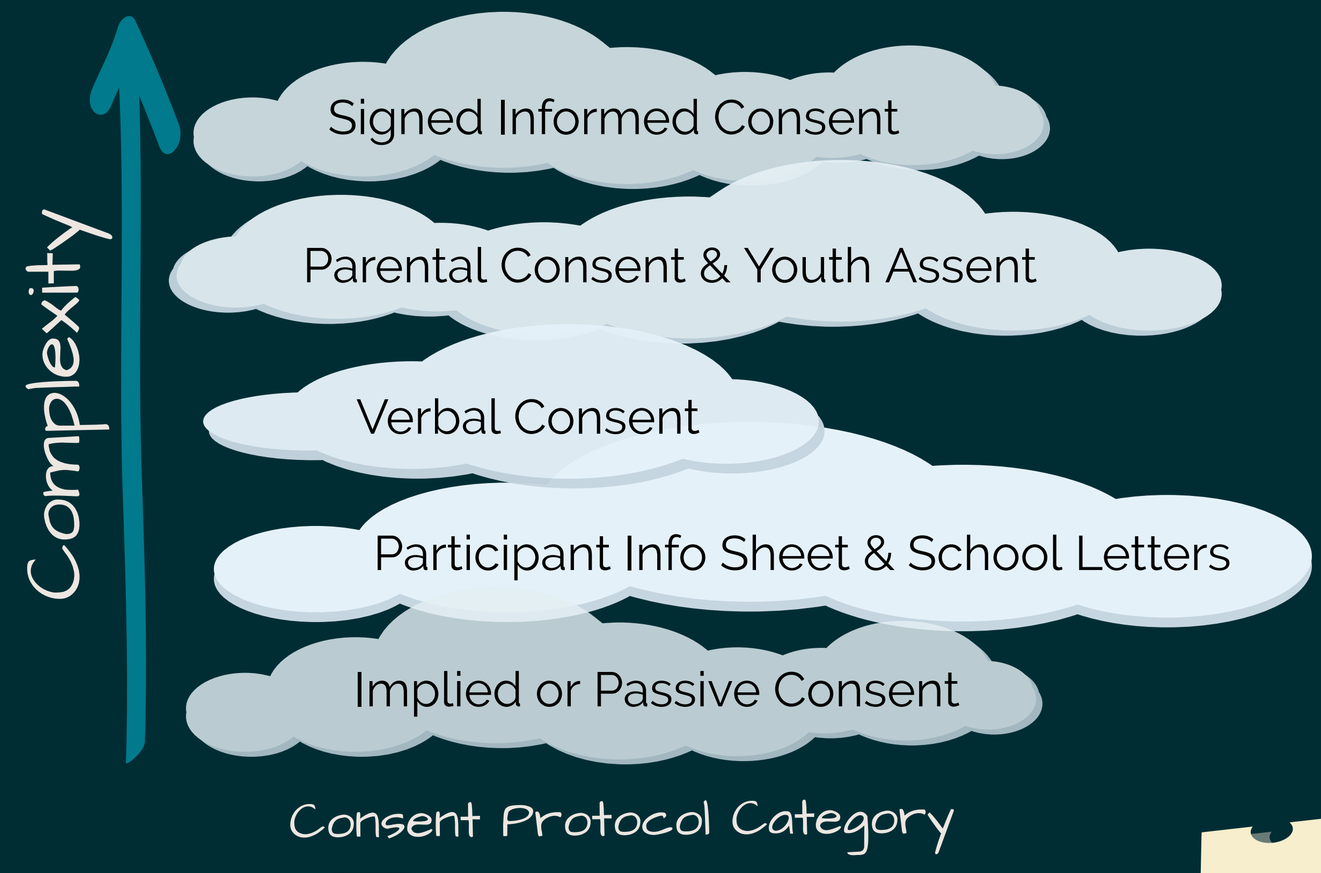
A Quick Reference: Informed Consent in Evaluation

Informed + **Consent** + **Process**

A person is knowledgeable and understands what is being asked of them and why, + they make the voluntary decision to participate, + and are actively engaged by the investigators during their participation.

Every person you collect data from should be given the opportunity and information to make a decision to participate or not - **this is informed consent!**



The way you obtain consent varies in complexity by:

> who is providing you information
> the type of information you are gathering
> what type of protocol you implement
> the materials you need

Generally, anonymous information requires the fewest protections. Whereas sensitive information collected from individuals considered *vulnerable* require the most protections.

Participants should know about the risks and benefits of their involvement, what is required from them (time and effort), and how the information will be used (e.g., evaluation of a program). This information allows them to make an informed choice. You can provide this information to prospective participants through written or verbal means.

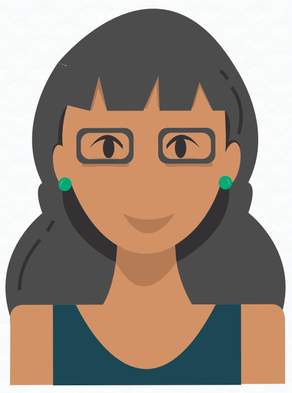
A written consent form is commonly used to obtain participant consent, but there are other options too!

History

Consent forms and protocols emerged following the National Research Act of 1974 which gave rise to the Belmont Report. This report charges researchers and investigators to follow basic ethical principles when conducting research.

Maximize Benefits & Minimize Risks

- Keep procedures brief and convenient
- Do not ask unnecessary questions or private information unless needed
- Materials and information (verbal) should be plain and free of jargon (8th grade reading level)
- Informed consent is an active process
- Answer questions and provide contact information



ADULTS

18 years and older

This chart assumes your organization has informed all participants/clients/patients that information is gathered for purposes of evaluation. This is typically included in a consent to general services within organizations.

Start

Is the information collected confidential or anonymous?

Anonymous

Are you asking sensitive information (e.g., domestic violence, suicide)?

No

You do not need signed informed consent. Do inform them they have the right to not participate, not answer any question, and whether or not their participation will impact their services or access to services. If they complete the anonymous survey, they have consented - this is known as **implied consent** or **passive consent**.

Yes

Anticipate any potential harms or distress that may result from the sensitive questions at the time of administration. Be prepared to provide support in the form of resources, referrals, etc.

Are you asking sensitive information (e.g., domestic violence, suicide)?

No

You should obtain signed consent. Participants should be told what is expected of them (time), what potential risks or benefits, how the evaluation info will be used, etc.

Yes

Anticipate any potential harms or distress that may result from the sensitive questions at the time of administration. Be prepared to provide support in the form of resources, referrals, etc.

Confidential

Are you only <u>reviewing existing information</u> (e.g., case files, archival data)

Yes

In reviewing existing records or files for the purposes of evaluation, you do not need to obtain informed consent.

No

Is there significant time or effort required, such as a focus group or interview?

No

Are you asking sensitive information (e.g., domestic violence, suicide)?

No

You do not need signed informed consent. Inform anyone they have the right to not participate, answer any question, and whether or not their participation will impact their services or access to services. Consider providing a written notice known as a **participant informational sheet**.

Yes

Anticipate any potential harms or distress that may result from the sensitive questions at the time of administration. Be prepared to provide support in the form of resources, referrals, etc.

Yes

Are you asking sensitive information (e.g., domestic violence, suicide)?

Yes

You should obtain signed consent. Participants should be told what is expected of them (time), what potential risks or benefits, how the evaluation info will be used, etc.

No

You do not need signed informed consent. Inform anyone they have the right to not participate, answer any question, and whether or not their participation will impact their services or access to services. Consider providing a written notice known as a **participant informational sheet**.

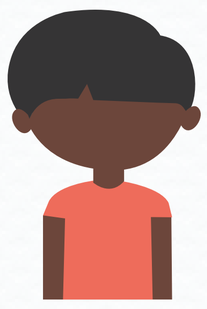
If you are collecting information in a group setting (e.g., focus group), inform participants that what is shared may become public. While you might try to reduce the risk by making it clear the information being shared is private, you cannot guarantee other group members will not share the information.

IMPORTANT POINT!

Consider if a verbal consent protocol offers more protection. In some cases a signed consent becomes the only risk to participants - breach of confidentiality.

Child
Younger than 7 years of age

Youth
7 to 17 years of age



Start

Parents/guardians should be notified (written/verbal) about the voluntary evaluation.

Parental or guardian consent is a legal requirement for any minor under the age of 18.

Is the information collected confidential or anonymous?

Anonymous

Are you asking sensitive information (e.g., domestic violence, suicide)?

No

Are you asking sensitive information (e.g., domestic violence, suicide)?

No

Is there significant time or effort required, such as a focus group or interview?

No

Are you asking sensitive information (e.g., domestic violence, suicide)?

No

Child
<7 years

Youth
7 -17 years

After obtaining parental consent, youth should be given the choice to participate. This is known as minor assent.

Youth
7 -17 years

Child
<7 years

You do not need signed informed consent. The parent/guardian can request their child(ren) not participate - and youth can also choose to not participate.

Yes

Anticipate any potential harms or distress that may result from the sensitive questions at the time of administration. Be prepared to provide support in the form of resources, referrals, etc.

Document attempts to contact parents - calls, paper notifications, etc.

Yes

Anticipate any potential harms or distress that may result from the sensitive questions at the time of administration. Be prepared to provide support in the form of resources, referrals, etc.

Youth
7 -17 years

Child
<7 years

After obtaining parental consent, minor youths should be given the choice to participate.

Yes

Are you asking sensitive information (e.g., domestic violence, suicide)?

No

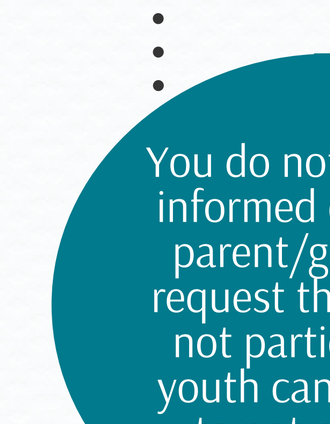
Are you asking sensitive information (e.g., domestic violence, suicide)?

Yes

Youth
7 -17 years

Child
<7 years

You do not need signed consent. Participants and their parents/guardians should be told what is expected of them (time), what potential risks or benefits, how the evaluation info will be used, etc. This can be done via school letters.



Youth assent alone is not sufficient to allow minors to participate - you must have parent/guardian consent.

Confidential

Are you only reviewing existing information (e.g., case files, archival data)

Yes

Child
<7 years

Youth
7 -17 years

In reviewing existing records or files for the purposes of evaluation, you do not need to obtain informed consent.

Anticipate any potential harms or distress that may result from the sensitive questions at the time of administration. Be prepared to provide support in the form of resources, referrals, etc.

Youth
7 -17 years

Child
<7 years

After obtaining parental consent, minor youths should be given the choice to participate.

You should obtain signed consent from parents/guardians. Parents and participants should be told what is expected of them (time),what potential risks or benefits, how the evaluation info will be used, etc.

If you are collecting information in a group setting (e.g., focus group), inform participants that what is shared may become public. While you might try to reduce the risk by making it clear the information shared is private, you cannot guarantee other group members will not share the information.

Good practices & other considerations

"All evaluation information should be kept confidential."

Protected Health Information (PHI)

The HIPPA Privacy Rule provides federal protections for PHI. Elements of PHI include: names, addresses, telephone numbers, and photographic images. Participants should be informed if any evaluation information gathered, particularly information that is sensitive in nature will be stored within agency files (e.g., electronic health record).

Mandatory Reporting in Evaluation

This can be a complicated situation, but there is a legal requirement to disclose certain information you learn through an evaluation. A best practice is to consider in advance any types of disclosures that may result from your evaluation procedures. Inform people that any information they share about certain circumstances, such as a threat of harm to self or dependent abuse will be disclosed to the appropriate authorities to ensure safety and/or in compliance with mandatory reporting. Seek consultation if this situation should arise (supervisor, technical assistance support, Institutional Review Board).

Maintaining Confidentiality

- Do not discuss private details about specific individuals, including with other staff.
- Collect information in private locations where it cannot be seen or overheard.
- Keep all information in a locked, secure location.
- Electronic information should be password protected and encrypted.

Vulnerable Groups

Certain groups, such as those economically disadvantaged are considered to have a compromised capacity for consenting, or could unduly be influenced by potential benefits. For this reason you should be especially considerate and sensitive to ethical and practical considerations. Other groups considered vulnerable include: minority groups, terminally ill or the very ill, pregnant persons, incarcerated persons, those with intellectual disabilities, children, and fetuses.

More Info

IRBs and Research with human subjects – hhs.gov/ohrp
Guidance on Conducting program evaluations – cdc.gov/eval/resources/index.htm
Informed Consent FAQs - hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html

Is it Research?

The CDC defines program evaluation as *the systematic collection of information about activities, characteristics, or outcomes of a program to make judgements about the program, improve program effectiveness, and/or inform decisions about future program development. If your evaluation includes experimental interventions (like a randomized control trial) or the intent is to publish or share information to contribute to* ***generalized knowledge*** *(like theoretical frameworks or to be replicated) then you may want to consult your funder and/or local Institutional Review Board (IRB) about consent and human subjects protections. You may need IRB approval.*

Consider

- **Fair and equal treatment** of participants - *same access to resources, treatments, incentives, etc.*
- **Benefits** in exchange for participation -*gift cards, food, other incentives should be reasonable and not excessive*
- **Disruptions** to participant's life - *time, energy, emotional consequences, safety concerns, and social harm (damage to reputation or emotional well-being)*
- **Respecting autonomy** - *allowing people to act freely and make their own choices to participate*
- **Organizational or system benefits** - *improving programming, positive outcomes, or changes for future participants as a result of lessons learned*
- **Protecting data** - *how is information being gathered and protected (stored, kept) from unauthorized disclosures or access*

Created in partnership between Strategic Prevention Solutions (SPS) and the Pennsylvania Coalition Against Domestic Violence (PCADV)

STRATEGIC PREVENTION SOLUTIONS
Bringing Communities to Wellness Through Research, Evaluation and Training

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PENNSYLVANIA COALITION AGAINST DOMESTIC VIOLENCE