

# II3B PR1 Sharing Study Findings with Participants

---

## Overview

Research study findings can encompass a broad spectrum of information, some of which may have possible health and safety significance that could impact the management of a study participant's clinical, psychological or reproductive health, safety or welfare and be in the best interest of participants to know. This procedure addresses considerations for University of Nevada, Reno (the University) and affiliate investigators related to sharing study findings with participants, including when it may be appropriate for research information to be shared with research participants and what information the principal investigator should provide to the participants.

*Note: The recommendations herein are limited to information specifically derived from research aspects of the study and are not intended to limit investigators' abilities to provide information appropriate to her or his dual role as a research investigator and treating clinician.*

## II3B1 Conditions for Sharing Findings with Participants

### II3B1a Routine Disclosure of Findings to Subjects

In research that involves regular contact with study participants, researchers may include a standard plan in which the investigator offers to share individual results with each participant. In some research, it may be reasonable for the investigators to offer to share a summary of findings with all participants or those who express an interest in receiving the research results. In this case, the investigators must take care to insure that subject privacy and data confidentiality are adequately protected.

### II3B1b Anticipated Findings, Preparatory to Research Implementation

Investigators and the Institutional Review Board (IRB) should anticipate to the degree possible any potential for findings with possible health or safety significance to participants or findings of potential interest to participants that may be foreseeable because of the nature of the study (e.g., brain imaging studies). The decision of whether to inform participants of the information about them and the plan for doing so when indicated should be considered by the investigator while the study is being designed and prior to the protocol being submitted to the IRB.

Plans to share study findings should describe what information will be disclosed, and how and when the communication will occur. In some cases, the investigator or IRB may believe that the results of the specific tests or procedures to be performed may be best handled as a routine communication for all participants, especially when findings are foreseeable because of the nature of the study (e.g., brain imaging studies). For other studies, it may be more appropriate to define specific thresholds for sharing

study findings (e.g., studies involving diagnostic assessments for mental illness). Situations also exist in which a participant's preference about receiving study results must be considered.

Regardless of whether such communications will occur for all participants, a subset of subjects whose individual results meet certain thresholds for research findings, or only for those participants who wish to learn of important findings, the IRB must assess all of the factors involved to determine whether sharing study findings is warranted and if the plan for doing so is in accordance with applicable regulatory requirements, state and federal laws, University of Nevada, Reno policies and ethical considerations.

### **II3B1c Sharing Findings from Post-approval Monitoring**

While it is important for investigators to make every effort to anticipate incidental and other study findings with possible health and safety significance prior to the intervention, the potential also exists for study findings to emerge that were not anticipated either in nature, or in magnitude or frequency of occurrence. Some findings may occur that were outside the parameters of subject participation as described during the consent process. In such cases, requests to share study findings with participants must be reviewed and approved by the IRB prior to communicating the results unless such disclosure is necessary to protect the health and welfare of subjects or others. (See IRB Policy II2F and related procedures for definitions and reporting requirements for adverse events and unanticipated problems involving risks to subjects or others.)

### **II3B1d Sharing Incidental Findings**

It may happen that in the course of conducting the research, the investigator discovers information about an individual research participant that has potential safety, health, reproductive, welfare or psychiatric importance when such findings are beyond what was required to achieve the aims of the study. These incidental findings may or may not be expected to occur among a portion of research participants. (For research that may involve incidental findings of depression or suicidality, see IRB guidance II3B GD2.)

## **II3B2 Factors for Assessing the Need to Share Study Findings with Participants**

Multiple variables must be considered by investigators and the IRB in assessing the appropriateness of sharing study findings with participants, whether the need to share the findings is anticipated or emerges during the course of the study. Factors include

- the potential usefulness of the information to be disclosed (e.g., findings may be clinically meaningful),
- psychological or other harms to subjects that may result from knowing the results, including risks of inadvertent disclosure,
- professional and ethical responsibilities or requirements for follow-up interventions, and

- the need for and existence of resources for participants once the information is known.

### **I13B3 Plans for Handling the Disclosure of Study Findings**

If it is likely that clinically-meaningful or other information about participants could be generated through the research, the plan to manage the disclosure of study findings should address the factors listed below both in the protocol and in the informed consent process. When such findings are not anticipated prior to implementation of the study, the information must be provided for IRB consideration when requests to share findings with possible consequence for participant health or safety are submitted, whether as an amendment to the protocol or adverse event report.

*Note: Not all of the elements listed below apply to all research.*

#### **I13B3a Minimum Requirements for the Content of the Plan**

As appropriate to the research, investigators should provide the IRB with a description of the type of information that may possibly be generated or was generated from the research-related testing, and the manner in which this information is derived. This information should address

- the extent to which the testing procedures are reliable and validated;
- whether the testing is to be performed by an individual who is qualified to perform the test, to interpret the clinical significance of the test in the standard course of practice, or both; and
- the triggers for disclosure of study results (e.g., certain responses on a depression inventory, clear presence of a brain tumor on examination of a brain scan).

#### **I13B3b Requirements for Informed Consent for Sharing Findings**

For studies in which consent will be obtained from participants, investigators must provide a description of the process used during consent to inform participants if research results with possible clinical significance may be shared. This description should address the following considerations.

The consent process should describe the method and content of any foreseeable communications with participants and the way in which clinically meaningful information will be generated and shared with participants (e.g., affected individual participants are personally contacted by the principal investigator or designee; all participants are contacted with their results that may have implications for the participants' disease state).

The consent process should indicate whether participants will be offered an opportunity to opt out of receiving such information or to designate a third-party recipient of the information (such as the participant's health care provider).

Participants must be informed of any implications for their well-being, including whether the information is such that it could reasonably lead participants to take action to protect their (or their family's) health, safety, or welfare.

Participants must be informed of any potential risks of disclosure of the test result, such as an impact on insurability, employability or reputation.

For studies in which consent has not been waived, participants should be told whether

1. identifiable information will be retained and used if findings with possible health and safety significance are uncovered, or
2. retention of identifiers is not deemed necessary or appropriate.

When identifiers are retained, subjects must be told that only members of the research team with authorized access to personally identifiable information will contact participants.

When it is appropriate to de-identify biological samples or data without maintaining a link to identifiers, rendering the data anonymous minimizes the possibility of unintentionally generating clinically meaningful results about identified human participants. When data are anonymized, subjects should be told that if the research generates clinically meaningful results, the investigators would have no way of associating study findings with individual subjects.

Participants should also be given information about the plan for monitoring the data and participant safety, for reporting study findings to the IRB and for sharing study findings with participants. Subjects should be told the time frame, frequency or both for reviewing research data during the course of the study to determine whether clinically meaningful information has been obtained. When applicable, subjects should be what study results would require prompt intervention by the investigators (e.g., suicidal intentions).

## **II3B4 IRB Approval Requirements**

In the context of a study where communication of test results to study participants is anticipated, the communication plan should be described in the protocol and approved by the IRB. When the potential need to share study findings with a research participant has arisen unexpectedly, the PI should submit a protocol amendment which describes the plan for communicating the results to the participant, for IRB review and approval.

The IRB will consider the plan as it relates to the study as a whole or for individual subjects, on a case-by-case basis, whichever is appropriate. The IRB will generally approve disclosing health or safety-related results to participants in the situations described below.

1. The research test or evaluation is standard-of-care and is performed consistent with good clinical practice by a qualified, certified clinician.
2. The research test is investigational in some aspect or is not performed by a clinician trained to interpret the clinical significance of the results, but extenuating circumstances warrant contacting the participant about the results. Such extenuating circumstances include the following:

- the findings are scientifically valid and confirmed (or confirmable);
- the findings have significant implications for the participant's health, safety or welfare; and
- a course of action to ameliorate or treat the participant's concerns is available.

*Note: See below for additional information about sharing results that are investigational.*

3. The information was not anticipated to be obtained but suggests an imminent risk of harm to the participant or others that has the potential to be ameliorated through re-contacting the participant.

### **II3B4a IRB Requirements for Sharing Findings that Are Investigational**

In cases where the methods used to produce the results are considered investigational (e.g., the test itself is experimental) or when the results may not be clinically meaningful or supported (e.g., a laboratory test performed by a laboratory that is not CLIA-certified or a brain scan reviewed by a non-clinician), the results may be shared with the understanding that the significance of the result is not verified. If the IRB approves a communication to notify participants of research results that may impact their clinical or psychological care under circumstances where the research test itself is investigational or the test is not performed by a trained clinician but circumstances warrant contacting the participant with research results, the IRB will typically request that any communication to the participants be accompanied by a referral for appropriate follow-up standard-of-care testing and discussion of any available treatment options.

### **II3B4b IRB Requirements for Qualifications of the Person Sharing Findings with Study Participants**

When the plan for disclosure is submitted to the IRB for approval, the study personnel responsible for disclosing the participant findings should be identified in the research plan. Disclosure of clinically meaningful findings should be conducted by a licensed physician (or psychologist, genetic counselor, or other professional as appropriate) whenever possible or any appropriately trained individual. If nonprofessional study personnel are responsible for conveying test results, they must be trained and supervised by professional or clinical study personnel, as determined by the principal investigator.

### **II3B5 IRB Consideration of Participants in Requests to Share Study Findings**

In making its determination of whether to approve the sharing of study findings with participants for the purpose of disclosing potentially clinically or personally meaningful information, the IRB may seek appropriate consultation, by conferring with other faculty with appropriate expertise or outside experts.

In its risk and benefit assessment of the study or event report, the IRB will weigh the possibility of the clinical or scientific importance of research findings with the possibility of uncovering information with

the potential to damage a participant's fiscal, legal, or societal standing or which indicates subjects may be at risk of harm mentally or physically if the findings are left undisclosed or the condition is left untreated. As with all assessments of risks and benefits in human subjects research, this evaluation applies to studies that pose minimal risk and to those posing greater than minimal risk.

In determining whether or not sharing results is in the best interest of study participants, the IRB will give weight to any possible consequence to the health, safety or welfare of participants and whether or not the participant was aware that the research was being performed.

### **II3B5a Retention of Participant Contact Information**

Investigators of protocols involving tests or measures that could reasonably be expected to generate findings requiring disclosure to study participants should retain a link to participant contact information while the test result is being analyzed. For instance, studies that involve administering validated, diagnostic psychological assessments that may require follow-up intervention or studies that involve brain scans that may uncover suspicious lesions should retain a means to contact participants until the outcome of the test is reasonably known. The link between test results and participant information should be maintained until the results are known, after which time the link to the contact information should be destroyed, unless it is required for subsequent research-related activities (e.g., long-term follow-up). In the consent process, participants should be told that such a link exists, the circumstances under which the link will be used to contact subjects and when the link will be destroyed.

### **II3B5b Sharing Findings in Research Involving Waivers of the Informed Consent Process**

If the research is performed pursuant to a waiver of the informed consent process (and HIPAA waiver of authorization, where applicable), the approval of such a waiver requires that informed consent has been deemed impracticable. This factor may weigh against attempting to share study results with participants since the participants are presumably unaware that the research-related testing or analysis has taken place. The IRB must weigh the importance of sharing individual findings against the risks to privacy in the identification and contact of participants.

### **II3B5c Participants' Express Desire for Nondisclosure of Findings**

Some studies may offer a choice of whether or not to receive their study results. The IRB will generally favor not sharing study results with a participant when she or he has expressed a preference to not receive a result. Extenuating circumstances in which a study result holds a major clinical impact or risk of imminent harm for the participant will likely warrant further consideration by the investigator and the IRB. In determining whether communication of the study results would be beneficial to the degree that the participants' preference would be overridden, the investigator and the IRB will consider the specific circumstances of what the participant was told regarding potential results, the risks associated with disclosure of the results and any benefits or changes to their clinical care that might reasonably arise from the disclosure. When the study by its nature may yield results with possible health or safety significance, it may be appropriate for participants who do not wish to receive their study results to simply not participate in the study.

## **I13B6 Other Considerations for Sharing Study Findings with Possible Health and Safety Significance with Participants**

### **I13B6a Mandatory Reporting Requirements**

Some types of incidental findings are associated with mandatory reporting requirements (see I1D GD2 Applicable Nevada State Laws). Participants should be told about any mandatory reporting requirements in the informed consent document. If a mandatory reporting requirement does not exist for a given incidental or other study finding, the IRB must then make the determination of whether disclosing the finding to participants or reporting the study finding to appropriate authorities is ethical and whether the disclosure or reporting will yield a net benefit. General considerations for the sharing of an individual's study result follows.

### **I13B6b Ethical Considerations**

Ethical considerations associated with the sharing of study findings with subjects include those set forth in the Belmont Report. These considerations presuppose investigators have an ethical duty to appropriately manage study findings with possible health, safety or welfare implications for research participants and to maintain research study integrity. In determining whether sharing results is warranted the IRB considers

- the responsibility of researchers to promote participant welfare by maximizing benefits and minimizing harms;
- the intent for reciprocity and justice to benefit participants based in part on the assistance that participants' involvement has provided to the research study;
- that individuals should be treated as autonomous agents and as such have entitlement to information about themselves;
- the respect for participant self-determination and consequent need for information relevant to their health and well-being; and
- whether a decision to share study findings with a participant may breach a participant's trust of the investigator or the research process in general.

The above ethical considerations must be weighed with the likelihood of false-positives (and false negatives) in the research results and whether the circumstances of the study finding are compelling enough to warrant trained intervention and if the likelihood of net benefit exists. The reliability (or unreliability) of the research results to be disclosed must be included when study results are communicated to participants.

### **I13B6c Considerations for University of Nevada, Reno Student-Participants**

University of Nevada, Reno students are considered to be a protected population by the IRB regardless of whether they are minors or adults. As such, additional campus resources exist to handle their unique

situations. A plan for appropriate follow-up for the study finding with possible health or safety significance involving University students will preferentially involve internal University services such as referring a depressed student to the University's Student Health Center or Psychological Services Center.