The figures below and on the back represent the authoring committee's recommendations for determining conditions for return of individual research results. To read the full report and the full text of the committee's recommendations, please visit nationalacademies.org/ReturnofResults.

Figure S-1: Determining whether laboratory quality is sufficient for investigators to return individual research results

This flowchart details Recommendation 3 and two critical aspects in the return of individual research results: (1) the use of the result in research protocols and (2) the result validity. If results will be used for clinical decision making in the study protocol, they must be generated in a CLIA-certified laboratory, and return is appropriate. If results will not be used for clinical decision making in the study protocol, there are additional pathways for the return of individual research results, as long as the result is accompanied with information on the limits of the test validity and interpretation. For IRBs to have confidence in the quality of a research result and determine that it is appropriate for return, investigators should do one of the following (see Recommendation 3): (1) perform their testing or get confirmation in a CLIA-certified laboratory, (2) use the NIH-led quality management system (QMS) for research laboratories once it has been developed (see Recommendation 2), or (3) use an alternate QMS or quality processes that a review process independent of the laboratory determines is sufficient. This flowchart is also applicable to a situation in which an investigator has an unanticipated result and is considering whether to return it to a participant.
HIPAA’s access right applies only to laboratories that are—or are part of—a covered entity and to results that are maintained within the designated record set (DRS) for that entity. This flowchart details which results should be included in the participants DRS and, thus, which results participants have a right to under the HIPAA access right (see Recommendation 12A). To maximize participant access to research results, minimize the risk of harm, and ensure consistency across institutions, only individual research results generated in CLIA-certified laboratories or under the externally accountable quality management system for research laboratories (see Recommendation 2) should be included in the DRS and returned to participants through the HIPAA access right. If laboratories are not part of a HIPAA covered entity or the results are not appropriate for inclusion in the DRS, participants may still access and receive their results pending IRB review of the quality processes in the laboratory (see Recommendation 3).

Figure S-3: Determining whether participants have the right to access their individual research results under HIPAA

NIH - National Institutes of Health
QMS - quality management system

* CLIA-certified includes tests run in a CLIA-certified, -accredited, or -waived laboratory.
* See Recommendation 2

CLIA - Clinical Laboratory Improvement Amendments of 1988
DRS - designated record set
HIPAA - Health Insurance Portability and Accountability Act of 1996