

# Training Needs Of Research Ethics Committee Members In Cameroon Regarding Research Participant Protection

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## Research Article

**Keywords:** Training needs, Research ethics committees' member, Participants' protection, Cameroon.

**Posted Date:** April 12th, 2021

**DOI:** <https://doi.org/10.21203/rs.3.rs-397098/v1>

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# Abstract

**Background** The capacity of the Research Ethic Committee (REC) members to review research protocol is one of the frequently raised problems. The purpose of this study was to assess training needs of members of research ethics committee in Cameroon regarding research participant protection.

**Methods** It was a cross-sectional descriptive study conducted in all the regions of Cameroon during the last quarter of the year 2020, assessing training needs of REC members' ethical evaluation of health research protocols. Data were collected from all eligible REC members by trained and supervised surveyors using a well designed questionnaire integrated in smartphones via ODK-collect. The data were analyzed by estimating proportions with 95% Confidence Interval using the EpiInfo software version 7.2.2.6.

**Findings** Out of the 79 ethics committee members reached, 64 (81.01%) accepted to participate including 28 (43.75) female. The result showed that, 21 (32.81%) of ethics committee members were not trained in research ethics evaluation including 68.75% not exposed to training on research participants protection during clinical trials. A given fraction of respondent was not aware of the existence of key national regulations (25%) and international guidelines like the Helsinki Declaration (32.81%). Participants identified and ranked their priorities in terms of training needs in research participant's protection, national text regulating research in Cameroon, evaluations' procedures of research protocol, organization of research in Cameroon, and protection of participants in research involving the transfer of biological materials. The workshop and e-learning courses were seen to be the main accessible source of training.

**Conclusion** Not all ethics committee members received training on ethical principles regarding research ethics review, review process and monitoring of research protocols, and on ethical issues associated to each study design including clinical trials. These gaps and the needs perceived by participants are to be taken into account when setting up a training program for RECs members on ethical evaluation in Cameroon.

## Background

Health research activities involving human subjects are being increasingly performed in developing countries(1). During the implementation of research projects, the rights of participants have in some case be intentionally or unintentionally violated by researchers for a variety of reasons including financial and/or career takes, exaggerated enthusiasm, influences from various sources and even ignorance(2–4). Members of Research Ethics Committee (REC) through Research Ethics Committees, review and monitor the implementation of research protocols involving human subjects to ensure that they comply with internationally and locally recognized ethical standards(5–8). Studies conducted in African countries in recent years have revealed that many of these members are limited in playing their role because they are not properly trained(9). This may compromise the quality of ethics review by ethics committees, limiting their ability to play their role in protecting research participants.

The first ethics committee in charge of reviewing health research protocols was set up in Cameroon in 1987, but the regulatory text organizing the ethics review system was signed by the Minister of Public Health in 2012 (10, 11). The training for REC members was assessed and used to develop an online and free access course available for them in 2009(12).

Due to the fact that a certain number of ethics committees have been set up in Cameroon without benefiting from a standard and evaluated training program and due to the fact that the regulations and guidelines in terms of ethical review have evolved both at the national and international levels without necessarily being taken into account in the different training offers, it has become necessary to take stock of the training needs of the members of health research ethics committees(6, 8, 13).

In this light, the purpose of this study was to assess training needs of research ethics committee members in Cameroon regarding research participant protection during ethical evaluation of research projects. This was based on; evaluating the knowledge and the use of Human Health Research ethical guidelines; previous and perceived training needs of the REC members on ethical evaluation of research projects.

## **Methods**

### **Study design**

It was a cross-sectional descriptive study conducted in the last quarter of the year 2020 targeting all members of Research Ethic Committee in Cameroon. The data were collected by trained and supervised surveyors using a well-designed questionnaire administered face to face, to members of Research Ethics Committees in Cameroon. This questionnaire were designed from the Kobo Toolbox Platform and deployed in smartphones via the ODK-collect software. The data were analyzed by estimating the priority training needs perceived by research ethics committees' members, the training channels preferred by research ethics Committee members and their knowledge and used of the regulatory texts/guideline on research ethics.

### **Study Site and period**

This study was carried out in the Research Ethics Committees officially existing in Cameroon and in those located in the different Research institutes, Training institutes in Biomedical Sciences and Health institutions visited during the survey. Data were collected in the last quarter of 2020.

### **Study population**

All members of National, Regional and Institutional Ethics Committees involved in research ethics evaluation in Cameroon were eligible to participate in the study. Those who refused to participate and those absent during the period of the study were excluded from the study.

### **Data collection tools**

Data were collected using questionnaires designed based on a pre-existing questionnaire(9, 14). It was design in both official languages of Cameroon on Kobo Toolbox interface and deployed in smartphones via the ODK-collect software. The used questionnaire was pre-tested on former research ethics committees' members and comments integrated before deploying the final version in smartphones. The main variables were collected on socio-demographic characteristics, knowledge of ethical considerations in a research protocol, knowledge of research ethics regulations/guidelines; previous training received in research ethics; and priority training needs perceived by REC members

### **Data collection procedures**

The data were collected face-to-face by trained and supervised interviewers. Four teams, each consisting of three interviewers and one supervisor were assigned to the 10 regions of Cameroon. Heads of REC were met to present objectives and targets of the survey and also to obtain their permission to collect data from their REC members. Before questionnaire administration, the interviewers submitted all relevant information about the study to the participant in simple and understandable language. Each consenting participant was invited to sign the informed consent form.

### **Data management**

Data quality control was done at two levels. All data were double checked for consistency and completeness; firstly by the field supervisors before its transmission to the cloud server and secondly by the data manager at the central level on daily bases. Any discrepancies observed at each of these levels were corrected as soon as possible. Prior to analysis, data were screened for accuracy and a reliable system of coding data was established during data analysis. .

### **Data analysis**

The data were keyed and cleaned with Microsoft Excel 2010 software. It was analyzed using EpiInfo version 7.2.2.6 software. Descriptive data analysis was done on all variables by ranking and estimating proportions. The values of the different indicators were estimated with a 95% confidence interval.

The Research Ethics Committee members were asked to identify in order of importance, their first four priority themes on which they would like to be trained. At the end of the data collection, the trainings topics were coded and a list of 16 trainings was drawn up. Scores were then assigned to the different trainings topics as follows: 4 points if the REC member has chosen the training topic as his or her first choice, 3 points for the second choice, 2 points for the third choice and 1 point for the fourth choice. The sum of points attributed to each training contents was estimated per trainings content. Training contents were ranked in descending order from highest average to sum and the first 4 were selected as the training priority.

### **Ethical consideration**

All REC members were informed of the survey through an explicit information notice that has been translated into the two official languages spoken in Cameroon and their written consent was obtained

prior to the interview. The respondents' data were coded and accessible only by the data manager staff and investigators' team. The ethical approval was obtained from the Cameroon National Ethics Committee for Human Health Research (N°2020/10/1305/CE/CNERSH/SP).

## Results

### 1.Characteristics of committee members

Out of the 79 ethics committee members reached, 64 (81.01%) accepted to participate in the study. Table 1 shows the distribution of participants per research ethic Committees type, sex, basic training, method of appointing a member and status of participants within the REC. Forty-four (68.75%) of the ethic committee members were from institutional ethic committee. The main primary disciplines of respondents were; medicine (37.50%) and social sciences (12.50%). The majority of participants were appointed by their institution to be a member of the ethic committee.

Table 1  
Characteristics of research ethics committee members

<b>Characteristics</b>	<b>frequency</b>	<b>Percentage (%)</b>
Proportion of members per research ethics committee type		
Institutional	44	68.75
Regional	14	21.88
National	6	9.38
<b>Sex</b>		
Male	36	56.25
Female	28	43.75
Respondent's basic training		
Medicine	24	37.5
Other	18	28.13
Social Sciences	8	12.5
Basic Sciences	5	7.81
Pharmacy	4	6.25
Public Health	3	4.69
Law	2	3.13
Method of appointing a member		
Designated by my institution	49	76.56
Coaptation	10	15.63
Call for tenders	4	6.25
Other	1	1.56

## 2. Previous training received by members

During the survey 43 (67.19%) of ethics committee members received training in human health research ethics. The three main topics of training received by the ethic committee members were international text regulating research (54.69%), fundamental of research ethics (51.56%) and procedures for evaluating research protocol (43.75 %). The various themes covered by this training are presented in Table 2 below.

Table 2  
Different themes covered by the training received by the ethic committee members

Aspects covered by the training	Frequency (N = 64)	Percentage (%)
International texts regulating research	35	54.69
Fundamentals of Research Ethics	33	51.56
Procedures for evaluating research protocols	28	43.75
Role of the Investigator in Participant Protection	26	40.63
Evaluation of the research participant's free and informed consent	24	35.50
Evaluation of the respect of the rights of the research participant	23	35.94
Procedures for the submission of research protocols	23	35.94
Protection of research participants during field trials	22	34.38
National texts regulating research in Cameroon	21	32.28
Protection of Research Participants in Clinical Trials	20	31.25
Good Clinical Practices	19	29.69
Protection of participants in research involving the transfer of biological materials	18	28.13
Procedures for monitoring the implementation of research protocols	16	25.00
Assessing community involvement in protecting research participants	15	23.44
Protection of research participants in vaccine trials	15	23.44
Other	3	4.69

### 3. Members' knowledge on some principles of research ethics

Table 3 shows the knowledge of REC members on some aspects covered by scientific validity and participant's informed consent. The main aspect concerning the scientific validity known by the REC members was "the usefulness of the results in the context of the country's health problem". "Guarantee the independence of the participant" was known for the majority of the members (89.06 %) as aspects of participant's informed consent.

Table 3  
Members' knowledge on some principles of research ethics

Member's knowledge	Frequency (N = 64)	Percentage (%)
Aspects covered by scientific validity		
Usefulness of the results in the context of the country's health problems	51	79.69
Research objectives respected during the implementation of the project	47	73.44
The study must take into account the social, political, cultural and religious environment in which it is conducted	44	68.75
Other	9	14.06
Aspects covered by the participant's informed consent		
Guarantee the independence of the participant	57	89.06
Disclose information in culturally and linguistically appropriate formats	38	59.38
Involve the community in establishing participant recruitment procedures	27	42.19
Other	8	12.50

#### 4. Knowledge and used of human health research ethics guidelines and regulatory texts

Table 4 below shows the different texts/guidelines known, read and used by the REC members. The most known, read and used were declaration of Helsinki, Order establishing Research Ethics committee and decision on obtaining Administrative Research Authorizations (ARA).

Table 4  
 knowledge and used of human health research ethics guidelines and regulatory texts by ethic committee members (N = 64).

Guidelines/regulatory texts	Known		Read		Used	
	freq	Percentage	freq	percentage	freq	percentage
Regulation establishing Research Ethics committee in Cameroon	48	75,00	40	62.5	37	57.81
Declaration of Helsinki	43	67.19	39	60.94	31	48.44
Nuremberg Code	38	59.38	30	46.88	19	29.69
Decision on obtaining Administrative Research Authorizations (ARA)	37	57,81 "	31	48.44	28	43.75
ICH/Good Clinical Practice	30	46,88	22	34.38	20	31.25
Belmont Report	20	31.25	14	21.88	10	15.63
CIOMS guideline	18	28.13	14	21.88	14	21.88

## 5. Perceived Training Needs of Research Ethics Committee Members

All the REC members surveyed responded for need to be trained on research ethics. The ranking of scores attributed to the perceived importance and priority of training topics are presented in Table 5. This ranking shows that among training topics identified as important, the top four were: procedures for monitoring the implementation of research protocols, national text regulating research in Cameroon, evaluations' procedures of research protocol and organization of research in Cameroon.

Table 5

Ranking according to sums of scores associated to respondents' perception of priority of proposed training topics on research ethics

<b>Training topics</b>	<b>Sums of Scores</b>	<b>Ranking by Decreasing order Of priority</b>
Procedures for monitoring the implementation of research protocols	42	1
National text regulating research in Cameroon	34	2
Evaluations' procedures of research protocol	32	3
Organization of research in Cameroon	28	4
Protection of participants in research involving the transfer of biological materials	24	5
Protection of research participants during field trials	18	6
Procedure for the submission of research protocols	14	7
Roles of the Investigator in Protecting Research Participants	14	8
Protection of Research Participants in Vaccine Trials	08	9
Involvement of the community in the implementation of research projects	12	10
Protection of vulnerable persons in the implementation of research projects	08	11
Bioethics	08	12
How to sanction in case of plagiarism	8	13
Ethics of online research	8	14
Legal aspects of human health research	8	15
Evaluation of Institutional Ethics Committees	08	16
General Ethics	6	17
National and international texts regulating research	06	18
Confidentiality in research projects	06	19
Safety of therapeutic products in clinical trials	04	20
Conflicts of interest	02	21
Consequences of non-compliance with research ethics standards	02	22

## 6. Accessible sources of training for research ethics committee(REC) members

The accessible sources of training for REC members are presented in Fig. 1 below. The workshop and e-learning courses were seen to be the main accessible source of training.

## Discussion

The purpose of this study was to identify the training needs in research ethics of REC members in Cameroon. The results show that, twenty one (32.81%) of ethics committee members were not trained in research ethics evaluation including 68.75% not exposed to training on research participants protection during clinical trials. A given fraction of respondent was not aware of the existence of key national regulations (25%) and international guidelines like the Helsinki Declaration (32.81%). Participants identified and ranked their priorities in terms of training needs perceived in research participant's protection.

International standard on research ethics review propose to train periodically, and each new joining member of research ethics committee involved in review of research protocols involving human participants on ethical aspects of health related research, ethical considerations apply to different types of health research, and on how the REC conduct its ethics review(15).In the present study, the distribution of previous participants to training in health research ethics varied according to topic with 43.75% and 31.25% of responding RECs members claiming to have received training in the ethics review process and in ethical considerations involving clinical trials. This heterogeneity of access to training in human health research ethics has been described by studies conducted in several contexts at relatively different times, highlighting the lack of rigor or follow-up in the standardization of training curriculum for ethics committee members(9, 16, 17). This situation may compromise the quality of ethics review in any context and limit the protection of research participants and should be taken into account in the development of national ethics regulations. Pending such regulation, ethics committees should identify gaps in training coverage for their members and encourage them to be trained using the open source training materials that currently exist(12, 18, 19).

International guidelines disseminate ethical principles that are contextually adjusted by national regulations to ensure the best possible protection of participants in human health research(6, 8, 11, 15, 20).Those that apply to each context and type of protocol should be accessible and used by ethics committee members to guide the ethical review and monitoring of human health research protocols. But as described in a number of studies, this is not always the case(14, 21). The present study describes as in previous studies, a diversity of knowledge, reading and use of international guidelines and national regulations for the protection of research participants among research ethics committee members. It also reveals that a certain fraction of the members of the Ethics Committees are not aware of the national ethics regulations and a lesser fraction have read and used them. This situation questions the monitoring of the functioning of ethics committees by the institutions in charge and the quality of ethical evaluation.

The expected benefit of a health intervention depends on the beneficiary's perception of the proposed solutions(22). For this reason, the present study asks to prioritize their needs in research ethics training. The ranking of the perceived training needs shows that among training topics identified as selected priority, the top five were: procedures for monitoring the implementation of research protocols, existing national text regulating research in Cameroon, evaluations' procedures of research protocol by REC members, organization of research in Cameroon, and protection of participants in research involving the transfer of biological materials. These themes relatively differ from the priority themes identified by REC members a decade earlier(9).No data was collected that can guide the understanding of the difference but it may be related to the actual situation of participants in terms of training received or variation of type of protocol submitted to their ethics committee for evaluation. These results are to be taken into account when planning the training of ethics committee members.

Despite the fact that nearly one-fifth of the participants in this study did not participate in the study, we believe that its results can be used to plan for and address the perceived needs of Cameroonian ethics committee members for research participant protection, because it covered both legally constituted and non-legally constituted ethics committees and the different categories of exiting ethics committees.

## **Conclusion**

About one-third of responding RECs members were not trained in research ethics evaluation. Coverage of participants in terms of training received varied per training topic with 68.75% not exposed to training on research participants protection during clinical trials. The three-fourth of respondents was aware of both the existence of key national regulations and international guidelines such as the Helsinki Declaration respectively. Participants identified and ranked their priorities in terms of training needs in research participants' protection.

We recommend standardizing the content of the training in research ethics evaluation of RECs members and include in the development of national ethics regulations. And also the obligations to receive this training before being involved in research ethics evaluation. Regulatory authorities should identify gaps in training coverage for their members and encourage them to be trained using the open source training materials that currently exist. Minimum regulatory documents and international guidelines guiding research ethics evaluation have to be provided to all RECs members, to take into account perceived training needs of RECs members when planning the training of ethics committee members.

## **Abbreviations**

RECs: Research Ethic Committees

BREEDSAFCA: Strengthening the regulatory framework to upgrade ethical review of clinical research and drugs safety monitoring in Cameroon

SOP: Standard Operating Procedures

# Declarations

## Ethics approval and consent to participate

The ethical approval was obtained from the Cameroon National Ethics Committee for Human Health Research (*N°2020/10/1305/CE/CNERSH/SP*). All REC members were informed of the survey through an explicit information notice that has been translated into the two official languages spoken in Cameroon and their written consent was obtained prior to the interview. Data that could reveal the identity of participants were coded.

All methods were carried out in accordance with relevant guidelines and regulations.

## Consent for publication

Not applicable.

## Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author for reasonable requests.

## Competing interests

The authors declare that they have no competing interests.

## Funding

This project was funded by EDCTP (European and Developing Countries clinical Trial Partnership).

## Authors' contributions

IMKD coordinated field activities and contributed to the writing of the manuscript. JA conceived and designed the project supervised field activities and contributed to the writing of the manuscript. FFK led data management and data analysis. RKD assisted data analysis and contributed to the writing of the manuscript. PNN, FN, FKL, CEB, KHTN, APG and AZKB contributed to the writing of the manuscript. Manuscript revision for intellectual content: PNN, IMKD, AJ, FFKD. All authors approved the final version of the manuscript

## Acknowledgements

We thank the EDCTP (European and Developing Countries clinical Trial Partnership) for funding of this research project.

We equally express more gratitude to the following departments of the Cameroon Ministry of public health for their contribution in validating the protocol of the present study:

- The Division of Operational Health Research
- The Department of Pharmacy, drugs and laboratory
- The Cameroon National Ethics Review Committee for Human Health Research.

We also thank Yakum Marting, for his contribution in developing the application of the project that funded the development of the present article and all Cameroonian, health training and research institutions that permitted data collection from their researchers.

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## Figures

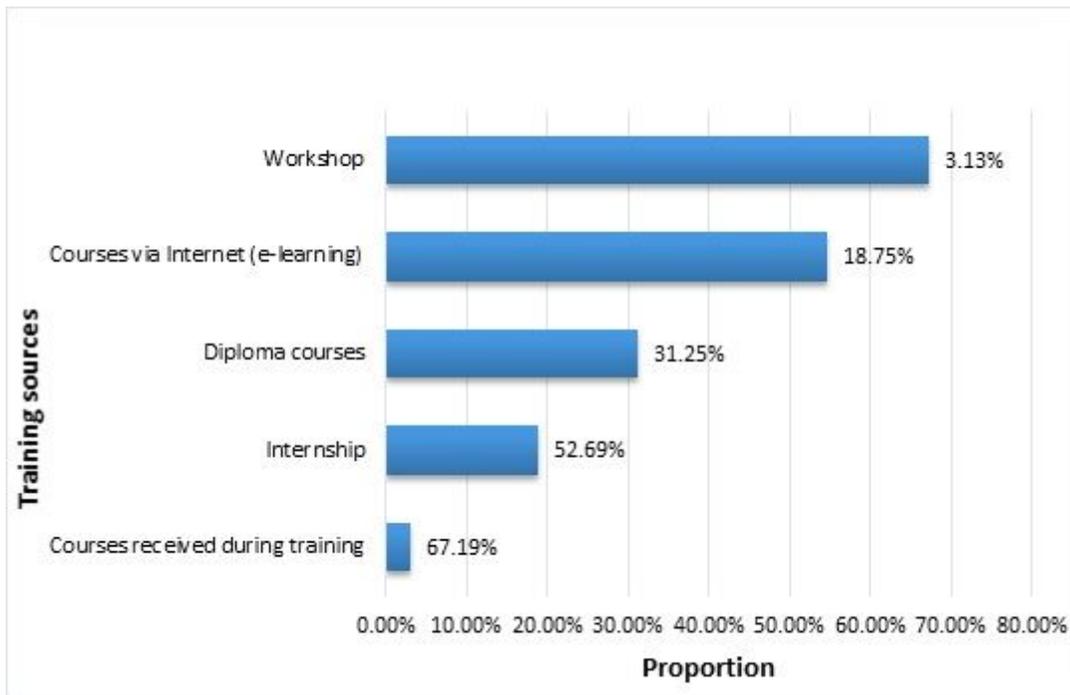


Figure 1

Accessible sources of training for the research ethics committee members