Online Ethics Center
FOR ENGINEERING AND SCIENCE

When Should We Accept Consent?

Stuart Youngner

June 29, 2012

View online: https://onlineethics.org/cases/when-should-we-accept-consent

You are the principal investigator of a phase II study of refractory depression funded by a large pharmaceutical company. Mr. Smith has been unsuccessfully treated by a psychiatrist in the community. This psychiatrist has referred Mr. Smith to you at the academic medical center where you work and are conducting the study.

The study involves hospitalization, a washout period of four weeks, and assignment to a placebo or treatment arm. Mr. Smith agrees to the study saying, "I don't care anymore. I don't care if I get the medicine or the placebo. What difference does it make?"

- Do you think Mr. Smith should be allowed to participate in the study? Why or why not?
- What other information would you want to help you make this decision?

Caroline Whitbeck introduced methods and modules for discussing numerous issues in responsible conduct of research at a Sigma Xi Forum in 2000. Partial funding for the development of this material came from an NIH grant.

You can find the entire sequence on the OEC at Scenarios for Ethics Modules in the Responsible Conduct of Research. Some information in these historical modules may be out-of-date; for instance, there may be a new edition of the professional society's code that is referred to in an item. If you have suggestions for updates,

please contact the OEC.

All in the Interpretation

Simil Raghavan

September 6, 2011

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Kate is a graduate student in Professor Brigg's lab. She started a project examining the effects of certain video games in children during her first year of graduate school. She knows that some of the funding for her project comes from a video game manufacturer, but the money does not give the company control over how the research is conducted, and she believes she has been careful not to let the source of funds influence her project design and data collection.

Discussion:

1. Might a researcher’s source of funding create a bias or the perception of bias? How might Kate (and the research community in general) deal with potential bias?
2. In what ways might industry funding influence a researcher and affect his/her research?
3. Even if Kate believes the source of funding will not influence her research, should she be concerned with how the presence of industry funding may affect her credibility with colleagues and the public?
4. What should Kate and her institution do to help preserve her scientific integrity in this case?

Kate has collected all of the data for her project, and she has been carefully examining the trends. Looking back, she might have changed some of her data-collection methods if she could do it over again; but she knows that is the nature of research, and that lessons learned in one project generate new questions to ask in

the future. She is excited to see a clear trend in her data that indicates a positive effect of educational video games, but the effect washes out after about a year or two, and she is unsure how to interpret it. She creates a rough draft of a paper that carefully outlines all of her analyses and gives it to Dr. Brigg for review. Later in his office, Dr. Brigg explains that the “Results and Conclusions” section of her paper is very weak. He says that she does not make a strong case for the importance of her research, and that the quality of the journal where her paper will be published depends largely on her ability to interpret the data. “I’m not saying to leave out data,” he says, “but the story you tell about the data is at least as, if not more, important than the data themselves.”

Kate knows that research papers are rarely air-tight. In fact, members of her lab will often spend lab meetings ripping apart a paper from another group in order to stimulate discussion about the author’s conclusions and generate ideas for future research. She feels she must choose a black or white stance in her interpretation of the effects of gaming in order to create a strong paper. She also knows that if she emphasizes the positive effects of the games, she could easily write another grant to the video game manufacturer to study the later wash-out period with a high probability of funding.

Discussion:

5. What is Kate’s responsibility in presenting her research findings? Is Dr. Brigg correct in stating that her story is as important as the data themselves? Is Kate correct in assuming she must choose one side and stick to it?
6. How might the possibility of future funding influence a researcher’s presentation of his/her findings? What should be done to minimize the undue influence of funding on the way a scientist interprets and presents his/her findings?

After thinking about it for a few days, Kate decides that the initial trend in her data is interesting enough that it should be emphasized in her paper. She writes another draft that emphasizes this trend and only briefly mentions the wash-out as a subject for further research. When she gives the draft to Dr. Brigg he is very excited. He says the results are very compelling and suggests they submit to a nationally-recognized journal. The paper is published, and Kate receives a great deal of recognition and congratulations from others within the university. She also receives a number of requests from news reporters to discuss her findings. The reporters

seem not to notice that the numbers wash out and do not ask about it. Kate knows that all the press is good for her career, but she is also not skilled at giving interviews and she is happy to have Dr. Brigg speak with many of the reporters for her. Dr. Brigg is delighted to receive the publicity for his lab, and each time he is interviewed he is careful to emphasize the value of these games for young children.

Discussion:

7. Knowing that most people will not look up the original article when they hear a news report, does Kate's and/or Dr. Brigg's responsibility to the public change in any way when interacting with the press?
8. How might she approach the situation if Kate feels that the results are not as cut-and-dry as Dr. Brigg's interviews seem to imply?

Eventually Kate's paper is challenged by a competing research group. Their results indicate a deleterious effect of the games over a longer time period. At this point Kate is working in her own lab on another research topic. She is tired of speaking to reporters, and she is still not comfortable giving interviews. She is also a little worried that the interpretation of her research may have encouraged parents to have their children play games that may ultimately be harmful. Some reporters are even suggesting that her interpretation of the data was motivated by her industry funding, although she doesn't think that is true. She decides to adopt a policy of not communicating with any members of the press.

Discussion:

9. Does Kate (or do researchers in general) have a responsibility to communicate with the media?
10. If Kate feels that her research is misrepresented in the press, how might she approach the situation? Is she ultimately responsible for the information that is disseminated to the public?
11. How might the appearance of bias be controlled at this point?
12. This case was inspired by the following articles in **Time** and the **Denver Post**. Consider how the controversy is presented in those articles. Is it presented fairly? Why or why not? How do you think it might affect the public perception of science? What do you see as the responsibilities of the researchers and the reporters and editors in this situation? Does the above case present the same or different ethical issues?

Articles:

- Park, Alice. 2007. Baby Einsteins: Not So Smart After All. *Time*. Posted: Monday, Aug. 06, 2007, http://content.time.com/time/health/article/0,8599,1650352,00.html?iid=sr-link1.
- Auge, Karen. 2011. 'Baby Einstein' DVD creators find redemption in documents suggesting negative study was flawed. *The Denver Post.* Posted: 06/30/2011, http://www.denverpost.com/news/ci_18381772.

Order Out of Chaos

Daniel A. Vallero

February 14, 2012

View online: https://onlineethics.org/cases/order-out-chaos

Dr. Abbot Oceedee is a senior research physical scientist who leads the inverse problems program in the National Environmental Systems Laboratory (NESL). This program has its own policy about authorship, which Oceedee discusses with each new member who joins his lab. He states that only those who have made a significant intellectual contribution to a project will be included on any paper. He also states that he is the final authority regarding what is defined as a significant intellectual contribution, in the event that a disagreement arises. Everyone in the program is quickly made aware that Oceedee will be included as last author on any paper that is the result of research done in his program.

You are a post-doc in Oceedee's lab, working to characterize a novel Bayesian approach that applies chemical space concepts to microbial risk assessments, beginning with *Entamoeba histolytica*. Based on systems medicine and bioinformatics, you are able to adapt an off-the-shelf model to characterize the absorption and distribution of this microbe in a way that has never been done (to your knowledge).

You share a cubicle and equipment with another post-doc, Dr. Conrad Inarms, a biomedical engineer with a strong background in biostatistics and systems medicine. He has given you many great ideas, even a few that relate to your work. You log them away in your memory, however, you seldom write them down.

You also work with Dr. Bill Melater, an exposure scientist in a different NESL program. Melater is the task lead for Biomarker Research; that is, he is responsible for submitting task descriptions and milestones to the National Program Director for inclusion in the National Research Action Plan. This is how all of your research is funded. In fact, you meet with Melater's task group every other week to discuss your project, along with the other projects under Melater's task. Two scientists are particularly vocal and often helpful with ideas on how to proceed in your research. Dr. Ira Gent has sent you three articles on informatics, with lengthy emails from which you have gleaned a number of insights that ultimately made it into the discussion section of the paper. Perry Fural, who has been with the NESL for 25 years understands the research planning process and has been a branch chief in the past. He usually gives you insights on how to work the system to get the extramural funds for the project. This is always in sidebar discussions after the meeting or during open discussions on the agenda items.

Bea Cuyette, a technician in Oceedee's lab, has worked very closely with you on running some routine R programs. She has done most of the trouble shooting and optimization for your meta-analysis. She also developed a novel method of using Many-Eyes to sort through droves of data.

Shore Tymer is a student services contractor. Tymer is a first year graduate student who is currently doing a six-week rotation through Oceedee's lab. He assists you in a tightly controlled and highly focused project that compares exposure of other eukaryotes to *Entamoeba*. In fact, it was his project that provided the critical evidence that this microbe would be a good indicator for what you now call "microbial space."

Another group outside of NESL who is part of the Biomarkers project is the National Biomarker Center (NBC), whose liaison with NESL is Dr. Indira Pendant. There is a joint NESL/NBC meeting every Wednesday, which is a free-for-all discussion on the ongoing projects. You receive a lot of input, but much is not all that useful, from these meeting. Pendant has told you and Oceedee that she believes anyone working on a project and providing good ideas should be included as authors. Indeed, that

does seem to be NBC's policy. So far, eight different NBC scientists have given you input during these meetings. One in particular has been quite helpful. Dr. Will Fundid has a large abiotic chemical space project that parallels your project. In fact, Fundid needs your data to do a complete risk simulation that is one of his milestones this fiscal year.

You have also consulted your advisor/mentor from your PhD program at the Raleigh State University, Dr. Fuller Pride, an internationally recognized expert in sociometrics. In fact, one of the R programs you have run is based on a homework assignment from one of the classes you took at RSU, as well as independent research for one of your dissertation chapters.

Oceedee encouraged you to submit the data for publication as quickly as possible. You do the writing, give the paper to Inarms for review, and then present the data at the lab meeting the following week. Following the meeting, Oceedee sends an email to you, copying Cuyette, discussing authorship assignments for the paper. He notes that since Cuyette offered novel ideas to the project and helped in trouble-shooting and in the review of the paper that she should be included as second author. He further recommends you consider Pendant's authorship policy. Cuyette replies to Oceedee's email that Oceedee should be the last author on the paper since the work was done in his lab and supported by funds from his program.

The working title of the paper is: "Applying Microbial Space to Inform Risk Characterization." You hope to submit it to the *Journal of Systems Biomarking.* You have asked Inarms and Melater for clearance reviews.

Discussion Questions:

1. What do you suggest as the order of authorship for this manuscript?
2. Who should receive an acknowledgment? Who should not be omitted completely?
3. Besides the typical literary resources, what work should be cited in the references?
4. Do you agree with the recommendations by Oceedee? Why or why not?
5. Do you agree with the recommendations by Pendant? Why or why not?
6. Do you agree with the recommendations by Cuyette? Why or why not?
7. Is it ethical to include Cuyette (the technician), but not to include Tymer (the graduate student) on the list of authors for this paper?

8. Does it matter that Tymer is a contractor? Does it matter that he is rotating through the lab and not a regular project member?
9. What constitutes a significant intellectual contribution in this case? Who should decide?

Nixing a Good Apple?

Daniel A. Vallero

February 14, 2012

View online: https://onlineethics.org/cases/nixing-good-apple

Dr. Mitch Woodjade joined the National Environmental Systems Laboratory (NESL) as a post-doc. His mentor was Dr. Val Daniels, a widely published and respected senior scientist. During his stay in Daniels' lab, Woodjade hoped to learn certain techniques of systems ecology that he would employ in his own research. To allow Woodjade to do this, Daniels assigned him a leading role in a new project that the lab was undertaking. This entailed many meetings of an eclectic group of NESL researchers, as well as several from the well-funded National Institute of Xenobiotics (NIX), which shares a campus with NESL. After ten months, the data collection and analysis were completed. In the meantime, Dr. Woodjade had accepted an appointment at the University of Alaska, with only infrequent telephone contact with Daniels and her previous NESL and NIX colleagues. Ultimately, many drafts of the paper were prepared.

Daniels was the corresponding and last author on the version of the manuscript that was cleared and submitted to the *Journal of Systems Discoveries*. Woodjade received the cleared, final version from Daniels. On this version, several new names were added to the four originally suggested by Woodjade, including the director and deputy director of NIX and two others who had submitted data, but otherwise were not involved in the analysis. Woodjade had never worked with three of the new authors on any technical aspect of the project.

Woodjade called Daniels and questioned the additions. Daniels stated that, due to prior collaborations, it was a longstanding policy to err on the side of inclusion on all publications coming out of NIX. NESL's policy is that an author must provide a "substantial contribution" to the paper. Woodjade complained that he did not feel that the two managers and some of the other authors were qualified on this particular paper since they had not made a substantial contribution to the work being published. Daniels replied that Woodjade had no standing on this decision since policy of NIX was time-tested. Woodjade maintained his position against the additional authors and told Daniels that if the names were not removed, then, as first author, Woodjade would not allow the paper to be submitted. Daniels responded, "Well, you can withdraw your name, but the work was done here in our laboratory and we plan to submit the manuscript for publication, with or without you."

Questions:

1. What do you think of the reciprocal agreement between NESL and NIX? Were Woodjade's concerns worthy and legitimate? Why?
2. Woodjade now held a faculty position at a different institution from Daniel's lab. Under these circumstances it may have been relatively easy for him to voice his concerns to Daniels. What difficulties might a post-doc in NESL or NIX have in handling this situation? How might those difficulties be overcome?
3. The results of this project are significant and provide a novel insight into the field that could prove beneficial to many investigators in the area. Therefore, should Woodjade compromise with Daniels so that the paper can be promptly published? Does authorship trump publication; that is, is proper attribution more important than getting out the vital information? Is protecting the environment a more important value than scientific integrity? Can these be separated?
4. What do you think of Daniels' rationale in the concluding sentence of the case? Would it be appropriate for Daniels to proceed with publishing the paper? What are Woodjade's and Daniel's rights with respect to the data and the publication of the data?
5. Assume that any of the added authors in fact reviewed and commented on all drafts of the paper in question. Could this contribution to the effort be significant enough to merit authorship?

(A number of the ideas and questions in this case are a based on those presented in *Teaching the Responsible Conduct of Research Through Case Study Approach: A Handbook for Instructors*, Stanley G. Korenman and Allan C. Shipp, Eds., 1994. This case has been adapted from an academic environment to a national government owned, government operated (GOGO) Laboratory setting. A government owned, contractor operated will have similar issues, but will vary because it includes both public and private sector conditions.)

Obligation to Client or Employer?

Michael Davis, Arthur E. Schwartz

June 26, 2012

View online: https://onlineethics.org/cases/addressing-problems-research-ethics/obligation-client-or-employer

Joe Engineer worked for a private engineering company in the field of water rights. The firm was hired by a client to complete a water-rights analysis in which Joe participated. Joe, along with one other employee at the firm, stamped the final document. These types of analyses quantify water rights and provide terms and conditions for future use that must be approved by the local courts. Typically, the court process takes years to complete, and in short, it includes the following steps:

1. Application (proposal)
2. Engineering to support application
3. Objections from the public/other water users
4. Rebuttal of objector's comments
5. Mediation or trial

Joe worked on the project up through step No.2 and resigned from the firm to work for the State. The State is typically an objector in most cases, and it is an objector in this specific analysis.

Joe feels that he can and should support the work he performed and which was included in the stamped report, but he is concerned about the remaining steps in the court process. In his current employment, he has been isolated from the State's case in the matter, and his current position does not include opposing this or other cases.

To what extent is Joe obligated to continue to represent the client? In what ways might this cause conflict with his current employer?

Bringing a Neanderthal to Life

Edward L. Queen II, Roberta M. Berry

April 10, 2013

View online: https://onlineethics.org/cases/problem-based-learning-pbl-fractious-problem-case-assignments/bringing-neanderthal-life

Practice Problem

Examining a fully analyzed Neanderthal genome might illuminate some of the genetic differences between Neanderthals and modern humans and their significance. But what if scientific curiosity extended to attempts — potentially successful — to bring a Neanderthal to life?

You are staffers for a senator in the state legislature who has heard that bringing a Neanderthal to life might be possible and that there are researchers within the state who are contemplating joining a research team to attempt the feat. These attempts, and, if the attempts were successful, the birth of a Neanderthal might occur within the state. The senator has asked you to prepare a presentation for her and fellow members of the state senate’s committee on scientific research and innovation.

She asks you to include in your presentation your findings about the current status of research on the Neanderthal genome and on the possibility of bringing a Neanderthal to life; the ethical and policy issues that attempts, including successful

and unsuccessful attempts, would present; and your assessment of how these issues ought to be resolved.

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Neuroimaging and Violence in the Educational Setting

Gillian Hue Beckford, Roberta M. Berry

April 10, 2013

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Neuroimaging is the generic term given to a variety of techniques used to study and evaluate the structure of the brain and its functioning. These techniques have been developed only recently, but research and innovation in the field has seen explosive growth in the last decade. The use of neuroimaging techniques is rapidly expanding in both clinical and research settings.

You are members of a joint task force on violence in education created by your state's Board of Regents (the agency that administers the state's public higher education system) and your state's Department of Education (the agency that administers the state's public kindergarten through 12^{th} grade education system). These agencies are concerned about incidents of violence on campuses and of bullying and aggression in schools. The agencies are considering whether they

should recommend to the state legislature enactment of a law permitting or requiring the use of neuroimaging tests as an aid to predicting the likely future dangerousness of students identified as “at-risk” by campus or school health, educational, or administrative personnel. The purpose of the tests would be to help determine whether these students (1) should be required to undergo therapy as a condition of their continuing enrollment, both for the sake of their own well being as well as the safety of others, or (2) if all of the evidence indicates a very high level of potential dangerousness, should be expelled from colleges and universities or, in the case of school children, diverted to alternative school settings tailored to the needs of at-risk children.

The joint task force is charged with presenting these two agencies with findings regarding the current scientific status of neuroimaging techniques and their potential value in making these determinations and regarding the ethical and policy issues associated with their use in making these determinations. The joint task force is also charged with making recommendations about whether a law regarding the use of these tests should be enacted and, if so, what the law should provide.

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Patenting Genes and Life

Edward L. Queen II, Leslie E. Wolf, Roberta M. Berry

April 10, 2013

View online: https://onlineethics.org/cases/problem-based-learning-pbl-fractious-problem-case-assignments/patenting-genes-and-life

Problem 2A

Patents are property rights created by national governments. Patents grant inventors the right, for a limited period of time, to exclude others from using, selling, or distributing the patent holder's invention without permission—typically, in the form of a license in exchange for a fee to the patent holder. The chief policy justifications for issuing patents are: (1) they promote investment in research and development to the benefit of the public by ensuring that inventors can reap the fruits of their labors, and (2) because inventors are required to disclose detailed information about their inventions in exchange for the issuance of patents, patents benefit the public by encouraging the flow of potentially useful information during the term of the patent and the production and sale of less expensive versions of the invention after the conclusion of the patent term.

Many ethical and policy controversies surround the issuing of certain patents, including patents involving human genes. These concerns include whether these patents are, on-balance, of benefit to the public given their potential effects on research and on the costs of and access to diagnostic tests and treatments. Concerns also surround the creation of property rights in parts of human beings.

Prepare findings, analysis, and recommendations regarding patents involving human genes.

- Should these patents be issued?
- If so, under what conditions?

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Forensic DNA Identification

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As genomic technologies improve, there has been increased demand for the collection, storage, and use of DNA samples. DNA samples have been collected for a number of purposes, both by government agencies and private entities, including to identify rare but harmful genetic conditions in newborns, for research purposes, and to exculpate or exonerate persons who are currently suspected of committing crimes or who have been convicted of committing crimes previously.

In addition, both the federal and state governments have authorized the collection of DNA samples from persons who have been arrested or convicted of certain crimes for the purpose of creating DNA databases that can be used to help identify persons who commit future crimes. Some have argued that these DNA databases should be expanded in various ways, perhaps even to include information from DNA samples taken from everyone who is born in or who enters the U.S. There are many unsolved crimes and these databases might help bring more perpetrators to justice for their crimes as well as prevent future crimes. These expanded databases might be used for other important purposes as well, such as identifying missing persons, fatalities from natural disasters, or victims of terrorist attacks. Others have expressed concerns about constitutional, ethical, policy, scientific, and technological issues associated with current and potential practices in creating and using DNA databases for forensic identification.

Prepare findings, analysis, and recommendations regarding current State of Georgia and federal practices regarding the creation and use of DNA databases for forensic identification and whether these current practices should be restricted or expanded or otherwise revised.

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Ethical and Policy Problems in Synthetic Biology: Emergent Behaviors of Integrated Cellular Systems (EBICS)

Roberta M. Berry, Kathy Kinlaw

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The rapidly advancing field of synthetic biology seeks novel solutions to old problems in environment, energy, and health through the integration of biology and engineering knowledge and know-how. The goal is to engineer biological machines — biological systems that do not occur in nature — to perform human-directed functions.

The potential range of applications for these systems is vast, and the potential value of these applications — in effectively and efficiently addressing environmental problems, energy needs, and therapeutic goals in health — is enormous. The potential of synthetic biology is well known to policymakers and governmental agencies, including the National Science Foundation (NSF), which is funding research in the field. But policymakers and governmental agencies are also concerned about the ethical and policy problems that may be associated with the development and application of these machines — and about our capacity to identify, understand, and address them.

NSF recently funded the synthetic biology research project of researchers spanning Massachusetts Institute of Technology, University of Illinois at Urbana-Champaign, and Georgia Institute of Technology (Georgia Tech). The research team was awarded $25 million for a 5-year Science and Technology Center (STC) in Emergent Behaviors of Integrated Cellular Systems (EBICS). This NSF-funded EBICS STC will perform research in the following three areas:

1. Cellular systems that sense the level of substances, such as glucose, in the human blood stream, and then instruct other cellular systems to produce and secrete drugs, such as insulin.
2. Test-bed cellular systems that mimic the behavior of human organs, such as the heart or liver, to be used in screening drugs for safety and efficacy, reducing or eliminating the need for animal testing in drug development.
3. Cellular systems that sense the level of neurotoxins in water and signal other cellular systems to produce substances that eliminate the neurotoxins.

The cellular machines described above might be produced by one of two methods under investigation by EBICS researchers: either as engineered systems or as emergent systems. Engineered systems are produced by inducing stem cells to differentiate into particular cell types, such as nerve cells or muscle cells, which are then assembled into machines to perform a desired function. Emergent systems are produced by interventions to steer the differentiation and evolution of stem cells into different components that interact naturally to perform a desired function. This method mimics the way in which, for example, embryos develop into adults in nature: by interactions and communication among stem cells that result in differentiation into interacting clusters of cell types.

You are a diverse group of graduate and professional students drawn from Georgia Tech, Emory University, Georgia State University College of Law, and Morehouse School of Medicine. You are participating in an experimental ethics course funded by NSF and designed by diverse researchers spanning these and additional institutions; the NSF-funded project of which you are a part reflects the broad concern of NSF that the next generation of science and engineering professionals, aided by colleagues with expertise spanning multiple disciplines, develop competency in understanding and addressing challenging ethical and policy issues associated with the science and engineering enterprise.

The NSF-funded course in which you are enrolled is collaborating with the NSF-funded EBICS STC. This collaboration aims to serve both the broad concern of NSF to build capacity in the next generation of professionals to address ethical and policy issues in science and engineering and the particular concern of NSF regarding identifying, understanding, and addressing the ethical and policy problems that may be associated with the field of synthetic biology.

You are charged with investigating and providing real-time ethical and policy analysis and recommendations to the EBICS STC. Select one of the three areas listed above and one of the above methods (engineered or emergent systems) as your focus of study. In performing your analysis and arriving at your recommendations, you will have access to members of the EBICS research team, including faculty and graduate student researchers, and the opportunity both to learn from them and engage with them on the ethical and policy issues associated with their work. You will deliver your presentation and your report with analysis and applications to the EBICS STC in December, 2010.

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