Quarterly Compliance Quandary

Dr. Brian German is a Professor at an academic medical school. One of Dr. German's responsibilities is to teach a course on laboratory techniques to first year dental and medical students. Under proper supervision, the students draw blood from one another, labeling the blood samples with the students' names. Lymphocytes are isolated from the blood of each student and the presence and amount of a specific protein is determined. The data acquired from this experiment demonstrated that the students successfully performed the required laboratory techniques.

Dr. German also has developed a protocol to examine the presence and amount of the same specific protein on the cell surface of human lymphocytes, so as the students were cleaning the laboratory equipment used in this experiment, Dr. German told the students to give him their left over lymphocytes labeled with their names because the professor wants to use these lymphocytes in his own research. Dr. German said that this donation of cells was not mandatory. Nevertheless, all of the students gave Dr. German their unused lymphocytes.

What are the research compliance implications of Dr. German's request ?

Things to Consider
Is an IRB-approved protocol required before Dr. German uses the lymphocytes for his own research?

Do the students need to read, understand and sign an Informed Consent Form (ICF)?

To be compliant with HIPAA regulations, does Dr. German need to obtain authorization from the students for his current approved research protocol and any future defined research with their cells? What if Dr. German does not know how he will study the lymphocytes in the future?

Answers
Yes. Dr. German cannot begin these experiments without approval by the IRB. A number is assigned to all approved protocols.

Yes. Again research cannot begin until the human subjects (in this case the students) have read and signed an ICF specific to the approved protocol. Signing this document means that the subjects understand the purpose of the research, how the research will affect the students; i.e., the ICF includes a list of possible adverse events, and whether the investigators or their Institution has a significant financial gain that depends on the outcome of the experiments.

Yes. Signing an ICF is different from signing a HIPAA Authorization form. Unlike the ICF, the rules for HIPAA Authorization depend on the type of research being performed. For example, if the cell surface protein mentioned above is associated with HIV infection, this Personal Health Information (PHI) must be secure and confidential under most situations; one exemption that can override confidentiality of PHI may be due to State laws.

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