

Bioethics Research

Prof. Fatchiyah, Ph.D.

Molecular Genetics Lecturer, Biology Dept. Brawijaya University

Director, Biosains UB

<http://fatchiyah.lecture.ub.ac.id>

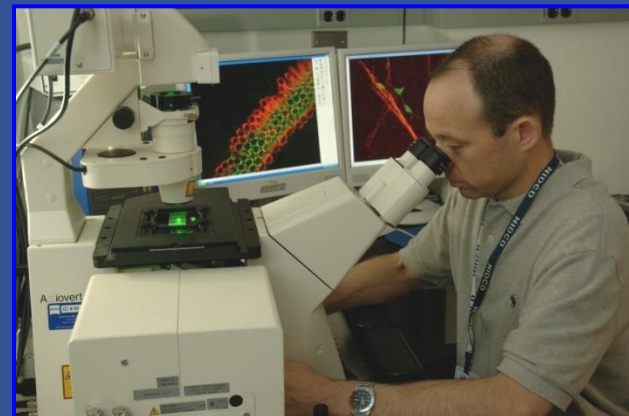


When most people think of ethics (or morals) they think of **rules for distinguishing between right and wrong**. Most commonly “ethics” are: norms of conduct that distinguish between **acceptable and unacceptable behavior**.



“Science in pursuit of **fundamental knowledge** about the nature and behavior of living systems ...

and the **application of that knowledge** to extend healthy life and reduce the burdens of illness and disability.”



Contect of Bioethics Research

❑ Definition and Meaning

❑ Importance of Research Ethics

❑ General Basic Principals of Ethics:

- ✓ Isu-isu dalam bioteknologi,
- ✓ Integritas ilmiah/Konflik kepentingan

❑ Philosophy of Research: Authorship ,Plagiarism, Peer Review, Pemahaman masyarakat tentang ilmu (Sains) dan ilmuwan Pertanggungjawaban ilmuwan untuk mengkomunikasikan ilmu-ilmu (Sains)

❑ Research With Animals: Penanganan hewan, uji medis/biassay, animal welfare, anastesi, cara mematikan, mengurangi rasa sakit

❑ Research With Human Subjects:

- ✓ Eugenika (*Eugenics*), Projek Genom Manusia (HGP)
- ✓ Pengujian genetik, Terapi gen, Tes DNA (*DNA profiling*) & Teknologi genetik
- ✓ Penelitian jaringan fetus, Biologi tentang jenis kelamin yang disukai (*Sexual preverence*)

Bioethics

- ❑ **Morality** is a unique feature of the life of human beings. It is deeply influenced by several cultural factors, such as history, traditions, education, religious beliefs, etc.
- ❑ The intellectual analysis of this human dimension in all of its complexity is the goal of the discipline called Ethics. **Ethics does not create morality or moral behavior.**
- ❑ The goal of ethics is much more modest: to explore the **nature of moral experience, its universality and its diversity.**
- ❑ Ethics and morality are generally taken as synonyms, because they
- ❑ originally had the same meaning: the study of the disposition, character, or attitude of a specific person, group of people or culture, and ways of promoting or perfecting it.

WHAT'S ETHICS MEANS?

- It is the branch of philosophy that deals with morals or right and wrong
- DEFINITION: Ethics are the principles and guidelines that help us to uphold things we value.
- Ethics in research are important you are young to conduct and experiment. It should be applied on all stages of research such as in planning ,conducting and evaluating a research.
- Thus research ethics educates and monitors a scientist conducting a research to ensure a high ethical standards.

IMPORTANCE OF RESEARCH ETHICS

- Promotes the **aims of research** (such as knowledge ,truth ,and avoidance of error)
- Promotes the **values that are essential to collaborative work** (such as **trust ,accountability ,mutual respect ,and fairness**)
- Help to ensure that researchers can be held **accountable to public**
- Help to **build public support for research** (as people more likely to fund research projects if they trust the quality and integrity of research)
- Promotes **moral and social values**(such as social responsibility, human rights , animal welfare etc.)

15 February 2001

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Nuclear fission

Five-dimensional
energy landscapes

Seafloor spreading

The view from under
the Arctic icepack

Career prospects

Sequence creates new
opportunities

naturejobs

genomics special

nature

THE INTERNATIONAL WEEKLY JOURNAL OF SCIENCE

THE
FUTURE
IS BRIGHT

Reflections on the first ten
years of the human genomics age



GENOMICS

**THE END OF
THE BEGINNING**

Eric Lander on the impact of
the human genome sequence

PAGE 187

METHODS

**MORE BASES
PER DOLLAR**

Elaine Mardis on the march
of sequencing technology

PAGE 198

HEALTH

**FROM LAB
TO CLINIC**

A road map to
genomic medicine

PAGE 204

NATURE.COM/NATURE

10 February 2001 \$10



16 February 2001

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Vol 291 No 5507
Pages 1145-1434 \$9



GENERAL BASIC PRINCIPALS OF ETHICS

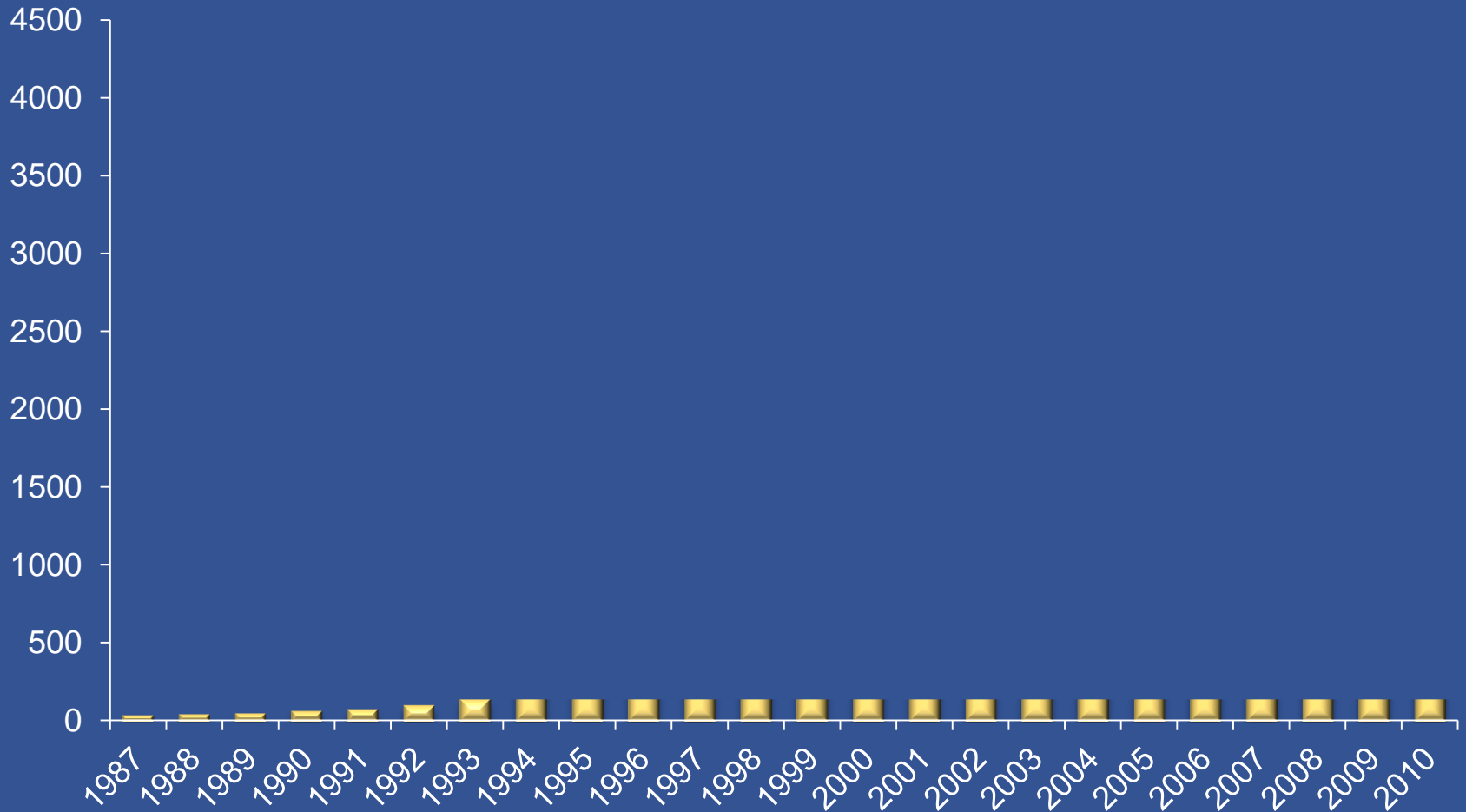
- 1. **Honesty** : Honestly report data ,results ,methods and procedures and publication status. Do not fabricate, falsify or misinterpret data.
- 2. **Objectivity** : Strive to avoid bias in experimental design, data analysis, data interpretation ,peer review etc.
- 3. **Integrity** : Keep your promises and agreements, act with sincerity, strive for consistency of thought and action.
- 4. **Carefulness**: Avoid careless errors and negligence . Carefully and critically examine your own work. Keep good record of research activities such as data collection, research design and correspondence with agencies or journals
- 5. **Openness**: Share data, results, ideas, tools, resources

Be open to criticism and new ideas

GENERAL BASIC PRINCIPALS OF ETHICS

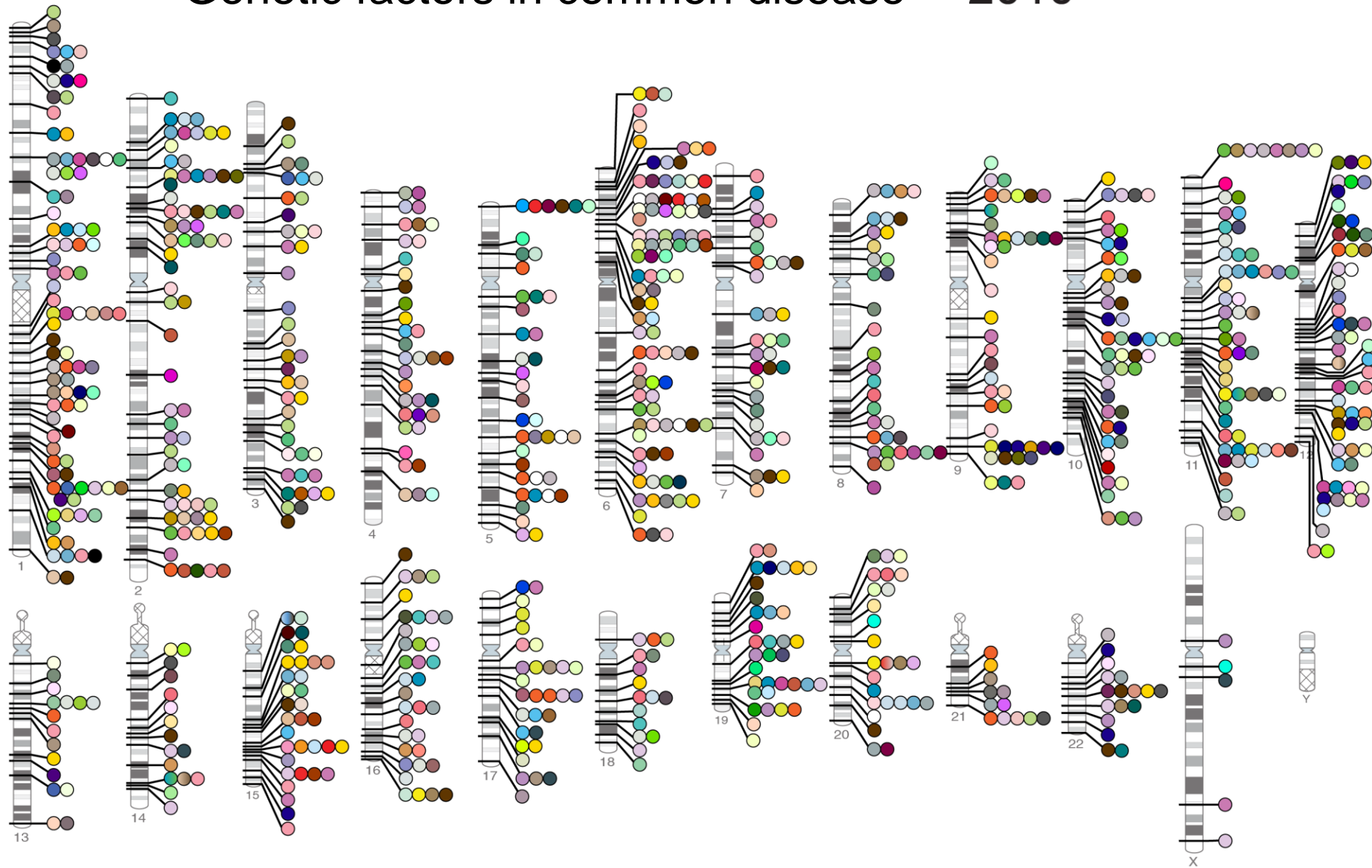
- 6. **Respect for intellectual property**: i) Honor patents, copyright and other forms of intellectual property. ii) Do not use unpublished data , methods or results without permission iii) Never plagiarizes
- 7. **Confidentiality**: Protect confidential communication such as paper or grants submitted for publication, personnel records, trade or military secrets and patient records
- 8. **Respect for colleagues**: Respect your colleagues and treat them fairly
- 9. **Non discrimination**: Avoid discrimination against colleagues or students on the basis of sex, race, or other factors that are not related to their scientific competence and integrity
- 10. **Social Responsibility**: Strive to promote social good and prevent social harms through research, public education and advocacy

Disorders with Known Molecular Basis

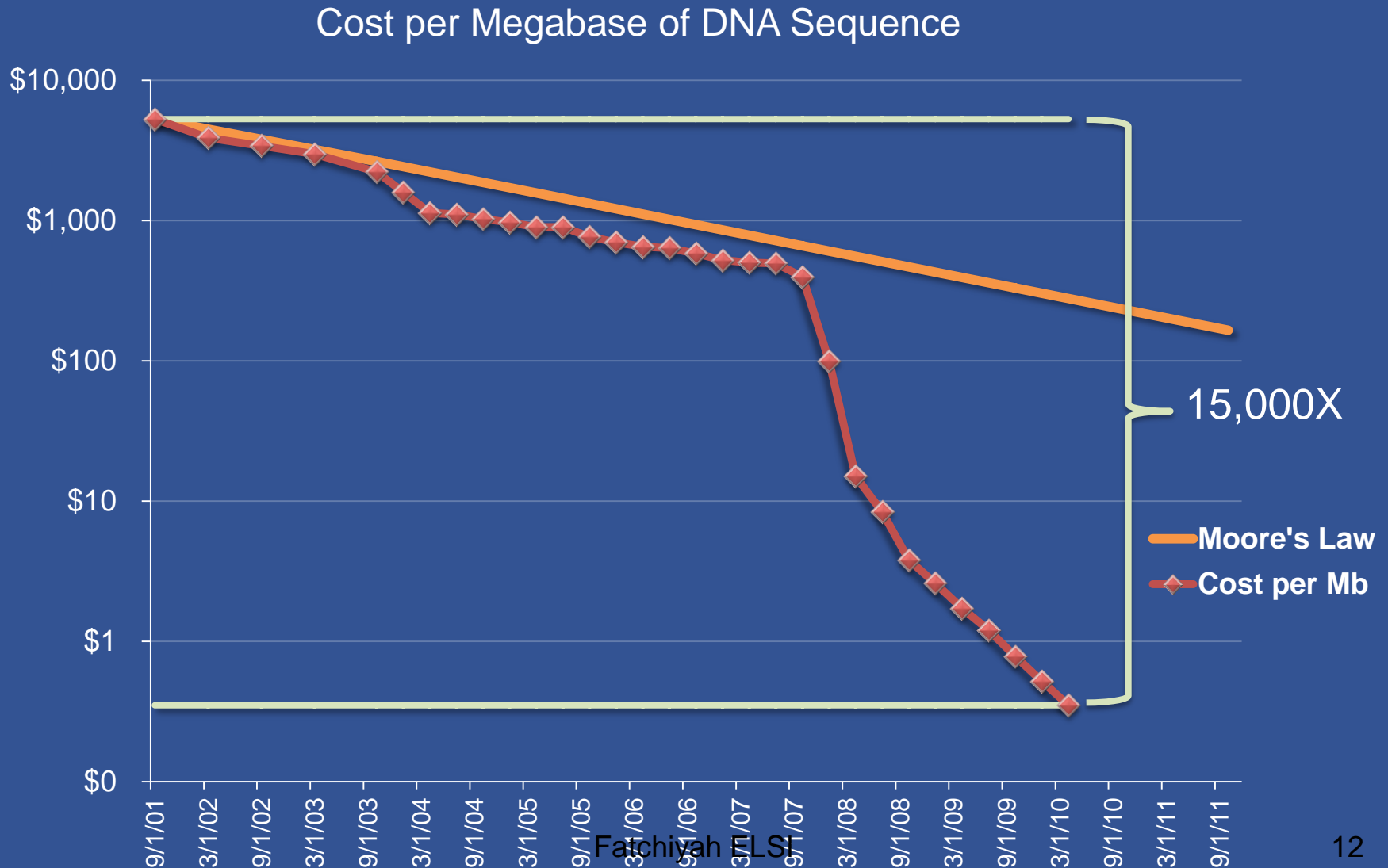


Source: Online Mendelian Inheritance in Man, Morbid Anatomy of the Human Genome

Fatchiyah ELSI



Sequencing Costs Decrease Rapidly ...



Charting a course for genomic medicine from base pairs to bedside

Eric D. Green¹, Mark S. Guyer¹ & National Human Genome Research Institute*

Francis S. Collins, Eric D. Green, Alan E. Guttmacher and Mark S. Guyer on behalf of the US National Human Genome Research Institute

Psychosocial and ethical issues in genomics research

Psychosocial and ethical issues in genomic medicine

Legal and public policy issues

Broader societal issues

Fatchiyah ELSI

BOX 5

Genomics and society



Effectively examining the societal implications of genomic advances requires collaborations involving individuals with expertise in genomics and clinical medicine and experts in bioethics, psychology, sociology, anthropology, history, philosophy, law, economics, health services research and related disciplines.

Psychosocial and ethical issues in genomics research. These include ensuring appropriate protection of human research participants and addressing the perceptions of risks and benefits of participating in genomic studies; expanding the diversity of research cohorts; incorporating biological ancestry markers and self-identified race and ethnicity as variables in genomic studies; accomplishing effective community engagement; and including vulnerable populations (for example, children and the disabled) and deceased individuals in genomics research.

Psychosocial and ethical issues in genomic medicine. These include communicating with patients about the uncertainty and evolving nature of predictions based on genomic information; interpreting information from direct-to-consumer genetic tests; ensuring fair access to genomic medicine; assessing the effectiveness of genomically informed diagnostics and therapeutics; using genomic information to improve behaviour change interventions; addressing issues associated with pre-implantation, prenatal and postnatal genetic diagnoses; and determining how constructs of race and ethnicity relate to the biology of disease and the potential to advance genomic medicine.

Legal and public policy issues. These include intellectual property in genomics; insurance reimbursement for genomic services; regulation of genetic testing; regulatory and non-regulatory approaches for dealing with direct-to-consumer genetic testing; the regulation of pharmacogenomics and genomics-based therapeutics; protection against genetic discrimination and stigmatization; and uses of genomics in non-medical settings.

Broader societal issues. These include the implications of increasing genomic knowledge for conceptualizing health and disease; for understanding identity at the individual and group levels, including race and ethnicity; for gaining insights about human origins; and for considering genetic determinism, free will and individual responsibility.

AUTHORSHIP Definition and importance :

- Process of deciding who names belongs on a research paper in many cases research evolves from collaboration and assistance between experts and colleagues
- It decides which colleagues should be listed as authors or co-authors and which should receive acknowledgments
- **Ethical guidelines** :- Each person listed as an author on an articles should have significantly contributed to both research and writing as well as must be prepared to accept full responsibility for the content of research articles
- **Who can be co-author** ? i) Contributed substantially to the research ii) Wrote or revised all or part of the manuscript. iii) Approved the final version of the entire article

PLAGIARISM and Ethical Guidelines

- **Plagiarism:** Act of passing of somebody else ideas, thoughts, pictures, theories, words or stories as your own If a researcher plagiarizes the work of others they are bringing into question, the integrity , ethics and trust worthiness of some total of his or her research. Either intentionally or unintentionally plagiarism it is not tolerated by scientific community
- **Ethical Guidelines** :- A researcher preparing a manuscript should cite the original source if he or she
Quotes another persons actual words, either oral or written ii) Paraphrases another persons words, either oral or written iii) Uses another persons ideas opinion and theory iv) Borrows facts statistics or other illustrative material unless the information is common knowledge

PEER REVIEW

- PEER REVIEW :- **Process** in which an author submits a written manuscript or article to a journal for publication and journal editor distributes the article to the experts experts- as reviewers editor- then enter the peer review process.
- PEER REVIEW PROCESS: **Reviewers and editors read and evaluate the article.** Reviewers submit their reviews back to the journal editor. Journal editor takes all comments including their own and communicates back to the original author
- ETHICAL GUIDELINES: Two most important ethical concept in peer review process:- **1. Confidentiality 2. Protection of intellectual property.** Reviewer should not know the author they are reviewing And the author should not be told the names of the reviewers No person involved in this process can publically disclose the information in the article

REASEARCH WITH ANIMALS

- (i) Animals play a significant role in research Used in testing new pharmaceuticals ii) As teaching tools for medical students iii) As experimental subjects for new surgical procedures

*** Research projects that use animals have to reviewed**

- ETHICAL GUIDELINES

- ✓ To ensure that animals intended for use in research facilities or for exhibition purposes or for use as pets are provided human care and treatment
- ✓ To assure that human treatment of animals during transportation in commerce
- ✓ To protect the owners of animals from theft of their animals by preventing the sale or use of animals which have been stolen

RESEARCH WITH HUMAN SUBJECT

- The issues concerning research with human subjects involves topics ranging from voluntary participation in research to fair selection and justice. This variety makes the topics surroundings research ethics with human subject a challenging one.
- Respect for persons- Informed consent Involves voluntary participation by subjects who understand what participation entails
Research for persons- privacy confidentiality People have right to protect themselves and information gathered during research participation could harm a person by violating their right to keep information about themselves private Risk benefit and beneficence- It means doing good. Biomedical research strives to do good by studying disease and health data to uncover information that may be used to help others

ETHICAL GUIDELINES:

- Human subject must voluntarily consent to research and be allowed to discontinue participation at any time
- Research involving human subjects must be valuable to society Research participant must be protected and safe Researchers must avoid harm, injury and death of research subjects and discontinue research.
- Research must be conducted by responsible and qualified researchers

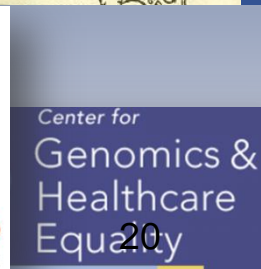
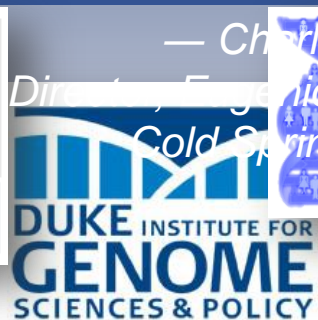
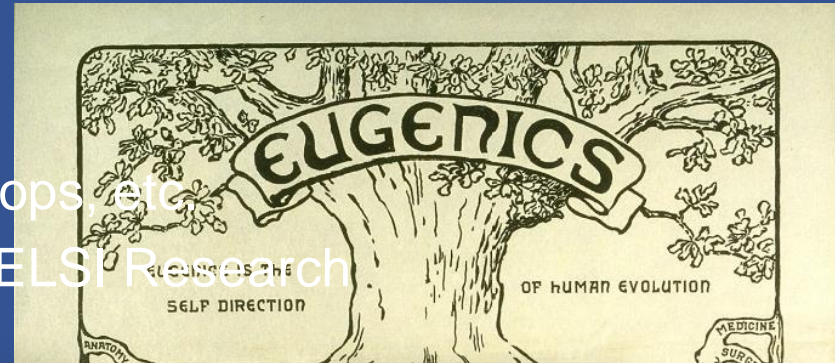
ELSI: Response to the Past; Vision for the Future

Ethical, Legal, and Social Implications Research Program

- Historical concern: eugenics
- ELSI established in 1990 as an integral part of the Human Genome Project
 - 3–5% of HGP annual budget
 - Remains active today

- ELSI at NHGRI

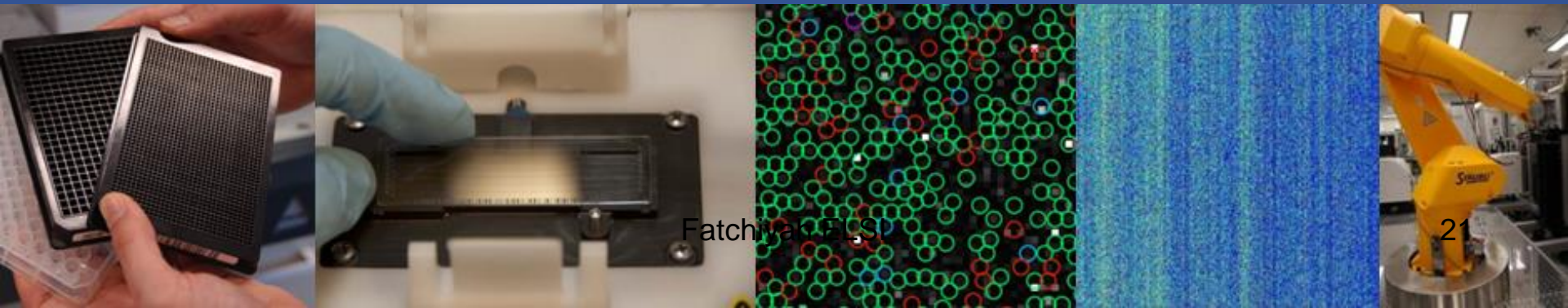
Eugenics is “the science of the improvement of the human race by better breeding”



Fatchiyah ELSI

Some Ethical Issues in High Throughput Technologies

- Genetic discrimination

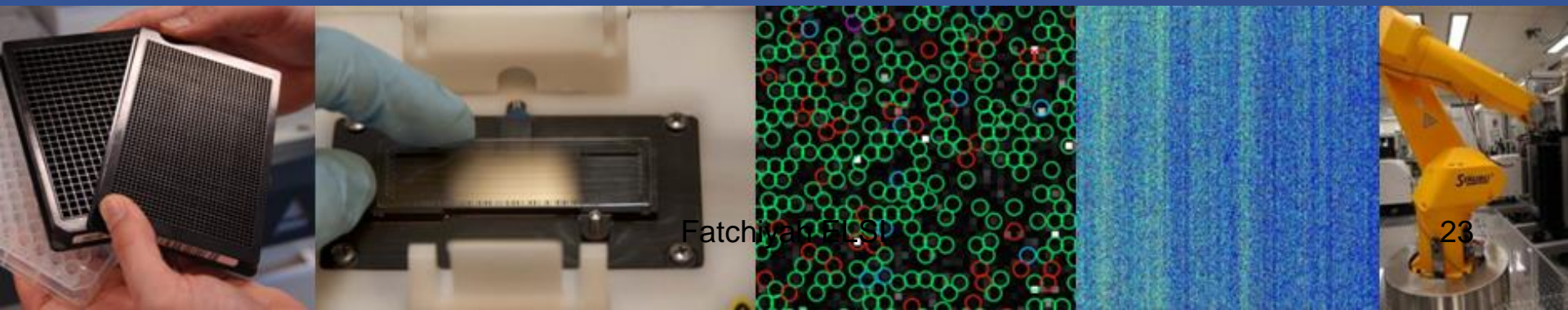


Unresolved potential risks of genetic discrimination

- Life insurance
- Long term care insurance
- Disability insurance
- Educational opportunities
- Military service
- Court decisions about child custody

Some Ethical Issues in High Throughput Technologies

- Genetic discrimination
- Incidental findings and return of research results



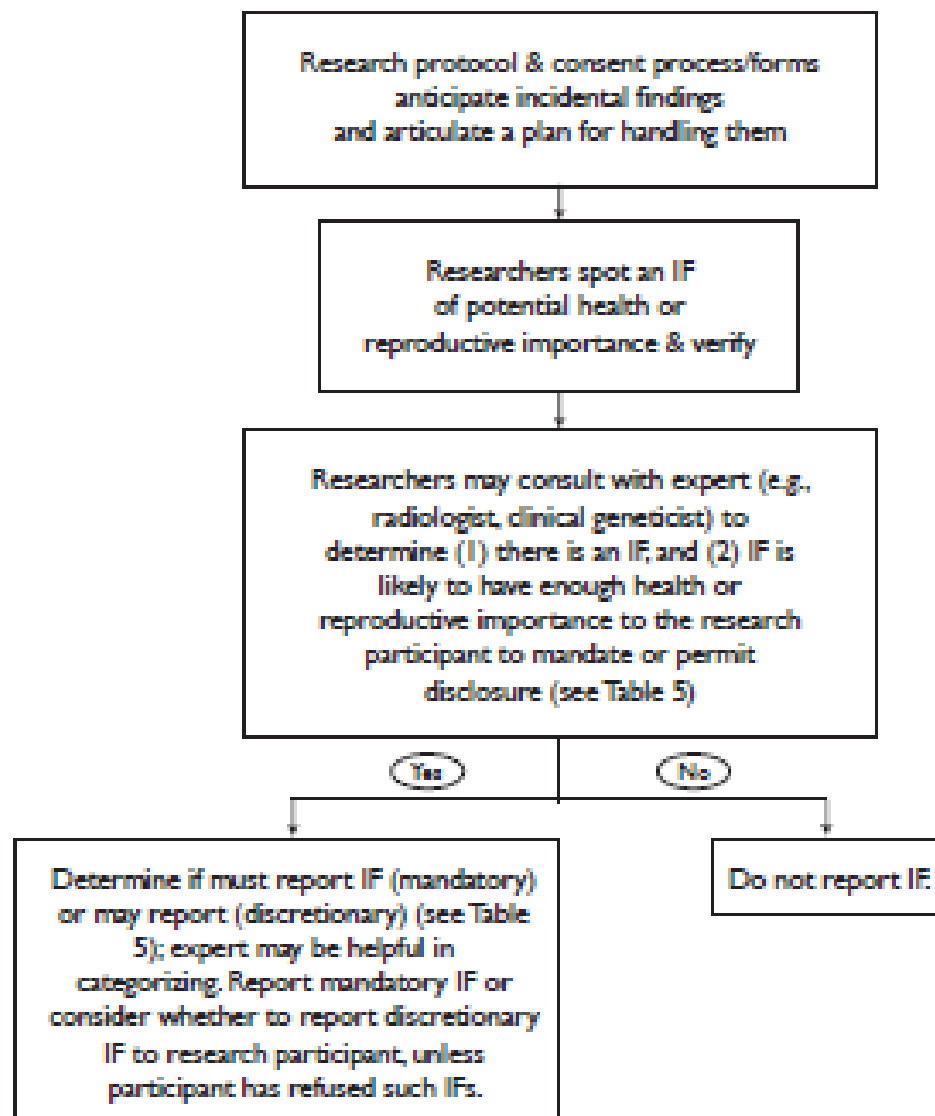
NEWSFOCUS

What Would

Science, 11 February 2011

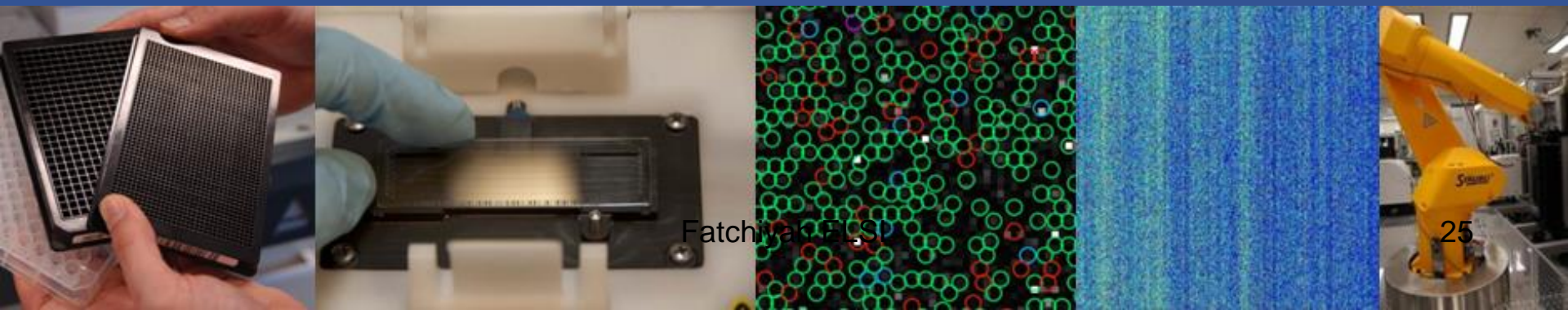
Table 4

Recommended Pathway for Handling IFs in Research



Some Ethical Issues in High Throughput Technologies

- Genetic discrimination
- Incidental findings and return of research results
- Forensic applications of DNA analysis



DNA and Forensics/Courts

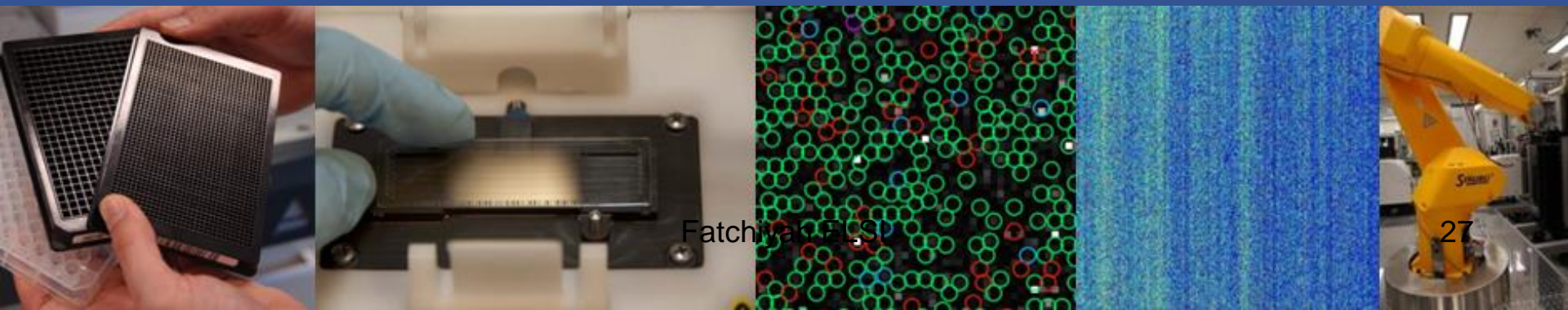
- Surreptitious collection
- Tracking through relatives
- Predicting age
- Predicting ancestry
- Predicting physical appearance
- Predicting recent travel (microbiome)
- Assessing presence of disease
- As a defense in a criminal case?



Science, 18 February 2011

Some Ethical Issues in High Throughput Technologies

- Genetic discrimination
- Incidental findings and return of research results
- Forensic applications of DNA analysis
- Neuroimaging

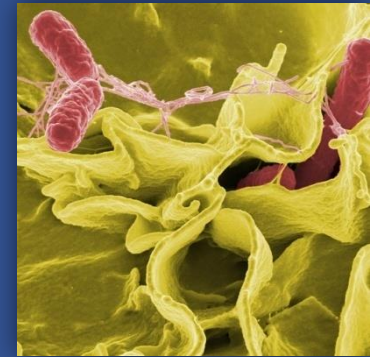


Neuroimaging – some ethical issues

- Incidental findings
- Lie detection
- Personality prediction/profiling
- Neuromarketing
- Exploration of spirituality
- Limited consciousness states
- Prediction of future disease risk

“We must not allow our technology to exceed our humanity.”

~ Albert Schweitzer



A well known biomedical ethicist stated that “When no one is watching, it is the character of the investigator that determines the moral quality of research and if research integrity is problematic we must start and end with the investigator. Thus, All the basic principles of ethics are derived from the concept that we individual should treat others as we wish them to treat us.

Bioethics Research

Prof. Fatchiyah, Ph.D.

Molecular Genetics Lecturer, Biology Dept. Brawijaya University

<http://fatchiyah.lecture.ub.ac.id>

Thank you for your understanding

