American Society for Investigative Pathology
Investigating the Pathogenesis of Disease

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Roger Servino
Director, Office for Civil Rights
U.S. Department of Health and Human Services
Attention: RFI, RIN 0945-AA00
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, SW
Washington DC 20201

Dear Mr. Servino:

Thank you for the opportunity to provide these written comments on behalf of the American Society for Investigative Pathology (ASIP) to the Request for Information on Modifying HIPAA Rules Docket No.: HHS-OCR-0945-AA00. ASIP is a nonprofit educational 501(c)(3) organization primarily representing the academic pathology research community. We are a society of biomedical scientists who investigate disease, linking the presentation of disease in the whole organism to its fundamental cellular and molecular mechanisms. Our members use a variety of structural, functional, and genetic techniques, seeking to ultimately apply research findings to the diagnosis and treatment of patients. Our society represents approximately 1,000 physicians and doctoral scientists who perform or are involved with pathology research in academic medicine, government, and private industry.

Our comments on the RFI speak to **research concerns only** and are focused on decreasing the regulatory burden of HIPAA and removing regulatory obstacles. As ASIP supports research that advances our understanding of the human body at its most fundamental cellular and molecular levels, comments are particularly relevant to the RFI question 54, which allows commentary on broad areas of concern.

ASIP holds the following core principles relevant to the discussion on ways to decrease HIPAA's regulatory burden and remove regulatory obstacles to high quality biomedical research. Each of these core principles is discussed in detail below.

- There is a significant and ongoing conflict between HIPAA regulations and statutory language in the Clinical Laboratory Improvement Act (CLIA).
- HIPAA regulations should be updated to specify under what circumstances research results must be released to research participants and to resolve the conflict with the CLIA statutory language of 42U.S.C.§ 263a.
- Requiring release of research records poses a significant administrative burden on research laboratories; thus, HIPAA should be narrowly interpreted to require the release of research records only in cases where the research results are to be used in clinical patient care.

- If the apparent conflict with CLIA statutory language 42U.S.C.§ 263a can be resolved, HIPAA regulations should be clarified such that research results may be released to research participants in any of the following scenarios: (a) when testing becomes part of a research participant's clinical record and may be used in prevention, diagnosis or treatment; (b) when the research protocol includes provisions for either the release of individual study results to research participants or return of incidental findings. When the researcher believes that a finding should be further corroborated by a CLIA-certified laboratory. Outside of these three scenarios, HIPAA should not be interpreted to compel the release of research results.
- Potential research subjects should be fully informed of what laboratory test results will be shared, might be shared and will not be shared.
- ASIP believes that individual researchers and their associated IRBs should be the entities tasked with determining whether and under what conditions individual research results will be released to research participants.
- Release of individual laboratory results should occur within the same ethical framework developed for release of other clinical data/observations gathered during a research study.
- HIPAA should be clarified to state that access to genomic information is not a civil right established by the Genetic Information Nondiscrimination Act (GINA).

There is a significant and ongoing conflict between HIPAA regulations and statutory language in the Clinical Laboratory Improvement Act and subsequent Amendments (CLIA).[1] CLIA regulations are applicable to laboratories providing patient care services; however, some research is conducted in both CLIA-certified laboratories and non-CLIA-certified laboratories. CLIA standards set an appropriately high bar for clinical care and support careful communication allowing for appropriate incorporation of laboratory findings into the care and treatment of patients. Research laboratories may not be CLIA-certified for a variety of reasons including when testing will not be used in the care or treatment of patients or when CLIA certification is prohibitively expensive and would impact a researcher's ability to conduct the research.

CLIA statute and regulations prohibit the return of non-accredited results for treatment or health assessment purposes. HIPAA regulations state that research participants have the right to access their research data held in the designated record set regardless of the environment in which these results were generated. The HIPAA right to information holds regardless of whether the laboratory is CLIA-certified or not, as it looks solely to whether the institution is a regulated entity. These two regulations are fundamentally in conflict when results are generated outside of a CLIA-certified laboratory. HIPAA supports the return of these results and CLIA prohibits the return. ASIP has sought regulatory clarification of this conflict on several occasions (see Enclosures A, B & C). The need for further clarification was also highlighted in the recent National Academies of Sciences, Engineering & Medicine report entitled "Returning Individual Research Results to Participants: Guidance for a New Research Paradigm[2]" and the 2015 recommendations of the Secretary's Advisory Committee on Human Research Protections (SACHRP).[3]

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[1] Research Testing and Clinical Laboratory Improvement Amendments of 1988 (CLIA) Regulations, CLIA Resource, v. 12/10/2014 as accessed on December 19, 2018 from https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/Research-Testing-and-CLIA.pdf

[2] The National Academies Press "Returning Individual Research Results to Participants: Guidance for a New Research Paradigm. DOI10.17226/25094 as accessed on December 19, 2018 from https://www.nap.edu/catalog/25094/returning-individual-research-results-to-participants-guidance-for-a-new

[3] September 28, 2015 letter from SACHRP to the HHS Secretary Attachment C: Return of Individual Results and Special Consideration of Issues Arising from Amendments of HIPAA and CLIA as accessed on December 19, 2018 from https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2015-september-28-attachment-c/index.html

HIPAA regulations should be updated to specify under what circumstances research results must be released to research participants and to resolve the conflict with the CLIA statutory language as contained in 42U.S.C.§ 263a.[4] HIPAA has been incorrectly interpreted by some to imply that all research records, when held by a HIPAA-covered institution, must be disclosed to a research participant upon request. Correct reading of HIPAA regulations indicates that research results release is required only when research records comprise part of the 'designated record set.' The definition of a 'designated record set' should reflect that research records are not part of the set unless: (a) the laboratory test was performed in a CLIA-certified laboratory; **and** (b) there is anticipation that the research findings will be used in patient care. CLIA-certified laboratories should be the entities responsible for providing information used in patient treatment. Absent a specific exemption, findings in a non-CLIA certified laboratory, whether or not part of a HIPAA covered entity, should not be used in patient care and should not be part of the designated record set. This should be clearly stated: (i) in the research proposal that is reviewed by the Institutional Review Board (IRB); (ii) in the informed consent signed by the research participant; and (iii) on any research results that a researcher shares with study subjects.

Requiring release of research records poses a significant administrative burden on research laboratories; thus, HIPAA should be narrowly interpreted to require the release of research records only in cases where the research results are to be used in clinical patient care. Even when research is conducted in a CLIA-certified laboratory, ASIP generally discourages the release of individual research results to research subjects because such release would require a costly reporting framework during a period of limited research funds and may leave research laboratories subject to litigation from patients who may not fully comprehended the essential difference between clinical tests and research tests. The potential for legal liability requires a careful discussion and analysis of the costs associated with provision of necessary legal protections to researchers (and their institutions) who voluntarily provide research results. Furthermore, ASIP strongly urges that the return of individual research results be performed through a physician or healthcare worker qualified to interpret the research results, including clear identification of risks such as the potential for false positive and/or false negative findings. In an era of decreased funding for scientific research, administrative burden and cost implications should be considered when determining an appropriate course of action.

If the apparent conflict with CLIA statutory language 42U.S.C.§ 263a can be resolved, **HIPAA regulations should be clarified such that research results may be released to research participants in any of the following scenarios.**

a) When testing becomes part of a research participant's clinical record and may be used in prevention, diagnosis or treatment.
b) When the research protocol approved by the IRB and consented to by the research participant includes provisions for either:
    a. the release of individual study results to research participants; or
    b. return of incidental findings to participants.
c) When the researcher believes that a finding should be further corroborated by a CLIA-certified laboratory (this would further address another HIPAA/CLIA conflict in which CLIA currently prohibits this (see Enclosures A, B and C).

Outside of the three scenarios described above, HIPAA should not be interpreted to compel the release of research results. SACHRP has proposed a rebuttable presumption of return of individual results (2016 SACHRP).[5] Concerns

[4] United States Code Title 42- The Public Health and Welfare, Subpart 2-Clinical Laboratories § 263a. Certification of laboratories.

[5] July 21, 2016 letter from SACHRP to the HHS Secretary Attachment B: Return of Individual Research Results as accessed on December 19, 2018 from https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-return-individual-research-results/index.html

about funding levels, research reproducibility, administrative burden and potential liability are reasonable concerns that may appropriately factor into a researcher's ability and willingness to release research results. The presumption of return of individual results can be adequately rebutted in situations such as the following:

- Research is performed outside of a CLIA-certified laboratory and established quality management standards;
- Where release of individual research results to research participants would require a costly reporting framework detracting from the economical use of limited research funds and may leave laboratories subject to expensive lawsuits from patients who have not fully comprehended the essential difference between clinical testing and research tests; or
- Where research funding does not support availability of a health professional (generally a physician or genetic counselor) qualified to interpret the research results to patients, including clear identification of risks such as the potential for false positive and/or false negative findings.

Potential research subjects should be fully informed of what laboratory test results will be shared, might be shared and will not be shared. HIPAA should support clear communication with research participants, especially given the broad consent mechanisms available under the revised Common Rule effective January 2019.[6] Regardless of whether research is conducted in a HIPAA-covered institution or in a non-covered institution, IRBs should carefully consider the issues involved in approving a particular study. Obligations to research subjects should not vary depending upon the nature of the institution conducting the research. Instead, the nature of the research should be the focus.

ASIP believes that individual researchers and their associated IRBs should be the entities tasked with determining whether and under what conditions individual research results will be released to research participants. Individuals who sit on IRBs are trained and can proactively address issues around return of individual-specific research results with an understanding of study-specific concerns. Regardless of whether research is conducted in a HIPAA-covered institution or in a non-covered institution, IRBs carefully consider the issues involved in approving a consent form that informs the subject of potential risks and benefits. ASIP believes that this responsibility should be independent of whether an institution is covered under HIPAA. Obligations to research subjects should not vary depending upon the nature of the institution conducting the research. Instead, the nature of the research (clinical care versus research) should be the focus.

Release of individual laboratory results should occur within the same ethical framework developed for release of other clinical data/observations gathered during a research study. The release of individual research results should be governed by the broader recommendation developed in 2016 by SACHRP[7] on the return of individual research results to subjects, which sets forth the rebuttable presumption of return of individual results discussed earlier. Concerns about research rigor and reproducibility, administrative burden, and potential liability, all of which are discussed in this letter, are critical factors affecting a researcher's (and the sponsoring institution's) ability and willingness to release individual research results. The decision is best made at the level of the researcher in collaboration with the IRB as it allows researchers and funders to account for any needed, costly reporting framework, ensuring that researchers and funders can make relevant decisions regarding the economical use of limited research funds and account for potential liability concerns.

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[6] Revised Common Rule, Department of Health & Human Services, 45 CFR Part 46, RIN 0937–AA02 as accessed on December 19, 2018 at https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-01058.pdf

[7] Secretary's Advisory Committee on Human Research Protections, Attachment B-Return of Individual Research Results, Letter to the Secretary, July 21, 2016. https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-return-individual-research-results/index.html

HIPAA should be clarified to state that access to genomic information is not a civil right established by the Genetic Information Nondiscrimination Act (GINA).[8] Genomic information should be treated, as it has been in the past, as laboratory information no different from other results generated in a clinical laboratory. ASIP believes that there is nothing unique about genomic information that warrants different protocols beyond what is offered today in protecting health information. Access to genomic information may be limited fairly to the three scenarios described previously. A few articles have incorrectly sought to establish genomic information as a civil right established under GINA.[9] This erroneous assumption has been rebutted in the literature.[10]

Thank you for the opportunity to submit these comments. If ASIP may be of further assistance, please contact Dr. William B. Coleman at wbcoleman@asip.org.

Sincerely,

William B. Coleman, PhD
Executive Officer

Enclosure A – October 18, 2017 letter to Committee on the Return of Individual-Specific Research Results Generated in Research Laboratories, The National Academies of Sciences, Engineering, and Medicine

Enclosure B – August 18, 2017 letter to Committee on the Return of Individual-Specific Research Results Generated in Research Laboratories, The National Academies of Sciences, Engineering, and Medicine

Enclosure C – June 23, 2015 letter to Secretary's Advisory Committee on Human Research Protections

[8] The Genetic Information Nondiscrimination Act of 2008 and subsequent amendments as accessed on December 19, 2018 at https://www.eeoc.gov/laws/statutes/gina.cfm

[9] The American Journal of Human Genetics, 102 (2018) 5-10. doi:10.1016/j.ajhg.2017.12.004

[10] The American Journal of Human Genetics, 103 (2018) 163-165. doi:10.1016/j.ajhg.2018.06.003