The experience of Senegal in conducting ethical research

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History of CNRS

- **In 1990's ad hoc Committees, Institutional Committees** (University, AIDS Program,….)
  No diversity in member composition

- **1995 Ethic Committee of Pasteur Institute**
  Members from several institutions including MoH, Mo Family and Social Dev, Fac Medicine and Pharmacy, University

- **2001 Official creation by a departmental (Health Ministry) order of two national advisory bodies** for evaluation of projects on Health Research
  - **Scientific Committee**
  - **Ethic Committee**

History of CNRS 2

- **2004 Modification of the functioning by a departmental order establishing the Senegalese National Health Research Council (CNRS) regrouping the two bodies**

  Evaluation of both scientific and ethics aspects of projects

- **2007-2008 : Following the evaluation make by a working group of the issues raised by the practice :**

  - Draft of a **specific bill on Health Research Ethics** to have legal framework

  - Draft of a **presidential decree** for modification of CNRS status and its legal recognition as an independent body with institutional funding by the governmen**t**

Why all these successive changes?

These different modifications are the translations of issues raised by daily practice and the attempt to find better/adapted solutions:

- Avoiding of conflicts of interest, need of transparency, adequate scientific expertise, legal status, recognition by researchers, need of professional and social diversity : lead to the prior establishment of two structures with different missions (Scientific and ethic review)

- Low efficiency, time consuming of two review process, limited means, limited human resources : regrouping of the two committees

- Absence of devoted budget and personnel : attempt to change the present legal status to another for more autonomy and financial independence

- Absence of specific health research law/regulation leads to decisions by some people (CNRS) on sensitive matters without national guidelines : attempt to propose a draft of health research national law

Missions of CNRS

The Senegalese National Health Research Council is the national consultative body in charge of:

- advising the Minister of Health on research matters;
- ensuring the scientific quality of research projects;
- ensuring the respect of ethical and legal principles pertaining to health research;
- leading and developing reflection on the ethical and legal issues raised by the practice of health research;
- sensitising research personnel to the importance of ethics so as to guarantee a proper balance between intellectual freedom and duty to society.

Challenges raised by the diversity of CNRS missions

- Not only an National Ethic Committee in charge of the ethic review of research projects

- But at the same time, having different roles to play

  - role in capacity building in ethics among the different stakeholders while building its own expertise,

  - role in sensitization, communication on ethics matters

  - role in establishing the foundation of national legal framework while processing

  - role of monitoring the respect of ethics principles on the ground

Composition of CNRS

- Representatives Ministry of Health
- Representatives of Health Research Institutes : Pasteur Institute of Dakar (IPD), Institute for Research and Development (IRD), Institute for Health and Development
- Representatives of Faculty of Medicine and Faculty of Law
- Representatives of Health Professional Organizations
- Representatives of Civil Society
- Representative of patients associations
- Representatives of Christian and Muslim religions
- Experts on Ethics and Research (epidemiologist, statistician, Pharmacologist)

Challenges raised by the diversity of CNRS members

- Scientific evaluation could be difficult to follow by non-scientific members conducting to feeling of being of no use, disinterest, progressive withdraw
- Level of awareness of ethics matters/principles insufficient with the same consequences
- Overworked people and as a consequence a lack of assiduity
- No or very low compensation (while the review process of projects and specially clinical trial projects, is really time consuming) with the same consequence
- Turn over of the members with a need to have regular training sessions

CNRS functioning

- Ordinary sessions every two months
- But sessions tend to be monthly (due to increasing number of protocols to review)
- Quorum of 2/3 needed
- New meeting if quorum not reached the 1st time
- Research of consensus for decisions
- If consensus not reached, voting (majority of 2/3)
- External experts for scientific aspects of specific areas when the competence is not present in members

Texts utilized for projects review

- National laws (Health, Civil Code, Family Code, Penal Code,…)
- National texts organizing Health and Health professions
- Legal text from Ministry of Health creating the Committee and indicating its functioning modalities
- Internal regulations (SOP,)
- Information document to researchers for project
- Document of standard procedure for protocols review
- Internationals texts

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Projects Review Process

- Scientific review
  - Scientific Background
  - National Health Research priorities
  - Methodology
  - Feasibility in our country
- Ethic aspects
  - Evaluation of risks versus benefices
  - Confidentiality,
  - Process of inform consent and review of documents and forms
  - Medical cares
- Practical aspects :
  - Budget, insurance,
  - Process of report of SAE
  - Process of report of results to communities, to authorities

Means for CNRS functioning

- Coordination and daily administration of CNRS is assured by the Department of Research and Training of the MoH.

  But at present no specific funding exits nor dedicated personnel. So the coordinator and the other personnel that give an help to CNRS activities can only devote part of their time while being overworked by other business

- Funds from International organisations that are partners for development on specific activities (training workshops, conferences, …

- Fees for submission
  - 250,000 FCFA (500 $) for Institutions
  - 100,000 FCFA (200 $) for independent researchers
  - Free for students

CNRS activities

- Projects Review (approx 40 – 50 per year)
- Workshops for conception and validation of working documents
- Workshop for writing draft of legal texts on Ethics of Health Research, Reorganisation of Committee
- Organization of the 1st Meeting on Bioethics for West and Central Africa (June 2005)

  Thema : What Ethics for Research in Africa?
- Participation in the organization of the2nd and 3rd meetings on Bioethics for West and Central Africa (Yaounde, Cameroun, 2006 and Lome, Togo, 2007)
- CNRS was also involved in the organization of the first french AMANET workshop for the training of members of national and institutional ethics committees

Details on reviewed projects

From 2000 to 2006

- 234 Protocols reviewed (327 in 2008)
- 44 Protocols approved at first exam (20%)
- 134 Proposed for re-exam after clarifications
- Others to be resubmitted or rejected at first exam
- 1 month for total process of a project accepted at the first review but more if the project has to be resubmitted.

  Can be several months for some kind of research clinical with potential high risk (vaccine trials for ex) where extensive study is performed with external consultation

Issues raised throughout the time of CNRS functioning

Practical issues

- Funding for functional management
- Personnel for daily administration as there is no devoted personnel so not enough time to dedicate to CNRS activities/secretariat (percentage of time allocated through personal commitment)
- Infrastructures (independent office) and equipments
- Adequate training for all members
- Assiduity of members
- Limited critical mass of experts (possible conflicts of interests)
- Monitoring during research (Means for going to the field, motivation of members,….)

Issues raised throughout the time of CNRS functioning

Specific issues

- Obligation to give a decision on subjects that would need to have a general/national consensus and/or national guidelines
  - Level of standard of care that should be provided to research participants during a trial
  - what kind and what level of benefit should be provided, to whom (individuals, communities, health system,…) without leading to indue incentive
  - Conditions for the conservation (biobanks) and the transfer of biological products
- Obligation to give a decision while no sufficient information /expertise on the subject (those who are experts in the area are those involved in the project)
- Need to take into account as an ethical need the benefit sharing while negotiating with companies on these matters is beyond the mandate and the capacity of the committee

Challenges

- Finalisation and approbation of a specific bill on Research Ethics to have legal framework
- Finalisation and approbation of a decree for a legal status of CNRS as independent body with a secure functioning budget
- Creation of a database for electronic archiving
- Creation of a website dedicated to CNRS
- Sensitization of researcher, communities, policy makers to research ethics
- Workshop for developing reflection on specific ethic issues (conditions of informed consent, children assent, data collections, biobanks, notion of benefice vs indue incentive, translation of the notion of standard of care…)

In conclusion

All the challenge of CNRS can be summarize as

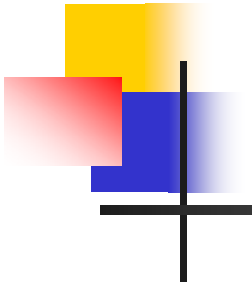
Working while building

Working efficiently for an ethical conduct of research while building the foundation for a good work (means, legal framework,..)

Working on ethics while developing awareness of policy makers as well as civil societies and communities on ethic challenges

Working while building your own capacities on ethics

BUT with the commitment of our group really engaged in the development of ethics and the help of partners, we are progressing in all these matters and building step by step the ethics edifice



THANK YOU