Responses to School of Pharmacy Faculty Council Questions on Potentially High-Risk Experiential Learning: Policy on Student Genetic Testing

Overall
We appreciate the careful review and comments provided by the SOP faculty council. We have attempted to address each of their questions and comments below.

1. When will the ad hoc committee be formulated for Appendix A?
At such time as a course proposes student genetic testing that goes beyond the tests currently being used in SOP and SOM courses.

2. Appendix C. Section III, "this does not mean the test must be CLIA approved." This should really read “does not mean the test must be FDA cleared.” All tests in a CLIA lab are either approved or in the process of being approved.
Both statements may be correct. In this guidance document, we seek to be as concrete as possible. The additional information regarding the FDA clearance process is not directly relevant to the student genetic testing policy, so we recommend keeping the language as stands.

3. Appendix D. Section 2a. “headed by a licensed physician” implies that any licensed physician can be a lab director. CLIA states that the physician must be board certified in Pathology. A physician can be a lab director but must have other qualifications, especially experience. Also, a PHD (like myself) are lab directors with certain qualifications/experience. Is this a direct quote from the letter to UC Berkeley from CPDH? How about changing to "headed by a licensed laboratory director”
Appendix D is informative only. This statement refers to the guidance provided to UC Berkeley by the California Department of Public Health. The UCSF policy does not include reference to a license physician but only to the need for a CLIA certified laboratory. In the CDPH letter to UC Berkeley, the reference to “licensed physician” refers to the California Business and Profession code §1209, which contains a fairly long first sentence on who can qualify as a laboratory director (which is earlier stated in another section as the only individual qualified to run a lab that returns results of tests to individuals), and the first sentence begins with “duly licensed physician or surgeon” followed by lesser standards for individuals performing waived tests, and finally a final clause which states that “or is licensed to direct a clinical laboratory under this chapter and who substantially meets the laboratory director qualifications under CLIA for the type and complexity of tests being offered by the laboratory.” It seems that should have been included beyond licensed physician.
4. Appendix D, section 4 contains a double negative, “not all tests which are not listed in Appendix A are high risk.” Suggest changing to: “Appendix A is not a comprehensive list of the pre-approved tests covered by this policy.” We should mention that “There will be new tests, yet discovered, that could be included in Appendix A and considered by the ad hoc committee to be non-high risk and qualify for testing of students.” Appendix D is informative only. We recommend keeping the language as is. The suggested language might lead instructors to think that there is a separate list of pre-approved tests. That is not true. The policy – and policy guidance – make it clear that additional tests may be proposed as non-high risk and approved for use in student genetic testing in an educational context.

5. In terms of style, bullet points don’t require statements like “the first requirement, the final requirement, etc.” These points refer to the requirements of the policy itself, which are stated earlier in the document. We believe these references help clarify the object of the stated bullet points.

6. Of the policy itself, section 3b, i): “must be performed in a CLIA certified lab, as required by CLIA and CA DPH.” CLIA is the Clinical Laboratory Improvement Amendment, and amendment to the Public Services Act of Congress. CLIA compliance for clinical laboratory testing is regulated under the Centers for Medicare and Medicaid (CMS) not the Act or Amendment itself. Suggest change to “as required by CMS and CA DPH.” With respect to the policy itself and the statement “as required by CLIA,” while CLIA is the act it is common language to say laws or regulations “require,” as in they set standards, rather than saying the agency which enforcing them requires. In this case, while CMS handles the accreditation under CLIA, and the FDA categorizes tests based on complexity, and the CDC provides other services, quality improvement, and technical consultation, the certificate requirement is imposed by the act itself. Under 42 U.S.C. §263a (a) and (b), which defines clinical laboratory, CLIA states that no person can solicit specimens/samples for analysis from a person unless the lab has a certificate issued by the secretary. So in this case, the act itself is imposing the requirement, not merely CMS.