Human Subjects
Office of Research
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Return of Results, CLIA, and HIPAA

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Common Rule Element of Consent

- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. (45 CFR 46.116 (c)(8))

Common Rule Element of Consent, Three Parts

- Are clinically relevant research results obtained?
- If yes, participants must be told whether or not they will be disclosed.
- If results will be disclosed, participants must be informed of the criteria for disclosure.

"Clinically Relevant" Considerations

- Relevant to the health and welfare of a participant?
- Actionable?
- Validated?

Common Rule Element of Consent, Other Considerations

- Protocol changes may be required for congruence with consent information.
  - Investigators may need to supply a protocol and/or template for return of results.

- Clinically relevant results may be
  - Primary research findings or secondary.
  - Anticipated or unanticipated.

CLIA (Clinical Laboratory Improvement Amendments)

- Centers for Medicare & Medicaid Services (CMS)
- Regulatory requirements for all laboratories that examine “materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.”
- Laboratories must obtain a CLIA certificate appropriate to the kind of tests it conducts.

CLIA, Continued

- "Research laboratories" are excepted from CLIA requirements.
- Research laboratories: Those "that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients."

CLIA, Continued

- CMS considers any return of results to violate the research exception.
  - Including when participants are told to seek confirmatory diagnosis.
  - The decision to seek out testing is a medical decision.
- Research laboratories that return test results to participants must comply with CLIA, either by:
  - Becoming CLIA certified, or
  - Obtaining confirmatory testing from a CLIA-certified lab.

CLIA and IRB Review

- CMS guidance is that IRBs should not and cannot determine CLIA applicability.
- "IRBs that consider human research subject protection considerations would not be expected to consider the applicability of the CLIA regulations."
- "[E]ven if they did, IRBs would have no authority to authoritatively opine on the applicability of those CLIA provisions."

HIPAA (Health Insurance Portability and Accountability Act)

- Requires that patients have access to their Protected Health Information (PHI).
  - Research results may be withheld while research is conducted.
- Do not take into account non-CLIA research laboratories.
- Only apply to HIPAA-covered entities.

IRB Review Takeaways

- Ensure informed consent is adequate and compliant.

- Review investigator protocol for handling research results and any templates.

Other Ethical Considerations

- Respect for Persons & Transparency
- Beneficence
- Difficulty in interpretation of results
- Value of information
- Who bears the cost?
- Genomic research

References

- Research Testing and Clinical Laboratory Improvement Amendments of 1988 (CLIA) Regulations, https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/Research-Testing-and-CLIA.pdf
- CLIA in the Research Context, Dana-Farber Cancer Institute, https://www.dfhcc.harvard.edu/crs-resources/OHRS_Documents/02_-_Investigator_Resources/IS_-_Guidance_-_CLIA_Requirements.pdf
- SACHRP Recommendations, Attachment B: Return of Individual Research Results, https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-return-individual-research-results/index.html
- SACHRP Recommendations, Attachment C: https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2015-september-28-attachment-c/index.html
- Common Rule consent elements: 45 CFR 46.116
- Common Rule Bulletin #3: Biospecimens/Data Requirements in ICF, NIH OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS (OHSRP) GUIDANCE ON THE REVISED COMMON RULE, https://irbo.nih.gov/confluence/display/ohsrp/Common+Rule+Bulletin+3