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 guidance addresses considerations for sharing incidental study findings with participants to disclose this information.

The possibility that a research study may uncover information of potential health and safety significance or other incidental findings should be anticipated in all research studies that have the potential to generate these findings. The decision of whether to inform participants of such information should be considered by the investigator while the study is being designed and prior to the protocol being submitted to the IRB. If communication of results is anticipated, the plan for informing participants should be outlined as part of the protocol application to the IRB. Any requests to share study findings that were not anticipated either in nature or in magnitude or frequency at the time of IRB approval must be reviewed and approved by the IRB prior to communicating the results to participants. (Note that for unanticipated problems involving risks to subjects, investigators should refer to IRB Policy 710, Reporting Adverse Events and Unanticipated Problems for further information.) Plans to share study findings must provide detail on what information will be disclosed and how (and when) the communication will occur. In some cases, the investigator or IRB may feel that the results of the specific tests or procedures to be performed may be foreseeable because of the nature of the study (e.g., brain imaging studies). Some studies may have incidental findings that are best handled as a routine communication for all participants or at least foreseeable because of the nature of the study (e.g., brain imaging studies). For other studies, defining specific thresholds for sharing study findings may be appropriate (e.g., studies involving diagnostic assessments for mental illness). Regardless of whether such communications will occur for all participants or for only for a subset of individuals that meet certain threshold research findings, the IRB will determine whether sharing study findings is warranted and in accordance with applicable regulatory requirements, state and federal laws, Yale policies and ethical considerations. In determining the appropriateness of sharing study findings with participants, the IRB will also consider the potential usefulness of the information to be disclosed, any psychological or other harms to knowing the results, any risks of inadvertent disclosure and whether standard follow-up interventions or resources exist once the information is known. A participant’s preference about receiving study results, if known, will be considered when determining whether disclosure of study findings to the participant is appropriate.

While it is emphasized that investigators should make every effort to anticipate incidental and other study findings with possible health and safety significance prior to the interventions that have the potential to generate them, this may not always be the case.

IRB Consideration of Participants in Requests to Share Study Findings

- In making its determination of whether to share study findings with participants for the purpose of disclosing potentially clinically meaningful information, the IRB may seek appropriate consultation, such as with other faculty with appropriate expertise, or outside experts.

- In research that involves regular contact with study participants, researchers may offer to share with the participants those results that may be specific to the research participant as a standard plan.
The IRB will consider how the possibility of generating clinically meaningful information or the possibility of uncovering information with the potential to damage a participant’s societal standing affects its risk/benefit assessment of the study, including studies assessed by the PI as minimal risk.

Many times the plan for communicating research results is incorporated into the protocol. Generally, a participant should be informed of the communication plan (if one exists) before enrolling. Some studies may offer a choice of whether or not to receive their study results. However, 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.

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.

- If the research is performed pursuant to a waiver of informed consent (and HIPAA waiver of authorization, where applicable), 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 will generally favor not sharing study results with participants when the participant 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. 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 will be considered in determining whether communication of the study results would be beneficial.

- 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. Additional considerations regarding disclosure of investigational test results are found within 400 PR.3, Use of Genetic Tests and Investigational Genetic Tests in Human Research.

Plans for Handling the Disclosure of Study Findings

The following elements should be considered and provided to the IRB as part of the plan to manage the disclosure of study findings in the protocol and informed consent process if there is a likelihood that clinically-meaningful or other information about participants could be generated through the research. If the information is not provided in the initial application, then it must be provided for consideration when requests to share findings with possible consequence for participant health or safety are submitted. Employ these as appropriate.

- 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, including:
  - The extent to which the testing procedures are reliable and validated;
  - Whether the testing is to be/was performed by an individual who is qualified to perform the test and/or to interpret the clinical significance of the test in the standard course of practice; 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, etc.).
For studies in which consent will be obtained from participants, a description of the process used during consent to inform participants whether research results with possible clinical significance will be shared, including:

- 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 PI or designee; all participants are contacted with their results that may have implications for the participants’ disease state).
- 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).
- Any implications for the participants’ 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.
- Any potential risks of disclosure of the test result, such as an impact on insurability, employability or reputation.
- A description of whether identifiable information would be retained and used if findings with possible health and safety significance are uncovered, or if retention of identifiers is not deemed necessary or appropriate, including:
  - When identifiers are retained, that only members of the research team with authorized access to personally identifiable information will contact participants; or
  - When it is appropriate to de-identify biological samples or data without maintaining a link to identifiers, rendering the data anonymous to protect participants’ privacy. Such anonymization, when possible and appropriate, minimizes the possibility of unintentionally generating clinically meaningful results about identified human participants.
- The data and safety monitoring plan for reporting any study findings to the IRB and for sharing study findings with participants, including the time frame and/or appropriate frequency for reviewing research data during the course of the study to determine whether clinically meaningful information has been obtained and should be conveyed to participants. Investigators should keep in mind that certain types of information such as indications of suicidal intentions may require urgent intervention.

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

Some types of incidental findings are associated with mandatory reporting requirements (see 100 GD.7 Select State and Federal Laws and Regulations Applicable to Human Research). Participants must 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.

- Ethical considerations include those set forth in the Belmont Report, and presuppose an ethical duty to appropriately manage study findings with possible health, safety or welfare significance as part of investigators’ responsibility to research participants and for maintaining research study integrity. In determining whether sharing results is warranted the IRB considers 1) the responsibility of researchers to promote participant welfare by maximizing benefits and minimizing harms; 2) the intent for reciprocity and justice to benefit participants based in part on the contribution that participants’ involvement has provided to the research study; 3) that individuals should be treated as autonomous agents and as such have entitlement to information about themselves; 4) the respect for participant self-determination and consequent need for information relevant to their health and well-being; and 5) 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; 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 should be included when the study results are communicated to the participant.

• Of special note are Yale students, who are considered to be a protected population by the Yale IRBs, regardless of whether they are minors or adults. As such, additional campus resources exist to handle their unique situation. A plan for appropriate follow-up for the study finding with possible health or safety significance involving Yale students will preferentially involve internal Yale services, such as referring a depressed student to Yale Health Services.