

## Waiving Consent, Assent and Parental Permission to Participate in Research Involving Human Participants, a Behavioral Science Perspective.

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### **Introduction**

The IRB has been given the authority by the federal regulations to allow modifications to as well as waiver of the consent process for participation in research when appropriate. The minimum requirements of informed consent are set forth in the federal code under Title 45 of the public welfare code part 46.116- General requirements for informed consent and 46.117- Documentation of informed consent. The application of these requirements when minors are involved are set forth in §46.408- Requirements for permission by parents or guardians and for assent by children.

While there are exceptions specified for some types of research, most of these exceptions do not apply to social and behavioral research and therefore are outside of the scope of this document. It should also be noted that there may be other special requirements for the informed consent process for research involving other defined vulnerable subject populations such as prisoners and persons with cognitive impairments.

Keeping in mind that obtaining an informed consent of a person to participate in research is a process that needs to be undertaken by the researcher, there are certain requirements set forth in the federal regulations. For instance, the standard method of obtaining and documenting consent of a subject to participate in research is through the use of a signed consent document that contains a number of required elements listed in 45 CFR 46.116.

If an investigator wishes to alter this method of documenting that informed consent was obtained from a participant, the investigator must request the waiver in the protocol. Either the SBSIRB membership through a vote at a convened meeting or in some cases, the SBSIRB chair would have to approve the modification or waiver of consent as documented in the research protocol.

### **Minimum Federal Requirements when all participants can give legal consent to participate (adult participants)**

The following minimum requirements apply to what can be allowed by an IRB as outlined by the federal regulations:

1. **Exemptions- Waiving or modifying the consent process (45 CFR 46.101b).** If the IRB chair or board concurs with an exemption request (a study must be determined to present no greater than minimal risk to participants in order to qualify for an exemption), they **may** waive or modify all requirements of informed consent. Assuming that the concurrence does not trump the ethical obligation to express respect for persons by obtaining their consent, however, the IRB may require that some form of informed consent be obtained from participants before granting the exemption and/or that an information sheet including all of the required elements of consent is provided to participants.
2. **Studies that do not qualify for an exemption- Waiving or modifying the documentation of consent (45 CFR 46.117).** If the IRB finds that a study poses no greater than minimal risk to participants, it may waive or modify the informed consent process only under either of the following conditions:
  - a. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
  - b. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In case A, the option to sign a consent document must be presented to participants. This is not typical but could be acceptable (and the best way of protecting participants) when participation in a study itself could put someone at risk. Example of this type of study might be an interview on political views in a country where free speech is not allowed or a study of motivations behind illegal activities in which participation in a study implies guilt (although both of these example studies may be greater than minimal risk).

Case B can usually be accepted when there is no direct contact between the research team and the participants such as in a mailed, telephone or web based survey in which either verbal consent or some action implies consent (such as clicking a submit button on the web). This can also be accepted if there is direct contact and cultural concerns exist but typically some form of information sheet should be provided along with a verbal consent mechanism.

Some form of active response (verbal or an action like returning a survey) after providing information typically required in a consent document to a potential participant must be present in this both of these cases. The information may be provided verbally but it is typically required that an information sheet including all of the required elements of consent is provided to participants in most cases.

3. **Studies that do not qualify for an exemption- Waiving or modifying the consent process (45 CFR 46.116d).** If an IRB finds that a study poses no greater than minimal risk to participants, it may waive or modify the informed consent process only under the following conditions:
- a. The research involves no more than minimal risk to the subjects;
  - b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
  - c. The research could not practicably be carried out without the waiver or alteration; and
  - d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Condition A is usually met if a study does not address sensitive topics or present other significant risks to participants.

Condition B is typically satisfied in the case of a retrospective records review. It can also be met by providing to the subjects and explaining an information sheet that contains all the elements of consent but no place for signatures of participants. In this way the participants are informed of their rights and the waiver does not adversely affect them.

Condition C is often the most difficult to justify when there is contact between the researcher and the participant. The protocol would need to state why it is not practicable to carry out some form of consent (either verbal or written or implied by an action).

Condition D is sometimes met because it is not appropriate or even possible to provide additional information (such as when data is collected anonymously). In other cases, this can usually be met easily enough by sending a study summary or other information to participants who request it after the study is completed.

Even when a waiver is granted, the SBSIRB will typically require that an information sheet including all of the required elements of consent is provided to participants in most cases.

4. **Studies that are greater than minimal risk (45 CFR 46.117).** If the IRB finds that a study poses greater than minimal risk to participants, it may waive or modify the informed consent process only under the following conditions:
- a. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

The option to sign a consent document must be presented to participants. This is not typical but could be acceptable (and the best way of protecting participants) when participation in a study itself could put someone at risk. Example of this type of study might be an interview on political views in a country where free speech is not allowed or a study of motivations behind illegal activities in which

participation in a study implies guilt (although both of these example studies may be greater than minimal risk).

Even when a waiver is granted, the SBSIRB will typically require that an information sheet including all of the required elements of consent is provided to participants unless providing this sheet would also put the participant at risk.

**Minimum Federal Requirements when all participants cannot give legal consent to participate (minor participants) (45 CFR 46.408).**

When a study involves minors, obtaining informed consent is a two step process; 1. Assent of the minor (using an age appropriate mechanism) and 2. Permission of the parent unless the child is not capable of Assenting (agreeing to participate) in the research in which case parental permission is all that is needed. The obvious example of this would be a study involving infants where assent would be impossible to obtain. Depending on the complexity and topic of the study, a case could be made for not obtaining assent of a minor up to age 5 or 6 but parental permission would still have to be obtained.

As with adults, the standard method of obtaining and documenting parental permission and assent is through the use of signed documents that contain a number of required elements. The method of obtaining parental permission and assent can be different from a signed document in many cases if the IRB sees the risk as not greater than minimal or in cases where a signed document would not be an appropriate method for obtaining assent of the minor participant (for example with a 4 or 5 year old it may be more appropriate to obtain verbal assent). A convincing argument for the alteration of the normal signed document process must be made in the research protocol. At times this argument is easily made (like waiving the assent requirement for infants) and at times it is more difficult to justify the alteration.

The following minimum requirements apply to what can be allowed by an IRB as outlined by the federal regulations when minors are involved. These requirements can be seen as an extension of the requirements for waiving or altering the consent process for adults and the parallel section for adult participants should be used as a starting point for determining what is allowed with the further requirements below added:

1. **Exemptions- Waiving or modifying the consent process (45 CFR 46.101b).**  
Just like studies involving only adults, if the IRB chair or board concurs with an exemption request (a study must be determined to present no greater than minimal risk to participants in order to qualify for an exemption), they **may** waive or modify all requirements of informed consent. The IRB may however require that some form of parental permission and/or assent are obtained before granting the exemption or that an information sheet including all of the required elements of consent is provided to participant/parents.

If permission and assent are waived, the IRB may request that parents are notified of the research before it begins and that students are given a description of the project they are taking part in before it begins. The investigator must convince the IRB in the protocol that not obtaining permission and assent before conducting the research is either in the best interest of the subjects or not feasible because of the nature of the research. Convenience of the researcher in obtaining a sample is not usually a convincing reason for waiving parental permission or assent.

Two further notes. First, survey and interview research involving minors cannot be exempt. Second, federal FERPA regulations may apply to some research using school records and although the exemption could be granted by the IRB, parental permission to view school records may be required under FERPA.

2. **Studies that do not qualify for an exemption- Waiving or modifying the documentation of consent (45 CFR 46.117).** If the IRB finds that a study poses no greater than minimal risk to participants, it may waive or modify the informed consent process only under either of the following conditions:
  - a. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
  - b. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In either case when research involves minors, the conditions set for adult participants must be met for both the Assent and Parental Permission portions of the consent process. This means that an active response to participate must be solicited from both the minor and the parent. This might be done by sending an information sheet to parents and then using a phone call (with an appropriate script) to obtain permission for the minor to participate and keeping a chart with the following headings to document this: Participants Name; phone number; Parent/guardian spoken to; Participant Assent (date and time); Parent permission (date and time).

Note that a non-response to a notice does not imply permission or assent. This is analogous to a student not returning a signed permission slip to the school not being allowed on a field trip.

3. **Studies that do not qualify for an exemption- Waiving or modifying the consent process (45 CFR 46.116d).** If an IRB finds that a study poses **no**

**greater than minimal risk** to participants, it may waive or modify the informed consent process only under the following conditions:

- a. The research involves no more than minimal risk to the subjects;
- b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- c. The research could not practicably be carried out without the waiver or alteration; and
- d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

This is a high hurdle to clear when minors are involved. A and D are usually easy enough to meet in the same manner as for adults but B and C pose problems.

The main issue in this is the practicability of obtaining parental permission. While it is often convenient to recruit through a massed audience like at a school or career fair, it is not impracticable to obtain participants through a process by which the parents do provide permission (e.g. getting minors to sign up on a list, sending the materials to them and their parents through the mail and getting a parent to sign and return a permission form before proceeding with the research with their child). While this type of procedure would cost time and effort to follow, unless a strong argument that the delay in response and/or potential reduction in response rate would effect the scientific validity of the study, it would not be impracticable to conduct the study in this manner.

While a parents' right to know what their child is doing and be able to choose for them to do or not do it (in this case participate in research) may be legally waived if the project meets all of the above criteria, the SBSIRB is hesitant to do so where any risks may be presented to a minor. The argument for waiving the parents right must be made by the investigator in the protocol in terms of both the impracticability of obtaining parental permission and the low risk nature of the project. If a practicable manner of obtaining parental permission or a potential risk to the participant can be identified, the SBSIRB will not typically allow parental permission to be waived.

Even when a waiver is granted, the SBSIRB will typically require that an information sheet including all of the required elements of consent is provided to participants/parents in most cases.

4. **Studies that are greater than minimal risk (45 CFR 46.117).** If the IRB finds that a study poses greater than minimal risk to participants, it may waive or modify the informed consent process only under the following conditions:
  - a. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

Like with adults, the option to sign a permission and assent document must be presented to both parents and minors. Furthermore, for studies that are greater than minimal risk **both** parents must give their permission, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

Waiving parental permission in a greater than minimal risk study will not be done lightly and investigators are cautioned that a decision of this type will only be made after considerable deliberation by the board. There are very few cases in which a study that is greater than minimal risk involving children would be allowed to proceed without a signed permission document from **both** parents and in these cases, risks other than those related to confidentiality should be non-existent.

5. **Studies where there is a non-existent or harmful parental involvement with a child (45 CFR 46.408c).** If the IRB determines that a research protocol is designed for conditions or for a subject population, for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements (including parental permission) provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted.

The mechanism may involve a third party advocate (such as a social worker or counselor) who grants permission for the child to participate after considering the case for the individual child's involvement in the research and documents this by signing a permission form.