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Mandatory Companion Studies

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Background

Some national study groups and study sponsors want to require that participants in treatment studies also participate in other research activities, such as registries, data repositories, and collection of biological specimens and/or genetic materials. Such mandatory companion studies raise a serious ethical issue and conflict with regulations pertaining to human subjects research:

- Participation in research should be voluntary.
- Undue pressure is created if subjects are told they cannot receive a potentially beneficial (though experimental) treatment unless they also agree to participate in the additional study.

Preferred Method for Including a Companion or Ancillary Study

Participation in ancillary studies should not be required for enrollment in a study involving experimental treatment that might benefit subjects. The IRB generally will not approve such linked studies, but will instead ask that the ancillary study be made optional.

How to make provisions for separate voluntary consent:

- The preferred method is to use a separate consent form.
- Alternatively, describe the ancillary study in a separate section within the main consent form. Provide separate lines for subjects to initial if they agree to participate in the ancillary study.

Consent reminders

- The companion study consent form must be written using in the UCSF format [1]; do not submit an unedited sample consent form from a cooperative group or sponsor.
- Additional consent guidance is available on the Research Using Human Biological Specimens page [2].
- Describe in the consent form and IRB Application how participants? identities will be shared and protected if the bank or registry uses personally identifiable health information.

Exceptions: When a Mandatory Companion Study May Be Allowed

Under the circumstances described below, participation in a companion study may be required as a condition of enrollment in the main study. Eligible participants who from the onset do not wish to participate in the ancillary study may be denied enrollment in the main study.

Main study has no potential direct benefit to subjects

If there is no potential direct benefit to participants in the main study, it is permissible to require participation in registries, data banking, collection of biological specimens or genetic material, and similar ancillary activities as a condition of enrollment in the main study.

Ancillary activities necessary to answer main research question

Participation in the ancillary activities may be required if it can be shown that results of the ancillary activities are necessary to answer the questions asked in the main study ? in other words, there would be no scientific knowledge gained from participants who did not take part in the ancillary studies. In these circumstances, the IRB encourages ? but does not require ? incorporating a minimum of extra procedures into the main study rather than requiring enrollment in a separate registry or bank.

Important Note: Applications for approval of ancillary activities must describe how participants? personally identifiable health information will be shared and protected. Use of a limited data set under HIPAA may be appropriate.

Participation required by law (e.g. tumor registries, STD reporting)

Participation in a very few registries is required by law. Examples include tumor registries and sexually transmitted disease reporting. Because participation is not voluntary, participants are not asked for consent.

It may be appropriate to mention other required reporting in a research consent form, if participation in the study may directly lead to the reporting. For example, the consent form might state, ?If the study tests show you have certain sexually transmitted diseases, we are required to report those results to the city?s Department of Public Health, who may contact you and your sexual partners.?

Cancer patients are enrolled in the tumor registries regardless of their participation in research

studies; it is not necessary to mention the registry in research consent forms. Upon admission patients are informed about the state cancer registry in the Terms and Conditions of Admission to UCSF form.

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Links
[1] http://irb.ucsf.edu/node/216
[2] http://irb.ucsf.edu/node/871