant Gardner" was watched and participants had to analyse the ethical and practical issues that can arise during the informed consent process in a research setting. Details of theoretical and practical topics covered are shown in the workshop program (Annex 1).

Topics covered included; the background and importance of research ethics using examples of research atrocities that gave rise to research ethics. Theoretical topics such as fundamental principles of research ethics, vulnerable populations, risk/benefit analysis, informed consent, confidentiality in the African context, institutionalizing research ethics committees, compensating research participants, dissemination of research results and research misconduct, in-depth analysis of the ethics review process, ethical issues in international collaborative research and public health research ethics were covered. Specific practical sessions were designed in such a way that they link to the theoretical topic and all the participants (see annexes 2,3,4).

A post-test was administered on the last day of the workshop to evaluate the knowledge acquired from the weeklong training. The lowest mark from the pre-test was 40% and the highest was 75%. Results from the post-test showed significant improvement in knowledge with the lowest mark being 45% and the highest being 80%.

Figure 1: Pre and Post Test Results

Participant Code	Pre-test Mark (%)	Post-test Mark (%)
001	55	Absent
002	55	60
003	65	80
004	50	65
005	40	65
006	50	65
007	50	65
008	75	60
009	75	75
0014	45	30
0015	80	Absent
0016	Absent	60

The average mark in the pre-test was 58% while the average for the post-test was 63%. Unfortunately some participants missed either the pre or post-test, as the attendance fluctuated during the week, making it difficult to generalize results. However, the overall performance shows evidence of learning.

Key Identified Barriers

1. **Lack of Research Ethics Review Capacity**

1.1 Currently Swaziland has a limited capacity to conduct research and ethics reviews. This is partly due to lack of clearly defined structures and process to guide the review process. For example, at the moment the country does not have a national research governance framework to regulate all health and health related research activities conducted in the country. The country operates with a self-constituted ethics committee that caters only for the scientific community.

1.2 Lack of research ethics review-guiding documents such as research agenda, research policy and standard operating procedures. Therefore, there is an urgent for support to establish and

2. Lack of official recognition and undefined roles and responsibilities.

The REC expressed that it is not legally constituted hence lack of official recognition and a legal framework to support the establishment and operation of a National Research Council (NRC) to enhance the existence of the National Research Ethics Committee (NREC) and Institutional Review Boards (IRBs). Furthermore, the roles and responsibilities of the committee are not clearly defined.

3. **Lack of resources**

Lack of resources such as well-qualified human resources; infrastructure, including: office space and essential equipment to ensure the RECs efficiency; computers, telephone, printer, photocopier, vehicle and an information management system. The lack of resources is mainly attributed to lack of financial support from government or external grants. This inadequacy applies both to the currently voluntarily constituted scientific ethics committee (SEC) and the newly established research Unit at the MoH.

4. Training

There is need for basic and advanced continuous training for all research stakeholders in research ethics, particularly specialized training on ethical issues in clinical trials and public health ethics.

Table 1: Key issues and recommended solutions

The following key issues were identified as major challenges, and the proposed solutions were ranked on a scale of short, mid and long term.

ISSUE	Objective	MID TERM	LONG TERM
1. Lack of infrastructure (office space, supplies, vehicles, information management system) and human and financial resources resulting thus limited capacity to conduct research and ethics reviews	To have a fully functional SEC secretariat and ensure effective and efficient management of the committee.	Have designated officers to provide the secretariat Charge research fees and mobilize from external sources To rent office space and solicit supplies and equipment from MoH	Full time employment of qualified staff To assign a budget to the research responsibility centre Build a research Institute
2. Lack of opportunities for continued education and training	A highly skilled, competent and motivated SEC	Short term trainings Mentoring Benchmarking Networking	Long term trainings on Human and Research Ethics for the Secretariat. Opportunities for SEC members to attend regional, global workshops and conferences
3. Inadequate appreciation and recognition of SEC roles and responsibilities and importance	To improve compliance to ethical conduct in human research	Advocate for recognition of the SEC by policy makers (meetings, workshops and IEC) Sensitize researchers and the public (meetings, workshops and IEC, BCC)	Development of a plan for sustained advocacy and social mobilization on research ethics
4. Lack of national research guiding documents (Research Agenda, Research Policy, Research Bill, Standard Operating Procedures)	To ensure quality assurance of research	To liaise with the research unit to develop a research agenda	Availability of national research governance framework guided by documented regulations and guidelines.
5. Inadequate composition of the current committee regarding its diversity, commitment and the small number of members	To ensure an effectiveness and efficiency of SEC	To update current guidelines to include the new developments Re- constitution of membership (appointment of chairperson, vice - chair and the skills mix)	Appointing an authority that can ensure that the tenure is adhered to.
6. Limited capacity to conduct research and ethics reviews	Availability of sound research evidence and products	To develop a National Research Agenda (Channelling research needs)	Sustainable Training of researchers & reviewers

To further address the needed capacity in Swaziland, participants were further requested to identify topics of interest that they would like to see included in the initial training curriculum for the research ethics committees, by prioritizing according to a rating scale of: 1= Must be taught, 2= Can be taught if time allows 3= No need to be taught. Results are reflected in table two below.

Table 2: Rating of Research Ethics topics to be included in the training curriculum

Topic	GROUP 1	GROUP 2
Foundational Bioethics (History, Philosophy, moral reasoning, fundamental principles, ethical Codes)	1	1
Establishment of RECs	1	1
Drafting National Research Guiding Documents (Application forms, Research Guidelines, SOPs, Research Bill)	1	1
Responsibilities of the Sponsor, Investigator, Institution Participant and RECs in the research ethics review process	2	1
Ethical issues regarding: Study designs and methodology	2	2
Challenges of conducting international research in developing countries	2	2
Science of Clinical Trials and Scientific Evaluation of Clinical Trial Protocols	2	2
Informed consent	2	2
Risk /Benefit Analysis	1	1
Essential Elements of the REC Review process (Expedited/Full, continuing review, amendments, close outs, adverse events)	1	1
Informed Consent Process	1	2
Special topics in research ethics: Vulnerable Participants, Privacy and confidentiality, Compensating research participants, Conflict of interest	1	1
Monitoring an Auditing approved studies	1	2
Participant Recruitment Procedures	1	1
Dissemination of study results and research misconduct	1	2
Quality Assurance Guidance and Legal Enforcements	1	1
Organizing and Administering Research Ethics Committees	1	1
Public Health Ethics	1	1
Grant Proposal writing	1	1

The above ratings conclude that participants needed further continued training on both basic and advanced research ethics topics. Participants were also exposed to the current direction that other countries are taking, in order to improve the management of the ethics review process, by using a web-based platform known as: Research for Health Innovation Organizer (RHInnO; www.rhinno.net). RHInnO was developed by COHRED and is intended to replace the current complex paper based system widely used by RECs across Africa[5]. The advantages of the platform includes:

- Improving RECs efficiencies through speeding up the research ethics review process.
- Prevents loss of submitted materials, delays in communication between RECs and researchers hence bringing about accountability.
- Standardization and harmonization of the ethical review process
- Enhanced control of research activities
- Less resources needed e.g. personnel, stationary
- Sharing or use of standardized research regulation documents like SOPs and research guidelines.

One of the partners pledged to support the implementation of RHInnO ethics in Swaziland following tremendous interest from the REC members.

Recommendations

- The Ministry of Health should take the lead to engage the ethics committee to discuss some of the cooperative steps to improve EC/Research.
- The REC should disseminate information on the importance of research to all institutions of higher learning in Swaziland.
- Swaziland must establish a national research ethics Committee to coordinate health research oversight in Swaziland.
- Establishment of a Health Research Unit with a Secretariat to manage NREC.
- Implementation of the REC information management system for submission and review of protocols (RHInnO Ethics).
- Review and finalization of the national research governance documents currently in draft form (Research Agenda, Research Policy, SOPs, Research Guidelines, Human Research Bill and Application documents).
- Continued training in research ethics at both basic and advanced level.
- Plan strategies for an on-going support mechanism from both national governments, internal and external donors for sustainability of established RECs.
- Collaboration of the Ministry of Health and Ministry of CST to set up a national research coordinating body and finalize the national research bill that will encompass the Human Research Bill.
- Identifying research ethics networks for Swaziland to participate such as the discussion forums on the MARC website.
- Identifying capacity building opportunities for the national research unit coordinator
- Separation of clinical trials review and the need to set up sub committees for expert reviews.

Workshop Evaluation

A detailed analysis of all completed evaluation forms was done, which revealed a gender imbalance in the Swaziland SEC with majority being females (73%). Participants had qualifications in medicine, Public Health, Management, IT, Laboratory Technology, Research, Nursing and Epidemiology. The participants job titles varied; Director, lecturer, Research Officer, Strategic management Manager, Statistician, IT Manager, Laboratory Technologist and Program Coordinator. Only two participants had formal research ethics training as part of their academic programs, while only two participants had attended research ethics workshops before. Overall, the workshop was rated as either good or excellent, most reasons being: excellent training materials provided, the practical and interactive discussions, which enabled participants to relate to their experiences. One participant was happy about being taken through the research ethics challenges

from the historical perspective, fundamental principal and topical issues. All the participants agreed that the training had been relevant to their work setting and to the ethical issues encountered in health and health related research. The participants alluded that the training had enhanced their understanding of some of the ethical challenges in health research, the different questions that need to be answered to make improvements in protecting the rights and welfare of research participants, the different approaches to ethical review of research and had improved their review skills and capacity. Participants also agreed that the training had provided them with awareness about the tools and resources available for quality review of proposals.

The duration of the training was rated as good, visual aids and handouts were good and the workshop venue was rated as very good. When asked what they liked the most about the workshop, most participants highlighted the interactive nature of combining presentations and case study discussions, which brought out real life experiences. One participant described the workshop as a motivation to venture into research ethics as a profession in order to become an effective and efficient SEC member. Two participants expressed their disappointment about poor time management by some of their colleagues and recommended that the next training be held at a venue far from participants' places of work.

Recommendations for future workshops included use of a bigger venue far from participants/ places of work, gender balanced group and research methodology and design to be included in the program. Finally, participants were also asked to list three things they would do better after the workshop. These mostly included:

- Use of information and materials provide to improve review process
- Make decisions about the review with reference to research guidelines
- Critically review the consent form
- Take time to identify ethical issues in a protocol

Conclusion

The workshop increased participants' awareness about the importance of building and strengthening capacity of NREC in Swaziland. There seemed to be a consensus among the participants regarding the existence of gaps in the clinical trial regulatory oversight systems including the need for more training in research ethics and establishing/improving REC information management systems. Participants committed to working together towards sensitizing their institutions, governments, clinical trial sponsors and other donor agencies about the importance of investing more into strengthening the capacity of the NREC to enable the integration of ethics. The workshop served as a very engaging platform through open dialogue among REC members, it enabled very fruitful discussions and sharing of best regulatory practices. The forum

also acted as a gateway to new and future collaborations between COHRED/PSI /Swaziland MoH/URC and PEPFAR.

Closing Remarks

The workshop was wrapped up with a formal closing session, at which, the COHRED Africa Director (Boitumelo Mokgatla-Moipolai) highlighted COHRED's mandate and commitment in developing and strengthening the research for health governance systems in low and middle income countries (LMICs). She highlighted that COHRED partners with governments, institutions and civil society organizations in their efforts to use research, innovation, science and technology to achieve equity and national development. She also outlined COHRED's initiatives in building and strengthening the research ethics landscape in Africa. The PEPFAR Swaziland country Director (Peter Ehenkranz) emphasized the commitment of the American people to improve health systems in Africa by helping to build and strengthen these systems. He noted that the goal of evidence-based research needs particular attention to all the systems from defining the standard operating procedures to analysis of data. He reiterated the need to answer questions through research supported by epidemiology. He also pointed out the need for integration, collaboration, networking among all research stakeholders as well as the importance of data sharing to avoid blocking research. He committed to support health research initiative in Swaziland.

The Swaziland Ministry of Health Director (Rejoice Nkambule) extended a note of appreciation to the workshop organizers, the participants and the facilitators. She emphasized her commitment to support SEC and the research unit in their efforts to improve health research capacity in Swaziland. She requested the participants to document all their requests and recommendations and submit to her office, following which, she will set up a meeting to tackle the raised issues. However, she pointed out that although the issue of setting up the National Research Council is beyond the Ministry of Health, she will initiate its advocacy.

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Annex 1: Workshop Program

Monday 22nd July	Activities	Responsible
8:00 am –08:30am	**Registration**	
08:30am – 08:45am	Opening Remarks	MoH & PEPFAR
08:45am – 0900am	Introductions Workshop Overview	BM
09:00 am – 09:30am	Pre-Test	Participants
09:30am – 10:00am	Overview of Research ethics in Swaziland	NREC Chairperson
10:00 am – 10:20 am	**Social Break**	
10:20am – 11:00am	Background and Importance of Health Research Ethics	BM
11:00 am – 12:30 pm	Fundamentals of Research Ethics	MK
12:30 pm – 13:30 pm	**Lunch**	
13:30 pm – 16:00 pm	Case Study: 1	Group Work
16:00pm – 16:30 pm	Wrap Up	

Tuesday 23rd July	Activities	Responsible
8:15 am –08:30am	**Registration**	
08:30am – 08:45am	Recap of Day one	Participant
08:45am – 10:45am	Informed Consent Process	BM
10:45 am – 11:00 am	**Social Break**	
11:00am – 12:00pm	Case Study 2	Group Work
12:00 am – 13:00 pm	Risk/Benefit Analysis and Standard of Care	MK
13:00 pm – 14:00 pm	**Lunch**	
14:00 pm – 16:00 pm	Research with Vulnerable Populations	Group Work
16:00 pm – 16:30 pm	Wrap up	

Wednesday 24th July	Activities	Responsible
8:15 am –08:30am	**Registration**	
08:30am – 08:45am	Recap of Day two	Volunteer
08:45am -10:30am	Institutionalizing Research Committees	MK
10:30 am – 11:00 am	**Social Break**	
11:00 am – 13:00 pm	Group Exercise & Discussion	MK
13:00 pm – 14:00 pm	**Lunch**	
14:00 pm – 15:00 pm	Compensating Research Participants	MK
15:00pm – 16:00pm	Confidentiality in the African Context	BM
16:00 pm – 16:30 pm	Wrap Up	

Thursday 25th July	Activities	Responsible
8:15 am –08:30am	**Registration**	
08:30am – 08:45am	Recap of Day three	Volunteer
08:45am – 10:30am	Research Ethics Review Process	MK
10:30 am – 11:00 am	**Social Break**	
11:00 am – 11:45 pm	Ethical Issues in International Collaborative Research	BM
11:45am – 13:00pm	Preparation for simulated REC /Research Proposal	Participants
13:00 pm – 14:00 pm	**Lunch**	
14:00 pm – 16:00 pm	Simulated Research Ethics Committee	Group Work
16:00 pm – 16:30 pm	Wrap up	

Friday 26th July	Activities	Responsible
8:15 am –08:30am	**Registration**	
08:30am – 08:45am	Recap of day four	Participant
08:45am – 09:15am	Post-Test	Participants
09:15am – 11:00am	Dissemination of Research Results & Research Misconduct	MK
11:00 am – 11:20 am	**Social Break**	
11:00 am – 11:45 pm	Public Health Research Ethics	MK
11:45am – 12:45pm	Exercise: Swaziland NREC Capacity Building	Group work
12:45pm – 13:00pm	Wrap up	BM
13:00pm – 13:15pm	Closing remarks	MoH CDC
13:30 pm – 14:30 pm	**Lunch**	

Annex 2: Case Study 1: A treatment for Central Nervous System.

This case study was aimed to at assisting participants to differentiate between clinical care and research and appreciating the thin line between the two.

Dr W is a neurosurgeon in a hospital in one of Asia's major metropolitan centres. He earned his medical degree in that city and then studied in the United States of America before returning to practise in his own country. Over the past 3 years, Dr W has treated more than 500 patients with central nervous system (CNS) conditions – including amyotrophic lateral sclerosis (ALS, also known as Lou Gehrig's disease), Parkinson's disease, stroke, paraplegia, and tetraplegia – by injecting these patients' brains or spinal cords with olfactory stem cells harvested from the noses of aborted fetuses. Dr W is convinced that this intervention, which he describes to patients as an "innovative therapy," is effective, and he has declined to conduct a controlled clinical trial of this method. Cell transplantation experiments have been undertaken for several decades and continue to be pursued in several countries. Dr W's method is unique, however, because he uses olfactory ensheathing cells from fetuses aborted at 16 weeks. The women who agree to allow the cell harvesting of their aborted fetuses all provide consent and do not receive payment or other compensation. Using a hypodermic syringe, Dr W transplants the culled cells into paralysed patients above and below the damaged area of the spinal cord; ALS patients receive the injections directly into the atrophied area of the frontal lobe of the brain, through a small hole drilled in the skull (a burr hole).

Despite having only an incomplete explanation of how the injections produce their results, Dr W is convinced by his patients' outcomes that the method works. Both lay and medical publications have reported the positive results of the treatment, and Dr W recently submitted an article to a local journal describing his success. Many of his current patients come from other countries to receive his treatment. Long-term follow-up data on Dr W's work remains preliminary. However, patients – particularly those who have spinal injuries – whom he has contacted by e-mail several months after their operations have reported continued progress. The only adverse effect noted had been pain that accompanied restoration of feeling in some patients. Dr W claims that the surgery stabilizes the condition in about 50% of his patients, and that it causes an improvement in the quality of life (QOL) in about 70% of patients. His estimates are derived from videos he has taken of patients before and after surgery, as well as a survey he conducted of 142 patients, using criteria for function assessment established by a North American spinal injury association.

a spinal neurosurgery programme at a leading North American university, have urged him to conduct double-blind trials to meet the scientific standards of developed countries. Since no recognized treatments can reverse the CNS conditions that his patients have, the intervention given to the control group in a double-blind study would be an injection of an inert fluid instead of the stem cells or "sham surgery" on the skull or spine (surgery to drill a hole and then close up the site, without putting in any cells). Research trials of this type have been used previously for other cellular treatments for neurological diseases, but Dr W refuses to do this, asserting that such studies would be unethical. "Even if the whole world refuses to believe me, I would not do a control test," he says. "These patients are already suffering. If we open them up just for a placebo test, it will only do them harm. We would be doing it for ourselves not for the patient."

Questions

1. Is Dr W providing innovative therapy; conducting an experiment; or carrying out medical research? How are these different, generally or in this case?

2. Would it be unethical to conduct a placebo-controlled trial, as Dr W maintains?

3. How does the use of placebo in a setting where "no treatment" is the standard of care differ ethically from simply providing no treatment?

4. How might Dr W demonstrate that this method is effective (other than by conducting a controlled clinical trial)? Is there an international standard for determining effectiveness?

5. In a hospital setting, whose responsibility is it to monitor the activities of physicians? In general, whose Responsibility is it to monitor activities of physicians?

Annex 3: Case Study 2: This case was based on a movie 'The Constant Gardner'

The movie (Constant gardener) was shot in Kibera, the largest slum in sub Saharan Africa, located in the capital city of Kenya, Nairobi. Second day of the training was kicked off with the viewing of the movie 'Constant Gardener', which was shot in Kibera, the largest slum in sub Saharan Africa, located in the East African country of Kenya. The movie shows Kenya as a developing country burdened with many public health challenges including HIV/AIDS and tuberculosis. Lesson learnt from the movie were highlighted by the importance of having an informed consent, and informed consent as a process rather than just signing the form. The importance of participants' differentiates between routine clinical care and research, the importance of sensitizing and the public about research and also empowering them. Research conducted in vulnerable and impoverished with communities was also portrayed in the movie – and this highlighted the need for extra protections especially in circumstances were participants see that they only way to have access to treatment is through participation in research. This special vulnerability was also further discussed during the session on research with vulnerable populations.

The need for a very simple, well documented and easily digestible consent form was noted, and the complexity of consent in the African context was discussed, with the role of the REC being outlined. Participants took keen interest in the discussions that followed the movie and tried to identify the ethical and practical implications of unethical conduct of the informed consent process in a research setting. Participants pointed out the research therapeutic misconception common in vulnerable research populations. They recommended the need to sensitize the public about research and empowering them. Participants also raised concerns about research conducted in vulnerable and impoverished communities as portrayed in the movie – and this highlighted the need for extra protections especially in circumstances were participants see that they only way to have access to treatment is through participation in research. This special vulnerability was also further discussed during the session on research with vulnerable populations. Participants recommended that consent forms should written in a simple language that participants understand, The complexity of the informed consent process in the African context was discussed at length, and the role of the REC in this process.

Annex 4: Case study 3: Establishing Research Ethics Committees

This case study portrayed a scenario where Swaziland National Research Ethics Committee (NREC) was awarded a grant of $8 million over a period of three years to develop and implement strategies for setting up and strengthening the capacity of the NREC. Participants were requested to identify the major challenges currently hampering the establishment of a NREC; propose short and long term solutions to these challenges. Using the findings from the needs assessment study implement the identified needs to come up with a country and regional plan to promote the regulatory oversight system in Swaziland. The results of this exercise are shown in Table 1 above.

Challenges identified	Objective	Short-term solution	Long-term solution

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Annex 5: Participants List

	Name		Name
1	Buthelezi Gcinile	7	Mndzebele Comfort
2	Dlamini Xolisile	8	Nomcebo Phungwayo
3	Gindindza Hendry	9	Nhlabatsi Nhlanhla
4	Lukhele Sisi	10	Simelane Zanela
5	Haumba Damson	11	Shongwe Babazile
6	Maziya Rudolph	12	Zwane Fortunate
Facilitators			
1	Boitumelo Mokgatla-Moipolai		
2	Mary Kasule		
PSI Representatives			
1	Victoria Masuku		
2	Bonsile Bhembe		

Annex 6: Training Photos



We sincerely thank PSI Swaziland for initiating research for health capacity building initiatives in Swaziland.