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Training and Resources in Research Ethics Evaluation

Vision 2012 & Beyond

A report on activities and plans

October 2012

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Executive summary

TRREE (Training and Resources in Research Ethics Education) is a not-for-profit consortium dedicated to promoting high quality health research based on respect for the rights of human participants. TRREE was founded in 2006 by a group of interested experts with an initial grant from the European and Developing Countries Clinical Trials Partnership (EDCTP).

Working with strong partnerships and networks from low- and middle-income countries and guided by a training needs assessment, much has already been achieved with funds received. High quality basic learning materials in research ethics and the regulation of health research have been created and made available in four languages, free of charge. Negotiations are underway to translate the training materials into a number of other widely spoken languages such as Chinese, Spanish and Russian. Eight National Supplements developed by local experts are currently online with a further eight to be released shortly. In addition, there are thematic modules on research ethics evaluation and informed consent currently online with further modules on Good Clinical Practice (GCP) and on the Ethics of HIV Vaccine Testing forthcoming. An increasing number of institutions and professional bodies are providing formal recognition of TRREE learning materials. TRREE is particularly mindful of the technical constraints related to internet access in many low-income countries and is working to devise solutions to overcome these.

TRREE has now met its original objectives and is looking to expand its geographic and thematic reach in response to requests from around the world. The primary aim of TRREE is to contribute to the development of learning opportunities in research ethics both with new thematic modules and through National Supplements from countries throughout Africa as well as in other regions of the world. The creation of a searchable database allowing for comparative research to be carried out using the different National Supplements would provide many benefits. Moreover, leadership in this quickly evolving world will continue to place TRREE at the forefront of research ethics as work towards developing standards for on-line training in ethics continues.

TRREE's strategic plan is to have National Supplements from all of the countries in Africa on-line by the year 2018. As increased participation in the thematic learning modules has been shown to be directly related to the availability of National Supplements, the numbers of people registering for the introductory modules on research ethics will also increase. This impact is significant as the development of a culture of high quality, ethical health research will enable low-income countries to ensure that the human rights of participants are protected while simultaneously attracting needed funding for local health research. In order to achieve this, TRREE will continue to build strong partnerships with networks from low- and middle-income countries and will strive to ensure that its training programmes and resources remain accessible to all stakeholders. To achieve these goals, TRREE is looking to double its funding received to date.



1. Background

Mission

TRREE (Training and Resources in Research Ethics Education) is a not-for-profit consortium dedicated to promoting high quality health research based on respect for the rights of human participants.

History

TRREE was founded in 2006 by a group of interested experts¹ with an initial grant from EDCTP (European and Developing Countries Clinical Trials Partnership). The goal of TRREE is to develop freely-accessible e-learning material and resources on the ethics of health research involving human participants. Adopting a bi-directional learning approach (South to North, North to South) based on partnerships and capacity building at the local level, TRREE originally focused on developing training materials for sub-Saharan African countries. The structure of the e-learning material consists of thematic modules and National Supplements, as described in **CHART A**. Within this framework, new research teams are created for each module, thus promoting the direct involvement of experts from the South and the North in the preparation of modules, as well as providing important opportunities for capacity building. The National Supplements, which describe the regulatory framework applicable to health research in a given state, are produced in participating countries by local experts who follow the methodological framework developed during the initial phase of TRREE's operations.

CHART A: OVERVIEW OF THE TRREE LEARNING PROGRAMME

Level 1 Introduction	National Supplements	
	On-line:	In preparation:
Mod 1 – Introduction to Research Ethics	Cameroon	Burkina Faso
Level 2 Research ethics explained to different stakeholders	Germany	Ivory Coast
Mod 2.1 – Research Ethics Evaluation	Mali	Latvia
Level 3 In-depth analysis of selected themes	Mozambique	Lithuania
Mod 3.1 – Informed Consent	Nigeria	Portugal
Mod 3.2 – Good clinical practice (GCP) (forthcoming 2012)	Senegal	Romania
Mod 3.3 – Ethical issues raised by HIV vaccine testing (forthcoming 2013)	Switzerland	South Africa
	Tanzania	Taiwan

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Major Achievements

- Conducting a training needs assessment in 4 countries: 3 African, 1 European and publication of its results.²
- Developing high quality basic learning material in research ethics and regulation in 4 languages that is free of charge and accessible despite limitations in band-width. This includes having four (and soon 6) modules conceived and drafted using a collaborative approach with experts from countries in the South and the North.
- Creating a module on *Good Clinical Practice* (GCP) that is integrated within research ethics training. This module will focus on roles and responsibilities in the conduct of clinical trials. The GCP module is of special importance as researchers are often required by clinical trial sponsors to have GCP training. By providing free and certified on-line training on GCP, TRREE will ensure its access for researchers in low-income countries while consolidating the links between research ethics and GCP.
- In just over 3 years, TRREE has issued 3500 certificates to 3200 registered participants who have completed training modules in research ethics. There have been over 55 000 hits from repeat users. Just over half of the registered participants are from African countries with the rest of the users located in all other regions of the world.
- TRREE has developed a methodology to enable countries to identify, collate and analyse their national regulatory frameworks on health research and ethics and to put these on-line as National Supplements. In several low-income countries, this process allowed electronic versions of national legislation to be made publicly available for the first time. Additionally, the development of National Supplements has permitted local legal researchers to make connections between existing provisions and health research within a range of different regulatory instruments, thereby allowing for a thorough assessment of the national legal landscape as it relates to research involving humans.
- Eight – shortly to be 16 - National Supplements have been completed by local experts.
- The translation of the TRREE learning programme (web-site and substantive modules) into new languages in addition to the existing English, French, German and Portuguese versions. A Chinese translation is currently underway as is a Polish version.
- Receiving formal recognition as a credit awarding continuing education programme from the Swiss Medical Association and the Swiss Pharmacists Association. The forthcoming GCP module has also been certified by the Swiss Drug Agency (Swissmedic) as basic training for investigators conducting drug trials. In addition, the National Health Research Ethics Committee of Nigeria and the National Research Ethics Committee in Cameroon are working on making completion of TRREE modules part of their requirements for RECs members and investigators.

² Ateudjieu Jérôme, Williams John R, Hirtle Marie, Baume Cédric, Ikingura Joyce, Niaré Alassane, and Sprumont Dominique, "Training Needs Assessment in Research Ethics Evaluation Among Research Ethics Committees Members in Three African Countries: Cameroon, Mali And Tanzania" *Developing World Bioethics*, Vol. 10 (2) August 2010, Pages: 88–98



- According to our survey, one third of TRREE users are students and the training modules are increasingly being used as initial learning resources within university-based training programmes for health professionals. For example, in several Universities in Senegal, South Africa, Switzerland and Cameroon, it is a pre-requisite to complete at least one of the thematic TRREE modules prior to commencing advanced training in health research ethics and regulation.
- Complementary projects facilitated by TRREE:
 - Collaboration in the Health Research Web with the Council on Health Research for Development (COHRED)
 - Contribution to the National Ethics Committee of Cameroon's successful funding proposal to the Volkswagenstiftung for the organisation of a workshop on "Research Ethics Evaluation" in Yaoundé in 2009
 - Organisation of 2 internships at the University of Neuchâtel's Institute of Health Law for the development of national supplements and thematic modules (for a physician from Cameroon and a social scientist from Mali) with support from the International Institute of Research in Ethics and Biomedicine (IIREB)
 - Participation in and contribution to over 50 international workshops and conferences on the ethics of health research and e-learning
 - Organization of an exchange program for medical students from Switzerland and the University of Bamako

Funding

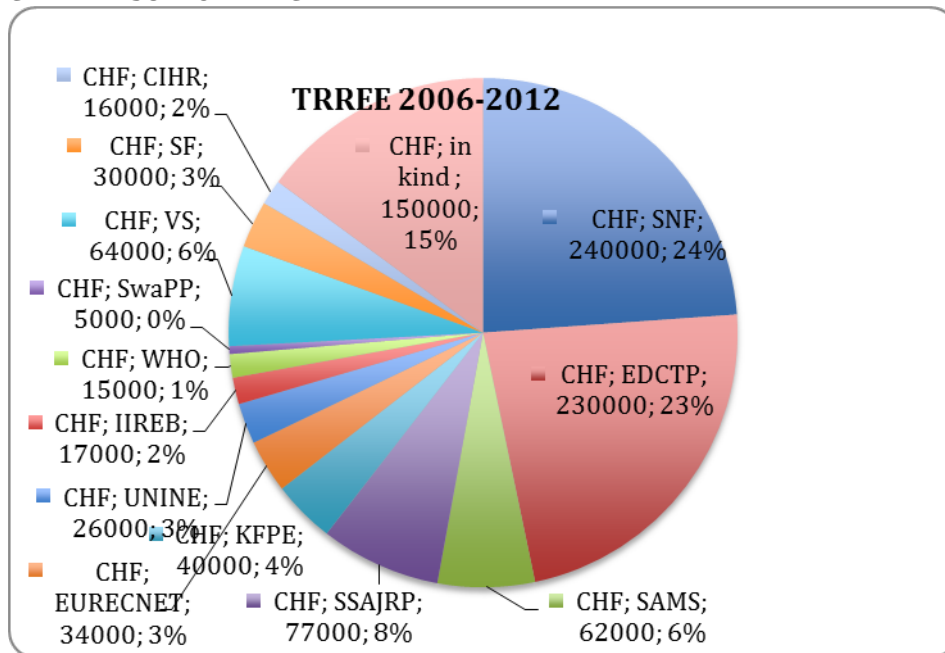
TRREE has received financial support (grants, internships) from a number of sources. Some of this has been direct support while other financing has been provided as part of a pool with other partners. These include:

- [SNF](#) (Swiss National Science Foundation)
- [EDCTP](#) (European and Developing Countries Clinical Trials Partnership)
- [SAMS](#) (Swiss Academy of Medical Science)
- [SSAJRP](#) (Swiss South African Joint Research Programme)
- [KFPE](#) (Commission for Research Partnerships with Developing Countries)
- [EURECNET](#) (European Research Ethics Committees Network)
- [UNINE](#) (University of Neuchâtel)
- [IIREB](#) (International Institute of Research in Ethics and Biomedicine)
- [WHO](#) (World Health Organization)
- [SwaPP](#) (Swiss Association of Pharmaceutical Professionals)
- [VS](#) (Volkswagen Stiftung)
- [SF](#) (Sidaction France)
- [CIHR](#) (Canadian Institutes of Health Research)

Middle- and high-income countries have developed their national modules (and in some cases translations of modules) using their own funding. In kind support has also been provided by the University of Neuchâtel and individual experts who have contributed their time for the drafting of certain modules. Taking all of these sources of funding into account, the overall budget totalled approximately 1 000 000CHF for the first 6 years of TRREE's operations.



CHART B: SUPPORT RECEIVED



Fundraising for the expansion of TRREE's activities is ongoing as increasing numbers of requests are being received from low-income countries wishing to collaborate on the development of training materials and other resources. The strategic priority is for funding to be secured to complete National Supplements from all remaining African countries and to then turn to other regions of the world.

Management team

Given the collaborative structure of TRREE and the desire to use resources as efficiently as possible, management and administrative expenses have been minimised (there is one part-time Coordinator, 2 part-time Managers - one for the overall project and one for South-South partnerships) with basic administrative support being provided by the University of Neuchâtel. Management and administrative costs thus account for only 13% of the overall budget.

2. Expanding TRREE: Objectives for the future

Since its creation in 2006, TRREE has met its original objectives and expanded to meet the needs expressed by its partners. This year has seen a significant increase in the number of countries actively seeking collaboration with TRREE through the provision of their own National Supplements and, in some cases, requesting permission to translate existing modules and parts of the website. While attempting to accommodate this growing interest, TRREE also has its own strategic objectives that it will pursue over the next 6 years. These can be summarized under three headings.



Continued learning opportunities

- **Developing new modules:** The TRREE learning platform was designed from the outset to allow new thematic modules to be added as they become available. There is a great need for training in research ethics; however, it is vital to ensure that resource materials are developed in an incremental and logical manner with a view to gradually addressing all of the gaps that currently exist. A new module on the *Ethics of HIV Vaccine Trials* is being developed by a team led by experts from South Africa as a response to an observed lack of readily available information on the subject for ethics committees as well as researchers involved in vaccine trials. A module on Benefit Sharing is also under discussion as is the idea of drafting an introductory module that specifically addresses the roles and responsibilities of health researchers. A further training needs assessment will be undertaken next year and the results of this will inform the choice of topics for future modules.
- **National Supplements:** Currently, TRREE has 16 National Supplements either already on-line or forthcoming. One of the consortium's objectives is to assist all remaining interested countries in Africa to develop a National Supplement. This focus has been prompted by two important observations:
 1. Identifying and understanding the national regulatory framework applicable to the conduct of research involving humans is critical if research funders are to be attracted to engage in and support research on health issues that are of priority concern to local populations;
 2. Many African countries do not, however, have legislation that specifically addresses research involving humans. This leads to the perception that there are no regulations on research involving humans and makes potential sponsors reluctant to conclude local agreements for clinical trials or other health research. In the process of developing National Supplements, all of the general legal provisions within existing legislation that apply to health research are identified and collected, thereby demonstrating that there is a solid regulatory environment.
- **The translation of the TRREE learning programme** (web-site and substantive modules) into new languages in addition to the existing English, French, German and Portuguese versions. A Chinese translation is currently underway as is a Polish version. Negotiations are also proceeding for the translation of TRREE training modules into Spanish, Russian and Italian. As members of ethics committees and local researchers often have English as their second or third language (if at all), it is important to provide this basic ethics learning opportunity in a language they can understand more easily.
- **Encouraging face-to-face seminars and on-site training to complete the introductory on-line learning:** As part of its extension of the on-line self-learning experience, TRREE intends to collaborate with Universities and other academic institutions so that they develop more advanced courses for their students, using TRREE as a spring board. This will promote South-South partnerships and capacity building.



Infrastructure

The existing TRREE infrastructure needs to be maintained and updated so that it remains functional and accessible. New information technologies are also being explored to offer innovative features that are still capable of operating in low bandwidth locations. These hardware and software requirements include:

- Maintenance, upgrading and development of the Moodle platform on which TRREE is based.
- Keeping the website updated and responsive to the needs of low-income countries.
- Updating existing modules and National Supplements
- Creating a searchable database using the National Supplements: This database will allow the comparison of regulatory frameworks across different jurisdictions.

Leadership and Partnerships

The promotion of TRREE at the international level by the coordinator and other individuals and institutions affiliated with the consortium is encouraging its development and use world-wide. Networking and building collaborative partnerships with dedicated experts from around the world remain at the core of the TRREE mission. This reliance on a network-based structure ensures the international and interdisciplinary depth that is necessary to guarantee that the activities of TRREE remain relevant for its stakeholders. Continued leadership will promote:

- **The identification of new countries interested in developing National Supplements.** In the past, TRREE has been contacted by interested partners to develop National Supplements for their countries, as this is the case for Burkina Faso or Ivory Coast. For the future, it is envisaged that necessary resources will be secured to engage in outreach activities to involve more partners, using the existing model developed with the support of EURECNET.
- **Obtaining formal recognition from organizations requiring training.** The possibility of achieving formal recognition or academic credits for doing the TRREE on-line training provides an additional incentive for participants to undertake ethics training. Many aspects of ethics and the regulation of research involving humans are more effectively acquired via experiential approaches to learning. For this reason, TRREE provides access to resource materials developed by experts so that various organisations (universities, professional bodies) may use them in training and continuing education activities.
- **The development of training standards in research ethics:** In high-income countries, the teaching opportunities made available by the internet have led to on-line training programs being developed at the international, national and institutional levels. Building on the premise that research ethics are based on universally recognized human rights and that basic ethical principles are also the subject of international consensus, TRREE has initiated a meeting of on-line ethics training developers to discuss and develop common quality standards for on-line research ethics training.



3. The way forward

To continue to offer current services while pursuing its strategy of developing new training modules and resources, TRREE must ensure that it has adequate structures and processes in place to allow it to grow. This includes the following elements.

Operational & Marketing Plans

On the basis of the small amount of literature currently available on the topic³, TRREE has concluded that low-income countries are in dire need of training that is consistent with international standards and yet nationally applicable. Travel to other countries is not feasible or possible for all potential ethics committee members, researchers, students and regulatory authorities involved in research involving humans. From the outset, TRREE on-line modules have been accessible free-of-charge and particular attention has been paid to ensuring access despite poor band-width. All of the contributors share the belief that the goal of the initiative should be to enable as wide a constituency as possible to learn about the national and international standards applicable to health research ethics.

In just over 3 years, over 3200 registered participants have taken the TRREE on-line training course, which amounts to an average of over 1000 trainees per year. Recruitment to take TRREE training has mostly been via word of mouth, through university course requirements and through presentations at conferences. Local partners have been crucial to the promotion of TRREE training. This has led to a snow-ball effect. To increase uptake as well as to provide additional incentives for participants, TRREE is seeking to increase its recognition as a credit awarding training programme.

The website serves as the platform for the training programme and for communications. Plans in the near future involve transforming the informal “What’s New” section of the website into a more formal Newsletter communication tool aimed at participants, partners and collaborating institutions. Technical support for the website and modules is continually needed. In keeping with the spirit of collaboration, partnership and capacity building, there are plans to involve an information technology expert from a low-income country. Given that the Moodle platform has been customised to meet the needs of TRREE, the technical teams in the South and in the North will work closely together.

TRREE has, thus far, accomplished its work using a network of dedicated part-time consultants and staff. To achieve all of its ambitious new objectives, more regular support is required.

³ E.g., Carel IJsselmuiden and Stephen Matlin “Why Health Research?”; Ghaffar, Abdul; IJsselmuiden, Carel; Zicker, Fabio, “Changing Mindsets: Research capacity strengthening in low- and middle-income countries” 2008<<http://www.cohred.org/publications/cohred-publications/joint-publications/why-health-research> Ateudjieu et al.



Funding

TRREE has operated using grants that have enabled it to develop a rigorous and innovative learning programme on ethics and regulation. TRREE has consistently met the targets outlined in grant applications and, on many occasions, it has surpassed these and provided additional outputs not contained in the initial proposal. TRREE is determined to work effectively and to spend the maximum amount of its funding on developing new learning and resource materials rather than on administration, management or overheads. Travel costs have been kept, for the most part, at a low-level by grafting TRREE meetings onto other events that bring ethics experts together. Nevertheless, a lack of guaranteed core funding and a commitment to ensuring that open access remains at the heart of the programme, mean that TRREE is continually seeking alternative donors for its activities.

Challenges and risks

While TRREE is a relatively young partnership, its members come from a number of different disciplinary backgrounds and possess a great deal of experience. There are, nevertheless, a number of challenges ahead. These include guaranteeing that the core functions of TRREE can be maintained while simultaneously allowing new objectives to be pursued:

- Ensuring continued support for TRREE infrastructure and the recurrent costs of running a website along with its further development
- Maintaining e-resources that are accessible and regularly updated
- Consolidating the structure of TRREE, which is currently a consortium of experts under the auspices of the University of Neuchâtel.

