



The Social Responsibility of Institutions Engaged in Innovative Research

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What is Innovative Research?

- Refers to high-risk, high-reward research that could ultimately lead to critical discoveries or major advancements that will accelerate various areas of biomedical research

Characteristics of Innovative Research

- introduce a new paradigm
- challenge current paradigms
- look at existing problems from new perspectives, or
- exhibit other uniquely creative qualities

Disciplines

- Basic science: Genomics, Genetics, Molecular Biology
- Behavioral, epidemiological, bioengineering, biotechnology, and community and clinical investigations that bear on various medical problems
- Multidisciplinary efforts

What is 'Social Responsibility'?

- Responsibility to
 - Society
 - Community
 - Specific populations, i.e. vulnerable populations
 - Future generations
 - Environment and Biodiversity

Who is (are) responsible for evaluating social impact of research?

- Do institutions have in place, mechanisms to evaluate the social impact of research?

UNESCO Declarations

- Universal Declaration on Bioethics and Human Rights
- Universal Declaration on the Human Genome and Human Rights
- Universal Declaration on Human Genetics Data and Human Rights

Who is (are) responsible for evaluating social impact of research?

- No single body has the capacity or duty to determine the ultimate desirability of research projects
- No single body that determines what studies should be implemented quickly and what should be relegated to the back burner
- The responsibility of assessing the social effects of research is widely diffused: researchers, government (FDA, DOST), academic institutions, NGOs (advocacy groups and charities), the public at large

Social Responsibility in the context of Genomics Research

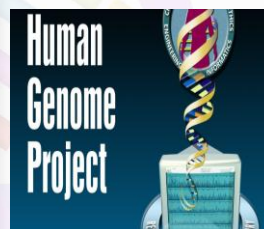
Genomics

- Study not just of single genes, but of the functions and interactions of all the genes in the genome
- Genome- refers to the full genetic complement of an organism
- Involves:
 - the systematic identification of all human genes and gene products
 - the study of human genetic variations, combined with changes in gene and protein expression over time, in health and disease

Genomics Research

- HGP produced a functionally complete genome of human beings & other organisms
- HGP developed the technology for mapping and sequencing and uncovering the way genes function
- Technologies are being developed and applied to harness the medical benefits of the HGP
- This has given rise to Genomic Medicine

Advent of Genomic Medicine



- a major driver for the current period of biomedical discovery
- yielded improvements in "genetic medicine"

Genomic Medicine

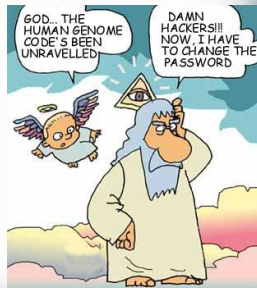
- Enables medicine:
 - To make reliable assessments of the individual risk to acquire a particular disease
 - To improve the classification of disease processes
 - To raise the number and specificity of drug targets

Applications of Genomic Medicine

- Biomarker science
 - Molecular diagnostics
 - Discovery of new drug targets
- Targeted therapeutics development
- Personalized medicine
- Lifestyle planning – predictive testing and risk assessment

Ethical, Legal, and Social Implications of Genomic Medicine

- Evaluation of new genetic and genomic tests and technologies, and effective oversight of their implementation, to ensure that only those with confirmed clinical validity are used for patient care, is needed.



Ethical, Legal, and Social Implications of Genomic Medicine

- Much effort is being devoted to trying to anticipate, understand, and address the ethical, legal, social, and political implications of genetics and genomics.
- Society is concerned about the effect genetic knowledge will have on the well-being of individual persons and groups.

Social Effects of Genomic Medicine

- One of the primary effects of genomics research – to increase the information available about an individual
- Some tests will identify not only the root cause but also *predictors* of disorders- These predictive tests estimate only the likelihood that a disorder will or will not manifest
- Employers and insurers are also interested in these genetic predictors

Social Effects of Genomic Medicine

- Genetic interventions will affect social groups (race, ethnicity, geographical isolation) and result in stigmatization
- Genetic research will deepen the social divide between the haves and have nots.

UNESCO Declaration on the Human Genome and Human Rights

- Recognizes that research on the human genome and the resulting applications open up vast prospects for progress in improving the health of individuals and of humankind as a whole.
- Emphasizes that such research should fully **respect human dignity, freedom and human rights**, as well as the **prohibition of all forms of discrimination based on genetic characteristics**

Research on the human genome

"No research or research applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people."

Article 10: UNESCO Declaration on the Human Genome and Human Rights

Protection from all forms of discrimination based on genetic characteristics

"No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity."

Article 6 UNESCO Declaration on the Human Genome and Human Rights

Elements on the Use of Genetic Information*

- What are some potential implications of genetic information?
 - The patient may be more likely to require expensive therapy
 - The patient may be more likely to be injured by certain types of exposure
 - The patient may present a danger to others in the future
- What principles need to be taken into account, recognizing that none are absolute?
 - Protection of autonomy
 - The public health
 - The importance of inclusiveness
 - Allocation of costs
- Who decides whether the test will be done?
 - The patient
 - The patient's employer or another private third party
 - The government
- Who decides what to do with the results?
 - The patient
 - A private third party
 - The government

**From: Clayton, EW. 2003. New England J of Medicine: 349;6*

Social Responsibility of Institutions

Ensure that the framework for genomics research is based on:

- Respect for human dignity, freedom and human rights
- Prohibition of all forms of discrimination based on genetic characteristics

Article 10: UNESCO Declaration on the Human Genome and Human Rights

Evaluate nature and scope of research projects

- whether projects improve the quality of life
 - of many people only a little
 - of just a few people a great deal

Institute an Ethical, Legal and Social Implications (ELSI) program

- ELSI should consider
 - Privacy and fairness in the use and interpretation of genetic information
 - Clinical integration of new genetic technologies
 - Issues surrounding genetic research
 - Public and professional education

Share benefits from research on Genomics

- Benefits from advances concerning the human genome shall be made available to all with due regard for the dignity and human rights of each individual
- Applications of research concerning the human genome shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole

Article 12: UNESCO Declaration on the Human Genome and Human Rights

Ensure the protection of future generations

- The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.

Article 16: UNESCO Declaration on Bioethics and Human Rights

Respect and protect the environment, the biosphere and biodiversity

- Due regard is to be given to the interconnection between human beings and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity.

Article 17: UNESCO Declaration on Bioethics and Human Rights

*Thank you
and
Good Day!*