

# ART Issues and Regulation: a global perspective

Lori P. Knowles BA LLB BCL MA LLM



# International Issues

- Expanded parenthood
- Consent issues
- Embryo transfer
- Commercialization
- Safety
- Traceability
- Governance structure

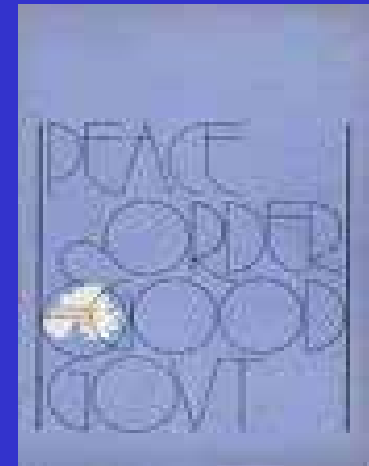


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# Understanding Foreign Approaches to ART governance

- Historical
  - German Nazi regime
  - US Tuskegee scandal
- Cultural values
  - UK (freedom of science)
  - US (individual liberty)
- Religious values
  - Irish, Italian
- National temperaments
  - US (fear of government intrusion)
  - Canadian (fear of unfettered individualism)



# General Regulatory Frameworks

- Little or no legislation: ad hoc judicial precedent; regional regulation (IRBs/REBs)
- Specific legislation (cloning legislation; embryo research legislation)
- ART legislation
- Human Subjects Research legislation
- [Advisory Panels/Commission Reports]
- Professional self-regulation
- Combination of these

# Ad hoc/Regional

- No regulation: gender selection
- Ad hoc:
  - Issues such as parental rights, dispositions of embryos, hESC research
- Regional and self-regulation
  - practice of IVF (number of transferred embryos)
- Regional oversight
  - IRB, SCRO

# Comprehensive ART Legislation: The UK

- *Human Fertilisation and Embryology Act, 1990*
- Created Non-Departmental Public Body
  - *Human Fertilisation and Embryology Authority [HFEA]*
- Scope: private and public clinics and laboratories
- Set up Licensing scheme for
  - Treatment services, storage of gametes and embryos, embryo research
- Set out limits and restrictions on use of embryos
- Violation of Act is a criminal offense
- *Human Reproductive Cloning Act 2001*

# HFEA Functions

- License treatment services, storage of gametes and embryos and research on embryos
  - through licensing committees
  - clinics licensed for up to three years to provide particular treatments
- Monitor/inspect premises and activities carried out with license
- Maintain information registry about donors, treatments (outcomes) and children born from treatments

# HFEA Functions

- Produce a Code of Practice as guidance for clinics about the conduct of licensed activities
- Make policy with respect to novel issues
- For embryo research: prior approval by local IRB
- Individual research protocols are licensed only for purposes specified in the Act
- Possible to create embryos for research
- Possible to use CNR for those purposes

# UK RATE

- 2005 creation of the Human Tissue Authority
- In 2009 combine HFEA and Human Tissue Authority to become Regulatory Authority for Tissue and Embryos (RATE)
- “Bringing all matters concerning human tissue, gametes and embryos under a single framework will ensure consistency of approach.”
- *Human Tissue and Embryo Bill* now having open consultation

# EUTCD 2004/23/EC

- Combining regulation of donation, procurement and supply of blood, blood products, whole organs, part organs, tissues, cells, embryos, gametes for human application.
- Becoming the single competent authority under EU Tissue and Cells Directive (EUTCD)
- 2006/86/EC traceability of all donated material
- 2006/17/EC selection and biological testing criteria

# France

- Prior to 2002 interventions not in interest of the embryo are not permitted – no embryo research
- Reproductive cloning explicitly prohibited
- Bioethics Law 2004 - Agence de la biomédecine
- Only public body in Europe to combine organ procurement, procreation, human embryology and genetics
  - Oversight of Infertility treatments, prenatal diagnostics and embryo research
- Permit stem cell research on surplus IVF embryos only – would not allow research cloning

# Germany

- *Embryo Protection Act (1990)*
- Criminal statute
- Interventions not conducted for the well-being of an embryo are prohibited.
- Law bans reproductive and therapeutic cloning and derivation of ES cells
- Law in force July 1, 2002
  - permits importation of ES Cells – very strict restrictions
  - only produced before Jan. 1, 2002

# AUSTRALIA

- *Research Involving Human Embryos Act 2002*
- NHMRC Licensing Committee
- Only addresses surplus embryos
- Offence using non-excess ART embryo for non-therapeutic purpose – 5 years max imprisonment
- *Prohibition of Human Cloning Act 2002*
- Intentionally creating a human embryo clone or placing it in a woman's body – 15 years max
- Independent review of both Acts every 3 years

# Canada

- *Assisted Human Reproduction Act*
- Guiding principles: embedded in Act
- Treatment, storage and research
- Commercial transactions – surrogacy included
- Public and Private research

# Purposes of AHRA

- Protect health safety of Canadians using ART
- Prohibit unacceptable practices
  - prohibited activities
  - criminal sanctions
- Regulate AHR activities and related research
  - controlled activities
  - licensing scheme
- Establish National Oversight body
  - Assisted Human Reproduction Agency

# AHR Agency

- Operate as a separate organizational entity from Health Canada reporting to the Minister of Health;
- Have up to 13 members on an interdisciplinary Board of Directors
- Be responsible for licensing, monitoring and enforcement of the Act and its regulations
- Maintain a donor/offspring registry
- No reproductive cloning
- No research cloning
- Stem cell research permitted on surplus IVF embryos

# Common Guiding Principles

- Respect for human life and dignity
- Quality and safety of medical treatment
- Respect for free and informed consent
- Non-commercialization of reproduction
- Minimizing harm ; Maximizing benefit
- Protection of children's health and well-being

# Common Prohibitions

- Cloning
- Creation of hybrids/chimeras\*
- Cross-species implantation
- Commercialization
- Germ-line interventions
- Creation of embryos for research\*

# Elements of a Governance System

- 1. Licensing Schemes
- 2. Consent of donors of human biological materials
- (b) Confidentiality systems for donors/information registries
- 3. Legislative Review
- 4. Ancillary development of infrastructure
- 5. Methods for public consultation or facilitated public discussion

# Elements of a safeguarding system

- Licensing Schemes
  - inspections; audits; power of revocation/suspension
  - limits that keep research protocols of high scientific and ethical quality:
    - Previous protocol review, scientific and ethical
    - No animal model possible for the proposed research
    - Means of research are scientifically valid
    - Ends of research are desirable and necessary (benefits to humanity)
    - 14 day limit
    - # of embryos/oocytes requested in protocol are necessary

# Elements of a safeguarding system

- 2. Consent of donors of human biological material
  - Informed, written and specific
  - E.g. human research cloning – oocyte donation (need for regulation of supply of oocytes)
  - No coercion at point of supply
  - Conflicts of interest management
  - Restrictions on commercialization
- (b) Confidentiality systems for donors/information registries

# Elements of a safeguarding system

- Legislative Review
  - Sunset clauses (Aust); moratoria for limited periods
    - In light of scientific/medical developments
    - Changing social views
  - Review of research protocol outcomes after period of time
  - Review of shortages/surplus gamete and embryo supply

# Elements cont'd.

- Ancillary development of infrastructure
  - MRC bank for stem cell lines
  - Reproductive cloning bills/Acts
  - Changes in embryo donation/oocyte donation laws
  - Regulatory structure for what is done with stem cells once removed from embryos e.g. secondary ES cell research outside HFEA remit
  - Research in human regs
  - Regulations for international exchange human biological materials
  - Access/benefit issues wrt potentially medical beneficial research – IP issues

# Elements of a safeguarding system

- Methods for public consultation or facilitated public discussion
- “It should be recalled that the purpose of bioethics is not to ban upfront scientific advances particularly in the field of medicine, but to define the limits of the socially desirable and ethically permissible”
  - Bioethics Advisory Committee of Israel National Academies of Science and Humanities