Chapter 17
Special Research Topics

This chapter focuses on special research topics. Some topics discussed in this chapter are not subject to IRB review, other topics that are of misconstrued as human subjects research.

17.1 Secondary Data Analysis

Any research that involves secondary use of data where individual identifiable subject records are involved requires IRB review. For example, an investigator who plans to analyze an existing data set obtained from another source should submit an application for IRB review if the data set contains records on individual human subjects. If the data set contains no identifiers (either direct or linked code numbers), the project is not human subjects research (refer to Section 7.1 - Human Subjects Research: What is and What is Not for definitions of "human subject").

If the data set contains identifiers, and does not contain private information, the project is not human subjects research. Otherwise, the project may be eligible for expedited review. The IRB may waive informed consent if research is minimal risk, the rights and welfare of the subjects are not adversely affected, the research could not practicably be carried out without the waiver, and, when appropriate, subjects are provided with pertinent information after participation.

17.2 Survey Research

Survey research is a research method that obtains data through the use of surveys, questionnaires, interviews, and focus groups. Because of the methodology, it is often assumed that all survey research is minimal risk. However, survey research may involve greater than minimal risk. For example, a survey or interview that asks questions about sensitive topics (childhood abuse, sexual functioning, immigration status) are not minimal risk. These questions may cause emotional stress, discomfort, or may have legal or social implications, and therefore may require full IRB review.

The term anonymous is sometimes confused with the term confidential. In human subjects research, anonymous means that there is no link or identifier to the subject. If a link exists elsewhere, but is not available to the researcher, the IRB must determine the category of risk, and/or difficulty of discovery of the subject's identity, the IRB cannot consider the information anonymous.

Survey research may be classified as exempt from the regulations if the information obtained is recorded in a way that the subject cannot be identified (either directly or through a code number or link), in other words, if the research data is anonymous.

A survey or interview study may also be considered exempt from the regulations even when the data is not anonymous if the information being gathered could not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

If a study is not anonymous and contains information that, if known, could be damaging as described above, but it does not rise to the level of more than minimal risk, it may be given expedited approval. Although the IRB application gives the investigator the opportunity to indicate a classification, the IRB makes the final determination as to the classification of exempt or expedited.

For minimal risk surveys (mail-out or web-based), it may be appropriate to request the IRB to waive the requirement for the subject's signature on an informed consent form. When the subject's signature requirement is waived, generally the investigator provides all of the required elements of consent in an Information Sheet, with a statement that returning the survey or questionnaire will constitute voluntary agreement/consent to participate in the research study. For additional information, refer to Section 10.10 – Waivers of Informed Consent.

If survey research is supported by or conducted in collaboration with the Department of Defense (DOD), follow DOD requirements for additional review (refer to Section 3.2 - Research Supported by the Department of Defense).

17.3 Internet Research

Research conducted over the internet creates new challenges for those charged with maintaining protections for human subjects participating in such research. Internet research is has two distinct differences; one is collecting data online, the other is studying

internet/social media itself. Internet-based research is no different than other human subjects research in terms of regulatory oversight and requirements. As investigators design research protocols, particular issues must be addressed in order to maintain protections (violation of privacy, legal risks, and psychosocial stress). Human subjects research that is designed to recruit participants or collect data through the internet must be reviewed by the USC IRB.

Internet Research that may require IRB review includes studies with:

- questionnaires completed online via the Internet
- questionnaires downloaded from the Internet and returned by mail
- questionnaires incorporated into an e-mail and returned the same way
- qualitative interviews or discussions conducted over the Internet
- experiments conducted over the Internet
- use or housing of large public use databases
- recruiting volunteers over the Internet
- observation of individual behaviors via the Internet (such as "chat rooms")
- taking part in a measurement system which tracks web usage using specialist software installed on the user's computer
- a study that analyzes the age group correlation to Facebook addiction

The following are options to consider when conducting research over the Internet

Regulatory requirements and institutional oversight for human subjects research must be followed.

- Internet consent should include all the elements of the regular signed consent. The consent line should read, *"By completing the survey you are agreeing to participate in the research"*. Internet-based surveys should include "I agree" or "I do not agree" buttons on the website for participants to click their choice of whether they consent to participate or not.
- If a subject completes an anonymous survey and sends it to the researcher, the

researcher will be unable to extract identifiable data from the researcher's database and the participant may not have it withdrawn.

- If the IRB approves research and requires documented consent and the PI does not plan to maintain the anonymity of participants, the researcher may email the consent form to participants who may type their name and date into the spaces provided on the consent form, and return it to the researcher via email.

Privacy and Confidentiality in Internet Research

Privacy and confidentiality raise a particular challenge in Internet Research. The challenges relate to the "unseen-ness" of the researcher as well as the subject. In some cases, the subjects will not know they are being observed, and in other cases they are being recruited and are willfully participating. The researcher must consider in which situation his/her research will be taking place and address the risks to the subject, to the security of the collected data, and to the validity of data gathered from unseen subjects.

Interactions and activities occurring in public chat rooms or public message boards are considered public behaviors while some chat rooms and message boards have restricted access. Interactions in restricted chat rooms and message boards are considered private behaviors.

Recruitment and Compensation in Internet Research

The text of the recruitment script, the context in which the recruitment takes place (posting a message on a newsgroup, mass e-mailings, and websites created for recruitment of participants) must be reviewed and approved by the IRB.

When providing compensation, the following are recommended to maintain anonymity:

- electronic gift cards or certificates sent via email
- cash/gift card sent through the postal service (note: using the subject's mailing address prohibits research being anonymous)
- do not link compensation to contact information

Vulnerable Subject Populations in Internet Research

- Vulnerability pertains to how identified data is protected, whether subjects are knowing participants, and class of subjects.
- The researcher should address subject vulnerability issues in order for the IRB to determine protections are adequate.
- Age of participant: On the Internet age is difficult to verify. To exclude minors, the researcher may state the minimum age of participants on a web page, information sheet, and/or consent document at the outset of the study. Individuals should be able to press a "not eligible, please discontinue" button (give the location) if they are not yet 18 years old, or an "I agree to participate and certify that I am 18 years of age or older" button.
- The researcher must provide a plan for obtaining parental permission when applicable.
- If the study population includes minors, the IRB may waive assent from the minors and/or parental permission from the parents depending on the level of risk in the research. Generally, if the study involves a high level of risk, assent and parental permission is required. If the study involves minimal risk, assent and/or parental permission can be waived. The IRB may require the use of information sheets when child assent and/or parental permission are waived.

Online Survey Options

There are a variety of ways to conduct online surveys. One way is for the researcher to create a survey themselves using a program such as Word, and then sending it through email. Another option is to use an online survey provider such as Survey Monkey. The researcher must consider confidentiality of the data obtained.

Online survey providers offer different options to researchers for maintaining confidentiality. When subjects are told the survey will be anonymous, the online survey must be configured so that identifiers (IP address, email address) are made unavailable to the researchers. Each survey company will have their own method for accomplishing this. Contact the survey provider for information on how to maintain confidentiality. If a survey provider routinely supplies identifiers and the researcher has described the survey as anonymous, the identifiers/IP addresses should be deleted immediately.

Data being collected through the internet should be in an encrypted format. This helps to ensure that any data intercepted during transmission cannot be decoded, and that individual responses cannot be traced back to an individual respondent. All databases storing sensitive and identifiable information must be protected, regardless of whether they are created and maintained by commercial firms or by individuals.

Researchers are cautioned that encryption standards vary from country to country and that there are legal restrictions regarding the export of certain encryption software outside US boundaries.

Each communication below carries the risk of a breach of confidentiality. Email is not secure.

- Communication between the researcher and the subject
- Communication between the subject and the web server
- Communication between the web server and the researcher

Additional Recommendations

Researchers should inform subjects that the researcher is available to discuss the questionnaire before starting the study. The researchers must provide email addresses or contact information.

Researchers should design interactive consent/survey/participation processes that are tailored to potential subjects- for example, by identifying the subject's primary language and/or offering the consent/survey in that language.

When using an online survey vendor (survey monkey) to administer an online anonymous survey, the researchers should ask the vendor to withhold the IP addresses of the participants.

Given the nature of the study, consider the following: what information is being collected, how will it be transmitted, how long will the information be kept, the population being targeted, and are there any additional protections needed to protect participants' privacy or data confidentiality?

Researchers should convey to subjects:

- sites with URL's that begin with “https” or that display a small padlock are considered secure
- participants should completely log off the computer when finished to help maintain privacy
- Internet temporary files and cookies should be deleted so that subsequent users cannot “see” what sites were visited

Some online surveys are designed so that subjects cannot proceed without answering every question. Researchers must add the option of “no response” to all questions.

17.4 Incidental Findings in Research

Incidental Findings in research are results obtained/uncovered about an individual research subject, for which there is a potential health importance but is **beyond the aims of the study.** It may arise in collecting or analyzing research data/images or part of establishing eligibility or for purposes of the study itself (samples, eligibility, screening).

The research proposal should delineate how incidental findings will be managed in the research. The informed consent should be consistent with this plan. In general, it is contemplated that the health care provider/investigator will disclose the relevant information and ensure appropriate referral or care are recommended or provided.

Incidental Findings give rise to a wide range of practical and ethical challenges for recipients and practitioners.

Emerging medical technologies, changing cost structures, and evolving medical practice have increased remarkably the likelihood of discovering incidental findings in the clinical, research, and commercial direct-to-consumer contexts.

Current guidance in the biomedical community includes these recommendations for Incidental Findings

- Researchers should develop a plan to manage anticipatable incidental findings, including but not limited to those findings known to be significant and clinically actionable (and, when relevant, analytically valid and clinically valid). The plan should be reviewed and approved by an Institutional Review Board.

- Researchers should develop a process for evaluating and managing unanticipatable findings. The plan should be reviewed and approved by an Institutional Review Board. During the informed consent process, researchers should notify participants about the possibility of unanticipatable incidental findings, including lifesaving incidental findings, and the plan for their management. Researchers who discover an unanticipatable incidental finding of concern should assess its significance, consulting with experts as appropriate.

- Researchers should consider carefully the decision to actively look for secondary findings. In certain circumstances, with approval from an Institutional Review Board, researchers can justifiably adopt a plan that includes looking for selected clinically significant and actionable secondary findings. Approved plans should be disclosed to prospective participants during the informed consent process.

Researchers should consider that:

- Certain procedures have a higher rate of false positives and that should be considered when sharing incidental findings with research subjects (such as CT scans)

- Data should only be collected and disclosed as necessary for achieving research aims

- Findings that are not actionable may have health, emotional, and well-being impacts

USC David and Dana Dornsife Imaging Center (DNI) Policy: A progressive policy and process for handling incidental findings

The David and Dana Dornsife Imaging Center (DNI) is a research facility that is part of the College of Letters, Arts & Sciences and is **not** affiliated with the Keck School of Medicine or the University Hospital.

This DNI policy does not apply to biomedical researchers who conduct research at HSC. They are subject to additional internal policies established by their home division/department.

Researchers using or planning to use DNI services must familiarize themselves with the David and Dana Dornsife Imaging Center policies. The policies are accessible online:

http://brainimaging.usc.edu/index.php?topic=policies

Researchers utilizing the Dana and David Dornsife Imaging Center must follow the DNI policy as described above. Additionally, subject eligibility for Dornsife studies requires agreement to the mandatory neuroradiology scan per Dornsife policy.

DNI IRB Requirements

All human research protocols undertaken at the DNI must be submitted to the IRB for review and approval before conducting study activities. The IRB iStar application and the informed consent document must include an explicit description of the procedure for handling incidental findings (see "Mandatory Informed Consent Language" below). Additionally, the Principal Investigator is responsible for adhering to current Dornsife policy and for training and informing research personnel involved in the study of any changes to the policy.

Note: Clinical intervention studies utilizing the Dornsife Imaging Center should be submitted to the HSC IRB.

Mandatory Informed Consent Language

Investigators conducting human subjects research at the Dornsife Imaging Center must include specific mandatory language in the informed consent document.

Refer to Section 10.2 – Required Elements of Informed Consent to access the UPIRB informed consent Template which includes DNI mandatory language information.

17.5 Difference between Human Subjects Research and Quality Assurance Research

The term "quality assurance" is used for the specific instance of the process of reviewing, analyzing, or evaluating patient and/or provider specific data that may indicate (the need for) changes in systems or procedures that would improve the quality of care.

The distinction between quality assurance and human subjects research is intent. When an activity is specifically initiated with a goal of evaluating and possible improving the performance of institutional practice in relationship to an established standard, the activity is called quality assurance.

If a project is originally initiated as a quality assurance project but the findings may be of interest beyond the Institution, publishing the findings to benefit other systems does not make it human subjects research. However, if the individual who conducted a quality assurance project chooses to expand the findings into a research study, IRB review is required at that time.

In order to distinguish research from quality assurance, use the following criteria:

- Intent- the intent should be clear in the purpose/aim statement for the specific project. In general, quality assurance projects are aimed at improving local systems of care (nongeneralizable). If the intent is to promote "betterment" of a process of care or a clinical outcome, then the project is quality assurance.

If any of the following criteria are met, the study may require IRB review:

- Generalizability-if the primary intent of the study is to generate generalizable results
- Additional risk or burden-if the study will imposes risks or burdens on the subject/patient beyond the standard of practice it may be human subjects research
- Design-if a study involves randomization or an element that may be considered less that standard of care the IRB must evaluate

Studies that do not neatly fall into one of these categories are always challenging to evaluate.

Additional Notes:

- Federal regulators have made it clear that any publication describing a study as "research" and having an interaction or intervention with human subjects must have received prior IRB review and approval. Therefore, projects determined to be quality assurance initiatives ought not to be published as "research". Refer to OHRP Quality Improvement Activities - FAQs.
- Studies considered quality assurance must also maintain the highest integrity of confidentiality possible.

- Characterizing a study as quality assurance does not necessarily negate the need for informed consent.

17.6 Institutional Research

USC's approach for institutional research that is conducted for internal use , or to evaluate programs or to inform management practice and decision-making, falls outside the federal definition [45 Part 46] of "research" and hence does not need to undergo review by the IRB.

Institutional research involves data collection, analysis, or reporting about educational, administrative, or other aspects of a college or university for either institutional self-improvement or external reporting. In most universities, institutional research informs such issues as enrollment management; program evaluation; student outcomes assessment; space planning and utilization; financial analysis; and faculty or staff planning. Data most often include institutional databases, surveys, focus groups, interviews, tests, work samples, and archival materials.

These activities do not meet the definition of human subjects research as they are designed to provide data/information about the Institution itself and improving education and services. They are not gathering information about the individual (human subject).

Institutional research is specific and applied. It is not intended to generate theory, provide results that will be generalized beyond USC, or advance knowledge. It is intended to be of direct, practical value. While the term "institutional research" is most often used in an academic setting, the function is found in a wide array of educational, service, and other organizations. For example, many health care providers and service organizations have offices of Quality Assurance, Organizational Effectiveness, Planning and Assessment, or Evaluation.

17.7 Oral History Research

Oral history is not considered research as defined by the U.S. Department of Health and Human Services (DHHS) regulations. The DHHS Office for Human Research Protection does not consider oral history to meet the regulatory definition of "research" and therefore is excluded entirely from IRB review, without seeking formal exemption. If oral history projects **do not meet** the regulatory definition of research they do not require

IRB review. However, oral historians are encouraged to consult the IRB if they have questions.

Oral historians are encouraged to act in accordance with ethical and legal standards appropriate to oral history, not biomedical or behavioral research. For decades, oral historians have promulgated high ethical and professional standards, including their ethical requirement to gain informed consent prior to conducting an interview, and a signed legal release at the conclusion of the interview.

Simply talking with someone for background is not oral history. Oral history involves interviews for the record, explicitly intended for preservation as a historical document. Informed consent means that those being interviewed fully understand the purposes and potential uses of the interview, as well as their freedom not to answer some questions, and their identification in research and writing drawn from the interview.

Legal releases are linked to issues of evidence and copyright. If a researcher makes explicit use of an interview in written work (both in direct quotation and paraphrase), a citation in a footnote should be included so that others can identify and locate the information within the framework of the extant evidence. Recorded interviews involve copyright, and interviewees must sign an agreement that establishes access for those who use the interview in any way. If the interviews are deposited in a library or archives, legal releases will establish ownership of the copyright and the terms of access and reproduction. If the interviews are published, legal releases will satisfy publishers' concerns over copyright. For further information, see John A. Neuenschwander, Oral History and the Law.

17.8 Feasibility Studies

A pilot study is a preliminary investigation of the feasibility of a study, usually done a small scale and exploratory in nature. It is designed to help the investigator refine data collection procedures and instruments or prepare a better, more precise research design. Sometimes pilot studies are conducted to collect initial data in support of or preparation for a grant submission.

Pilot studies, sometimes called feasibility studies, involving human subjects require the same scrutiny as full-scale research projects and therefore, must be submitted for IRB review and approval. It is recommended to explicitly identify in an IRB submission when a study is intended as a pilot or feasibility study, because it helps the committee to contextualize the research, particularly when it comes to justification for the sample size

or research design. In regard to sample size, in particular instead of requiring a formal power calculation for the sample size, the IRB may be satisfied with a rationale as to why the proposed number of subjects was chosen (for example, "15 is the number of available subjects and is expected to provide enough data to determine whether the questionnaires are understandable").

Data from pilot/feasibility studies may be used in a future expanded study and have IRB approval.

Pilot testing to validate questionnaires and survey instruments before implementation in a study does not constitute feasibility/pilot studies and IRB approval is not required.

17.9 Research Using Deception

Deception is a technique that may be used in some research despite a general ethical concern about fully informed consent .For certain kinds of less than fully informed consent, exceptions to this prohibition are allowed primarily because there is not expectation of harm that will result. Examples of deception include studies in which the investigator does not disclose the true purpose of the research to subjects, does not explain the ultimate use of the subjects' data, or uses a "confederate" acting on behalf of the study team, unbeknownst to the subject. Studies using deception routinely receive expedited or Full Board review when the conditions of deception would be problematic for the subjects and pose risk of physical or emotional stress.

Deception Qualifying for Exempt Review

- The omission of minor facts is not equivalent to deception.
- Exempt studies using deception in surveys/games/focus groups where the deception is of no risk can receive the Exempt determination.
- Psychological research often justifies a need for use of deception to reduce biased responses that subjects may feel will reflect poorly on them. Study findings suggest that such deception is not harmful to subjects.

17.10 Management of Suicidal Ideation in Research

If there is an established risk of suicidal ideation there is need for identification and management of the potential for suicide. Study participants who express suicidal intentions present a delicate situation that requires sensitive attention and referral to a qualified clinician. The wellbeing and best interests of the research participant must always be maintained throughout a study.

Participants and the Potential for Suicidal Risk

The possibility of suicidal ideation or risk for suicide in an individual participant may not always be known in advance. For this reason, guidance is offered for assuring safety for both unexpected suicide risk and suspected suicide risk among research participants.

Standard mental health measures used in research to evaluate suicide risk include the following:

- Beck Depression Inventory (BDI)
- Columbia-Suicide Severity Scale – Screen Version (CSSR-S)

These evaluations include questions with regard to depression, hopelessness and suicidal ideation. They are commonly used in studies involving adolescents and adults.

If one of these measures is included in a research test battery, the research team may receive information that suggests that a participant might be suicidal. If a participant reports that he/she is considering suicide, the research team is then responsible for timely and appropriate follow-up to assure the safety of that participant. It is essential that a plan to ensure that timely and appropriate follow-up of research participants who are at increased risk for potential suicide is included in the research protocol and or IRB application. Researchers are encouraged to develop procedures, using the general guidelines, applicable to their particular research protocols.

Protocols that include the following elements require a management plan in the event suicidal ideation is identified:

- Questions regarding suicide as part of the testing, interview, or assessment protocol.

- Subject sample or research procedures that involve elements of depression or suicide risk, such as research on mood disorders, severe mental disorders, self-mutilation, debilitating illnesses, or use of a chemotherapy agent that is known to be associated with an increase of depression.

Assessment of Suicidal Ideation

- **Intentional assessment of suicidal ideation,** through questions posed during an interview, assessment, or administration of a measurement instrument, such as the Beck Depression Inventory, due to the nature of the research. If the question is posed, either by interview or questionnaire item, be prepared to quickly review and further evaluate a positive response. The suicide question or positive response should be reviewed immediately or as soon as possible, rather than weeks or months after the data collection. This is not applicable in cases of collecting anonymous data when there is no direct subject contact, such as anonymous web based questionnaires or questionnaires returned by mail without identifying information.

- **Unintentional assessment of suicidal ideation** may be revealed through disclosure on the part of subjects in those research projects involving subject populations or procedures that may be associated with mood disorders or debilitating mental or physical illnesses. In these instances a quick review and further evaluation of the disclosure would be necessary.

Elements of Assessment

Have clinicians or trained interview/data collection staff gather additional information[1] to evaluate lethality or imminent danger to self and guide intervention.

- **If the person collecting the data or conducting the interview is a trained clinician**, that is, a psychologist, nurse practitioner, psychiatrist, clinical social worker, or the like, then the clinician gathers his or her own information and can act on the information as clinically indicated, (assuming the clinician has experience with managing suicide risk).

- **If the person is not a clinician or is not familiar with suicide risk management**, then a system should be in place to gather the necessary information about lethality and/or contact the appropriate clinician or make an appropriate referral for further evaluation and treatment. For example, procedures for non-clinicians may include a list of questions to ask in the event of a subject endorsing current suicidal ideation, and the direct contact information for a research clinician or other agreed upon clinician to review the responses to those questions. The clinician can then direct or advise the non-clinician regarding the safety procedure to follow. The procedures would have to include a clinician being readily available in person, or by phone or pager, ordinarily within an hour, for direct consult.

An adequate assessment of lethality or imminent danger to self should, at minimum, include gathering information about the specific thoughts of suicide, whether or not the person has a plan, determine if the person has the means to carry out the plan, history of suicide attempts, family history of suicide; the person's mental health history, history of use of medication, alcohol or illicit substances that may lead to lowering of inhibitions, and the person's family or community support system.[2][3][4]

[1] Information collected to evaluate lethality or imminent danger should not be included in research records.

[2] Bongar, Bruce (2002). The Suicidal Patient: Clinical and Legal Standards of Care. Washington D.C.: American Psychological Association.

[3] Jacobs, Douglas G., M.D., Editor (1999). The Harvard Medical School Guide to Suicide Assessment and Intervention. San Francisco, California: Jossey-Bass Publishers.

[4] Simpson, Skip, J.D. and Stacey, Michael, J.D. (May 2004). Avoiding the malpractice snare: documenting suicide risk assessment. Journal of Psychiatric Practice, 10(3), 1-5.

Intervention

- All staff should be trained on how to assess for suicide risk and the emergency procedures to follow in the event someone is deemed at imminent risk of suicide. Ordinarily, giving research subjects a list of referrals or telling the subject to go to a hospital after disclosure or endorsement of seriously thinking about suicide would not be considered sufficient standards.

- **Clinical research staff should be readily available** if the interview or data collection is conducted by non-clinicians or research assistants, either in person, by phone, or pager response, ordinarily within an hour.

- If the person is evaluated as high risk for suicide, **the research staff should act quickly to protect the safety of the subject**. This may mean staying with the subject until assistance arrives or the person is transported to a hospital.

For non-clinicians, the emergency system should outline procedures for contacting research clinicians for guidance, or in the event that clinicians are not available or cannot be contacted, the services of LAC+USC Medical Center Emergency Psychiatric Evaluation - 24 hour clinic and 911 are both available for response.

- **For any results less than imminent risk**, research clinicians should be available to assist in developing a plan for safety with the subject. The plan for safety will depend on the level of risk and available resources.

  It may include contacting the person's personal physician, making sure the subject has appropriate referrals with a plan to contact subjects as a means to evaluate the subject following through with the referrals, encouraging the person to talk to trusted family members or other community support resources, or giving the subject suicide hotline information.

- For example, the clinician decides that although the subject has endorsed suicide ideation, there is no intent or plan, nor history of suicide attempts, but the subject does have bouts of depression. The clinician or clinician representative may provide the subject with referrals for treatment and the Suicide Prevention Hotline number, or discuss contacting the subject's primary physician or trusted family member to garner support or assistance.

  Documentation of the assessment and procedures ultimately followed is important.

Informed Consent Language

Inform the subjects about what will happen if they endorse suicidal ideation and, in particular, if they are deemed to be an imminent danger to self by way of the research informed consent process. This information would ordinarily go in the confidentiality section of the consent form or information sheet. Below is sample wording regarding the issue.

The research team may not be able to keep confidential any disclosure or endorsement of thoughts to harm yourself. In the event that you tell the research staff that you are thinking about killing yourself or you answer yes to a question about having thoughts about suicide, the research staff will ask you more questions about the thoughts. Depending on how intense your thoughts are or how much you feel like hurting yourself, the research staff may provide you with referrals for treatment, work with you to contact your personal physician, trusted family member, or therapist to discuss your thoughts of harming yourself; or work with you on a plan that may include getting you to a hospital for safety.

Adverse Event Reporting and suicidal ideation

Adverse event reporting in research on suicide or depressed individuals needs to be tailored to the individual study. If the study involves individuals with a high risk of suicide, then a suicide would not be an "unexpected" event. Other criteria may exist, such as a hospitalization - which may require the need for IRB submission in such a case. In a study without inherent need for monitoring for depression or mood changes, a suicidal event would be unexpected, and therefore potentially reportable. Do not hesitate to contact the IRB for guidance on this issue.

Chapter 18:

FDA-Regulated Research

Chapter Contents