

Guidelines for Confidentiality and Follow-up for Research Anticipated to Reveal Information about Risk of Serious Harm to Self or Others

These guidelines apply to test instruments that can provide a valid indication that an individual is at very high risk of seriously harming himself/herself or others, and when the likely occurrence of such an event can be anticipated in advance. They also apply to qualitative projects where the revelation of such information can be anticipated. These guidelines should be adjusted to take account of the particular research context.

1. Review the data immediately.
2. When possible and appropriate, the review should keep the identification of worrisome cases at arm's length from the participant/researcher relationship and any participant/teacher relationship. This could involve review by a third party who is not part of the research team, or consultation of the identifying key only by the third party.
3. Establish procedures in advance for follow up with highly worrisome cases, including the identification of a qualified individual who is available immediately when needed.
4. Keep the data confidential, but not anonymous.
5. When obtaining informed consent, clearly state the limits to confidentiality and the procedures that will be followed in the event that a person's data indicate that he or she is at very high risk of seriously harming himself/herself or others.
6. When stating the limits to confidentiality, be clear that the only information to be shared is that which concerns the risk of harm to self or others.
7. When applicable to a specific protocol, provide all participants with information about where and how to access help about problems that can be anticipated.
8. In the event a participant withdraws from a study, follow these guidelines if sufficient information has been gathered to identify risk and describe this intended practice in any letter of information and consent form.