Research Ethics Committees in France

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"Ethics Review of Biomedical Research Project"

Council of Europe Moscow 28 11 2011

Declaration of Helsinki (1964)
WMA

I. Basic principles

Article 6

The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance.

Research Ethics Committees in France

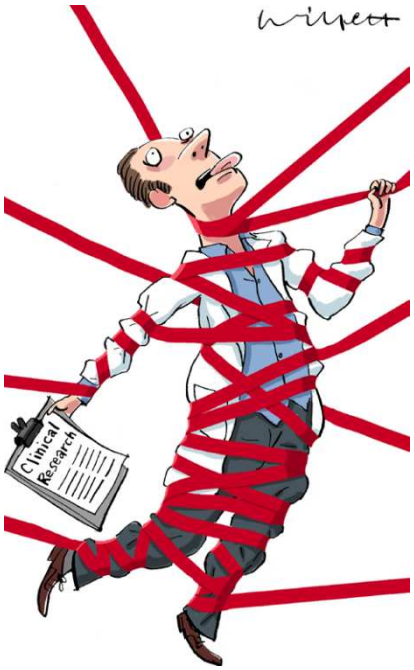
- **Before 1988, no external review of research protocols is necessary in France**
- **1988 : by law, clinical research needs ERC approval *(« comité consultatif de protection des personnes… »)* before it can starts**
- **only for *interventional* research (intervention: linked to or added by research, altering patients'care)**

Research Ethics Committees in France

- 2001 : European Union directive 2001/20
- 08-2004 transposition of the directive into French legislation :
  no major change
  - more control by CA
  - and by RECs : a favourable opinion is now mandatory
- 2008-12 : revision of the French law on clinical research ;
  enlargement the scope of the law (to non interventional research) ; new roles for RECs

Regulation—the real threat to clinical research

BMJ nov 2008



Regulation—the real threat to clinical research
Recent changes to research governance were intended to ensure that clinical trials are safe and effective. But Paul Stewart and colleagues argue that the regulatory burden is now obstructing high quality science

"…Increasing bureaucracy . . . is now the biggest single threat to the UK clinical research base…"

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Missions

- **Scope : the REC reviews all interventional research, but not observational (Academic research, around 50 %)**
- **an intervention : linked to, or added by research, altering patients' care** : Distinction between research and treatment is crucial +++

- **REC does not review only drug research ;**
  it reviews also: surgery, radiotherapy, pathophysiology, medical devices…

- **a debate as to the scientific evaluation of protocols ? Should it be done by RECs ?**

- **a positive answer is necessary to obtain before any trial starts**

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Missions

- Evaluation of:
  - global design of the trial: rationale, methodology, design,
  - qualification : research on persons ? data? biological samples ?
    If clinical research (: on persons) : interventional or not, drug research, phases 1, 2, 3…, minimal risk
  - risk/benefit balance
  - protection of confidentiality
  - qualification of investigators (in absence of certification)
  - information and consent forms
  - protection of vulnerable persons

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Protection of vulnerable persons

- children : consent provided by the two parents
- emergency research : waiver of consent initially ; then asked when the person regains consciousness
- (transient) incompetence : consent asked to family members or a person previously designated by the person

- the way information is delivered and consent obtained is not controlled

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Monitoring

- **The REC has in France practically no role in the monitoring of trials**
- **monitoring of trials is done by the sponsor and the competent authority (national drug agency, AFSSAPS) , which is ≠ from the Netherlands, for instance**
- **transmission of adverse events ? What for?**

- **practically, missions of RECs and competent authority are rather well delineated**

Research Ethics Committees in France

Composition and functioning

- 14 members :
    - 7 scientific (MDs, nurses, …)
        including methodologist/statistician
    - 7 lay people (lawyers, patients advocacy groups…)
- designated by the regional authority, after proposition by different organisms (faculty of medicine, research organisms…)
- renewal every 4 years
- each committee elects its president

- the list of conflicts of interests of each committee member is public

Research Ethics Committees in France

- committees are located near of or inside university hospitals

- there are 40 committees for France, 11 for the Paris area, 3 for Lyon

- they meet once a month, or every 2 weeks

- substantial amendments are also submitted to RECs

- RECs have to give their advice within 35 days

- after a negative answer, investigators may appeal ; submission to another committee, designated by the Ministry of health

- if not, the refusal is final and the protocol cannot be submitted to another committee

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"Single advice" for multicenter trials

- since 1988 in France, only one REC is solicited, even in the case of multicenter trials

- this provision has been endorsed by the EU, and is now written in directive 2001/20

- but major member states, like Germany and the UK, have maintained the submission to local committees

  - advantage of single advice : more rapid

  - inconvenient : when examined centrally, advice on local investigators and feasibility of the trial (locally) may be weak?

Research Ethics Committees in France

Limitations

- French RECs review only a part of clinical research:

In particular, they do not review observational research +++

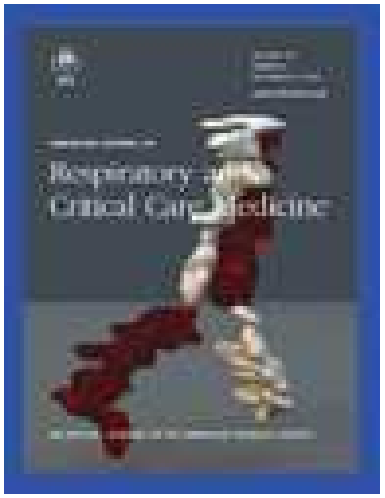
- French investigators have in the past experienced difficulties for publishing their results

Ethical review and publication

- Décembre 2008: Amer J Gastroenterology; X Roblin et al 103: 3115-22;
- mars 09: rétraction by authors
- mai 09: a letter to the editor de B Bonaz et al: « …this study should have been submitted to an ethics committee… »

La Recherche NI
Le problème de la publication

« The AJRCCM endorses the recommendations concerning human research that are contained in the Declaration of Helsinki. The Editors reserve the right to reject any manuscript containing studies that do not conform to these recommendations. All manuscripts reporting human research must contain a statement in the text that the institutional review board for human studies approved the protocols and written consent was obtained from the subjects or their surrogates if required by the institutional review board. »



AMERICAN JOURNAL OF
Respiratory and
Critical Care Medicine

Editorials

Do All Types of Human Research Need Ethics Committee Approval?

F Lemaire 2006; 174: 363

Research Ethics Committees in France

Limitations

- overlap with the Committee competent for data protection (CNIL) and the ministry of research for biobanks

- RECs are largely inhomogeneous nationwide ; law made them “independent”; but some of them do not apply proper legislation.

Research Ethics Committees in France

A new revision of the French legislation ?

A project of law is currently examined by the Parliament :

- a national Commission for improving coordination between committees

- obligation to submit observational research to RECs

- improvement of provisions concerning minimal risk research : the concept of “risk- adjusted” categories of research

- clarification of provisions concerning biobanks and data protection