INDIANA UNIVERSITY
CENTER FOR BIOETHICS

Report from the PredictER Expert Panel Meeting, November 2, 2007

Introduction and Background

As a result of advances in genetics and medical informatics, new types of research are underway. Large predictive health projects are being undertaken that combine health data from medical records with genomic data analyzed from DNA, tissue or blood samples to identify genetic and environmental factors associated with health and disease. Such studies aim to predict the risks associated with disease onset, and in so doing, to better prevent and treat disease. Many predictive health projects require researchers to obtain human biological materials that can be stored for immediate or later use and then linked to detailed health information from medical records, and other data from surveys.

Increasingly, predictive health studies proceed through partnerships with multiple institutions and businesses, and with collaborators across the country and around the world. These arrangements are designed to maximize both scientific and commercial use, and to speed the translation of knowledge into enhanced patient care. Inherent in such arrangements are issues about ownership/sharing of data and materials, conflicts of interest, priority setting and benefit sharing. Several ethical issues arise:

- *Informed Consent* – How much information should subjects receive, and how can researchers assess their understanding? Can subjects give consent for future, unspecified uses of their samples? Under what conditions should subjects be re-contacted for further studies?
- *Returning Health Information to Patients* – Under what conditions should research conclusions be given to subjects? Is it ever necessary to give information that has no diagnostic or therapeutic relevance? Is there ever a moral obligation to inform subjects of the test results in predictive health studies?
- *Management of Genetic Privacy* - Are current legal and social protections for individual privacy and confidentiality adequate? If not, what additional protections are necessary?
- *Ownership and Commercialization* – What rights do donors have to share in and control discoveries made with their tissues or health information? What rights should they have?

Successful predictive health research requires willing participants, public support, and equitable regulatory provisions. Robust participation should neither be assumed nor expected if scientists fail to fully engage the public in meaningful ways about the goals and methods of predictive health research and the implications of this research for individuals and society. Factors that may discourage an engaged, supportive community include the following:

- *Loss of Privacy* - Fear of improper disclosure of information to employers, insurance providers, and others.

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- *Discrimination* - Fear of genetic or health-related discrimination or worries about social stigma and ethnic "profiling".
- *Commercialization* - Concerns that current or future research will result in inequitable profits and access to care
- *Unanticipated Consequences* - Concerns that research will diverge from the original expectations or principle values of the participant.
- *Safety and Trust* - Public distrust following research scandals or bad press, examples include gene therapy deaths, health information security breaches, misuse of samples, and cloning fraud.
- *Frustration* - Lengthy or complicated research protocols and procedures.
- *Limitations in Health or Scientific Literacy* - Limited scientific understanding and other deficits in public understanding.

Expert Panel Goals

On November 2, 2007, the Indiana University Center for Bioethics convened an expert panel on predictive health research (PHR) as part of the Center's Program in Predictive Health Ethics Research (http://www.bioethics.iu.edu/predicter.asp) which is supported by a grant from the Richard M. Fairbanks Foundation. The goal of this meeting was to identify the major obstacles and opportunities for engaging the community in PHR. PredictER intends to use the results of this meeting as a first step toward more fully engaging the Indianapolis community in discussions about PHR. We have deliberately avoided defining "community" since the term can be applied to a variety of demographic groups including those defined by age, (e.g., the aging community, the pediatric community), cultural and ethnic status (e.g., the African American community, the Ashkenazi Jewish community), and disease (e.g., the breast cancer community, the community of people living with HIV/AIDS). This focus on engaging the public is a key feature of PredictER, a program which ultimately seeks to develop the capacity for open, community-wide discussion about PHR and its ethical and social implications.

Participants

The expert panel consisted of predictive health researchers in the Indiana University community. Because we were interested in portraying a broad spectrum of research interests, we specifically sought presenters and participants from several major disease, age, and population research initiatives. In addition to the presenters, the larger group of attendees was comprised of approximately 40 professionals from several specialties and research interests. We took the constant and productive crosstalk between different fields, researchers, and community advocates as a marker of a successful, interdisciplinary group.

Process

The expert panel was divided into four sessions:

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Session I used three case studies of current predictive health studies being conducted by researchers at Indiana University: pediatric obesity (Laura Haneline), breast cancer (Anna Maria Storniolo and Connie Rufenbarger), and neurodegenerative disease (Tatiana Foroud and Leo Rafail). These three cases were selected for two reasons: first, they represented a logical spectrum of disease from early life, to adulthood, to old age. Second, they were each at different stages of development: the pediatric obesity project was in the early design phase, whereas the Huntington's Disease roster (the example from neurodegenerative disease) has been in operation for more than 25 years. All of the researchers were asked to present an overview of their work along with a community advocate with whom they have been working. This allowed the panel to expand the scope of each presentation to include *how* this research/community collaboration was built, and what obstacles, if any, were overcome. To illustrate the later point, the pediatric obesity project has not yet identified its key community contact. Panel presentations were 30 minutes followed by a 15 minute session for questions and answers.

Session II provided a brief review of the current academic and public understanding of the ethical issues in predictive health research. The second section aimed to provide a follow-up on the predictive health presentations in the first session and to prime the group of experts to extend the current state of research in predictive health further. Following Jere Odell's overview of the literature on ethical issues (N = 1400 articles), five PredictER-funded researchers addressed the audience. Three of the presentations focused on empirical data and sought to understand the knowledge and attitudes of predictive health research participants and stakeholders, including: health professionals (Jody Harland), pregnant women (David Haas), and the general public (Jim Wolf). A fourth presentation focused on legal and regulatory issues (Jenny Girod). A summary of the evident "gaps" in knowledge was presented (Peter Schwartz).

Session III used a modified nominal group process (MNGP)[1] with three groups to identify the most pressing issues in predictive health with respect to community engagement. Each group was lead by a facilitator (Wolf, Quaid, Schwartz), and a student recorder. After randomly assigning participants, the three groups were adjusted to ensure that sufficient multi-disciplinarity was achieved. The MNGP occurred as follows:

- Participants were asked to silently list the most important issues and then share each of these issues in a group roundtable report. No judgment for or against any individual's ideas was allowed; similarly limited clarification of ideas was sought until a complete list had been elicited. Inspiration and brainstorming following from the ideas of fellow group members were encouraged.
- Once a complete list had been generated, group facilitators sought to clarify, divide, and/or combine ideas.
- After the group was satisfied with the list's appearance, individuals were asked to vote on ideas based on the importance of the idea with respect to engaging the community. Voting based on an issue's solvability or simplicity was discouraged.
- Lastly, the ideas which were judged most important were then opened for a discussion of solvability.

[1] Delbecq AL, Van de Ven AH, Gustafson DH. Group Techniques for Program Planning: A Guide to Nominal Group and Delphi Processes. Glenview: Scott Foresman, 1975.

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The end product of the third session was a non-uniform list of issues key in PHR and public engagement.

Session IV brought all panel members together again to present the small group results and to work toward a greater understanding of the issues of predictive health research and public involvement. The fourth session was a forum for open discussion moderated by another predictive health researcher (Doug Miller).

Outcomes

The goal of reaching a non-uniform collection of issues was achieved. On average, groups generated approximately 50 different issues to vote on, and while some groups were able to successfully combine similar ideas into larger themes, other groups found more success in remaining with their initial issues and voting on these. Groups selected the top issues by looking for a bimodal representation of point totals in the voting. The findings were:

Group 1

- Trust between research and community
- Providing incentives and motivations to participate
- Identification and involvement of community leaders
- Convincing community of the significance of health problems and possibility of impact
- Education on research topic
- Openly listening to community partners
- Open dialogue between researchers and community
- Distilling the public health message
- Engendering partnership and shared enthusiasm
- Addressing any ethnic disparities between researchers and the community

Group 2

- Strategies for engagement
- Educating researchers
- Shared vision

Group 3

- What's the message?
- Defining communities
- Target communities
- Understanding how the community wants to help
- Articulating the goals of engagement

The result of the final plenary session was a presentation of these ideas by each group along with a discussion to determine if different groups were saying the same thing or if the nuances in wording

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actually reflected a larger thematic difference in each groups' understanding. Our findings were that the latter, small differences in wording, actually reflected overall differences in groups' understandings of predictive health and public engagement.

For example, Group 2 identified a "shared vision" as an important issue, and Group 3 asked "What's the message?" While it was agreed that both points drew attention to the need for clear and consistent communication with the public, further discussion revealed that the group that asked about the "message" was actually seeking to clarify *what* researchers would convey to the public about PHR, whereas the group that focused on "vision" was more interested in *how* the message was derived; that is, will the message be the result of a vision shared by both researchers and participants, and will this shared vision be broadly marketable. Similarly, Group 1 provided a longer list of issues but chose to lump them into three large themes: how to create trust and partnership between researchers and the community; how to educate and motivate the community; and the need to address ethnic disparities between the community and researchers.

Lastly, the plenary group discussion also examined what is meant by "community", whether it is a selected population with an interest in a certain disease, an ethnic group, or a general collection of persons interested in predictive health. This question led to the comparison of an existing breast cancer biobank to a potential longitudinal study on multiple health risk factors. While the breast cancer researchers and community have been able to make use of high profile fundraisers to further increase public awareness and to encourage tissue donation, the plenary group expected that a multiple health risk factor study would lack a single coordinated community or event, and would have notably greater difficulty garnering support and engaging in community conversation.

Approaching the Community

The differences noted in communities, in engagement, and in engendering trust all focus on how the community is approached. Isolating a group of individuals and asking them to participate in a pre-determined research protocol has limited potential for ongoing collaboration with the community. The best results are achieved when predictive health researchers view the community not as the subject of research but as a partner in bridging the gaps between disease and health. More clearly, the success of a predictive health research project cannot merely be measured by the number of specimens in a biobank, but must also be measured by the understanding, trust, and cooperation achieved between researcher and community. Although a number of predictive health researchers were able to gather for a day of collaborative, interdisciplinary discussion, to identify a list of issues, and to begin to speculate on the how to solve them, PHR as a whole is still very far from successfully achieving a broad, public conversation on the benefits, concerns, and overall understanding of predictive health. Thus, the next step for the PredictER program is to meet with community leaders with the goal of working toward an understanding of the concerns and opportunities they see for the role of predictive health within their own communities**.**

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Expert Panel Participants

(Alphabetical)

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