HiREB
Hamilton Integrated Research Ethics Board

HiREB Guidance on Implied Consent

What is implied consent?

In most cases, express consent is required for participation in research. Express consent is when an individual explicitly provides their consent (either verbally or in writing) to take part in a research study. An example of express consent is a participant signing a consent form after having read and understood the relevant written information about the study.

Implied consent is when the research team concludes that the participant has given informed consent to participate based on the participant's subsequent actions. For example, when an individual is provided with the relevant information about the study and then goes on to complete a survey. Implied consent does not require the participant to clearly state/affirm their consent (e.g., by signing a consent form, by way of a verbal consent process, or selecting 'I agree' on an online survey).

Implied consent can only be used in limited circumstances, for example, when there is no other identifying information being collected about participants and the greatest risk to privacy would be from the signature on the consent form.

Implied consent cannot be used for:

- the collection, use or disclosure of personal health information (PHI) from a Custodian (as defined by PHIPA) for research purposes. Express consent is required except in limited circumstances, e.g., where a waiver of consent is appropriate.
- Studies subject to the United States (US) Code of Federal Regulations (e.g., studies funded or supported by the US federal government) where informed consent is required for participation.

What does the consent form look like when obtaining implied consent?

Implied consent requires that participants are provided with all the necessary information regarding the research study – there is no difference in the required content. This information is typically communicated in a consent form as a preamble to a survey, but implied consent may also be obtained verbally (orally). In all cases, the form or script must be submitted to HiREB for review and approval.

When using implied consent, the written information or script must include the statement (this replaces the standard signature blocks):

> By completing the *specify the research activity upon which implied consent is based, e.g., survey*, you are confirming that you have read and understood the information in this consent form, have had any questions answered, and agree to take part in this study.

Additional reminders:

- Wording may need to be adjusted in other sections e.g. to remove references to 'signing'
- As always, participants must be provided with the contact information for a member of the research team that they can contact with any questions that they may have.
- Studies relying on implied consent are usually anonymous, which in turn means that participants cannot withdraw their study data once the research activity has been completed. This limitation needs to be addressed in the consent form, for example:

> This survey is anonymous, which means that the researchers do not know who is taking part. It will not be possible to withdraw your responses once you have completed the survey, because the researchers will not know which answers are yours.

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Frequently Asked Questions

Question: When might a study be suitable for implied consent?

In most cases, express consent is required for participation in research. Implied consent can only be used in limited circumstances. A study may be eligible for implied consent:

- when the research is minimal risk, and
- where there is no need for direct (virtual or in-person) interactions with the research team (e.g., no email/phone communication as part of the study, interviews, etc.), and
- where there is no need to access other identifying information from or about the participant (including email), and
- where there is no need to obtain the identity of the participant for future linking of the data.

Question: I'm doing an online survey. Should I include an "I agree" checkbox after the consent information, and before participants proceed to the survey?

Yes, a checkbox should be included whenever possible. Technically speaking, this changes the consent model from implied to express but the guidance above still applies. Your checkbox should indicate:

> ☐ I confirm that I have read and understood the information in this consent form, have had any questions answered, and agree to take part in this study.

Question: I'm conducting an interview with participants. Can I use implied consent?

Research involving interviews or other direct interactions with participants are not generally suitable for implied consent.

Sometimes studies involve interviews that are conducted remotely (online), where requiring personally signed and dated consent forms from participants can be technically challenging or limiting for the study population. In this case, a verbal consent documentation process may be appropriate. Please see the verbal consent signature templates on HiREB's website at: https://hireb.ca/wp-content/uploads/2022/05/ICFSignaturePages_VerbalConsent_2022MAY24.docx

Question: Do I have to use the words "implied consent" in my documents?

No, you do not need to use the words "implied consent" in your documents (e.g., "by taking part, your consent is implied"). This is a technical term that some participants might not be familiar with. Instead, please use the statement above in the "What does the consent form look like when obtaining implied consent?" section, which explains the concept in less technical language.

Question: I'd like to talk to someone about using implied consent for my study. Who can I reach out to?

Please contact the HiREB staff involved in reviewing your study or, if you're not sure who this is, the HiREB general email at hireb@hhsc.ca.