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Sharing Results With Research Participants

The global research enterprise is preparing for a fundamental shift in the reporting of research results. That's good news for clinical trial participants, who overwhelmingly say they want to know the results of their trials. **LEARN MORE**

Simplifying, Strengthening the Informed Consent Process

Informed consent continues to prove problematic for many research organizations. Evidence-based recommendations, due later this year, are expected to offer some solutions, including new ways to shorten consent documents and assess research participants' comprehension. **LEARN MORE**

Embracing Opportunity

President and CEO Elyse I. Summers, J.D., invites the research community to join AAHRPP in furthering the discussion on how to advance research protections while taking advantage of unprecedented opportunities to gain new knowledge that benefits society. **LEARN MORE**

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- **Jaeb Center for Health Research Foundation, Tampa, Florida**
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Sharing Results With Research Participants

Preparing for a fundamental shift in the way study results are reported

BARBARA BIERER, M.D.

Studies show that the vast majority of clinical trial participants want to be told their trial results, yet that seldom happens. Now, however, the landscape is shifting, and the global research enterprise is laying the foundation for public reporting of research results.

Some of the most significant work in this area has been done by the **Multi-Regional Clinical Trials** (MRCT) Center at Harvard, which has developed guidance and a toolkit for creating and disseminating research results summaries (RRS). Barbara Bierer, M.D., MRCT Faculty Co-Director and Professor of Medicine at Harvard Medical School and Brigham and Women's Hospital, will cover this topic at the 2015 AAHRPP **conference** during her presentation, "Sharing Clinical Trial Data With Research Participants: Regulatory, Operational, and Ethical Considerations."

MRCT collaborates with life sciences companies, clinical research organizations, nonprofit organizations, industry associations, patients and patient advocates, and academic institutions to help improve the design, conduct, and oversight of multiregional clinical trials. The multi-stakeholder MRCT Return of Results work group was convened last year to provide practical guidance on developing non-technical RRS. The **guidance** document and **toolkit** appear online.

The work group effort recognizes both the importance of keeping research participants informed and the European Medicines Agency (EMA) decision to require public reporting of results, in plain language, beginning in 2016.

"Reporting results to research participants is the right thing to do," Dr. Bierer says. "It's a way of thanking them for their gift of participation, it's respectful, and it increases public trust.

"An engaged and informed public is always going to be a better partner," she adds.

AAHRPP addresses the dissemination of research results in **Standard** I-4, Element I.4.C., which states, "The organization promotes the involvement of community members, when appropriate, in the design and implementation of research and the dissemination of results."

Dr. Bierer acknowledges the practical concerns and other barriers to reporting results but is confident that the MRCT guidance and tool kit facilitate responsible sharing of study findings. Given the multinational and multicentered nature of most clinical trials, MRCT also calls for global harmonization on this issue.

"We know that next year EMA will require that results be reported for trials of all drugs being considered for registration in the European Union, so all pharmaceutical companies will have to comply with that directive," Dr. Bierer explains. "We don't want them to get in trouble in the U.S. for activities that are mandated in the EU. We also think that all research participants deserve the same information, involvement, and respect as those afforded in Europe."

Highlights of the MRCT guidance and tool kit follow:

- A discussion of key challenges in reporting results.
- Best practices for returning results to participants, including recommendations on timing and content.
- Considerations for returning results under special circumstances, such as studies involving vulnerable populations.
- Templates and examples for creating the RRS.
- Examples of easy-to-understand, neutral, nonpromotional language.
- An institutional review board/ethics committee checklist.

"Regardless of their affiliation, people care about providing true information and engaging the public in a responsible, transparent way," Dr. Bierer says. "We did our best to deconstruct the issues and then develop a process that meets the needs of those who want to communicate study results—whether they are companies, investigators in research institutions, nonprofit foundations, or patient advocacy groups."

Simplifying, Strengthening the Informed Consent Process

After years of struggling with the informed consent process (ICP), the research protection community is working diligently to achieve consensus on how best to help research participants understand the purpose, risks, and benefits of a study before enrolling.

The Clinical Trials Transformation Initiative (CTTI) is expected to release evidence-based recommendations this year on ways to shorten consent documents, gauge participants' comprehension, and train research staff in best ICP practices. A primary goal is to design ICPs that can be easily adapted depending on the needs of research participants.

"It's no secret that informed consent has long been an issue. Our goal was to identify and tackle a few key areas where change not only was possible but also could effect a difference," says Michele Kennett, J.D., M.S.N., LL.M., Assistant Vice Chancellor for Research at the University of Missouri-Columbia. Ms. Kennett is a member of the CTTI Informed Consent Project team and AAHRPP's Council on Accreditation.

"Our hope is that our recommendations will encourage people to look outside the box," Ms. Kennett adds, "to ease the process for obtaining consent and reduce barriers to participants' understanding."

CTTI is a public-private partnership that identifies and promotes practices designed to increase the quality and efficiency of clinical trials. Members come from government agencies, industry, patient advocacy groups, professional societies, investigator groups, academic institutions, and other interested groups. Past CTTI recommendations have addressed reporting serious adverse effects, use of central institutional review boards (IRBs) for multicenter clinical trials, and good clinical practice training for investigators.

Members of the CTTI Informed Consent Project Team presented their findings and sought input and consensus on proposed recommendations during a two-day experts meeting in March. PDFs of the presentations can be viewed and downloaded **online.**

Key messages include:

- **ICP should be an ongoing, interactive, participant-focused process.** Although the informed consent document is important, it should not be the primary means of obtaining consent. Instead, it should serve as the basis of an interactive discussion. Furthermore, research staff should reach out to participants throughout the course of the study to make sure they continue to consent.

  The CTTI team developed a checklist to help document the consent process and, perhaps even more important, provide reminders about obtaining consent in a nonthreatening environment, including family and friends as appropriate, tailoring the conversation to the participant's level of interest and understanding, evaluating the participant's comprehension, and other key considerations.

- **Training is essential for those involved in obtaining consent.** The proposed recommendations call for formal ICP training that covers federal requirements for obtaining and documenting informed consent, effective health communications, and writing an easily understood consent document. Training should recognize that informed consent is not a one-size-fits-all scenario and should identify opportunities to keep refining the ICP.

- **New formats can enhance participants' understanding.** CTTI team members presented alternatives to today's typical consent forms, which tend to be too long and difficult for laypeople to understand. Among the options are e-consent technology and a tiered-consent model that summarizes major points, written in plain language, followed by a lengthier explanation for those who want more information.

AAHRPP accreditation and informed consent

The final CTTI recommendations are expected to be consistent with AAHRPP standards, which require organizations to have policies and procedures that comply with informed consent regulations and promote an ICP that protects and informs

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research participants. AAHRPP standards include three references to informed consent:

- **Element II.3.F.** The IRB or ethics committee (EC) has and follows written policies and procedures to evaluate the consent process and to require that the researcher appropriately document the consent process.

- **Element II.3.G.** The IRB or EC has and follows written policies and procedures for approving waivers or alterations of the consent process and waivers of consent documentation.

- **Element III.1.F.** Researchers employ consent processes and methods of documentation appropriate to the type of research and the study population, emphasizing the importance of comprehension and voluntary participation to foster informed decision-making by participants.

Elyse I. Summers, J.D., AAHRPP President and CEO, and Sarah Kiskaddon, J.D., AAHRPP Director, Global Business Development and Public Affairs, attended the experts meeting and found much to support. "The proposed recommendations go a long way in addressing concerns about the informed consent process and ensuring that the emphasis is in the right place, which is protecting participants," Ms. Summers says.

For Ms. Kiskaddon, many of the presentations drove home the importance of training, observation, and continuous quality improvement activities that often are the purview of the IRB.

"So much depends on the individual who is obtaining the consent. That's why training is essential," she says. Ms. Kiskaddon encourages IRBs to take advantage of opportunities to observe the consent process and provide immediate feedback. "That's a very good training tool," she says.

AAHRPP Conference Features Sessions on Informed Consent

Informed consent will be the subject of three different sessions at the 2015 AAHRPP **conference** May 19-21:

- "Demystifying Consent Requirements"
- "Just Do It: Waivers and Flexibility in Informed Consent"
- "Valid Informed Consent Education (VoICE) Project"

2015 AAHRPP Conference: May 19-21

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Looking Back and Looking Forward: Compliance, Collaboration, and Community

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From the President and CEO

Embracing Opportunity

ELYSE I. SUMMERS, J.D.

These are exciting times. Advances in genomics, Big Data analytics, global connectivity, and other areas offer unprecedented possibilities to gain new knowledge and, ultimately, improve the health and welfare not just of individuals but of society as a whole.

As always, with new opportunities come new questions and challenges. What, for example, are our obligations to the close relatives of participants in genomic research? When is consent necessary for Internet research, and if consent is required, how do we obtain it?

These are difficult questions, and while we at AAHRPP don't necessarily have all the answers, we are pleased to serve as a resource and convener of the research protection community. In that role, we can raise the issues, further the discussion, and in the process, promote high-quality, ethically sound research.

That's why—in addition to presenting workshops and updates on AAHRPP accreditation—our 2015 **conference** will cover cutting-edge topics such as the sharing of clinical trial data with research participants, biobanking and large data sets, social media research, and engagement/patient-centered research.

The conference will be held May 19-21 in Chicago, and there's still time to **register**. Conference attendees will receive hard copies of all the speaker presentations. It's not too late to sign up, and I encourage you to do so as soon as possible!

In good company

From the beginning, AAHRPP was fortunate to count some of the research community's most respected individuals and organizations among our supporters. Our founding members include the Association of American Medical Colleges, the Association of American Universities, the Association of Public and Land-grant Universities, the Consortium of Social Science Associations, the Federation of American Societies for Experimental Biology, the National Health Council, and Public Responsibility in Medicine and Research.

As you can see from our conference **program**, we continue to enjoy excellent relationships with today's research leaders. Our speakers hail from highly regarded organizations in every sector of the research enterprise: government agencies, academic institutions, hospitals and health care systems, international entities, patient advocacy groups, and independent institutional review boards.

And indeed, two of our longtime friends lent their expertise to the development of this edition of our *Advance* newsletter and will be joining us at our conference in Chicago. Barbara Bierer, M.D., Faculty Co-Director of the Multi-Regional Clinical Trials Center at Harvard and Professor of Medicine at Harvard Medical School and Brigham and Women's Hospital, was our source for the article "Sharing Results With Research Participants." Barbara served as President of AAHRPP's Board of Directors from 2003 to 2007. She will present a plenary address, "Sharing Clinical Trial Data With Research Participants: Regulatory, Operational, and Ethical Considerations," at our conference.

Michele Kennett, J.D., M.S.N., LL.M., Assistant Vice Chancellor for Research at the University of Missouri-Columbia, has served as an AAHRPP site visitor and team leader and currently is a member of our Council on Accreditation. She also serves on the CTTI Informed Consent Project team and was an invaluable resource for our newsletter article called "Simplifying, Strengthening the Informed Consent Process."

On behalf of all of us at AAHRPP, I extend our deep appreciation to Barbara and Michele—and to all of you who share our commitment to safeguarding and respecting research participants and advancing quality research.

I look forward to seeing you, and speaking with as many of you as possible, later this month in Chicago.

Best regards,

Elyse I. Summers, J.D.
AAHRPP President and CEO