Health Informatics

Lecture 4

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HeLa Cells

• Cells from cervical cancer tumor of Helen Lacks
• Unique property: continued growing
Controversy

• Cells taken during surgery
• No consent given for use in research
• Identity was public
• Family couldn’t afford health insurance, yet pharmaceutical + other companies profited from cells
• Researchers contacted descendants in 70’s to get samples from them

• Legal, but ethical?
The Genomic and Transcriptomic Landscape of a HeLa Cell Line

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ABSTRACT HeLa is the most widely used model cell line for studying human cellular and molecular biology. To date, no genomic reference for this cell line has been released, and experiments have relied on the human reference genome. Effective design and interpretation of molecular genetic studies performed using HeLa cells require accurate genomic information. Here we present a detailed genomic and transcriptomic characterization of a HeLa cell line. We performed DNA and RNA sequencing of a HeLa Kyoto cell line and analyzed its mutational portfolio and gene expression profile. Segmentation of the genome according to copy number revealed a remarkably high level of aneuploidy and numerous large structural variants at unprecedented resolution. Some of the extensive genomic rearrangements are indicative of catastrophic chromosome shattering, known as chromothripsis. Our analysis of the HeLa gene expression profile revealed that several pathways, including cell cycle and DNA repair, exhibit significantly different expression patterns from those in normal human tissues. Our results provide the first detailed account of genomic variants in the HeLa genome, yielding insight into their impact on gene expression and cellular function as well as their origins. This study underscores the importance of accounting for the strikingly aberrant characteristics of HeLa cells when designing and interpreting experiments, and has implications for the use of HeLa as a model of human biology.
NIH

• Data available, but restricted to researchers
• Family included on committee processing requests
• Acknowledgment of Lacks + family in papers
Tuskegee experiment

1932 Syphilis study begins
1947 Penicillin becomes main treatment for Syphilis

Participants never given treatment or told they had syphilis
Study continued until 1972, when press reports on study
Specifically recruited black men
Subjects never told purpose of the study
Belmont report: 3 principles governing human subjects research (1979)

- **Respect for persons**
  - Acknowledge autonomy, “protect those with diminished autonomy”
  - Informed consent

- **Beneficence**
  - Weigh risk relative to possible benefits
  - Do not harm

- **Justice**
  - Fair recruitment, fair benefit from results
Some history

1949 Nuremberg Code – Participation should be voluntary and done w/informed consent
1964 Declaration of Helsinki – ethical principles
1979 Belmont report – 3 principles
1991 DHHS Common rule – governs federally funded research
Milgram

• Deception of subjects
  – Told research on punishment/learning
  – Actually on obeying authority
• Participants thought they were giving electric shock to another participant
What’s an IRB?

• Institutional Review Board
  – Must include at least one non-scientist, and one person from outside institution

• Reviews proposed studies involving human subjects

• **Must obtain approval BEFORE beginning study**

• Who needs approval?
  – Most universities have their own, and require approval for studies by those affiliated with university
  – Some journals require evidence of IRB approval
  – Required by federal funding agencies
Different institutions may ....

– Make different decisions about approval

– Have differing definitions of human subjects research

Multi-site studies require multiple IRB approvals
Stevens IRB

• Meetings scheduled monthly
  – PLAN AHEAD!
  – Must submit 2 weeks before meeting

• Contact Rachel Rosenhouse if you have questions

• Students need IRB approval too
  – Independent studies, research projects
  – Note: for some educational purposes, if study won’t lead to “generalizable knowledge” and is solely for course, may be exempt

https://my.stevens.edu/osp/humans/index.html
Review types

- Full
- Expedited
  - Often noninvasive, minimal risk
  - Secondary analysis of medical data
- Exempt (note, you cannot exempt yourself, still must submit protocol)
  - Existing non-identifiable data or data that’s publicly available
- Revision: if changes in protocol, e.g. eligibility criteria
Web-Based, Participant-Driven Studies Yield Novel Genetic Associations for Common Traits

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Abstract

Despite the recent rapid growth in genome-wide data, much of human variation remains entirely unexplained. A significant challenge in the pursuit of the genetic basis for variation in common human traits is the efficient, coordinated collection of genotype and phenotype data. We have developed a novel research framework that facilitates the parallel study of a wide assortment of traits within a single cohort. The approach takes advantage of the interactiveness of the Web both to gather data and to present genetic information to research participants, while taking care to correct for the population structure inherent to this study design. Here we report initial results from a participant-driven study of 22 traits. Replications of associations (in the genes OCA2, HERC2, SLC45A2, SLC24A4, IRF4, TYR, TYRP1, ASIP, and MC1R) for hair color, eye color, and freckling validate the Web-based, self-reporting paradigm. The identification of novel associations for hair morphology (rs17646946, near TCHH; rs7349332, near WNT10A; and rs15556547, near OFCC1), freckling (rs2153271, in BNC2), the ability to smell the methanethiol produced after eating asparagus (rs4481887, near OR2M7), and photic sneeze reflex (rs10427255, near ZEB2, and rs11856995, near NR2F2) illustrates the power of the approach.


Editor: Greg Gibson, Georgia Institute of Technology, United States of America

Received June 22, 2009; Accepted April 12, 2010; Published June 24, 2010
Facebook fiasco: was Cornell's study of 'emotional contagion' an ethics breach?

A covert experiment to influence the emotions of more than 600,000 people. A major scientific journal behaving like a rabbit in the headlights. A university in a PR tailspin.
What’s human subjects research?

NIH definition[link]:

Research is considered to involve human subjects when an investigator conducting research obtains

(1) data through intervention or interaction with a living individual

or (2) identifiable private information about a living individual
Some examples

• Focus group of children with diabetes evaluating new game to teach them about glucose control
• Analysis of medical records
• Cadaver samples, records from deceased persons
• Research on cell lines

When in doubt consult IRB!
IRB can declare your work exempt, you cannot exempt yourself.
Types of projects that may need IRB approval

• Surveying people about their attitudes on data privacy
• Comparing grades of past Stevens students to see whether online or on campus calculus courses are better
• Eye tracking experiment to test new EHR interface
• Mechanical turk workers answering surveys
Parts of an IRB proposal

- Purpose of research
- Importance of knowledge to be gained
- Involvement of subjects, study design
- Risks *(to be discussed)*
- Benefits (direct/indirect) *(to be discussed)*
- Compensation
- Inclusion/exclusion criteria, justification, recruitment protocol *(to be discussed)*
- Consent protocol *(to be discussed)*
CHECKLIST FOR NEW SUBMISSION

Approval is required by the Committees of the Protection of Human Subjects before starting research involving human subjects to be conducted by Stevens’ students, staff or faculty or by others conducting research subjects to the oversight of the Stevens CPHS.

Your submission should include the following (in order):
For your convenience, you may use the check boxes below to organize your submission.

1) □ IRB Application for the Use of Human subjects Form
2) □ Copy of grant for all federally funded research.
3) □ Consent form or request for waiver of consent or documentation of consent (as applicable) Consent form templates are available at:
4) □ Copy of all questionnaires, interview items, surveys, to be used in study.
5) □ Recruitment Materials (flyers, advertisements, letters, script for verbal recruitment)
6) □ Letters of support from external sites; other IRB approvals.
7) □ Part E: Certifications signed by Principal Investigator(s) (and faculty sponsor for student submissions)

Incomplete applications may delay the processing of the submission. Approval cannot be granted until the application is complete and all required items have been submitted.

All questions regarding new submissions should be directed to the CPHS at 201-216-5280. See www.stevens.edu/osp/humans/index.html for forms, information, and education requirements.
PART A: COVER PAGE

Project Title (identical to proposal or thesis/dissertation):

OR, if applicable:

Grant Title (if different from Project Title):

Principal Investigator (check one): [ ] Faculty [ ] Staff [ ] Student
Name: [ ] Dr. [ ] Ms. [ ] Mr. _____________________________
Phone #: __________________________ Fax #: _____________________________
Department/College: _______________________________________________________
E-mail Address: __________________________________________ Location: _________

Faculty Sponsor (required for all student investigators)
Name: ______________________________________
Phone #: __________________________ Fax #: _____________________________
Department/College: _______________________________________________________
E-mail Address: __________________________________________ Location: _________

List all key personnel (defined as individuals who contribute to the scientific development or execution of the project). Include their educational level, their role on the project (i.e., co-investigator, project manager, research assistant), and their institutional affiliation.
This project is (check all that are appropriate):

___ Unfunded Research
___ Candidacy/Professional Paper
___ Funded Research
___ Master's Thesis
___ Senior Honor's Thesis
___ Doctoral Dissertation
___ Pilot Study
___ Independent Study
___ Multi-Phase Study
___ Other (specify, _____________________)
___ Longitudinal Study

If this application supports a proposal for funding, indicate the name of the agency/organization/foundation: __________________________________________.
(One copy of the proposal must be included with this application.)

I think this qualifies for the following type of review:

[ ] Exempt Category #__________ (submit original only)
[ ] Expedited Category #__________ (submit original plus 2 copies)
[ ] Full Review (submit original plus 10 copies for Committee 1 and original plus 5 for Committee 2)

Note: Committee 2 includes all departments in the College of Liberal Arts and Social Sciences. Committee 1 reviews all others.
PART B: RESEARCH PROJECT REVIEW SUMMARY

1. State the specific research hypotheses or questions to be addressed in this study.

2. What is the importance/significance of the knowledge that may result?

3. **Proposed Start Date** (may not precede approval date): __________________________ OR
   [ ] Upon CPHS Approval

4. **Subject Population** (check all that are appropriate)
   [ ] Adults
   [ ] Cognitively or Psychologically Impaired
   [ ] Children or minors (<18 in Texas and most states)
   [ ] Non-English speaking
   [ ] Elderly (65yrs and above)
   [ ] Prisoners or Parolees
   [ ] Institutional Residents
   [ ] Stevens' Faculty, Staff, or Students

   a. Expected maximum number of participants __________________________

   b. **Age of proposed subject(s) (check all that apply):**
      [ ] Infants (2yrs and under)
      [ ] Children (3yrs–10yrs)
      [ ] Adolescents (11yrs-14yrs)
      [ ] Adolescents (15yrs-17yrs)
      [ ] Adults (18yrs-64yrs)
      [ ] Elderly Adults (65yrs and above)

   c. **Inclusion/Exclusion:**
      Describe criteria for inclusion and exclusion of subjects in this study. Include justification, how it will be determined, and by whom.
      
      **Inclusion Criteria:**

      **Exclusion Criteria:**

      **Justification:**

      **Determination:**
d. If this study proposes to include children, this inclusion must meet one of the following criterion for risk/benefit assessment according to the federal regulations (45 CFR 46, subpart D). Check the appropriate box:

- [ ] (404) Minimal Risk
- [ ] (405) Greater than minimal risk, but holds prospect of direct benefit to subjects
- [ ] (406) Greater than minimal risk, no prospect of direct benefits to subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition.

Explain the justification for the selected category:


5. If the research involves any of the following, check all that are appropriate:

- [ ] Interview
- [ ] Survey/Questionnaire
- [ ] Study of Existing Data
- [ ] Deception
- [ ] Venipuncture
- [ ] Data Analyses Only
- [ ] Clinical Studies
- [ ] Behavioral Observation
- [ ] Study of Human Biological Specimens
- [ ] Waiver of Consent
- [ ] Other (specify)

6. Location(s) of Research Activities:

- [ ] Stevens campus
- [ ] Other (specify)

Note: A letter of approval from sites other than Stevens must be included with the application. If it is not available, please explain:


7. Informed Consent of Subjects: Your study protocol must clearly address one of the following areas:

- [ ] Informed Consent. Signed informed consent is the default. A model consent is available on the CPHS website and should be used as a basis for developing your informed consent document. If applicable, the proposed consent must be included with the application. ATTACH COPY OF PROPOSED CONSENT DOCUMENT

- [ ] Cover Letter. You may request a waiver of documented informed consent with Appendix A – Request for Waiver of Documentation of Consent. ATTACH COPY OF PROPOSED COVER LETTER AND APPENDIX A.

- [ ] No Informed Consent. You may request a waiver of informed consent with Appendix B – Request for Waiver/Modification of Informed Consent. If applicable, a copy of the modified consent document is required. ATTACH APPENDIX B.

NOTE: Studies including deception must qualify for waiver of consent. A modified version of a consent document to be used in deceptive research studies as well as a debriefing form must be included with the application.
PART C: RESEARCH PROTOCOL

8. Describe the research study design. (Describe the research methods to be employed and the variables to be studied. Include a description of the data collection techniques and/or the statistical methods to be employed.)

9. Describe each task subjects will be asked to perform.

10. Describe how potential subjects will be identified and recruited? (Attach a script or outline of all information that will be provided to potential subjects. Include a copy of all written solicitation, recruitment ad, and/or outline for oral presentation.)

11. Describe the process for obtaining informed consent and/or assent. How will investigators ensure that each subject’s participation will be voluntary (i.e., free of direct or implied coercion)?

12. Briefly describe each measurement instrument to be used in this study (e.g., questionnaires, surveys, tests, interview questions, observational procedures, or other instruments) AND attach to the application a copy of each (appropriately labeled and collated). If any are omitted, please explain.

13. Describe the setting and mode for administering any materials listed in question 12 (e.g., telephone, one-on-one, group). Include the duration, intervals of administration, and amount of time required for each survey/procedure. Also describe how you plan to maintain privacy and confidentiality during the administration.

14. Approximately how much time will be required of each subject? Provide both a total time commitment as well as a time commitment for each visit/session.
15. Will subjects experience any possible risks involved with participation in this project?

Risk of Physical Discomfort or Harm  [ ] YES  [ ] NO
Risk of Psychological Harm (including stress/discomfort)  [ ] YES  [ ] NO
Risk of Legal Actions (such as criminal prosecution or civil sanctions)  [ ] YES  [ ] NO
Risk of Harm to Social Status (such as loss of friendship)  [ ] YES  [ ] NO
Risk of Harm to Employment Status  [ ] YES  [ ] NO
Other Risks  [ ] YES  [ ] NO

If yes to any of the above, please explain. Describe procedures, if any, to address risk (such as referrals to agency or other source).

16. Does the research involve any of these possible risks or harms to subjects? Check all that apply.

[ ] Use of a deceptive technique (attach debriefing)
[ ] Use of incomplete or generalized information to the subject regarding the actual purpose of the study (attach debriefing)
[ ] Use of private records (educational or medical records)
[ ] Manipulation of psychological or social variables such as sensory deprivation, social isolation, psychological stresses (attach debriefing)
[ ] Any probing for personal or sensitive information in surveys or interviews
[ ] Presentation of materials which subjects might consider sensitive, offensive, threatening or degrading
[ ] Possible invasion of privacy of subject or family (may require additional consent)
[ ] Other, specify: ___________________________  ___________________________

17. What benefits, if any, can the subject expect from their participation?

18. What inducements or rewards (e.g., financial compensation, extra credit, and other incentives), if any, will be offered to potential subjects for their participation?

PART D. RESEARCH DATA

19. Will you record any direct identifiers, names, social security numbers, addresses, telephone numbers, patient or student ID numbers, etc.?

[ ] Yes  [ ] No

If yes, explain why it is necessary to record findings using these identifiers? Describe the coding system you will use to protect against disclosure of these identifiers.
PART D. RESEARCH DATA

19. Will you record any direct identifiers, names, social security numbers, addresses, telephone numbers, patient or student ID numbers, etc.?
   [ ] Yes  [ ] No
   If yes, explain why it is necessary to record findings using these identifiers? Describe the coding system you will use to protect against disclosure of these identifiers.

20. Will you retain a link between study code numbers and direct identifiers after the data collection is complete?
   [ ] Yes  [ ] No
   If yes, explain why this is necessary and state how long you will keep this link.

21. Will anyone outside the research team have access to the links or identifiers?
   [ ] Yes  [ ] No
   If yes, explain why and to whom.

22. Where, how long, and in what format (such as paper, digital or electronic media, video, audio or photographic) will data be kept? In addition, describe what security provisions will be taken to protect these data (password protection, encryption, etc.). [Note: Stevens Institute of Technology policy on data retention requires that research data be maintained for a minimum of 3 years after completion of the project. All research data collected during this project is subject to the Stevens Institute of Technology data retention policy found at www.stevens.edu/osr/humans]
PART E: CERTIFICATIONS

PRINCIPAL and CO-INVESTIGATORS – I hereby acknowledge and accept the responsibility for protecting the rights and welfare of all participating subjects in accordance with federal and institutional policies and procedures. Furthermore, I certify that:

- NO involvement of human subjects in this project will begin before written approval of the Committees for the Protection of Human Subjects has been received.
- Any additions or changes to this protocol will require the submission of a Request for Revision form and for the review and approval by the Committees for the Protection of Human Subjects prior to initiation.
- Written documentation of any unanticipated problems or injuries connected with an approved protocol must be provided to the Committees for the Protection of Human Subjects (201-216-5280) within 5 working days.
- All signed consent documents will be retained for at least 3 years past the completion of the research activity. (Note: Faculty sponsors are responsible for retaining signed consents for student projects.)
- The institution has provided me with a copy of the approved Institutional Assurance (either the electronic or manual form) and has provided access to the Belmont Report and the appropriate sections of the Public Law governing this Assurance, 45 CFR 46.

__________________________________________________      _______________________
Signature of Principal Investigator                                                   Date

__________________________________  ________________________  __________    
Signature of Co - Investigator                                                         Date

*NOTE: Additional signature lines for Co-Investigators may be added as required.

FACULTY SPONSOR (required for all students) – I hereby acknowledge and accept the responsibility for supervision of this study to ensure the protection of the rights and welfare of all participating subjects in accordance with federal and institutional policies and procedures. After careful review of this application, I further certify:

- The accuracy of the information stated in this application AND
- The scientific merit of the proposed project.

__________________________________________________      ________________________
Signature of Faculty Sponsor                                                            Date

DEPARTMENT CHAIR/DEAN (not required if exemption is claimed) – I hereby confirm the accuracy of the information stated in this application. I am familiar with and approve of the procedures that involve human subjects.

__________________________________________________      ________________________
Signature of Chair/Dean                                                                  Department/College            Date
Risks

• All possible risks to subjects
• Harms:
  – Social
  – Economic
  – Physical
Benefits

• Usually not direct benefits to subjects but benefits to patients in future
• Note potential for coercion!
Inclusion criteria

• Who will be eligible to participate?
• Who will determine eligibility?
• Need to specifically discuss enrollment of women, minorities, and children
Vulnerable populations

• Some populations more vulnerable
  – Diminished autonomy, susceptible to coercion

• DHHS examples: children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons

• Other examples?
  – Students/subordinate employees
  – Emergencies (e.g. consent in ER/ambulance)
Examples

• Research with prisoners
  – Must be research specific to prison population
  – Special consideration of benefits of participation relative to ability to consent

• Children

• Employees/students

• Homeless
Recruitment

• Ensuring autonomy
• Reaching target population

Flyers commonly used
Clinicians can also tell eligible patients about study
Volunteers Needed for Health and Technology Study

We think there should be an easy way of tracking your meals, just like a pedometer tracks your steps. Instead of recording everything yourself, could your phone figure out when you’ve started eating, know if you’re eating a hamburger or a salad, and tell you how much you ate?

We are working to make this a reality by combining data from wearable devices like microphones and smart watches. This research could lead to computer-generated calorie counts that help you understand your diet and better treatment of chronic diseases such as diabetes and obesity.

If you are between the ages of 18 and 64, and do not have trouble chewing or swallowing you may be eligible. If you have a history of eating disorders, this study is not a good fit.

Wear sensors such as a smartwatch during your usual activities and track your meals for either 2 or 5 days. On two mornings we will provide breakfast at our lab in Hoboken, NJ and collect data while you eat and wear our sensors. In appreciation of your time, you will receive $50.00 (or $150.00 if you participate for 5 days).

If you are interested in participating or would like to find out more, please contact us at MELD@skleinberg.org or 201-216-5048.

This research study is led by Dr. Samantha Kleinberg, who directs the Health and AI Lab at Stevens Institute of Technology.

It was approved by Stevens Institute of Technology IRB Protocol # 2016-012N.
Reporting adverse events

Previously healthy subject in JHU study died. A month later OHRP briefly suspended all federally funded HS protocols at JHU

• Volunteer 1: persistent cough (~ week)
• Volunteer 2: ok
• Volunteer 3: cough, hospitalization, death
Other reporting

- Adverse events (to IRB, potentially funding agency)
  - Subject in cancer study dies of cancer
  - Subject in migraine study dies in car accident

- To Subjects
  - E.g. Tuskegee

- Incidental findings
  - nonpaternity, risk for disease, brain anomalies in fMRI
Consent basics

• Make clear nature of participation and research
• Make clear subject understands process
  – Written for non-expert audience
• Make clear participation is voluntary
HANDOUT – consent form
Elements (1)

• Description of research
• Description of nature of involvement, duration
• Can decline to participate, withdraw consent
  – Lets participants know that they can stop participating in study at any time, and what will happen to data already collected
• Rights of participants to ask questions, contact information for investigators
Elements (2)

• Benefits of research
  – May state that no direct benefits to the participating individuals are anticipated, but may further knowledge in an area and lead to future benefit

• Potential risks of research
  – Loss of privacy
  – Discomfort
  – Incidental findings
Waiver of informed consent

Sometimes consent not feasible
  – Retrospective analysis of 1000s of medical records
AND Risk minimal
  – Breach of privacy
AND subjects informed after if possible

AND waiver doesn’t affect rights/welfare
Finally...

• Need to assess understanding

• What would be good/bad questions to ask?
Today’s paper
Randomised controlled trials (RCTs) sometimes recruit participants who are desperate to receive the experimental treatment. This paper defends the practice against three arguments that suggest it is unethical first, desperate volunteers are not in equipoise. Second clinicians, entering patients onto trials are disavowing their therapeutic obligation to deliver the best treatment; they are following trial protocols rather than delivering individualised care. Research is not treatment; its ethical justification is different. Consent is crucial. Third, desperate volunteers do not give proper consent: effectively, they are coerced. This paper responds by advocating a notion of equipoise based on expert knowledge and widely shared values. Where such collective, expert equipoise exists there is a prima facie case for an RCT. Next the paper argues that trial entry does not involve clinicians disavowing their therapeutic obligation; individualised care based on insufficient evidence is not in patients best interest. Finally, it argues that where equipoise exists it is acceptable to limit access to their proxies) who are desperate to be placed on one particular arm of the study. They consent because the treatment they desire is available only through that study and are disappointed if randomised to the “wrong” arm. The problem usually arises when the RCT is investigating a new treatment into a serious or terminal illness for which current treatment options are limited.

Some argue directly that it is unethical to recruit desperate volunteers to RCTs. Others imply that it is unethical by arguing that it is right to recruit only participants who are indifferent between treatment arms. The issue has been discussed most in relation to patients with serious and terminal illness including HIV infection, AIDS\(^1\) and variant Creutzfeldt–Jakob disease. In the UK, the parents of two young men with this disease challenged in court the decision of doctors not to use a drug that was still in the early (animal) research stage. This raises the possibility that desperate volunteers could similarly challenge a placebo-controlled RCT.

In this article we defend the recruitment of desperate volunteers into RCTs, provided the condition of equipoise is met. As this is a term that is often understood differently by different people, we define it in the terms of the paper, for the privilege of discussion.
Example: secondary analysis of ICU data

- Objective: analyze data to find causes of complications in neuro ICU
- Inclusion: Age >18, confirmed stroke
- Exclusion: Age <18, stroke secondary to tumor
- Demographics: same as hospital
- Data sources: interviews, EHR
Example: secondary analysis of ICU data

- Recruitment: patient, family, waiver if neither available
- Withdrawal: patient or family at any time
- Risks: breach of privacy
- Mitigation of risk: remove identifiers, dates, store data on server with limited access
- Benefits: none direct
HOMEWORK: Write an IRB proposal

- Overview, inclusion, exclusion, recruitment, consent (sections: 1,2,4,10, 11)
- Procedure (sections: 8,9, 12-14)
- Risks, benefits (sections: 15-18)

DUE Monday at 3PM. Canvas will not allow late submissions.

Do not email submissions, HW is only accepted through canvas.
Hw does not include (but in reality you’d need)

• Recruiting flyer (IRB must approve this!)
• Telephone screening script
• Consent form

And for actual study:
Payment receipt form
Payment log