XV CURSO DE DERECHOS FARMACÉUTICO

Investigación Clínica y Pacientes

El creciente papel de los pacientes y sus asociaciones en los diversos organismos y comités del sector. Necesidad de una regulación que haga efectiva los derechos de los pacientes

Prof. Dr. Miguel Angel Ramiro Avilés
Director Cátedra DECADE
Universidad de Alcalá

- El acceso a los medicamentos comercializados y la investigación clínica debe desarrollarse en un entorno que garantice los derechos de las personas

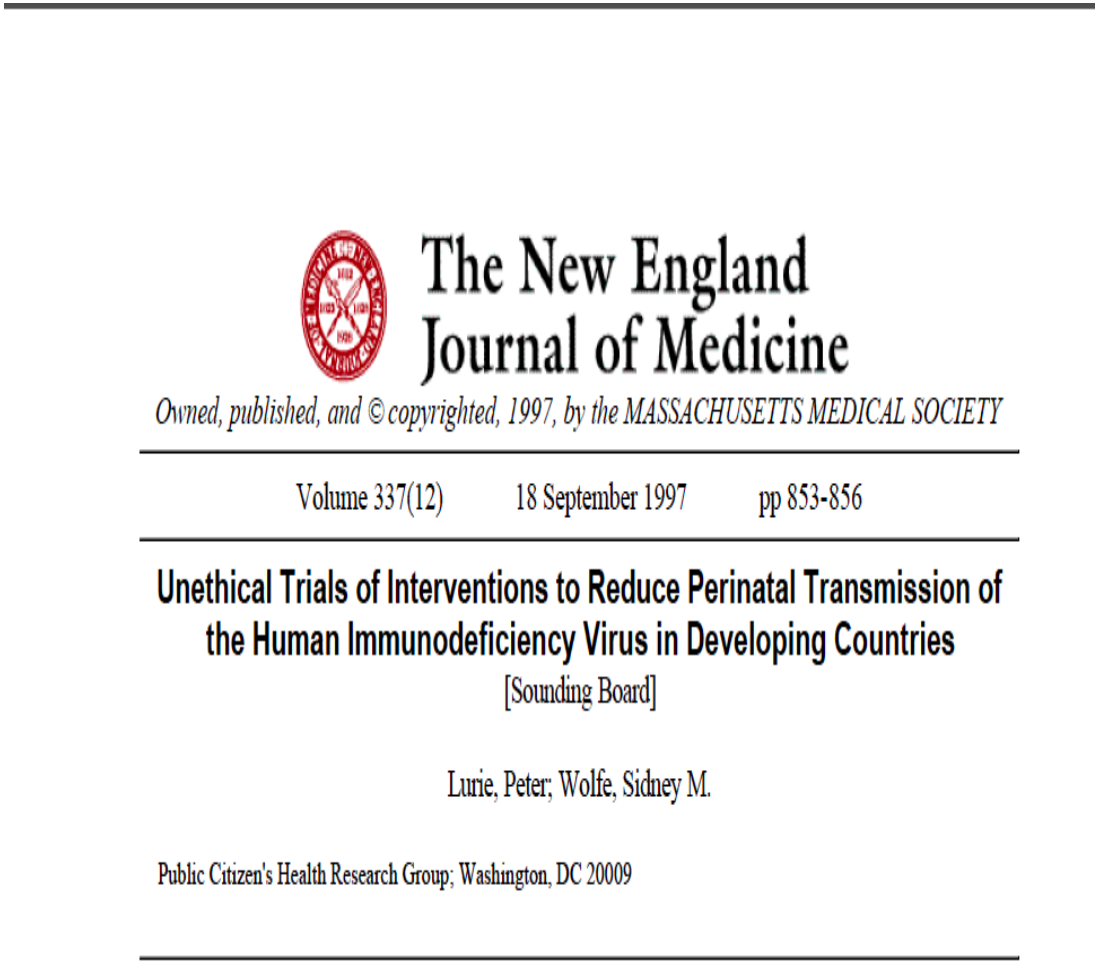
- Las personas que tienen una enfermedad (crónica) no son objetos de las políticas públicas sino que son sujetos políticos activos

nada sobre nosotros sin

NOSOTROS

- La IC se justifica por el **incremento del bienestar** al aumentar calidad de vida y mejorar la protección de la salud (menor mortalidad, morbilidad, discapacidad)

- **El fin no justifica los medios**: importa cómo se hace la IBC



The New England Journal of Medicine

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Volume 337(12) 18 September 1997 pp 853-856

Unethical Trials of Interventions to Reduce Perinatal Transmission of the Human Immunodeficiency Virus in Developing Countries

[Sounding Board]

Lurie, Peter; Wolfe, Sidney M.

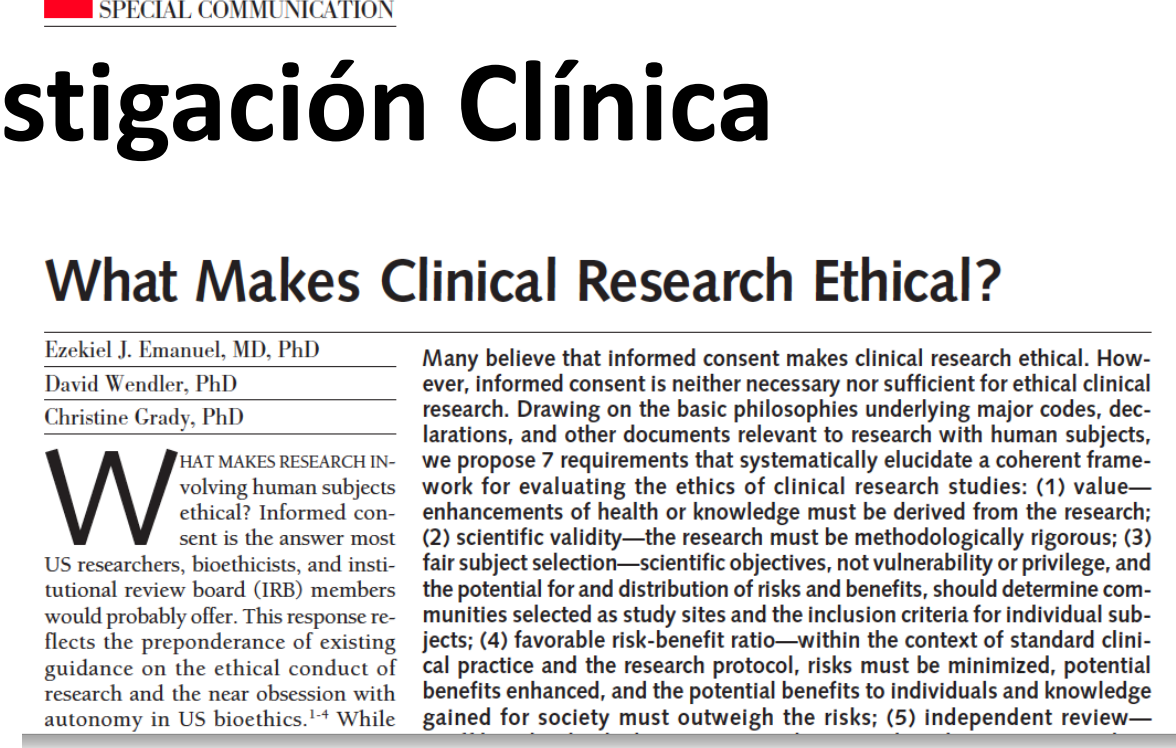
Public Citizen's Health Research Group; Washington, DC 20009

- **¿Por qué deben participar las personas con una enfermedad en los organismos y comités?**
  - dimensión de los derechos civiles y políticos
  - empoderamiento
  - ciudadanía integral (política y social)

- **¿Qué instrumentos de participación existen?**
  - Diseño de políticas públicas
  - Ética de la Práctica Asistencial
  - Ética de la Investigación Clínica

Investigación Clínica

- asociación cooperativa
- validez social
- validez científica
- selección equitativa de sujetos
- ratio favorable entre riesgos y beneficios
- revisión independiente
- consentimiento informado
- respeto de los sujetos potenciales y enrolados



SPECIAL COMMUNICATION

What Makes Clinical Research Ethical?

Ezekiel J. Emanuel, MD, PhD
David Wendler, PhD
Christine Grady, PhD

Many believe that informed consent makes clinical research ethical. However, informed consent is neither necessary nor sufficient for ethical clinical research. Drawing on the basic philosophies underlying major codes, declarations, and other documents relevant to research with human subjects, we propose 7 requirements that systematically elucidate a coherent framework for evaluating the ethics of clinical research studies: (1) value—enhancements of health or knowledge must be derived from the research; (2) scientific validity—the research must be methodologically rigorous; (3) fair subject selection—scientific objectives, not vulnerability or privilege, and the potential for and distribution of risks and benefits, should determine communities selected as study sites and the inclusion criteria for individual subjects; (4) favorable risk-benefit ratio—within the context of standard clinical practice and the research protocol, risks must be minimized, potential benefits enhanced, and the potential benefits to individuals and knowledge gained for society must outweigh the risks; (5) independent review—

WHAT MAKES RESEARCH involving human subjects ethical? Informed consent is the answer most US researchers, bioethicists, and institutional review board (IRB) members would probably offer. This response reflects the preponderance of existing guidance on the ethical conduct of research and the near obsession with autonomy in US bioethics.[1-4] While

PERSPECTIVE

What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research

Ezekiel J. Emanuel, David Wendler, Jack Killen, and Christine Grady
Department of Clinical Bioethics, Warren G. Magnuson Clinical Center, National Institutes of Health, Bethesda, Maryland

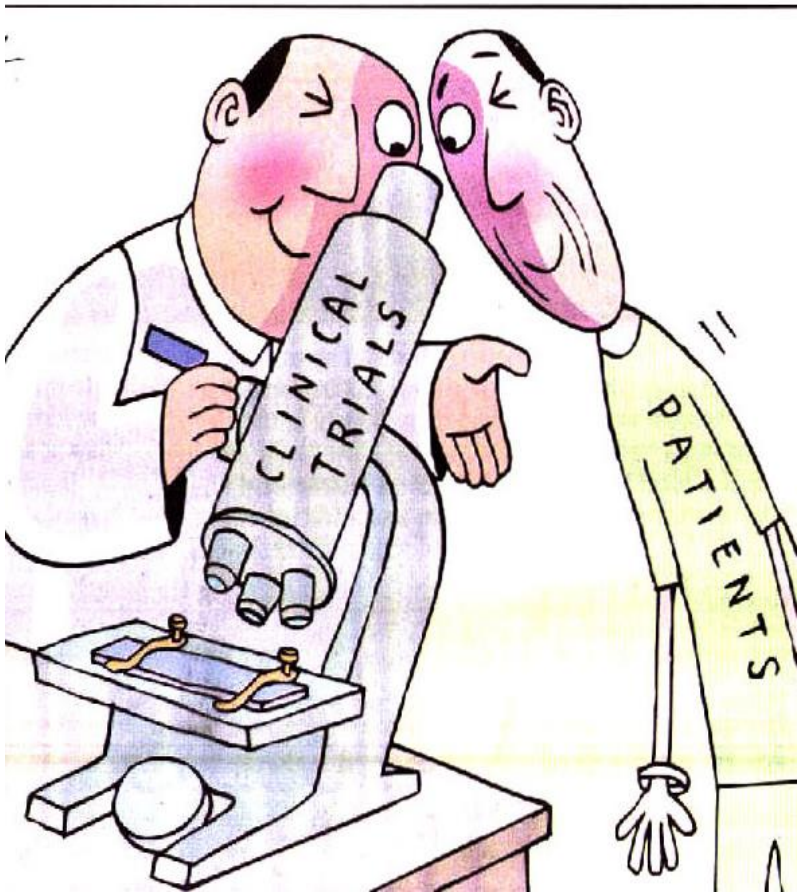
(See the editorial commentary by Kuritzkes, on pages 794–5.)

In recent years, there has been substantial debate about the ethics of research in developing countries [1–5]. In general, the controversies have centered on 3 issues:

research-ethics committees in assessing how well the enumerated ethical principles have been fulfilled in particular cases.

may be less well established, less supported financially, and less effective in developing countries. Guidelines for ethical research should minimize the risk of exploitation

- **asociación cooperativa**



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HIV update

08 June 2016

- Global access to HIV treatment improving, but still

Donate

sitting on something that could be the beginning of the end for the HIV epidemic – if only it were made available. The refusal to commission it for all those at significant risk is astonishing."

"There is an easy answer," commented Simon Collins of HIV i-Base. "The Secretary of State can authorise access to PrEP – which has already consultation and review – and fund numerous contingency budgets available for crisis situations."

In the House of Commons yesterday, public health minister Jane Ellison faced a hostile and protracted grilling by MPs on the issue. Fifteen MPs rounded on the minister variously accusing her, the government and NHS England of "having their head in the sand", of "passing the buck", and of being "incompetent".

Andrew Gwynne MP said: "Seventeen people are diagnosed with HIV every day. Each year, there are thousands of new infections. We know that PrEP has the potential to be a game-changer – yet as a result of this latest decision, this life-changing drug will remain inaccessible to people at risk of HIV."

Jane Ellison announced that NICE (the National Institute for Health and Care Excellence) would be asked to review the scientific evidence on PrEP over the next few months. NICE will provide a critical review of the strengths and weaknesses of the existing scientific

with HIV.

Find out more about this booklet in our blog >>

HIV-POGO – chronic pain study

Chelsea and Westminster Hospital in London is recruiting participants to take part in a study of chronic pain.

The study aims to find out more about chronic pain and neuropathy in HIV.

If you are living with HIV in the UK and are over 18, you may be eligible to take part.

View our webpage for more details >>

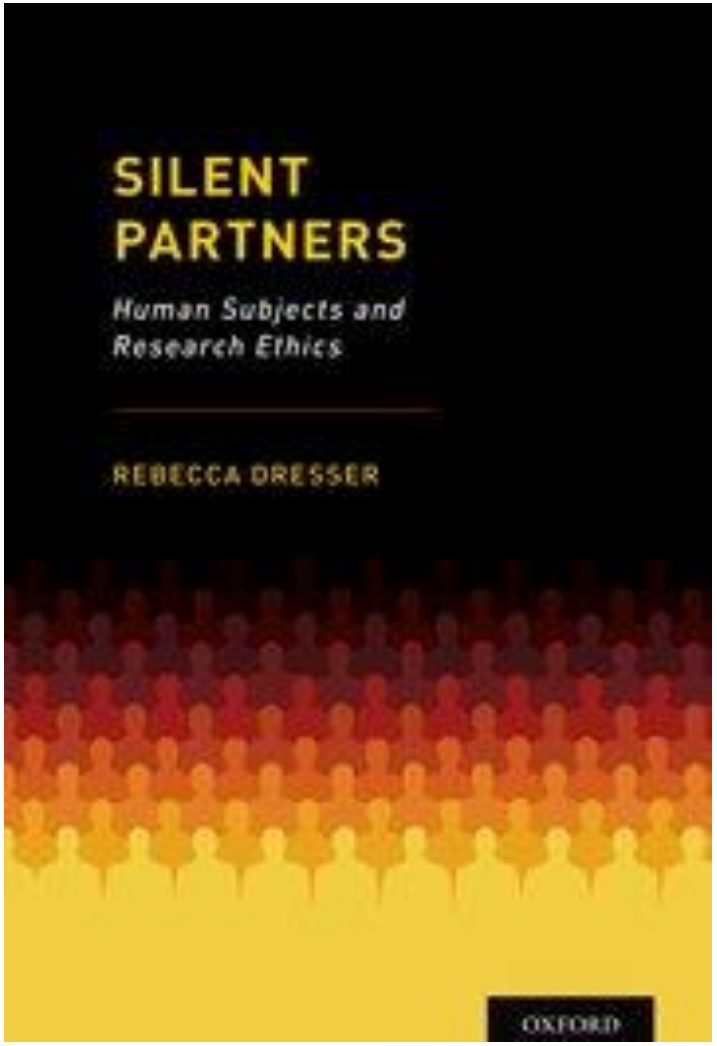
- Nuevo marco regulatorio R(UE) 536/2014 y RD 1090/2015
  - Registro español de estudios clínicos (REec) (arts. 47 + 48)
  - Comité de ética de la investigación con medicamentos (CEIm) (art. 2.b + 15)
  - Sujeto de ensayo (art. 2.1.v)

- Registro español de estudios clínicos
  - ECM autorizados y EPO clasificados por AEMPS
  - publicación de los resultado de las investigaciones registradas una vez concluidas
  - transparencia, accesibilidad

- Composición del CEIm (art. 15.1)
  - "El CEIm estará constituido por un mínimo de diez miembros, al menos uno de los cuales será un miembro lego, ajeno a la investigación biomédica o a la asistencia clínica, que representará los intereses de los pacientes"

- Sujeto del ensayo vs. Participante en el ensayo

“People participating in research can supply facts about the experience that are otherwise overlooked or downplayed by those who have never been in participants’ position” (Rebecca Dresser, *Silent Partners*, OUP, 2017)



Cuestiones de debatir

- ¿método de elección de los representantes de los pacientes seguido por los CEIm?
- ¿pueden llegar a tener conflictos de intereses?
- ¿hay suficientes miembros legos en un CEIm?
- ¿qué tipo de formación se requiere para poder participar en un CEIm?

A modo de conclusión

- Debería incorporarse una perspectiva basada en los derechos humanos para que la participación fuese más efectiva
  - diseño para todos
  - igualdad (de oportunidades) y no discriminación
  - barreras institucionales y actitudinales
  - ajustes razonables
  - perspectiva de género
  - sensibilidad hacia grupos vulnerables