Incidental Findings

Purpose
The purpose of this document is to provide investigators and staff with guidance on developing and implementing appropriate procedures for addressing incidental findings that may be relevant to a research subject's physical or psychological health, safety, rights, or welfare in human studies.

Definitions

a. Incidental Findings: A discovery concerning an individual research subject that has potential consequences for their health, safety, rights, and welfare that is discovered in the course of research but is beyond the information sought or required to achieve the aims of the study. Incidental findings may or may not be anticipated in a significant portion of the study cohort.

b. Sharing Subject Findings: Communication between a study team and a research subject either before or after his/her participation in the study has concluded, or within or outside of the parameters of the individual's participation as described in the informed consent, to share information with potential significance to the subject's health, welfare or safety.

Anticipated Incidental Findings
The potential for incidental findings in human subjects research (whether or not directly relevant to the actual research goals) with possible health or safety significance should be anticipated whenever possible. If the investigator believes that incidental findings are likely, given the population and/or procedures involved in the study, a plan to communicate such findings with the subject, or other clinicians as appropriate, should be included in the protocol submitted for IRB review and approval. The plan should include:

a. the anticipated time frame in which the tests or measures will be analyzed
b. the test thresholds that would prompt further action or communication
c. and details of the planned interventions

Unanticipated Incidental Findings
In cases where unanticipated information related to the possible health or safety of a subject is discovered during the course of a study, the IRB should be consulted promptly for guidance.
Example of research involving mental health measures:
An investigator is conducting a study in which people suffering from depression must be excluded. She selects the Beck Depression Inventory (BDI) as a screening tool for identifying depression.

The investigator should anticipate that depression may be identified in some potential subjects during the screening process. As a part of the plan for incidental findings, the consent form should inform those undergoing screening that depression might be identified and what will occur if that happens. Contact information for those being screened should be maintained and linked to responses until the result of the BDI is known. For example, study subjects can be referred to the Department of Psychiatry and other resources as appropriate. In some studies, subjects can be given contact information for suicide or other appropriate hotlines, with instructions to call these mental health service hotlines if they choose certain answers to specific questions. In cases where a delay in scoring instruments may exist, it is possible that a respondent may incorrectly believe that a researcher will read her or his responses and offer immediate assistance. To minimize the possibility that a subject may delay seeking help because of this assumption, consent form should inform subjects of either of the following:

1. This study does not allow the researchers to associate your identity with your responses. If you are experiencing symptoms of depression or suicidal thoughts, please seek immediate assistance by contacting [list names and contact information for researchers qualified to address subjects’ concerns] or by calling [list of local resources with contact information].
2. It is possible that the researchers will not view your responses for several days or weeks after you complete the surveys. If you are experiencing symptoms of depression or suicidal thoughts, please seek immediate assistance by contacting [list names and contact information for researchers qualified to address subjects’ concerns] or by calling [list of local resources with contact information].

In some studies, it is best to provide all subjects with information about resources available, regardless of the results on mental health measures. The IRB can help you craft an appropriate plan.

Example of research involving health screenings
An investigator is conducting a study in which a blood glucose level is obtained. He should consider how he will provide information regarding appropriate treatment if a subject’s test result shows glucose levels in the pre-diabetes or diabetic range. As a part of the plan for handling incidental findings, the consent form can be drafted so that subjects have the choice of allowing the investigator to pass along significant health findings to the subject’s primary care provider. If a subject does not have a primary care provider, investigators can provide information about where care can be obtained or make a referral for appropriate follow-up. The IRB can help you craft an appropriate plan.