

Transnational Standards for Scientific Research Involving Human Subjects

*Situating the Role of Good Clinical Practice
in Health Research*

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Francis P. Crawley

Good Clinical Practice Alliance – Europe

fpc@gcpalliance.org

Rights & Responsibilities in Transnational Scientific Research

- Science is a public good
 - the pursuit, and the results of science belong to humanity
- The pursuit of knowledge is an obligation and a responsibility
 - the embeddedness of research
- Research on human subjects is *never* a right, *always* a responsibility
- We need to complement a rights-based ethics with an ethics of responsibility
 - (the internalizing of the ethical disposition)

The Trust Deficit in Transnational Scientific Research

A tension regarding what people trust
and the reliability of what is trusted.

The need for transparency in all research
on human subjects, in all aspects of
such research.

The Development of GCP

- 1989 Nordic GCP Guidelines
- 1990 European GCP Guidelines
- 1995 WHO GCP Guidelines
- 1996 **ICH GCP Guidelines**
- 2000 South Africa GCP Guidelines
- 2001 **EU GCP Directive**
- 2005 WHO GCP Handbook
- 2005 PAHO GCP
- 2008 US FDA Ruling on GCP for Foreign Clinical Studies Not Conducted Under an IND
- 2009 **US FDA GCP Office** Opens

A US and Transnational Common Rule*

(A Proposal from a Transnational GCP Framework)

- A culture of research where sought health outcomes are rooted in a respect for persons
- A representative platform
- To deepen, specify, update, and simplify/harmonize regulations & practices
- Assure the public good of health research
- Assure transparency in all scientific research

*consider the US experience in developing the 'Common Rule' CFR 45,46 1974-1991