MEDICAL SCIENCES CAMPUS IRB:
CRISIS MANAGEMENT PLAN

WHAT DOES IT MEANS WHEN YOU ARE ASKED TO PROVIDE A CRISIS MANAGEMENT PLAN FOR YOUR RESEARCH?

A Crisis Management Plan is the process by which a researcher addresses and deals with expected and non-expected events or reactions experienced by human subjects participating in research.

Most researchers develop standard operating procedures in the eventuality an aspect of the research fails to address health or administrative problems. However, most tend to minimize the effect of the research intervention in the emotional state of the human subjects participant. Emotional discomfort can arise during the course of any study. If a researcher identifies participant emotional discomfort a structured process should be initiated by the research team to identify and treat these participants. Researchers need to identify participants who might be vulnerable to harm and be prepared to respond to negative emotional reactions that occur during the course of the research. It is precisely on the emotional reaction to certain interventions that this **Crisis Management Plan** refers to.

SOME DEFINITIONS

Emotional crisis = an intense and stressful response where emotions take over to the extent that it affects communication and performance.

Vulnerable populations = as defined by the policies are groups that require special safeguards such as: pregnant women, prisoners, children, cognitively or mentally impaired, legally incompetent, residents of skilled nurses facilities, students, employees and other vulnerable groups.

Vulnerable subjects include, for example, children, prisoners, individuals with emotional or cognitive disorders/impairments, and economically or educationally disadvantaged persons. (45 CFR 46.111 (a)(3); 45 CFR 46.111 (b); 45 CFR 46 Subparts B, C and D). The federal regulations require that IRBs give special consideration to protecting the welfare of particularly vulnerable subjects.

Contact Us
Human Research Subjects Protection Office
787-758-2525 Ext. 2510 - 2514
opphi.rcm@upr.edu
http://irbrcm.rcm.upr.edu/

IMPORTANT QUESTIONS AND ANSWERS

Q: Is it mandatory to have a crisis management plan?

A: Not necessarily. IRB members evaluate the research protocols seeking for compliance with the ethical principles of autonomy, respect of persons, beneficence, justice, equity and that no harm be done to human subjects. In this process IRB members may identify areas that could have the potential to elicit an intense emotional response from participants. If the board understands the research participants need the protection of a specific plan to address the emotional impact of the proposed intervention, then a **Crisis Management Plan** will be requested. If the investigator has already submitted this plan, the board will review it to insure compliance with the protection of human subjects.

Q: WHEN SHOULD A CRISIS MANAGEMENT PLAN BE SUBMITTED?

Is it desirable to submit a **Crisis Management Plan** when you are dealing with vulnerable populations and you are exploring sensitive topics in the context of that particular population.

What is sensitive and what is not is relative. However, you could use the rule of the common citizen as a guideline. As such, when exploring topics such as sexuality, violence exposure or violent experiences, issues regarding HIV exposure or diagnosis, use or abuse of drugs, or commiting a felony among others, you should think about how a regular person would feel addressing those topics in the context of the population you are dealing with.

The following are some examples of acute emotional discomfort in vulnerable subjects that suggest the need for a crisis management plan:

(a) Behaviors that suggest that the information obtained in the research is too stressful.
(b) Information that reveals a participant is considering hurting himself or herself or considering hurting someone else.
(c) Information that reveals a participant is experiencing acute distress, even when not at risk of imminent danger.
(d) Statements that reveal a participant might be in danger if another person knows the information provided in the research (safety concern).

Q: HOW DO I KNOW SOMEONE MIGHT BE EMOTIONALLY AFFECTED?

A: As stated above, an emotionally affected person usually shows either verbally or non-verbally (facial expressions, gestures, or general demeanor) that a particular emotion is taking over. It could be a range of emotions: from sad to depressed; from cautious to terrified; from frustrated to enraged. They may become disoriented, tearful, extremely silent and absent minded, or they may become verbally or physically aggressive. They may present sleep problems or an increase in physical symptoms.

In all instances the person's uncontrolled emotions will take over their usual pattern of behavior. This could happen during the intervention or afterwards.

Q: WHAT ARE THE MINIMAL ELEMENTS TO BE INCLUDED?

A: The priority of crisis intervention is to stabilize the research participant. It is intended to be time limited and goal oriented. It should provide:

- Evidence that researchers and/or researchers' assistants are aware of aspects in the project that may potentially elicit an intense emotional response from the subjects.
- Evidence of training for all research personnel about the proper procedures to follow if a subject becomes emotionally discomfort. To minimize the risk of negative emotional effects, the researchers need to:
  - (a) Identifying those who were particularly vulnerable to harm.
  - (b) Screening out those at high risk based on inclusion and exclusion criteria.
  - (c) Intervening if research participants became distressed during the course of the research
- Clear identification of areas potentially affecting vulnerable groups.
- For research projects where the subject material will likely invoke a strong emotional response from subjects, researchers should address those risks in the protocol and describe steps that will be taken to minimize those risks. It is important to inform details in the consent form, protocol and the IRB's electronic system of any situation that could arise emotional discomfort in the research.
- Plan for intervening as soon as possible.
- Resources available for mobilization in order to provide subjects with the tools they need to return to normal functioning.
- Evidence that a counselor or trained health professional will assists affected subjects in problem solving within the context of their situation. This could be provided through an appropriate coordination and referral system. Also provide a list of mental health resources available to the participants.
- It is important to establish protocols to protect vulnerable subjects that shows acute emotional discomfort and if there an imminent danger or a safety concern. In cases that vulnerable participants show acute emotional discomfort, the researcher should consider to stop the research according to the crisis management plan and evaluate whether the subject is a danger to self, others, or in need of immediate assistance. Notify to the appropriate authorities at the institution or agency for further guidance.

REMEMBER THE PURPOSE OF REQUESTING THIS PLAN IS TO PROVIDE ADDITIONAL SAFEGUARDS IN PARTICULAR SITUATIONS WHEN VULNERABLE GROUPS ARE INVOLVED AND THE AREA OF INTERVENTION MIGHT BE SENSITIVE OR HAVE THE POTENTIAL TO AFFECT ADVERSELY HUMAN SUBJECTS.