

# **Newsletter 2**

June 2020

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**Together** 

In June 2020, there were nearly 470,000 deaths worldwide due to COVID-19 disease, an emerging virus that we did not know last fall. Affecting the whole world, this virus has forced us to change the framework of our daily lives, individually and collectively. The Sars-Cov 2 has also affected the field of research, care and scientific expertise.

Again, Research Ethics Committees are placed in a fundamental role of regulation, vigilance, and maintenance of the rigorous rules that support the ethical evaluation of research protocols. Again, during an epidemic, their role is to guarantee the protection of the people who participate in research. They define the acceptability of the research which is first built within the affected communities but also for these communities. Again, they point out that, whatever the urgency, research cannot be conducted without a transparent, rigorous and fair assessment.

The ethics committees that are members of the AFREENET consortium have been mobilized since the start of the epidemic, and have implemented accelerated evaluation procedures to support research work.

REPUBLIQUE DE GUINEE

TRAVAIL – JUSTICE – SOLIDARITE

COMITE NATIONAL D'ETHIQUE POUR LA RECHERCHE EN SANTE

Conakry, le 26 Mars 2020

N°:036/CNERS/20

COMMUNIQUE SUR LE COVID-19

A l'Intention de la communauté scientifique nationale et internationale

Le Comité National d'Ethique pour le Recherche en Santé (CNERS) informe l'ensemble de la communauté scientifique nationale et internationale qu'il suit avec une attention particulière l'évolution de la situation de la pandémie du Coronavirus (COVID-19) en Guinée et dans le monde.

Le CNERS rassure les chercheurs Guinéens et étrangers qu'il continuera à

Tirant les leçons de l'expérience de l'épidémie de la maladie à virus Ebola, le CNERS décide d'activer la procédure de revue accélérée (y compris la revue électronique) des protocoles afin de faciliter la mise en œuvre des initiatives de recherche en Guinée.

Cette procédure de revue accélérée n'exclue pas l'application rigoureuse des principes éthiques fondamentaux qui visent notamment la protection des participants aux études.

Le CNERS félicite les chercheurs et les acteurs de la lutte contre la pandémie de COVID19 et invite les populations à observer les mesures de prévention en vigueur.





"In Guinea, the COVID-19 pandemic has awakened the painful memories of the Ebola epidemic, which we went through in 2014-2016, and during which our health systems were totally disrupted. COVID-19 plunges us today into the same situation with many more unknowns in the scientific, economic, socio-cultural and ethical fields.

For the CNERS of Guinea, the Ebola epidemic was a threat but also an opportunity that allowed us to strengthen our capacities as an ethics committee and to set up an accelerated procedure for reviewing protocols. This procedure allowed us to cope with the large number of protocols that needed to be evaluated urgently. We have therefore decided to reactivate it to face with this new pandemic (see press release). I am convinced that this pandemic will lead us to reflect together on many issues that will require concerted action and the mutual strengthening of our capacities."

Professor Oumou BAH SOW, President of the CNERS of Guinea

The AFREENET project continues its capacity-building activities for the Ethics Committees, particularly in the area of preparation for health crises. This newsletter retraces the actions carried out during the previous year.

Contact: afreenet@pasteur.fr

## A year under the sign of Formation

The 2nd year of the AFREENET project was rich in lessons. A series of training courses created specifically for Ethics Committees took place throughout the year in order to strengthen the capacities of the three Ethics Committees' members. All training took place in French, and alternated between theoretical sessions and practical exercises.



#### Training 1 - "The evaluation of research protocols by National Ethics Committees: Global approach and in-depth questions"

■ Duration: 4 days

☐ Location : Benin, Guinea, Ivory Coast

☐ Trainers: Virginie Pirard and Samira Ouchhi, Institut Pasteur

This training was organised within each committee, with the following objectives of:

- To distinguish the field of ethical evaluation from that of other types of evaluation (in particular moral or scientific), by specifying the key definitions of research ethics,, by screening the International Guidelines (Helsinki, CIOMS,...) and through practical exercises and case studies.
- \* To clarify the operating rules of the Committees which are in charge of evaluating the protocols, their role, composition, deliberation, as well as the framework necessary for a rigorous management of conflicts of interest.
- To put into practice the ethical evaluation, through case studies focused on the balance between benefits and risks, the protection of participants, and information and consent.

These training sessions were also a unique opportunity to address the community engagement' issue, and the specificities related to the information and consent of the population in each country, from the point of view of the Ethics Committees. It was also the opportunity to discuss several crucial ethical issues in relation to the development of genomic studies and "Big data".



**CNERS of BENIN** September 2018, Grand-Popo, Bénin



CNERS of GUINEA, Decembre 2018, Conakry, Guinea

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**CNESVS of IVORY COAST** November 2018, Abidjan, Ivory Coast



#### Training 2 - "Good clinical practices"

Duration: 3 days

Locations: Benin, Guinea, Ivory Coast

This three-day training was also organized in each of the three ethics committees involved in the AFREENET project. It focused on the drug cycle, the different phases of clinical trials, as well as the role of the different

- the investigator
- the regulatory authority.

Trainer: Marieme BA, Pharmalys stakeholders in a clinical trial: AFREENET - GUINEE independent ethics committees Marieme Ba 12-14 Juin 2019 promoter

A workshop organized at the end of the training permitted the committees to clarify certain articles of their operating procedures with regard to the training.



#### Training 3 - "Biobanking: ethical issues"

- Duration: 1 day
- Location: France
- Trainers: Jeanne-Hélène Di Donato, Elise Jacquier, Anne-Laure Morin, Louis

Pénali, Virginie Pirard, Marie-Noëlle UNGEHEUER

Research ethics committees are evaluating more and more protocols that include the storage and secondary use of human biological samples and data. This activity raises ethical issues such as the information and consent of donors, as well as the return of information to participants. This training addressed:

- the ethical framework for biobanking activities defined in international texts (Helsinki, Cioms, Taipei),
- the question of sharing and transferring samples within the international scientific community,
- good ethical practices for the management of samples and personal health data.
- participant information.

This training was illustrated with concrete examples of biobanks in Europe and Africa.



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#### Training 4 "Advocacy actions for Ethics Committees"

- ☐ Duration: 1.5 days☐ Location: France
- ☐ Trainer: Alexandra Phaëton

Research ethics committees play a key role in the implementation of ethical standards and regulation of health research at the national level. They are both in contact with research teams and health authorities. And they are able to identify needs in terms of research regulation, such as in the field of protection of personal data, and emerging topics in health research. This is why they may contribute to the improvement of the regulatory framework of research in their country.

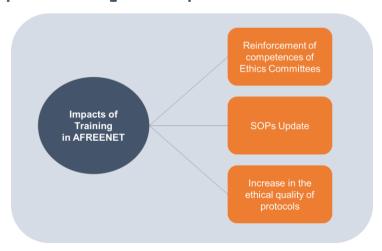
This training workshop included a theoretical component, on the fundamentals of advocacy practices, and a practical component on the implementation of a communication plan by each Ethics Committee, adapted to the local context.

## WORKSHOP AFREENET 2019 REGULATION & ADVOCACY

Plaidoyer pour l'amélioration du cadre de régulation de la recherche

Alexandra Phaëton Consultante indépendante Experte en plaidoyer professionnel

## Impact of training on the capacities of ethics committees



#### **AGENDA - Past events**

This year was also rich in exchanges. Very important subjects for Research Ethics Committees fueled discussions between the members, such as how to reinforce SOPs, how to prepare to health crises, and how to reinforce the legal framework of research.

### Second annual Workshop of the Consortium AFREENET (Conakry, Guinée)

Organized by the CNERS of Guinea, the Second annual workshop of the AFREENET project was held on March 26, 27 and 28, 2019 in Conakry, Guinea. This meeting launched the work of concertation between partners on the good practices to be followed in terms of Standard Operating Procedures (POS) as part of WP3.

The functioning of each ethics committee is detailed in SOPs, and differs from one committee to another, It may also changes over time. These SOPS are an element that structures the activities of ethics committees, from the appointment of committee members to the ethical evaluation of protocols. In addition to their operational role, they contribute to a transparent and fair operation from outside.



SOP

**STANDARD** 

**OPERATIONAL** 

**PROCEDURES** 

One of the challenges of these procedures remains their regular updating. The Conakry Workshop was the opportunity to set up, within the Consortium, an exchange forum to share the experience and good practices of each committee in this area. An exhaustive and systematic review of the procedures enabled the consortium to identify points of convergence, differences, but also actions for strengthening and potentially harmonizing their SOPs.

The work started during this workshop and will continue during the 3rd year of the project. It will lead to the updating and **strengthening of the SOPs** of the three ethics committees, as well as the harmonization of several aspects of the procedures.

## Workshop « Regulatory & Advocacy » (Paris, France)



Organized by the Institut Pasteur (Paris), coordinator of the AFREENET project, the "Regulatory and Advocacy" Workshop was held from November 18-21, 2019, in Paris, France, with the aim of exchanging on the experiences of each NEC regarding the regulatory framework for research in their country, and the impact of this framework on the ethical evaluation of research protocols.

A mapping of the regulations and the competent authorities for each country concerned, as well as a diagnosis of the areas to be reinforced, were at the heart of the subjects addressed by the participants.

This workshop was combined with a seminar aimed at strengthening the capacities of committees in the field of advocacy, and the development of an action plan.

Axes to be reinforced in priority according to the Ethics Committees:

- Protection of persons
- ❖ The legal environment of the Ethics Committees
- Benefit sharing



## **AFREENET CONSORTIUM**

AFREENET is a three year project involving 4 teams located in 4 countries, with the common aim to impulse a network of National Ethics Committees in West Africa. The project is coordinated by Institut Pasteur (France), and supports close collaboration between partners. Each partner is involved as leader of at least one activity, according its own expertise and experience. And all partners are invloved in all activities as contributors.



Institut Pasteur (France) Virginie PIRARD Samira OUCHHI Anne-Laure MORIN https://research.pasteur. fr/en/project/afreenet/

Comité National d'Ethique de la Vie et de la Santé de Côte d'Ivoire (CNESVS de Côte d'Ivoire) Dr Louis PENALI & Members

Mariam MAMA DJIMA Sibiri COULIBALY

http://www.comite-ethique.ci

Comité National d'Ethique de la Recherche et de la Santé de Guinée (CNERS de Guinée)

Prof Oumou BAH SOW & Members Prof Flore GANGBO & Members http://cners-guinee.org/

Comité National d'Ethique de la Recherche et de la Santé du Bénin (CNERS du Bénin)

http://www.ethique-sante.org/





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