Investigational test protocols must include informed consent

Q If a laboratory performs investigational testing on patients in a physician office laboratory, is the laboratory or its director required to have an ongoing manuscript or log of those results?

A A prime maxim of laboratories is that all results must be tracked and be subject to quality control. The short answer to your question is a resounding: Yes. If asked, you must be able to verify what samples were taken, from whom, how they were tested, and how the results were handled. The research protocol under which the samples are taken will probably have specific requirements for logging and tracking.

Other issues exist, however, that investigational testing raises, not the least of which are consent and reporting. In general, drawing blood for test purposes requires the permission and consent of the patient. If the investigational tests you are performing require additional blood be taken from the patient (separate draws or additional tubes), then the patient’s permission for you to collect the specimen is required. To simply draw an extra tube for investigational purposes “as long as you are there” is not permissible. Again, the investigational protocol should define informed-consent procedures very specifically, and they may be more detailed than those generally used in the lab. Be certain you know what the protocol requires in addition to general concepts of permission and consent.

For investigations performed on leftover samples drawn for legitimate testing purposes, the situation becomes a bit murkier. Certainly, the most cautious approach would still be to obtain the patient’s permission to use the blood for investigational purposes, but circumstances occur — such as parallel testing to establish the reliability of a new instrument or technique — where no additional permission is needed because the test being performed is identical to that ordered for medical purposes. In general, however, it is wise, if not always absolutely necessary, to obtain specific permission from the patient before performing any additional testing above and beyond that ordered by the physician for patient care.

When investigational testing turns up medically significant information — or even when it does not — the question becomes one of reporting. Just as the laboratory generally has an obligation to obtain the permission of the patient before performing tests, it also may be obligated to provide results to the patient or his physician. Best practice is to determine the policy and procedure for doing so.

I support giving the patient the option of having investigational results sent to his own physician, before a situation arises that causes a problem. Imagine, for example, running an investigational study of electrolyte levels and finding a critical potassium value in one of the patients. Regardless of the legal requirements of reporting and the question of physician-patient relationship, most laboratory professionals would agree: Getting that value to the patient’s physician is a moral imperative. Plan ahead for just such a situation, which is bound to arise.

Last, of course, is the issue of charges. Unless the test is medically required and ordered by the patient, charging the patient for investigational tests or supplies is generally not permissible.

What is informed consent?

Informed consent is an ethical obligation and a legal requirement spelled out in statutes and case law in all 50 states. According to the American Medical Association, informed consent is a process of communication between patient and physician that results in the patient’s authorization to undergo a specific medical intervention. The physician should disclose and discuss:

- diagnosis, if known,
- nature and purpose of proposed treatment/procedure,
- risks and benefits of proposed treatment/procedure,
- alternatives (regardless of cost/insurance coverage),
- risks and benefits of alternative treatment/procedure, and
- risks and benefits of not receiving or undergoing treatment/procedure.

Then, the patient should be able to ask questions to better understand the treatment or procedure, so that an informed decision can be made.

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