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CLIA and Research Testing

Laboratories performing testing on human specimens and reporting patient-specific results must be certified under the provisions of the Clinical Laboratory Improvement Amendments of 1998 ^[1] (CLIA). CLIA makes an exception for ?Research laboratories 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? (42 CFR 493.3(b)(2)).

If you wish to provide diagnostic results to subjects or use test results to alter care, you should have laboratory tests performed under a CLIA-certified clinical laboratory. The extent to which CLIA applies to a variety of tests used solely for research purposes is not clear, but caution requires complying with CLIA wherever possible.

Ethical Concerns

Risk/Benefit Ratio: The benefits of providing diagnostic results to individual subjects or their doctors?especially possible improvements in individual treatment?must be weighed against risks, including false diagnosis, diagnosis when no treatment is available and health insurance issues.

Right to Be Informed: Individuals generally have a right to be fully informed about research in which they participate, including receiving study results that may be useful or interesting to them. However, some test results may be of unknown value, and providing results may lead to misunderstanding, worry and unnecessary treatment.

Guidelines for Reporting or Withholding Results

Reporting results to individuals

If diagnostic tests (such as STD screening) done in the course of research will be made available to subjects or their physicians, the tests should be performed in compliance with all CLIA requirements, which usually means they will need to be performed by a clinical laboratory certified under CLIA. CLIA provides for ?waivers? that allow certain simple tests to be performed outside a clinical laboratory, but the testing site must obtain a Certificate of Waiver ^[2] and meet other CLIA requirements.

In the IRB Application, assure the IRB that the tests will be performed in compliance with CLIA requirements. Consult with experts in the Clinical Laboratories for details of the requirements (UCSF: 353-1723; SFGH: 476-1779, 206-8588; SFVAMC: 221-4810 x2260). You should consider how the benefits of providing results weigh against the risks and should try to minimize the risks.

See the Information Sheet for Clinical Laboratory Testing ^[3] for more information regarding CLIA and translational research at UCSF.

Withholding results from individuals

If novel or experimental tests ? including genetic tests ? will be performed outside of CLIA-certified auspices, one option is to not report the results of those tests to research subjects or their physicians and to not allow results to affect the subjects? treatment. When the meaning of results is uncertain, withholding individual results may be the best option.

Clearly indicate in the IRB Application that results will not be provided to subjects or their physicians. Also explain in the study consent form that you will not provide subjects with test results and why results are being withheld.

Possible exceptions

There may be situations where ethical considerations (discussed in more detail below) require

some use of results or reporting of results to subjects or their physicians, but the tests cannot be done under the auspices of a CLIA-certified lab. If you are contemplating such an exception, include all of the following in your IRB Application:

- An explanation of why doing the test under CLIA-certified auspices is not possible, preferably with supporting documentation reflecting unsuccessful attempts to arrange for involvement of a CLIA-certified laboratory. The greater cost of CLIA-certified testing generally is not a satisfactory explanation.
- An explanation of the ethical reasons for using and/or providing results.
- A detailed plan for communicating results to subjects or their physicians. In most cases, a process for discussing the results with subjects should be described and a written form for conveying results should be provided. Information to be conveyed should include a description of the unproven nature of the tests, explanation of the uncertified status of the laboratories, and cautions against the use of the results for diagnosis, prevention, or treatment of any disease or impairment, or the assessment of health of individual patients.

In determining whether to grant or refuse a request for an exception the IRB may consult with a variety of resources, including but not limited to clinical laboratory experts.

HIPAA and Consent Considerations

HIPAA: If test results will be recorded in our medical records, the results are protected health information under the HIPAA [4]. You must obtain a HIPAA authorization [4] from each research subject and specify to whom the results may be released.

Consent Issues:

- Consent forms should discuss the treatment implications of diagnostic tests, especially when the test is experimental or there is no clear course of recommended treatment.
- If test results may reveal a condition that is not already documented in the patients' medical records, the consent form should discuss the possible loss of insurability if test results become known to insurers.
- Researchers should consider allowing subjects to choose which specific test results will be reported to them or placed in their medical records.

Ethical Justifications for Providing Results in the Absence of CLIA Certification

There are situations in which it is unethical to withhold all results. However, citing one or more of the following ethical justifications for providing results is not in itself sufficient to ensure IRB approval. The IRB must consider the overall context of the study and will make decisions on a case-by-case basis.

The following are meant only as examples of ethical justifications that the IRB may consider:

1. Research subjects may desire and have a right to learn individual results of unproven tests to satisfy intellectual curiosity, to gain a greater sense of control of their own condition or for a variety of other personal reasons.

The Belmont Report [5] cites basic ethical principles which may be seen as supporting

research subjects? right to have access to information about themselves. The principle of Respect for Persons establishes the right of individuals to be fully informed about research in which they participate. The principle of Beneficence requires that benefits to the subjects be maximized while risks are minimized. Providing subjects with experimental test results may provide them with benefit, even if it is only the intellectual satisfaction and feeling of control of learning difficult-to-interpret information about themselves. Because individual interests may vary, studies may need provisions that allow individual subjects to decide whether or not to receive results.

2. The results of the experimental test or regimen of tests may point toward additional testing that could in turn lead to an improvement in the subject?s care.

For example, the Department of Health and Human Services recently placed a rapid screening test for HIV in a CLIA ?waived? category because the test could reasonably be presumed to lead the individual to a confirmatory test for clinical diagnosis and linkage to care. CLIA waivers generally require formal certification and adherence to specified procedures.

3. There are some studies in which subjects may refuse to participate unless they have access to the perceived benefit of test results.

If the study is well designed and could provide important scientific results, the benefits of completing the study may outweigh the risks of providing individual test results. This justification is stronger if refusals based on withholding results are documented for the same or a similar study.

4. In the absence of proven tests, an experimental test or regimen of tests may provide the best available guide to future action, and in certain circumstances it could be unethical to withhold such results.

For example, although CLIA certification attempts to address reliability within assays and between labs, it cannot address validity in the realm of genetic testing of complex disease where the knowledge base is still incomplete. Non-CLIA labs may have demonstrable high reliability within their own system, yet be unable to satisfy CLIA requirements that were based on a different set of expectations regarding the existence of standard methods or other already approved labs.

5. The design for an ethical and important study may require determining whether it is effective to change subjects? care based on the results of a clinical test that cannot be conducted by a CLIA certified laboratory.

Examples may include tests of viral fitness that determine whether changes in an antiviral treatment are effective; or early-stage pharmacogenomic studies.

Even when providing results seems ethically justified, the possible negative consequences of doing so must be considered and minimized.

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- [1] <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/>
- [2] https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Certificate_of_Waiver_Laboratory_Project.html
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