The National Academies of
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Committee on the Return of Individual-Specific Research Results Generated in Research Laboratories

Public Meeting Agenda
September 6–7, 2017

National Academies of Sciences, Main Building
Lecture Room
2101 Constitution Avenue NW
Washington, DC 20418
202-334-2222

Abbreviated Committee Statement of Task

The National Institutes of Health (NIH), Food and Drug Administration (FDA), and Centers for Medicare and Medicaid Services (CMS) have asked the Health and Medicine Division of the National Academies of Sciences, Engineering and Medicine to conduct a consensus study on the return of individual-specific research results generated in research laboratories (ROR).

The study committee will review and evaluate the ethical, social, operational, and regulatory issues related to ROR. To fulfill its task, the committee will:

- Review the current evidence and practices on ROR to individuals, including the potential benefits, harms, and value to the individual participating in the research and to society, and the operational requirements and potential implications for research laboratories.
- Review the current regulatory environment, including the Clinical Laboratory Improvement Amendments of 1988 (CLIA), the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and any other applicable federal or state laws, for conducting tests and ROR.
- Provide recommendations on whether, from a policy perspective, there are specific circumstances under which research results generated in research laboratories should be, or should not be returned.
- Provide recommendations on whether the current regulatory requirements and policies are adequate to address the return of research results in an appropriate manner and, if not, what new, revised, or alternative policies or regulatory requirements might better address the appropriate ROR.

The focus of the study is on results generated from biospecimens that are directly related to the research question (rather than incidental findings). The committee will consider both the routine return of results as well as the ability of participants to request individual results. The committee will not make recommendations regarding specific results to be returned, or the return of aggregate results.

Public Workshop Objectives:

- Explore current practices and key considerations in the return of individual-specific research results (ROR) including,
    - Participant preferences and implications for informed consent.
    - The benefits and risks associated with the return of research in different contexts.
    - Logistical and operational implications for researchers, institutions, and participants.
    - State and federal legal and regulatory policies relevant to the ROR and how they present real or perceived barriers.
    - The identification of communication strategies for the appropriate and effective ROR.
- Identify the circumstances under which ROR might be appropriately performed.

DAY 1: September 6, 2017

OPEN SESSION

Time	Event
8:30 a.m. – 8:45 a.m.	Welcome and opening remarks
Session 1: Participant and community perspectives	
8:45 a.m. – 10:15 a.m.	**Session 1: Participant and community perspectives** *90 minute session (brief 5-7 minute panelist presentations followed by discussion and Q&A)* Objectives: • Explore participant preferences and expectations regarding return of individual research results in different contexts. • Discuss participant experiences regarding return of research results and identify successes, challenges, and potential solutions. • Discuss the distinction from the participant's perspective between the routine disclosures of results vs the ability to request results. Panelists: TBD
10:15 a.m. – 10:30 a.m.	BREAK
Session 2: Current practices – Opportunities and barriers	
10:30 a.m. – 12:00 p.m.	**Session 2a: Perspectives of researchers and laboratorians** *90 minute session (brief 5-7 minute panelist presentations followed by discussion and Q&A)* Objectives: • Discuss how the current legal and regulatory environment informs the return of individual research results from labs involved in research. • Consider how the innovative culture of a research laboratory does or does not align with the required practices of clinical laboratories to ensure specimen control, assay validity, and reproducibility.

	○ Explore the costs, including opportunity costs, of asking research labs to produce clinical or near clinical laboratory level results. • Identify challenges researchers encounter when determining whether and how to return results (e.g. laboratory challenges of sequencing and interpretation). • Discuss any experience with participants requesting their results (due to new regulations under HIPAA) and the potential utility of more codified guidelines to help researchers determine when ROR is appropriate. Panelists: TBD
12:00 p.m. – 12:30 p.m.	LUNCH
12:30 p.m. – 1:15 p.m.	**Session 2b: Lunch keynote: Successes and challenges – CSER and eMERGE** *45 minute session (5-7 minute panelist presentations followed by discussion and Q&A)* Panelists: TBD
1:15 p.m. – 2:45 p.m.	**Session 2c – Experiences to date of returning results from different healthcare institutions** *90 minute session (brief 5 minute panelist presentations followed by discussion and Q&A)* Objectives: • Discuss current practices and perspectives pertaining to the return of research results for from different healthcare institutions. • Consider methods to best incorporate the return of research results and explore the potential impact of return on the health care system (ex: the physician case load). • Examine the potential utility of more codified guidelines in the ROR. Panelists: TBD
2:45 p.m. – 3:00 p.m.	BREAK
Session 3: Laws and regulations governing the return of results	
3:00 p.m. – 4:30 p.m.	**Session 3: Laws and regulations governing the return of results** *90 minute session (brief 5-7 minute panelist presentations followed by discussion and Q&A)* Objectives: • In the context of a more expansive practice of return of individual results discuss: ○ Potential legal or regulatory revisions to current regulations that could best address the real or perceive barriers in the return of results. Consider the possible benefits and harms of these regulatory modifications to participants, researchers, and institutions. • Discuss the distinction under current law and regulation between routine return of results and responses to participant requests for results. • Discuss the legal liabilities that may arise from the ROR or the failure to return results. Panelists: TBD

Session 4: Institutional management and oversight	
4:30 p.m. – 6:00 p.m.	**Session 4: Institutional management and oversight** *90 minute session (brief 5-7 minute panelist presentations followed by discussion and Q&A)* Objectives: • Discuss the institutional infrastructure and resources needed to support ROR • Identify approaches to the management of ROR. Consider institutional oversight and the role of IRBs in determining when and how a research study might return results. • Explore any necessary training and required expertise, cost, and other critical components necessary for the appropriate ROR. Panelists: TBD
6:00 p.m.	ADJOURN

DAY 2: September 7, 2017

OPEN SESSION

Time	Event
8:00 a.m. – 8:15 a.m.	Welcome and opening remarks
Session 5: Communicating Results to Meet User Needs	
8:15 a.m. – 9:45 a.m.	**Session 5: Communicating Results to Meet User Needs** *90 minute session (brief 5-7 minute panelist presentations followed by discussion and Q&A)* Objectives: • Describe current communication practices in the return of results and identify broad communication and individual-user needs. • Discuss what techniques are working well and consider how the current model of communication may be modified to more completely address the diverse populations and heterogeneity of research participants. • Identify innovative and emerging communication tools and strategies that might facilitate effective ROR. • Identify challenges and explore examples of adverse experiences of research participants in ROR — provide scalable techniques to overcome the challenges inherent in the communication of research results. • Consider any unique considerations regarding research conducted in children, people with cognitive impairments or other special populations. Panelists: TBD
9:45 a.m. – 10:00 a.m.	BREAK

Session 6: A discussion with workshop panelists: Reflecting and envisioning the future of return of results	
10:00 a.m. – 11:30 a.m.	**Session 6: A discussion with workshop panelists** *90 minute session (brief 5-7 minute panelist presentations followed by discussion and Q&A)* <u>Objectives</u>: • Discuss any strategic priorities that have been articulated over the course of the meeting that can be adopted by the key players. • Examine how key stakeholders can align to develop a cohesive approach for returning results. • Explore the needed investments and incentives to enable the appropriate return of results. • Identify methods to bridge the gap from regulation and policy to practice. Panelists: TBD
11:30 a.m. – 12:00 p.m.	**Public Comment** <u>Objective</u>: • Members of the public are invited to sign up to provide comments geared toward the workshop topic (3 minutes each).
12:00 p.m.	ADJOURN