(Friday) 17 December 2010

Memorandum

To: Curt & CLM

Fr: Me

Re: Specimen banking

Years ago, digging a trench in my yard, my neighbor asked if I had help. I told him I did. Curt, CLM, and Me but that Curt and CLM were not much help. Thus was born Curt, CLM, and Me.

Although neither Curt nor CLM have been much help around the house, they have been of immense help in focusing my thinking on various issues over the years. Blogging before there was blogging. Me as the blogger and as the bloggee.

There is nothing like pen and paper in crystallizing thoughts. I hate to think what our Declaration of Independence would be like if Thomas Jefferson had had e-mail and an iPad.

This memo is from Me to Curt and CLM with copies to others who might be interested in specimen banking.

Banking here refers to a process of collecting and storing specimens (blood, plasma, or other bodily fluids) from consenting persons for storage for future unspecified uses. Uses may be limited to investigators in the study or open to any qualified user, whether inside or outside the study investigatorship.

Specimen banking is practiced in most of the studies done in the Center. The motivation is an eureka moment, new insights regarding a disease or treatment process, or discovery of a surrogate marker serving to reduce sample size requirements of future studies.

Banking consent rules

Rule 1: Produce consents:

a. That indicate the nature and schedule of specimen collection,
b. That indicate that specimens will be stored for future, unspecified, uses,
c. That provide "yes-no" check boxes to indicate whether persons agree to banking,
d. That provide a separate "yes-no" check box for DNA analysis if such analyses are planned or contemplated,
e. Indicating whether persons will learn of results from uses of banked specimens,
f. Indicating whether persons can change their minds during the study concerning specimen collections and consequences to their participation in the study,
g. Indicating who will have access to specimens,

and

h. Indicating how long specimens will be kept.
Comment: Since specimens are collected for future unspecified uses, the usual approach is to indicate that persons electing to contribute specimens will not have any say in how they are used and that they will not be informed of results from analyses; tantamount to ceding specimens to the study as gifts.

Rule 2: Indicate if analyses of specimens will require access to identified study data.
Comment: The presumption is that they will. If so, persons should be informed that their data will be provided and that doing so carries risks of breaches of confidentiality.

Rule 3: Indicate that agreement to contribute specimens can be rescinded without consequence.

Rule 4: Indicate whether a person can have data on specimens expunged from study files.
Comment: Expunging data is a no no. The consent should indicate that data cannot be withdrawn. The form should indicate that a person can stop contributing specimens and have specimens withdrawn from the bank but that results of analyses done cannot be withdrawn.

Rule 5: In multicenter trials, produce a prototype consent form for use in IRB submissions.
Comment: A prototype is essential if there is to be any uniformity in consents and options offered.

Rule 6: In multicenter studies, review IRB approved consents for differences in information provided and in options offered; determine whether differences are acceptable or if they require investigators to go back to their respective IRBs for resolution.
Comment: If consents have times for when specimens will be destroyed, there has to be ways of honoring those commitments. If times differ by clinic, the entire repository will have to be destroyed at the nearest date in consents or the study has to have a system of destruction by date.

Rule 7: Options for collection checked on consent forms should be keyed.
Comment: There is no value in providing persons options on collections, if there is no way to ensure those choices are honored. The information on consent forms is needed in the study data system to manage collections and to monitor for unauthorized collections.

Banking operational rules

Rule 1: Select a qualified repository for specimen storage.
Comment: Give preference to locations experienced in banking as a business and to operations with good records of service and histories of longevity. Moving locations during collection because of performance problems or because the repository is closing are difficult to manage. When choosing a bank keep in mind that the bank has to be adept at receiving specimens and shipping specimens. Have a repository in place before specimen collection starts. Stockpiling specimens at collection sites until a repository is chosen should be avoided.

Rule 2: Inform IRBs of the location of the repository and of the protocol for specimen collections and shipping.

Rule 3: Outline the rules and procedures for requesting specimens from the bank.

Comment: In an ideal world these rules and procedures are established before any specimens are collected. In reality, they may not be established until requests are received. The rush then makes for bad rules and procedures.

Rule 4: Produce reports providing counts of specimens received at and shipped from the repository; produce at periodic intervals over the course of the study. If counts are provided by the repository, have counts verified by the study data center.

Rule 5: Instruct the bank as to what is to be done with improperly labeled specimens.
Comment: The normal practice is to destroy them and for the repository to inform the collection site and data center of the destruction and the reason for it.

Rule 6: Decide when specimens will be destroyed.
Comment: The general rule of thumb is to require destruction of specimens when funding for the study ends. An alternative is to transfer the specimens to some other group willing to assume responsibility for them. However, that alternative is not viable without patient identified data. Transfer of identified data may be precluded if such transfer is not mentioned in consents.

Rule 7: Require IRB approval of any proposal for use of specimens; approval required by IRB of investigator responsible for the specimen repository and by the IRB of the investigator scheduled to receive specimens.

Rule 8: Require a material transfer agreement in relation to any specimen request.
Comment: The agreement should require the recipient, as a condition of receipt, to limit use to that specified in the request and to protect the privacy of patient data.