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12 MRLR 548
Biomedical Ethics
IRB-Approved Plan for Incidental Findings Recommend by Bioethics Panel Workgroup


By Jeannie Baumann

Clinical investigators should adopt a management plan for incidental findings they encounter in the course of their studies, even though they have no specific duty to look for such findings, a working group said in draft recommendations presented Aug. 19 at a meeting of President Obama's bioethics advisers.

Christine Grady, a member of the Presidential Commission for the Study of Bioethical Issues, underscored at the meeting that the plan also should include provisions for making patients aware of such results that could seriously affect their health. "We want to be clear if it's serious and actionable, it should be disclosed," Grady said.

She added that the action plan should require consultation with someone competent to make a determination in cases where a researcher who discovers an incidental finding does not have the necessary background in that field or confidence in his or her judgment.

Grady, chief of bioethics at the National Institutes of Health Clinical Center, was part of the three-member working group of the bioethics commission that considered how to address incidental findings in research. She presented the working group's draft recommendations to the full commission on the first day of the panel's two-day meeting at the University of Pennsylvania's Smilow Center for Translational Research in Philadelphia.

The other two commission members on the incidental findings in research working group were Nita A. Farahany, a law and genomics professor as well as director of science and society at the Duke University Institute for Genome Sciences & Policy; and Nelson L. Michael, director of the U.S. Military HIV Research Program (MHRP) at the Walter Reed Army Institute of Research.

Defining "incidental findings" as "data gleaned from medical procedures or laboratory tests that were beyond the aims or goals of the particular laboratory test or medical procedure," the commission first began its discussions on the subject during its previous meeting in April (12 MRLR 329, 5/15/13) that built upon recommendations in an earlier panel report on whole genome sequencing (11 MRLR 827, 12/19/12).

The full report on incidental findings—to be released by the end of the year—will make ethical recommendations on returning such findings under several contexts, including research.

Some Incidental Findings Predictable

Grady said that with the increasing use of genetic sequencing, imaging, and biological specimens, it not only is possible to predict that incidental findings might arise, but that some evidence might be available about the implications of those predictable findings.

"Such evidence will help inform an evaluation of the extent to which the incidental finding provides useful information of potential net benefit to participants as opposed to, say, uncertain information or information that might cause unnecessary stress, unnecessary cost, or more burden than benefit," she said.

The plan should manage these types of predictable incidental findings as well as how to disclose to

Draft Bioethics Commission Recommendations
Recommendations of Working Group on Incidental Findings in Research

- Researchers should have an IRB-approved plan to address incidental findings in research.
- Experts should develop criteria to guide researchers, IRB on determining which findings need to be returned.
- Researchers may adopt an IRB-approved plan that includes looking for select or predictable incidental findings.
- Researchers still may encounter unanticipated findings, and in those cases, ethical obligations still apply.

research participants incidental findings that are known to be “significant and actionable and, when relevant, analytically and clinically valid or the equivalent of those things,” Grady explained.

Such a management plan would need to be reviewed and approved by an institutional review board and described in the informed consent process, the working group advised.

However, Grady noted that the term “predictable” is not synonymous with “common.”

Also, she said, “We wanted to be sure predictable is not synonymous with ‘has to be disclosed.’ The researcher needs to have a plan and say which of those he or she will inform participants of.”

Lists to Guide Researchers, IRBs

The working group also recommended that knowledgeable representative groups, including subject matter experts, should define the types of incidental findings that might predictably arise, then assess and develop lists to guide researchers and IRBs on the kind of findings that should, might, and should not be disclosed to the participants. Such lists would be evidence-based, accessible, and updated.

Grady said the working group believed these lists would help both researchers and sponsors in developing plans for managing incidental findings, as well as IRBs and any other oversight bodies that are reviewing the plans.

“We did recognize as a group that this kind of categorization may be more difficult for the modality of testing biological specimens than it would be for genetic sequencing ... only because the realm of possibility for biological specimens is so broad,” Grady said.

Farahany added that the working group believed it would be very helpful to have people who have knowledgeable expertise in the different modalities of research to define types of findings that may arise.

The Duke professor said the working group did not opine specifically on which findings should or should not be returned, nor did it want industry to do so. Instead, Farahany said, the lists would provide meaningful criteria for making those decisions.

Disclosure Plans, Unanticipated Findings

While researchers do not have a duty to disclose incidental findings, the working group proposed that researchers could adopt an IRB-approved plan that includes looking for select incidental findings or predictable incidental findings.

“The group recognized that research is different than clinical medicine or clinical care in that the primary goal is development of generalizable knowledge,” Grady said.

Finally, Grady said, the working group noted that even if researchers have developed a well thought-out plan for predictable incidental findings, and have no affirmative duty to look for incidental findings, they still may encounter unanticipated incidental findings.

“In this case, ethical obligations still apply,” she said.

“If you don't actually take the time to have a plan and educate the participants, you have no right to assume that participants understand that they are just in a research project.”

***—Amy Gutmann, chairwoman,
Presidential Commission for the
Study of Bioethical Issues***

The working group recommended that researchers should have a plan to address unanticipated findings and inform the study subjects that such findings may occur.

“We thought the researcher who encounters such an unanticipated finding should assess significance—and to the extent needed—seek help or consultation from other experts in order to do that,” Grady said. “If the finding is determined to be significant and actionable, the researcher

should propose to the IRB or to another appropriate specialized oversight body” an action plan to offer participants the option of learning about the incidental findings.

Positive Initial Reaction From Full Commission

After some clarifications and friendly amendments, commission members generally seemed to react positively to the overarching ideas put forth by the working group.

Amy Gutmann, chairwoman of the bioethics commission and president of the University of

Pennsylvania, said the subgroup's recommendation about informing research participants before enrollment about the possibility of incidental findings is important, as the line between research and clinical practice is very blurred.

"Even if it is clear in the researchers mind—which it often is—that this is research, often participants who are getting their brains scanned or getting their genome mapped ... have the expectation that if something abnormal is found, they'll know about it," Gutmann said. "If you don't actually take the time to have a plan and educate the participants, you have no right to assume that participants understand that they are just in a research project."

The bioethics commission chairwoman offered a friendly amendment stating that researchers should not have to go back to the IRB every single time an incidental finding comes up under the plan in order to prevent the process from overburdening research.

"That's regulatory parsimony," she said.

Farahany agreed and said Gutmann's amendment captures the intention of the recommendations.

When asked by an audience member about the costs of these proposals, Farahany replied that the working group discussed at length the impact on researchers and the research enterprise.

"We really sought to balance research enterprise being able to progress with science and respect for individuals who are participating in the research," she said.

In many cases, she said, the primary additional burden is one researchers already undertake: have a clear plan that communicates and addresses how they are going to think about incidental findings and return that information.

Farahany said the working group did not believe that the burden was large enough to require an economic analysis, but that it is always useful to invite other groups to undertake such analyses and consider the costs and benefits.

On Aug. 20, the commission was scheduled to begin its work on ethics and neuroscience considerations related to the Obama administration's Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative. In April, Obama unveiled the \$100 million research initiative, designed to revolutionize the understanding of the human brain (12 MRLR 266, 4/17/13). In addition to \$40 million in research grant funding from NIH in fiscal year 2014, the president directed the bioethics commission to explore the ethical, legal, and societal implications raised by this research initiative and other recent advances in neuroscience.

The next bioethics commission meeting is scheduled for Dec. 17-18 in Washington.

For More Information

More information, including archived webcasts, is available at <http://bioethics.gov/node/793>.

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