Information brochure (informed) consent

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Contents

Abbreviations

IRB	Internal Review Board
RERC	Research Ethics Review Committee

Definitions

Active (informed) consent	This implies that participants or their legal representatives must carry out an action to indicate their willingness to participate in the research.[i]
Anonymous	If data does not contain personal data it is considered anonymous in the GDPR sense of the word. If data does not contain a name, but can still be traced back to an individual, data are not considered anonymous in the GDPR sense.
Assent	When children who are by definition too young to give informed consent but are old enough to understand the proposed research in general, its expected risks and possible benefits, and the activities expected of them as subjects they preferably get asked to express their willingness to participate in research.[ii]
Consent	'Consent' of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by clear affirmative action, signifies agreement to the processing of personal data relating to him or her.[iii]
Covert research	Participant or non-participant observation in non-public spaces or experimental manipulation of research participants without their knowledge.[iv]
Deception	Use of deception in research means that researchers deliberately lie or trick the participants in the research setting so that the true purpose of the study remains unknown to them (until it is revealed in a debriefing once participation is finished). Researchers include deception in the design of the study if disclosing its real purpose would lead participants to modify their behaviour, thereby distorting the research objective. [v]
Gatekeeper	Responsible person, institution or authority who decides about access to data or people within the organisation.
Informed consent	Informed consent is one of the founding principles of research ethics. Its intent is that human participants can enter research freely (voluntarily) with full information about what it means for them to take part, and that they give consent before they enter the research. Consent should be obtained before the participant enters the research (prospectively), and there must be no undue influence on participants to consent. The minimum requirements for consent to be informed are that the participant understands what the research is and what they are consenting to.[vi]
Passive informed consent	Passive consent (opt-out) means that individuals' consent is assumed if they do not explicitly object to participation after they have been informed about the study.[vii]

0. Introduction

This information brochure aims to help researchers to decide whether they need (informed) consent from their prospective research participants or not.

The **flowchart** shows the default (when answers to the pink row in the middle can be answered with yes) and the alternatives. The alternatives are only recommended when there are valid reasons to deviate from the default. The **separate paragraphs** explain how these valid reasons could look like.

It is important to realize that (informed) consent can be needed for different reasons: to conduct research in an ethically sound manner and / or to comply with the General Data Protection Regulations (GDPR). In this document:

- Consent is used as one of the elements to comply with GDPR.
- Informed consent is used as an element of conducting research in an ethically sound manner.

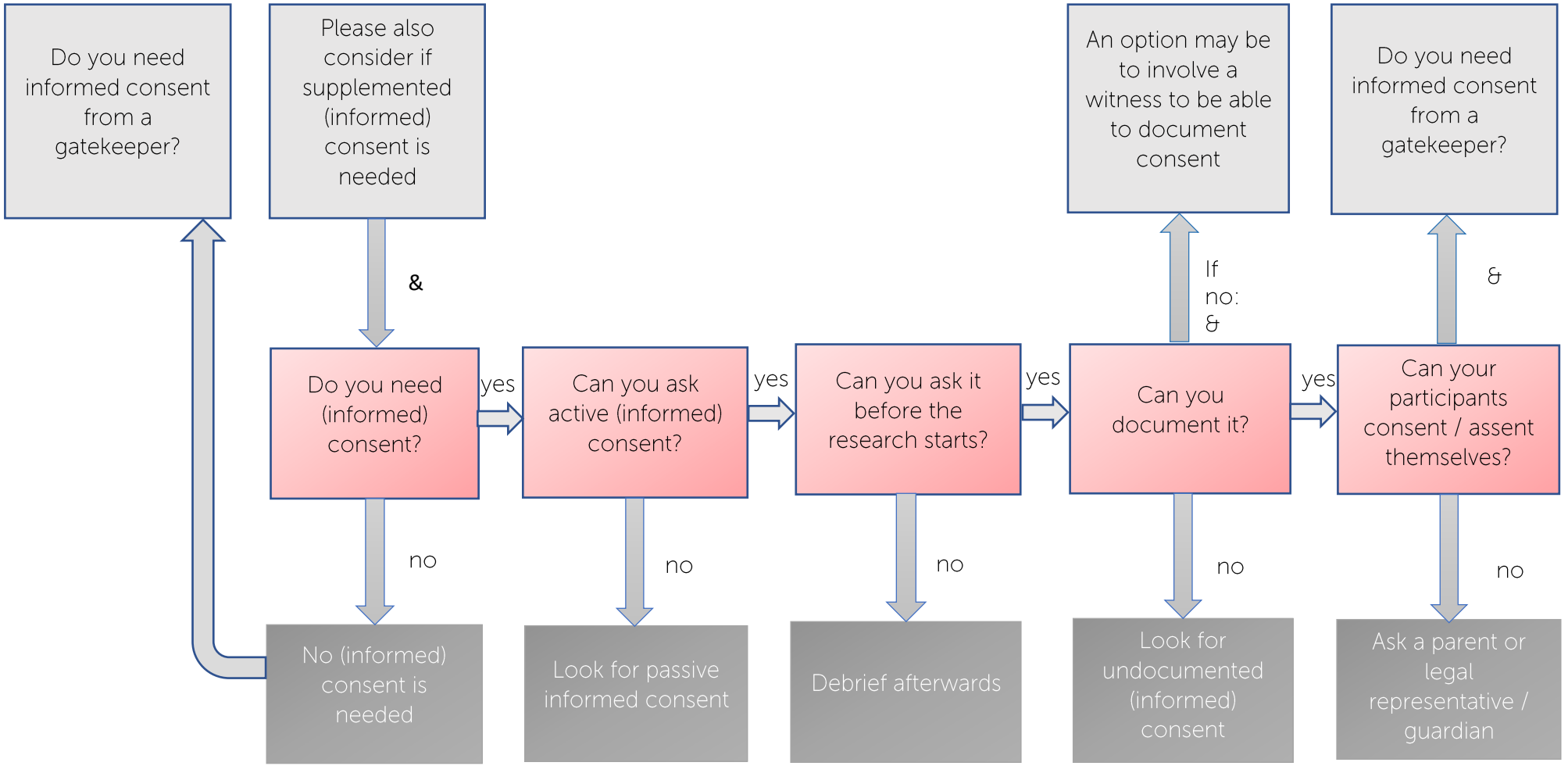
When (informed) consent is used, it refers to one of both, depending on the specific situation to which it is applied.

In addition to this brochure, EUR offers an Informed Consent **template** which provides for instructions on the different topics an informed consent form should (or may) address. This template is available on https://www.eur.nl/en/research/research-services/research-quality-integrity/ethical-review.

When there are reasons to deviate from the standard of (informed) consent: • researchers must provide arguments to the Research Ethics Review Committee / Internal Review Board for withholding the information from the participants and take measures to prevent any negative consequences thereof. • researchers must consult the privacy officer.

1. Flowchart: When and how to obtain (informed) consent

The preferred – default - way of obtaining (informed) consent is *active documented informed consent before the research starts*. This implies that participants or their legal representatives must carry out an action to indicate their willingness to participate in the research.



Questionnaire corresponding with the flowchart

Point of departure

When human beings are involved in your research, from an ethics perspective you ask for informed consent, because:

> "It must be made clear to prospective research participants that they are free to decide whether or not to take part in the research, and whether any data collected from and about them is included in analysis." (See paragraph 2)

In addition, it may be that you also need **consent** to comply with GDPR. (See paragraph 2)

When you work with previously collected data, for which informed consent is available, you may need **supplemented informed consent**. (See paragraph 3)

1. Does an exception to obtaining (informed) consent apply to my research? (See paragraph 4)

☐ Yes → Please explain to the RERC/ IRB the exception

☐ No → Go to question 2

2. Can I obtain *active* informed consent? (see paragraph 5)

☐ Yes → Go to question 3

☐ No → Go to question 3; and please explain to the RERC/ IRB why obtaining active consent is not possible.

3. Can I inform participants *before I start* my research? (See paragraph 6)

☐ Yes → Go to question 4

☐ No → Go to question 4; and please explain to the RERC / IRB why you cannot ask inform participants before starting the research and take care of a debriefing afterwards.

4. Can I *document* the Assent / Informed Consent Forms / Debriefing or Opt-outs? (See paragraph 7)

☐ Yes → Go to question 5

☐ No → Go to question 5; and please explain the RERC / IRB why you cannot document the Assent / Informed Consent Forms / Debriefings or Opt-outs.

5. Are the participants allowed and able to *assent / consent themselves*? (See paragraph 8)

☐ Yes → Go to question 6

☐ No → Go to question 6; and please explain to the RERC / IRB why participants cannot assent / consent for themselves and how you are going to arrange this in an alternative way? (See paragraph 8)

6. Do I need to ask informed consent from a responsible person, institution or authority (when the research takes place within an organization)? (See paragraph 8)

☐ Yes → Go to question 7

☐ No → Go to question 7

7. Please select who signs the Certificate of Consent[1] (See paragraph 9) and submit the Informed Consent form(s) / Assent form(s) / Debriefing(s) / Opt-out form(s) to the RERC / IRB.

2. (Informed) consent: Required or not?

The Ethics in Social Science and Humanities document of the H2020 programme states that: "It must be made clear to prospective research participants that they are free to decide whether or not to take part in the research, and whether any data collected from and about them is included in analysis. In most cases, this is secured through obtaining informed consent. In some rare cases, the anticipated social benefits of the research are so significant that certain individual interests carry less relative weight by comparison. However, these are exceptions in social science research, and strong justification must always be provided."[2]

Informed consent from an ethics perspective

According to the same document one of the overarching ethical principles is respecting individual autonomy and obtaining free and informed consent (as well as assent whenever relevant). These principles have among others been derived from Codes, Declarations, Reports[3] that address ethics in research in response to previous research practices which raised ethical issues.

"Most social science research endeavours are such that **from an ethics perspective** human participation requires evidence of the voluntary, free, and informed consent of those who contribute their time, insights, effort and data for the use of researchers. Informed consent, whether in writing (as is most usual) or given orally, is thus the default option."[4]

Hence, even when consent is not required from a privacy perspective (see below), informed consent may be desired from an ethics perspective.

[1] The Certificate of Consent is the second part of the Informed Consent Form and follows up on the Information Sheet
[2] https://ec.europa.eu/info/sites/default/files/6._h2020_ethics-soc-science-humanities_en.pdf, p.5
[3] More information available on: https://www.eur.nl/en/research/research-services/research-quality-integrity/ethical-review/purpose-ethical-review
[4] https://ec.europa.eu/info/sites/default/files/6._h2020_ethics-soc-science-humanities_en.pdf, p.13

Consent from a privacy perspective

Whenever you are collecting personal data for research purposes you must have a "lawful basis" for processing that personal data. The GDPR offers six legal bases for processing (consent, performance of a contract, a legitimate interest, a vital interest, a legal requirement and a public interest) of which consent is most often used for research purposes. Please consult your privacy officer when you think a different legal basis might be used.

In order to use consent as your legal basis you must use a procedure that meets the minimum standards of the GDPR. This requires consent to be given by a clear affirmative act establishing a freely given, specific, informed and unambiguous indication of the data subject's agreement to the processing of personal data relating to them. This may take the form of a written statement, which may be collected by electronic means, or of an oral statement. For additional details, see the documents Ethics and Data Protection, and the GDPR Informed Consent webpage.[5]

3. Supplemented (informed) consent[6]

Please also consider if supplemented (informed) consent is needed

It may be that you need to obtain supplemented (informed) consent: consent in addition to the consent which is already available. This may be the case when the following circumstances apply:

a. While collecting the data

Supplemental (informed) consent must be obtained when:

- the research takes *substantially longer* than was announced, or
- when there is a *significant change* in the nature or focus of the research or the burden or risk it causes.

b. For re-use of data for new research purposes or other sharing

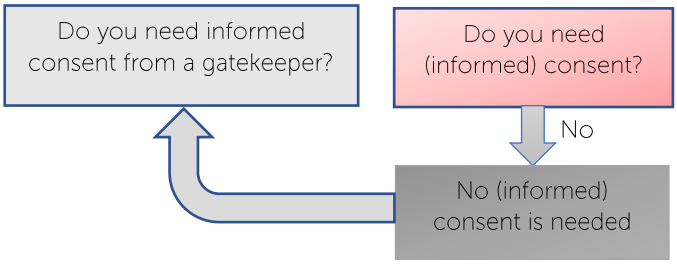
Supplemented (informed consent) may also be necessary when:

- data are to be re-used for new research purposes, or
- data is going to be shared (or deposited) in a repository which makes it available to a wider audience than consent was asked for originally.

When data are to be re-used for new research purposes, but (informed) consent from the original participants can no longer be obtained, a Research Plan detailing the nature and importance of re-use, and including the implications for privacy, shall be submitted for review to the Research Ethics Review Committee – after seeking the advice of the privacy officer -, who shall decide whether re-use is justified.[7]

[5] https://ec.europa.eu/info/sites/default/files/6._h2020_ethics-soc-science-humanities_en.pdf, p. 14
[6] Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants, D16
[7] Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants, E9

4. Exceptions to obtaining (informed) consent



While point of departure is that when human beings are involved in your research, from an ethics perspective you ask for informed consent it may be that there are reasons to deviate from this standard.

This may be the case when one of the following situations applies:

Please read the full explanation per topic to find out about conditions that need to be met in addition.

a. The research concerns observing behaviour in public spaces.
b. The research concerns social media or big data research.
c. The research concerns examining behaviour at group level.
d. Informed consent would not be in the interest of the participant.

a) The research concerns observing behaviour in public spaces and no personal data are collected and no information about specific individuals can be derived from the research data.

When observing behaviour in public spaces (e.g., shopping streets, underground stations or university campuses), no individual (informed) consent is needed provided the following applies:

1. The research is conducted with respect for privacy (and therefore does not require consent or a different legal bases for processing based on the GDPR). Either:

- no personal data are collected, or
- no information about specific individuals can be derived from the research data.

2. The investigation is not intrusive in other ways (e.g., involving extensive following of any individual). What counts as intrusive is determined by the context (i.e., nature of the research, local cultural values, environment, and people involved).

3. Data are collected only in situations where people being studied can reasonably expect to be observed by strangers. [8]

[8] https://www.utwente.nl/en/bms/research/ethics/explanation-webapplication/types-of-informed-consent/ & same as Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants, E6

b) The research concerns social media or big data research; the same conditions apply as to observing behaviour in public spaces.

When research investigates social media or concerns big data research no individual (informed) consent is needed provided the following applies:

1. The research must be conducted with respect for privacy (and therefore does not require consent or a different legal bases for processing based on the GDPR). Either:

- no personal data are collected, or
- no information about specific individuals can be derived from the research data

2. The investigation is not intrusive in other ways. What counts as intrusive is determined by the context (i.e., nature of the research, local cultural values, environment, and people involved).

3. Data are collected only in situations where people being studied can reasonably expect to be observed by strangers.

When collecting data from the internet, remember that just because data is publicly accessible, that does not mean that it can be processed by anyone for any purpose.

Bear in mind:

- The online environment where it is posted: Password-protected profiles and closed group discussions are obviously intended by their users to be private.
- Context and expectation (of what usually boils down to web scraping): if product reviews are analysed to aggregate a user's experience of a product, that is in line with the expected purpose of the person who reviewed the product and posted the text. If, however, the reviews syntax and vocabulary are analysed to find out whether the reviewer has a complex vocabulary or whether the reviewer has had an academic degree, that is not in line with the expected purpose of the user.
- The 'mosaic effect': there is a risk that disparate threads can be easily combined in a way that yields private information.
- Research with aggregated data sets may still cause harm to a group when retraceable to a (group of) individuals.

More information on Internet research and social media data in research can be found on: https://www.eur.nl/en/research/research-services/research-quality-integrity/ethical-review/informed-consent/social-media

c) The research involves examining behaviour at group level

When research involves examining behaviour at group level:

- it may not be possible to obtain informed consent from every individual and,
- in some cases, it could be undesirable, as it would affect the group process.

You might think of observations that do not interfere with a situation or interventions that fit the goal of the group setting, such as:

- observing residents of nursing homes,
- network studies of social interactions (including bullying) in the classroom,
- the effect of a teaching method on class performance,
- the effects of a new management technique on teamwork.

Requirements

In such cases, the researcher should ensure the following:

1. Informed consent must be obtained from the responsible person, institution or authority (e.g., the management of the institution or company).

2. Individual privacy and autonomy must be preserved: no personal data may be gathered without the active (informed) consent[9] of the individuals concerned or their legal representatives.

   This means that the data must also be anonymous to the researchers (i.e., it is not sufficient to separate or recode participant details).

3. Interventions and/or procedures must occur at the group level, and they must not be aimed at specific individuals. The effects of an intervention can obviously vary from one individual to another. For example, even if a measure is applied to an entire class, the behaviour of some children may change more than that of others.

4. The research results must be reported only at the group level. This also applies to reports made to the institution in which the research was performed. In this context, 'groups' may be sub-groups, as long as the data provided cannot be traced back to the individuals concerned.[10]

Please note, in the case of Dutch schools, depending on the nature of the research, consent may have to be obtained from the school's representative advisory board, constituted in conformity with the provisions of the Participation in Schools Act. This applies only to research that would affect any of the points listed in Article 10 (*Instemmingsbevoegdheid medezeggenschapsraad*) of this law.

d) Informed consent would not be in the interest of the participant.

"This is [most] often the case with consent from parents or legal representatives. One particular case in which a researcher could decide not to inform the parents is when the child explicitly opts for anonymity. For example, this could occur in the context of online self-help sites. In such cases, contacting the parents would be more intrusive to the child's privacy than not contacting them would be. In principle, the desire for anonymity should be respected, and it can be violated only in the following exceptional cases:

a) If failure to inform parents, healthcare professionals or authorities would clearly be contrary to the child's interests (e.g., if the child is in urgent need of medical or psychiatric care).

b) If failure to inform parents, healthcare professionals or authorities would bring serious harm to others (e.g., if a child mentions having committed or intending to commit a serious crime).

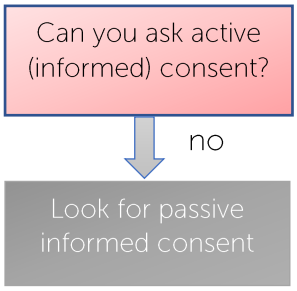
In some cases, even if the identity of the child is known, the involvement of parents or legal representatives might still be damaging to the child (e.g. in cases involving the investigation of

[9] From a privacy perspective, a different legal basis for processing may be used.
[10] https://www.utwente.nl/en/bms/research/ethics/explanation-webapplication/types-of-informed-consent/

abuse). Note that, in such cases, the gathering or use of personal data for research should be prevented, as doing so would also require parental consent."[11]

Please note, in cases where parents or legal representatives are not asked for (informed) consent, the researcher would still want the assent of the children involved. The assent form must include information on the duty of the researchers to violate confidentiality in specific cases.

5. Active or passive (informed) consent?



Active (informed) consent

By default informed consent is active, i.e. through a deliberate act of the participant ("opt-in").[12] Active consent implies that participants or their legal representatives must carry out an action to indicate their willingness to participate in the research. This can be done in several ways (See paragraph 7). Such action should obviously be carried out after the relevant information has been provided.

To be compliant with the GDPR, active consent is required if the research will involve collecting new personal data or the new use (including linkage) of personal data.[13]

Passive consent

Passive consent (opt-out) means that individuals' consent is assumed if they do not explicitly object to participation after they have been informed about the study. In principle, passive informed consent is considered undesirable because:

- there is no way of knowing whether the relevant information has been received,
- participants (or their legal representatives) may have been unable to perform the action required to indicate non-consent. This can lead to infringement of personal autonomy and privacy.[14]

[11] https://www.utwente.nl/en/bms/research/ethics/explanation-webapplication/types-of-informed-consent/
[12] Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants, D12
[13] https://www.utwente.nl/en/bms/research/ethics/explanation-webapplication/types-of-informed-consent/
[14] https://www.utwente.nl/en/bms/research/ethics/explanation-webapplication/types-of-informed-consent/

Special circumstances may call for passive consent ("opt-out"):[15] This is:

- if it would be extremely burdensome, either for the research participants or an intermediary organization involved, to obtain active consent from all individuals involved AND if the burden and risk of the research activities are very limited.

Please note, the following still applies: Whenever you are collecting personal data for research purposes you must have a "lawful basis" for processing that personal data.

Examples special circumstances:

This may be the case for situations in which the study fits within a generally accepted activity, as with research on learning performance in schools, evaluation of a service (hospital, company) or research on workflows and performance in work organizations.

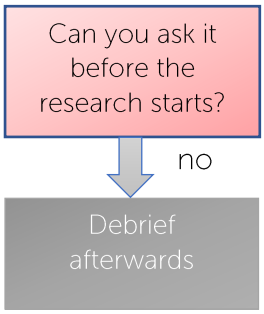
Requirements

In such cases, the researcher should provide convincing evidence that:

a) active consent leads to substantial and demonstrable disadvantages with respect to the quality or aim of the research, and/or the interests of the participants.
b) there is minimal burden and no risk for participants.
c) special care is taken to inform participants and/or their representatives of the study and the possibility to opt out.
d) the opt-out procedure is straightforward. Any opt-out procedure is to be reviewed by the Ethics Review Board. [16]

e.g., c/d: a school's policy should ensure that parents/caretakers are regularly (e.g., once a year) informed about the possibility that students might be involved in research during teaching activities. For every research, parents are informed and can withdraw participation for that particular research.[17]

6. Before the start of the research or afterwards? (withholding information / deception / covert research)



[15] Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants, D12
[16] Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants, E5
[17] https://www.utwente.nl/en/bms/research/ethics/explanation-webapplication/types-of-informed-consent/

Before the research starts

Information is provided to the participant sufficiently in advance. What counts as sufficient time depends on the nature of the research, with as a general rule: the higher the impact or burden, the longer the time period.[18]

Partly before, partly afterwards

- *Withholding information & use of deception*

In general, strong justification must always be provided for having recourse to withholding information or deception, and any study relying on it must be so designed as to protect participants' dignity and autonomy, despite the method used.

In the case of procedures that can cause physical or mental harm, information **must not be withheld, and no deception must be used**. Risk management and harm alleviation strategies must be in place.[19]

Withholding information

Information for participants may be withheld from them only when:

- the need to preserve the integrity of the research outweighs the participants' interests, or
- if it is shown to be in the public interest.

If information has been *withheld* from participants, they will be appropriately informed **after their participation** in such a manner and to such an extent that, to their judgment, the informed consent remains intact.[20]

- This happens as early as possible, immediately after participation, and no later than at the end of data collection.
- Participants must then also be informed that they have the right to withdraw their data without any negative consequences.[21]

Use of deception

Uses of deception are limited and a study must not rely on deception unless the use of such techniques can be justified by the likelihood that the study will have a significant scientific or applied value, and there is no other way to collect the data.

[18] Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants, D10
[19] https://ec.europa.eu/info/sites/default/files/6._h2020_ethics-soc-science-humanities_en.pdf, p6
[20] https://ec.europa.eu/info/sites/default/files/6._h2020_ethics-soc-science-humanities_en.pdf, p6
[21] Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants, E4

If your research design includes deception,

- Provide strong justification for the choice of method by showing the importance of the research objective and demonstrating that your research cannot be conducted in any other way
- Describe how you will debrief your participants and retrospectively obtain their informed consent
- Show that the use of deception will not harm your participants socially, emotionally or psychologically and that revealing the real nature of the research will not lead to any discomfort, anger or objections on their part, and finally
- Obtain local ethics committee approval for your study before it gets under way.[22]

Afterwards

- *Covert research*

Covert research should be the exception rather than the rule. Like deception, covert research requires strong justification and a demonstration of clear benefits of the chosen method over any other approach. Matters of social significance must be addressed in the research. Covert research should be avoided in principle.

Circumstances that may lend support to using covert methods include:

- settings where research participants change their behaviour because they know they are being studied.
- when it is the only method by which information can be gathered, and/or when access to the usual sources of information is obstructed by those in power.

Informed consent should be sought after the event wherever possible. Here the risk researchers face is, of course, that some participants may not give their consent retrospectively, which would mean that some or all of the data collected could not be used.

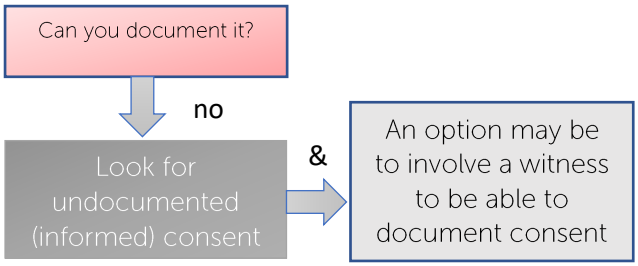
Covert research may be used in settings that pose no particular risk to participants or researchers and if the anonymity of those being observed is safeguarded.

If you plan to engage in covert research

- consult the legal department and the data protection officer (DPO) at your host institution to find out about the legal basis of your research and whether your research design poses any risk of breaking the law;
- abroad, ensure that you obtain local ethics approval from your host country as well and make sure the methodology you employ is compatible with the local legislation;
- remember that if you are working in non-EU countries, the proposed research must be legal at least in one EU member state;
- keep in mind that there are positive disclosure obligations in many EU member states that you must be aware of if you intend to conduct research involving terrorism or other criminal activities, for example;
- remember that safeguarding the anonymity of research participants is central. Ideally, where informed consent has not been obtained prior to the research, it should be obtained afterwards.[23]

[22] https://ec.europa.eu/info/sites/default/files/6._h2020_ethics-soc-science-humanities_en.pdf, p6
[23] https://ec.europa.eu/info/sites/default/files/6._h2020_ethics-soc-science-humanities_en.pdf, p.8

7. Documented or undocumented (informed) consent?



Depending on the type of research, any deliberate and plausibly demonstrable act of consent can be valid, whether transferred through writing, digitally, verbally, or by other means.[24] However, RERC's / IRB may have preferences, in general or in relation to different methodologies.

Documented (informed) consent

- Written consent

Obtaining written consent is the option that is most frequently used.

- Digital methods

Ticking a box, pressing a button or clicking a link can be acceptable alternatives to written consent. E-mail and a confirmation in a chat are also allowed.

In relation to the unambiguity of the request for consent via the digital method, researchers should consult a privacy officer to determine whether the design of the digital method suffices and is lawful, whenever they consider a digital approach.

- Oral consent

Instead of signing for consent, participants agree to take part by having their consent recorded.

- Consent by a witness

If standard procedures for obtaining written or oral informed consent may be harmful to participants, rather than protecting their interests, other consent procedures may be justified, including verbal undocumented informed consent. The recommended option, however, is then to involve a witness and document the signed form by the witness.

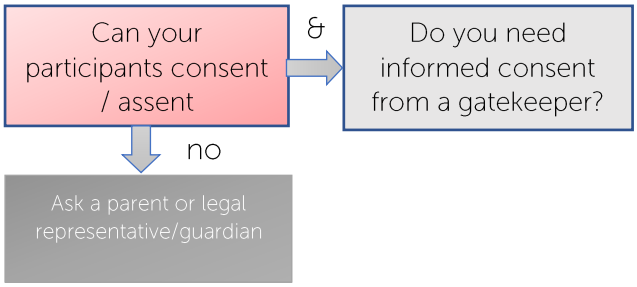
No matter in which way consent is recorded, the resulting file(s) should be stored securely alongside with other project files and archived according to the applicable retention periods. Reach out to your faculty's data steward for more information and recommendations regarding storage and archiving.

[24] Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants, D13

Undocumented (informed) consent

When it is not possible conducting the research with documented consent, please explain why and the circumstances under which the research took place, such as date and location.

8. Who can consent / assent?



Consent

The age on which people are permitted to consent to participate themselves in research differs per country.

- *The Netherlands*

The Netherlands uses the age of 16, based on the GDPR and the Dutch Medical Research Involving Human Subjects Act [*Wet medisch-wetenschappelijk onderzoek met mensen (WMO)*]. For some types of research, it may nevertheless be good practice to inform the parents or legal representatives.[25]

- *Other countries*

Researchers are responsible for finding out which age applies in the country where they perform their research.

If the age is below 16 years old, from a privacy perspective, researchers can use the age of the country where they conduct their research on the condition that the age is not below 13 years old. From an ethics perspective, the advice may be to hold on to the age of 16 years old.

Assent - in combination with consent by parents, legal representatives or guardians

When children who are by definition too young to give informed consent, but are old enough to understand the proposed research in general, its expected risks and possible benefits, and the activities expected of them as subjects they preferably get asked to express their willingness to participate in research.[26]

12 – 15 years old

"In case of minors older than 11 and younger than 16 years of age informed consent is obtained from both the minor and the parent(s) or legal representative(s)."[27]

The language of the Assent form should be tuned to the language level and level of experience of the child.

[25] Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants, D7
[26] https://www.csusm.edu/gsr/irb/consent.html
[27] Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants, D5

The Dutch Medical Research Involving Human Subjects Act offers the following guideline:
In principle research with subjects under 16 years old is not allowed, only when:

- The research benefits the target group.
- The burden and risks are very limited.

Please note: Children may have valuable ideas on how to organize the research in a way that the burden is reduced, e.g., how to make participation less boring.

Consent for participation in research by minors below 12 years old

"In case of minors younger than 12 years of age informed consent is obtained from the parent(s) or legal representative(s). It is good practice to also ask the child where possible."[28]

One or both parents / legal representatives or guardians

"In case of minors, consent from one parent is considered sufficient by default, unless the Research Ethics Review Committee or Internal Review Board decides that a particular research plan requires consent from both parents."[29]

Consent for participation in research by mentally incompetent participants

In case of a mentally incompetent participants, informed consent is obtained from the legal representative(s). It is good practice to also ask the participant where possible.[30]

Participants, especially those of reduced mental competence, are monitored for signs of discontent (including nonverbal signs) prior to, during, and where possible after the research, and such signs are acted upon appropriately by alleviating the discomfort or ceasing the research.[31]

9. Active documented (informed) consent: Who signs and how?

When consent is obtained, the consignee must prove that consent is given by the data subject. A *signature* is a legal binding method to prove consent, thus the easy way to prove consent. However, other ways may be sufficient as well to prove consent. Then, the specific circumstances of the case stipulate if consent can be proven. So this requires a case by case evaluation.

[28] Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants, D4
[29] Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants, D6
[30] Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants, D3
[31] Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants, D8

The Netherlands

- 16 years and older: this age group can actively consent to participating in research
- From 12 to 15 years old: this age group can actively assent to participate in research; in addition, consent from parent(s), legal representative(s) or guardian(s) is needed.
- Below 12 years old: parent(s), legal representative(s) or guardian(s) need to consent to participation in the research; obtaining assent is recommended
- Illiterate or low-literate people: can sign with a mark; a witness is asked to co-sign
- Mentally incompetent participants: consent from parent(s), legal representative(s) or guardian(s) is needed; obtaining assent is recommended
- People who are willing to participate, but unwilling to sign for various reasons: a witness signs, if possible

➢ The same rules apply to debriefing.
➢ In addition, the consent including the signature from a responsible person, institution or authority may be needed, when the research takes place within an organization.

One or both parents / legal representatives or guardians: "In case of minors, consent from one parent is considered sufficient by default, unless the Research Ethics Review Committee or Internal Review Board decides that a particular research plan requires consent from both parents."

Other countries

- Age categories for consent as well as for assent may differ from the above.

10. Specifics: Attention to people not actively participating in the research

Researchers also need to take care of the interests of people who perform in the research without playing an active role. The Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants points to the following.

- When recording voices or images of participants, Informed consent must be obtained unless the research consists solely of naturalistic observations in public places.[32]
- Researchers who collect information about individuals who are not actively participating (i.e., third parties from whom no informed consent has been or can be obtained), must indicate how they protect the interests (including privacy) of those third parties.[33]

[32] Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants, D9
[33] Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants, D15

11.Storage of (informed) consent, assent, debriefing, opt-outs

Researchers must keep adequate records of when, how and from whom informed consent was obtained, unless this could or proves to be detrimental to participants, or when a study is conducted anonymously). In these cases, it must be explained how voluntariness is established instead.[34]

The researcher secures that the informed consent forms are stored at a safe place. EUR policy[35] prescribes a retention period of 10 years after either the assignment of a persistent identifier or publication of a related work following project completion, whichever is later.

Endnotes

[i] https://www.utwente.nl/en/bms/research/ethics/explanation-webapplication/types-of-informed-consent/
[ii] https://www.csusm.edu/gsr/irb/consent.html
[iii] https://ec.europa.eu/info/sites/default/files/6._h2020_ethics-soc-science-humanities_en.pdf, p.7
[iv] https://ec.europa.eu/info/sites/default/files/6._h2020_ethics-soc-science-humanities_en.pdf, p7
[v] https://ec.europa.eu/info/sites/default/files/6._h2020_ethics-soc-science-humanities_en.pdf, p6
[vi] https://researchsupport.admin.ox.ac.uk/governance/ethics/resources/consent
[vii] https://www.utwente.nl/en/bms/research/ethics/explanation-webapplication/types-of-informed-consent/

[34] Code of Ethics for Research in the Social and Behavioural Sciences involving Human Participants, D14
[35] https://www.eur.nl/en/media/2021-03-bijlage-1-eur-rdm-policy-v10-20200814-1, 5.1, p.3