

ETHICAL PRACTICES IN ONCOLOGY RESEARCH IN TURKEY

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WHAT IS A CLINICAL TRIAL (oncology research in human body) ?

- Every kind of prophylactic, diagnostic and therapeutic interventions in human body are clinical trials.
- Clinical trials are studies in patients which are generally designed to confirm the safety and effectiveness of a new promising treatment.

ACTUAL REGULATIONS in Turkey

- *TURKISH GOOD CLINICAL PRACTICE GUIDELINES (İyi Klinik Uygulamalar Kılavuzu)* was published in December 1995 in “Turkish official gazette”
- 39 pages

REGULATIONS ABOUT CLINICAL TRIALS (Klinik Araştırmalar Hakkında Yönetmelik

- The Ministry of Health published “the new regulations about clinical trials” at **23rd December 2008 in terms of DIRECTIVE**
- **Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use**

ETHICS COMMITTEES from 1993 to June 2009 IN TURKEY

- You should first apply LOCAL ETHICS COMMITTEE (Institutional Review Board) Now, there are more than 80 local ethic committees in Turkey
- The local committee gives the final decision except in “clinical trials (drug trials in human)”
If you want to make a drug trial, LOCAL ETHICS COMMITTEE sends the trial to CENTRAL ETHICS COMMITTEE for final decision

What are the problems in Turkey?

1. with ethics committees
2. with “previous but still active regulations”
3. with co-workers and clinical trial room
4. problems related to investigator and team-workers fee
5. with patients

1. ETHICS COMMITTEES IN TURKEY

- Final approval takes many months
- Paper works are too much
- Some ethics committee members are not qualified
- In some centers, ethics committee meetings can not be regular (e.g. there is no meeting in summer)

2. Problems due to “previous but still active regulations”

- Budget was main problem
- If you didn't prepare a full sponsored “clinical trial”, you could not make it
- You should have insured all the patients
- This meant “investigator initiated clinical trials” were impossible

3. Problems due to team-workers and clinical trial room

- There is not enough “medical oncologist”
- There is not enough “site coordinator” or “data manager” or “nurse practitioner”
- There is no “pharmacist” like in U.S.
- There is no clinical trial room in many centers

“Investigators” should be “site coordinator” and “pharmacist” at the same time

4. Problems related to investigator and team-workers fee

- Investigator fee is cut approximately 75% by the hospital administration in terms of the Governmental regulations
- Investigators can not employ “site coordinator” or “data manager” or “nurse practitioner” within clinical trial budget because of the official regulations (only the hospital administration can employ staff)

CLINICAL TRIALS

- If you would like to make a clinical trial with a new cancer drug, you should give it to metastatic cancer patients at first to understand its distribution in human body and to find the maximum tolerated dose (phase I trial).
- You may conduct a phase II and phase III trials with a new drug for the treatment of a specific cancer

5. Problems due to patients

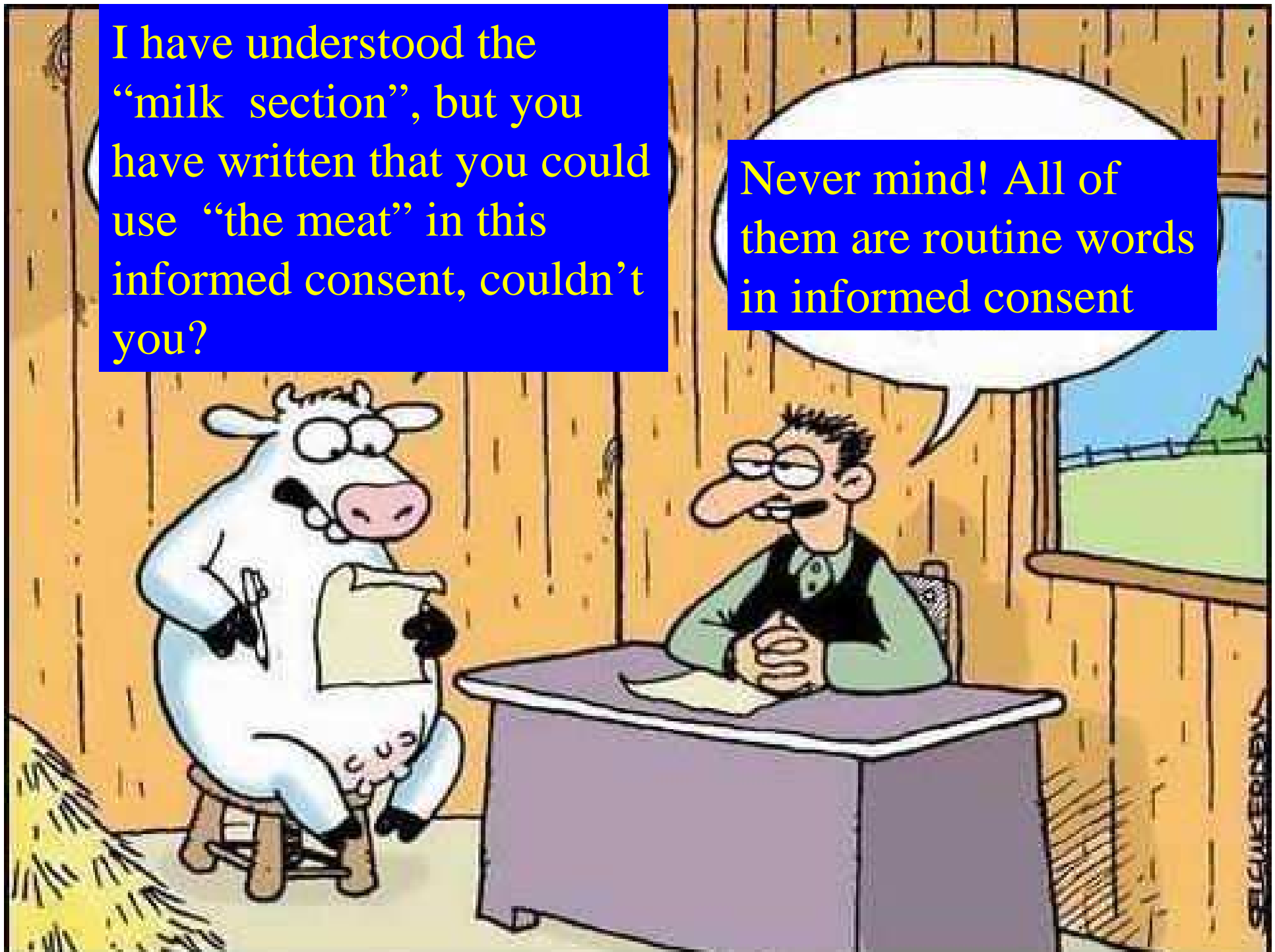
- They may refuse the clinical trials because of “the fear of to be a rat”
- Medical oncology centers are in big cities. Patients living in other cities can not be enrolled in clinical trials in many times
- There is no enough booklet to explain “what is a clinical trial?”

INFORMED CONSENT

- Whenever you invite a patient to enter a clinical trial, he or she can not decide to involve in a clinical trial. Because, it is often hard to understand or remember complex medical explanations. There are some booklets to explain what clinical trial is. The booklet answers to frequently asked questions about clinical trials.

I have understood the “milk section”, but you have written that you could use “the meat” in this informed consent, couldn't you?

Never mind! All of them are routine words in informed consent



THE NEW OFFICIAL REGULATIONS IN CLINICAL TRIALS IN TURKEY

- ETHICS COMMITTEES will be established instead of LOCAL ETHICS COMMITTEES
- The central “ADVISORY BOARD FOR CLINICAL TRIALS” will be replaced by “CENTRAL ETHICS COMMITTEE”
- Parallel application will be feasible
- Non-commercial clinical trial is described

What about THE NEW OFFICIAL REGULATIONS OF CLINICAL TRIALS IN TURKEY?

- “Good Clinical Practice” courses are ongoing for the new committee candidates because nobody can become a member of ethics committee unless he/she has not have this course
- “The guidelines for non-commercial clinical trials” are being prepared in these days by the Ministry of Health.

Problems due to co-investigators and investigator fee are ongoing

- “Site coordinators” are increasing in clinical trials but there is still no pharmacist
- Low investigator fee and few employment staff in a clinical trial budget is a problem waiting for solution



PLACEBO- CONTROLLED CLINICAL TRIAL

