Doing research concerning human health care in Africa

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Problem

- History proves ethic's committee being required.
- International Journal does not accept paper without clearing by ethic's committee.
- Unfortunately John Le Carré did not write "The constant Gardener" without information.

1. Meningitis antibiotic problem in Africa
2. HIV trials in South Africa.

Regulation

- All projects have to be cleared in country of origin (e.g. Belgium) following universal rules Helsinki etc

- And

- Cleared by committee in the African country . Conforming to local rules ,

Basic Principles Medical Ethics

- Autonomy.
- Beneficence.
- Non maleficence.
- Justice.

- Supplementary Problems:
- How free choice if no facilities?
- How do we respect follow up after experiment?

Regulations and Laws concerning human medical experiments

- Nürenberg Code 1947
- Helsinki Declaration 1964, 1975, 1983, 1996,2000,2008,2013
- Good Clinical Practice Rules EE C 1990., 2002,2006(Ema)
- International Conference on Harmonisation of GCP 1996
- GCP regulation: Europa.eu.int/eur-lex/com/dat/1999/eu_599 PC0193.htm
- Directive 2001/20/EG of the European Parliament and the Council of ministers of 4 april 2004
- « Wet Experimenten op de menselijke persoon » 7 mei 2004 BS p 39516 date 18.05.2004, additions and precisions
- Deontologic regulation by the national Council of Physicians .
- « Embryowet » and « Wet op weefsels ».
- Clinical Trial Regulation EU NR136/2014
- « Wet betreffende klinische proeven van geneesmiddelen» 7 May 2017 BS 22 May 2017 p 58619

Belgian law 7 May 2004
'Law about experiments on the human person'

- All research involving humans so not only "clinical trial", also medical experiments not using drugs (reserach with medical devices, surgical research, kine research, speech therapy , nursing , medical sociology, health economics, food research etc.)
- Since circular letter exclusion of retrospective studies (EC still needed by medical ethics and Helsinki but no insurance needed)
- Also excluded research on human material, corpses and human embryo in vitro; Absolute need of ethical approval but covered by other more strict law!!
- Insurance no–fault obligatory, not covered by standard insurance,

Supplementary legal prescriptions I

- *"Wet van 8 december 1992 voor de bescherming van de persoonlijke levenssfeer ten opzichte van de verwerking van persoonsgegevens"* Belgian privacy Law
- European Directive 95/46/EG and Law 11 December 1998.
- General Data Protection Regulation (de 'GDPR') EU 2016/679 coming in action on 25 May 2018
- ***"Wet** inzake het verkrijgen en het gebruik van menselijk **lichaamsmateriaal** met het oog op de geneeskundige toepassing op de mens of het wetenschappelijk onderzoek*" 19 Dec 2008, Human Tissue Law

Supplementary legal Prescriptions II

- "*Wet betreffende onderzoek op embryo's in vitro*" 11 May 2003 Embryo research law.
- "*Wet van 7 mei 2017 betreffende klinische proeven met geneesmiddelen voor menselijk gebruik*" New Belgian Clinical trial law B.S. 22 May 2017
- *KB van 9 oktober 2017 tot uitvoering van de wet van 7 mei 2017*, Royal Decree concerning the execution of the law of 7 May 2017 BS 10Nov 2017, p98252.

Deontological and Practical Rules

- National Order of Physicians code of practice.
- Code of conduct of the American Psychological association : research and publication.

- Cave: International journal with peer-reviews always asks ethics advice!
- No post hoc acceptance can be given.

Rules of GCP

- **Person**: human rights before science, info complete, Helsinki, in-and exclusion, privacy (medical secret), insurance.
- **Researcher**: Well trained, physician or dentist.
- **Quality control**: Procedures , sponsor and principal investigator ,data preserving , info about equipoise.
- **Control**: EC and competent authority monitoring and assessment,
- **Project : scientifically valid question respecting biomedical ethics**

Informed Consent

- Understandable (Hello, hello-it's English I speak J.Med Eth.,2005,31,664).
- Only acceptable if free will
- Stopping always allowed
- Explain Double blind , RCT (!!!) . *"Deception is not allowed".*

PH.D. Project

- Starts with PA (“Preliminair Advies”): Submission of outline of project, can be similar to outline for submission FWO, IWT or BOF. Gives answer in about 3-5 days after checking by chairman or representative about acceptability of outline.
- If project approved by research organistion (e.g. FWO) necessary submission of different phases of project , each phase separate doc A with information for volunteer and informed consent.
- Start project only possible after approval of doc A.
- If use of medication or medical device also approval of Brussels necessary (now still in Gent+ Brussels, from 2019 : Brussels and other university)

How to proceed?

- Submission project : letter to chairman EC with Outline for PA
- Project accepted: submission doc A per chapter of project,
- Templates doc A: EC.
- Template of information document and IC : Bimetra clinics website.
- DOC A with information document, IC and financial information (if needed) has to be sent to Bimetra clinics
- Bimetra Clinics covers insurance and sends to EC
- Submission EC,
- If needed interview subcommission Wednesday Morning 9, a.m. Univ Hosp.
- Time : 14-28 days.
- If master student added to protocol: Doc E and to robert.rubens@ugent,be.

“Research means Integrity”

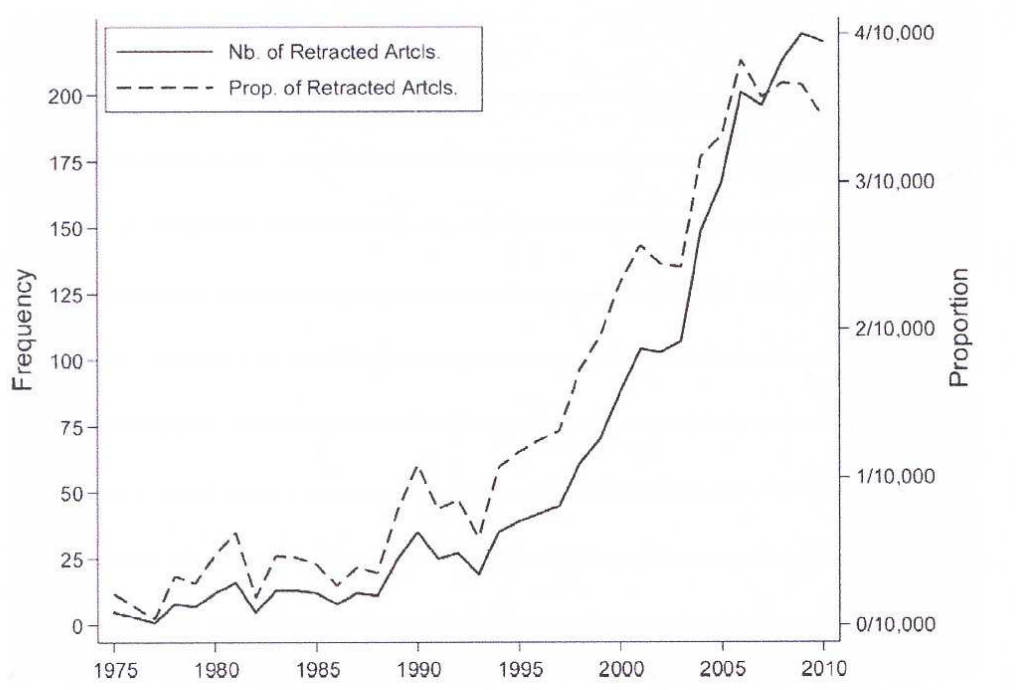

Fig. 1. Incidence of PubMed-indexed retractions. *Note*: The solid line displays the yearly frequency of retraction events in PubMed as a whole, all retraction reasons included. The dashed line displays the yearly retraction rate, where the denominator excludes PubMed-indexed articles that are not original journal articles (e.g., comments, editorials, reviews, etc.).

Take home messages

- Submit ethic's approval before starting,
- No human experiment without.
- There is no time problem in submitting.
- Ec is there to help!
- Website : https://www.uzgent.be//nl/overuz/ethisch-comite/Paginas/Ethisch-comite.aspx
- Phonenumber 09 332 33 36 Mrs Muriel Fouquet
- E-mail : muriel.fouquet@uzgent.be
- Bimetra clinics for templates :http://www.bimetra.be/clinics