The global strategy in promoting health research and research subject protection

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The Requirement for Biomedical Research

Even the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality.

(*Declaration of Helsinki*, Intro, Paragraph 6)

Value of Research

‘...continuing in uncertainty or, worse still, thinking that she knew which was better when she did not’

Claire Foster, The ethics of Medical Research on Humans 2001

The Cornerstone of Health Research Ethics

It is the duty of the physician to promote and safeguard the health of the people.

His or her knowledge and conscience are dedicated to the fulfilment of this duty.

(*DoH*, Intro, Paragraph 2)

“The public’s perception of Research, its benefits and its risks is shaped by the way research is conducted”

Protecting Study Volunteers in Research: CM Dunn and GL Chadwick 2002

International guidelines agree on:

- Independent ethics committee
- Informed consent
- Evaluate potential benefits and harms of study participation
- Vulnerable persons in research are entitled to special protection

Ethical Issues in Biomedical Research

- Placebo control
- Informed consent – *sign vs oral, individual vs community*
- Undue Inducement to participate in the trial as investigator and participant
- Standard of care
- What is owed to research participants at the end of the study?
- Publication

More issues….

- Monitoring (DSMBs)
- The role & responsibility of ethics committees (ECs)
- Medical treatment during the course of research
- Patient/Participant Confidentiality and Privacy
- Locating phase I, II, and III trials
- Stem Cell Research
- Gene Therapy
- Tissues
- etc….

Public Health requires independent and competent ethical decision-making.

Helsinki on Ethical Review 2000

3. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.

The Role of Ethics Committees

- Provide guidance to researchers
- To promote and protect the dignity, well-being, and rights of research participants & their communities
- To provide public assurance that research is appropriately undertaken

"… the time taken to get approval from several local research ethics committees and in overcoming bureaucratic and practical obstacles… has become a barrier to our research,. …. for ethics committees to have become barriers to ethical research, which could help to improve health care, is certainly immoral."

- Nicholl J. BMJ 2000;320:1217

Basic Knowledge for EC members

- Background: History of human Research, current structure and funding of research, current regulatory structure
- Foundation Knowledge: An introduction to clinical medicine, basic science, epidemiology, introduction to ethical principles, concepts, and issues
- Methodological issues: Identifying the elements of research design, randomization, the use and abuse of placebo model, vulnerable persons

Basic Knowledge for EC members

- Conflicts of Interest:
- Reviewing research proposals: determine if a proposal presents an important question, identify inclusion/exclusion criteria, risk-benefit, inform consent, conflicts of interest, confidentiality, monitoring and review
- Responsibilities of EC members

As things stand……

A survey of more than 200 developing-country health researchers has found that a quarter of clinical trials carried out in developing countries do not undergo any kind of ethical review in the host nation.

'Clinical trials still face gaps in ethical review '
Nicky Lewis, 1 March 2004
Source: SciDev.Net

The Need for Asian Dimension to Ethical Decision-Making

- multi-centre, multi-national clinical trials
- health issues affecting Asia as a whole
- ethical issues of an international dimension
- the need to exchange information & education
- the promotion of the Asian contribution to the international discussion on ethical issues in health research & human subjects protections

Promoting a Systematic Approach to Ethical Review in Asia

- National ethical review *systems*
- Independent and competent ethics committees with defined mandates (terms of reference)
- Responsible and transparent *operations* in ethical review, including accountability

Systems of Ethical Review

‘Countries, institutions, and communities should strive to develop ECs and ethical review systems that ensure the broadest possible coverage of protection for potential research participants and contribute to the highest attainable quality in the science and ethics of biomedical research.’

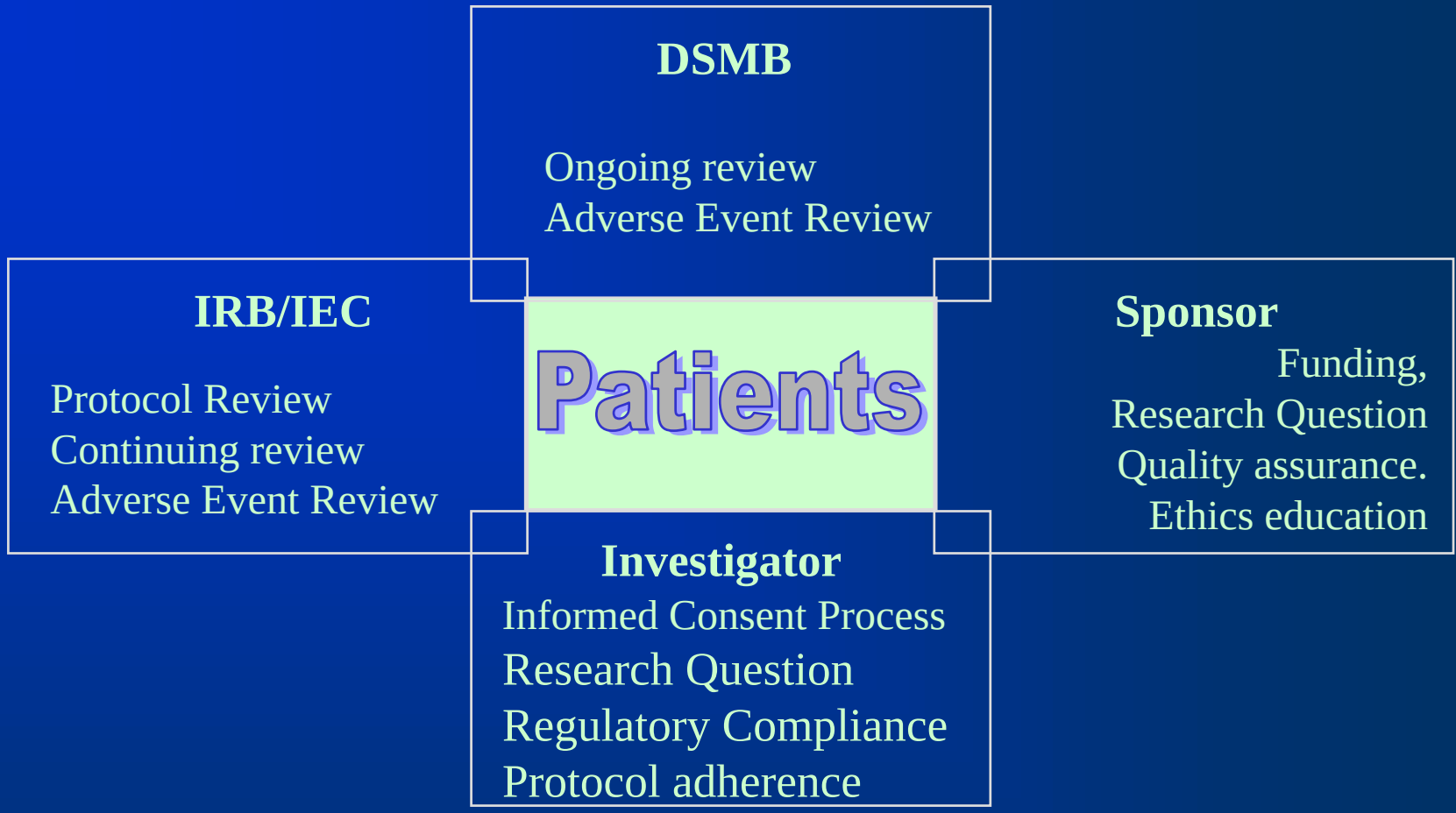
WHO, Operational Guidelines, p. 4

Avenues to Improving National Ethical Review Systems

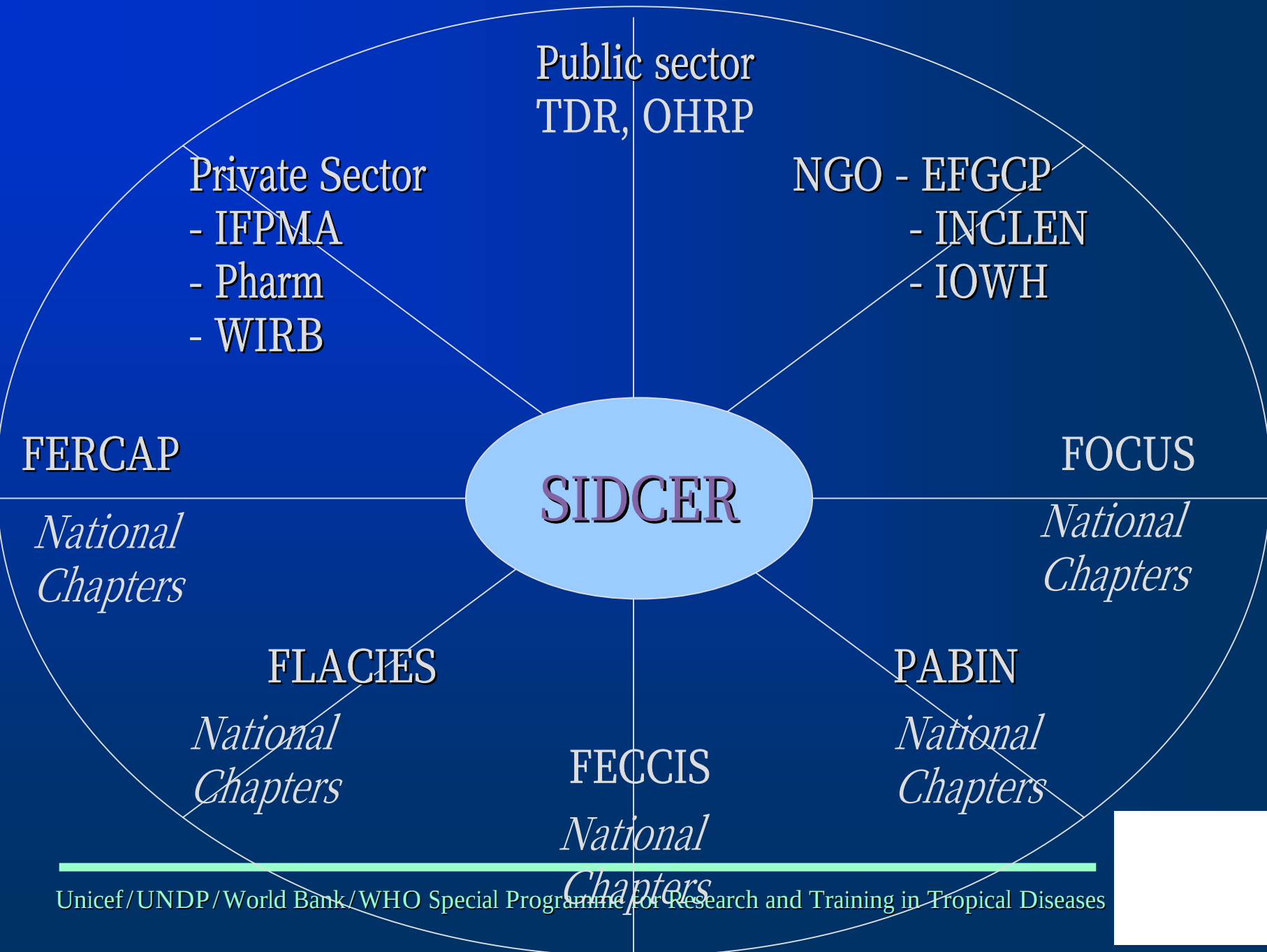
- Fostering the development of ethical review as an integral part of the clinical research process
- Promoting independence for ethics committees by defining further their roles
- Developing competence by promoting education and training for ethical review
- Establishing assurances of responsible ethical review operations
- Forum for Ethical Review Committees in Asia (FERCAP)

The Need for a Shared Ethical Framework in Biomedical Research

- A need for scientists and practitioners to share common standards/understanding
- A need for patients and subjects to be treated with respect & judiciously (equally)
- A need to ensure the public that patient/subject protections exist and that the ‘highest’ standards are implemented



There is a need for clinical studies to meet international standards of GCP as well as contributing to the needs of local communities.


Public sector
TDR, OHRP
Private Sector
- IFPMA
- Pharm
- WIRB
NGO - EFGCP
- INCLEN
- IOWH
FERCAP
National Chapters
SIDCER
FOCUS
National Chapters
FLACIES
National Chapters
FECCIS
National Chapters
PABIN
National Chapters

SIDCER network

- The project addresses the gap in ethical review by developing ethics committees where none existed; assisting countries in systematizing ethical review practices, developing in-country ethical and legal frameworks, creating education programs, developing human resources, establishing centers of excellence for ethics information and knowledge exchange, and promoting research into emerging ethical issues in developing countries as well as providing for resource development for sustained capacity in

Research

There is a need to ensure the public that patient/subject protections exist and that the 'highest' standards are implemented