
Yale University Institutional Review Boards

IRB Policy 720 Findings with Possible Health and Safety Significance for Research Participants

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Scope

The policy applies to all University human research investigators who obtain research results about which it may be in best interest of the participants to be informed. The policy defines the standards of when it may be appropriate for research information to be shared with research participants and what information the principal investigator (PI) should provide to the participants. This policy is limited to information specifically derived from research aspects of the study and is not intended to limit investigators' ability to provided information appropriate to a dual role as a research investigator as well as a treating clinician. The potential for findings with possible health or safety significance should be anticipated whenever possible and a plan made for the appropriate sharing of such findings with the participant.

If researchers are uncertain about whether the unanticipated findings are unanticipated problems involving risks to subjects or others, they should consult IRB policy 710 "Reporting Adverse Events and Unanticipated Problems".

Policy Statement

Pursuant to 45 CFR 46.111(a)(6), University researchers must make adequate provision for monitoring the data collected to ensure the safety of subjects. In the course of study monitoring, information incidental to the research goals may be identified which may impact the safety and/or wellbeing of the participants. When the severity or frequency of information obtained with possible health or safety impact is beyond that which was anticipated in the research protocol, the researcher should consider the relevant data and determine when it may be in the best interest of promoting the health or safety of the participant to contact, or re-contact the research participant to relate the relevant findings.

Many times, communications to research participants of health or safety-related results of tests performed solely for research purposes are approved by the IRB prior to sharing the result with the participants. The investigator may find it appropriate to inform the participants regarding whether or not research results will be shared with them, and the plan for this should be in the protocol. In some cases, these anticipated communications would be limited to incidental findings that fall above a pre-defined threshold or test score. When the communication to relate findings with potential to impact the health or safety of research participants is unanticipated, the communication plan may necessitate further IRB approval.

Studies that have a reasonable possibility of generating clinically meaningful findings should retain the ability to re-contact participants while the test result is being analyzed so that communication with the participant is practicable. The person responsible for communicating research results to participants must be appropriately qualified to do so, and suggested resources or referral information for clinical follow-up, if any is available, should be offered.

Reason for the Policy

There is no state or federal regulation and little guidance as to whether or not individuals should be informed about the results of tests or analyses performed on them (or on their biological samples or data) in the course of their participating in research studies. Thus, the IRB ultimately (and investigators initially when designing protocols) must make determinations about the advisability of disclosing research results to participants on a case-by-case basis. Conveying such information to participants should optimally be anticipated in every protocol application. If that is not possible, then consideration as to whether or not results are shared with the participants should be identified and addressed as soon as information that may impact an individual's health, safety or welfare are uncovered during the course of the research. Such a disclosure of information to the subject should be approved in advance by the IRB.

Definitions

Incidental and Other Findings: A discovery concerning an individual research participant that has potential safety, health, reproductive, welfare or psychiatric importance that is discovered in the course of research but is beyond the information required to achieve the aims of the study. Incidental findings may or may not be anticipated to be found in a portion of the research participants. Likewise, incidental findings may or may not surpass the frequency of results necessitating communication to participants expected within the studied population.

Sharing Participant Findings: A communication with a research participant either after his /her participation in the study has concluded or outside of the parameters of the individual's participation as described during the informed consent process. The purpose of the communication is to share information gathered during the individual's participation in research or obtained in the course of the research with the intent to convey findings with potential significance to the participant's health, welfare or safety. While the general possibility for a communication of this nature should be considered with every study that has the prospect of uncovering new data about an individual that could affect the care and safety of the participant, many times the necessity of sharing participant findings was not specifically anticipated for that individual during the informed consent process.

Policy Sections

0000.1 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 to the IRB for its review the plan for communicating the results to the participant. The IRB will consider the plan on either a study-wide or on a case-by-case basis as appropriate, and generally will approve the disclosure of results with possible impact on participant health or safety when:

- The research test or evaluation is standard-of-care and is performed consistent with good clinical practice by a qualified, certified clinician, or
- 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 when 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, or
- The information was not anticipated to be obtained but suggests an imminent risk of harm to the participant or others which has the potential to be ameliorated through re-contacting the participant.

0000.2 Qualifications of the Person Sharing Findings with Study Participants

Disclosure of clinically meaningful findings should be conducted by a licensed physician (or psychologist, genetic counselor, or other professional as appropriate) whenever possible. If non-professional study personnel are responsible for conveying test results, they must be trained and supervised by professional/clinical study personnel. The appropriately trained study personnel responsible for disclosing the participant findings should be included in the research plan when the plan for disclosure is submitted to the IRB for approval.

0000.3 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. The necessary information to retain may include contact information and be kept linked to the tests until the results are known, after which time the link to contact information can be destroyed as appropriate. 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. In another example, the IRB may determine that test results from secondary use de-identified samples with a retained link to identifiers -- if compelling enough -- may merit re-contacting the participant to disclose the result even in cases where the participant did not know the research was occurring. In this case, it may be appropriate for the investigator to alert a clinician with whom the participant is familiar to disclose the test result. An acceptable exception to retaining contact information is applying tests to anonymous samples where subject identifiers were never known to the investigator. Additional information on the use of biological samples in research is found within IRB policy 440, Repositories and Biological Specimens.

Related Information

Guidance 400 GD.2 Use of Genetic Tests and Investigational Genetic Tests in Human Research

Guidance 720 PR.1 Sharing Study Findings with Participants

Guidance 720 GD.1 Depression and Suicidality in Human Research

Policy 710 Reporting Adverse Events and Unanticipated Problems

Contacts

Subject	Contact	Phone
Biomedical Studies that could Generate Incidental Findings	Human Investigation Committee	785.4688 ysmhic@yale.edu
Social or Behavioral studies that could Generate Incidental Findings	Human Subjects Committee	436-3650 human.subjects@yale.edu

Roles and Responsibilities

Human Investigation Committee

The HIC serves as Institutional Review Boards or IRBs for biomedical human research conducted at Yale University.

Human Subjects Committee

The HSC is responsible for the review and oversight of social and behavioral human research.