Informed Consent and Information Letter Checklist for the GDPR

Version 1.2; 2020-08-17

The General Data Protection Regulation (GDPR) requires that specific information is provided to research participants before consent to use their data is obtained. The following summarizes the requirements described in the guidelines on consent and transparency produced by the Article 29 Working Party, a group that was responsible for providing advice on and interpretation of the GDPR. You should use this checklist to ensure that your informed consent forms and information letters meet GDPR requirements. Additional information on the GDPR and GDPR-specific definitions (e.g. terms such as *controller*) can be found here. For situations where obtaining consent is not feasible, contact the FGB Privacy Champion as early as possible in your project planning to ensure that you meet GDPR requirements.

- ✓ Consent must be freely given
  - **The participant must not feel compelled or pressured to consent**
    - *Consider whether there may be a power imbalance between you and the participant that may influence their participation*
    - *Ensure that consent to participate in research is not tied to a non-negotiable provision of service (e.g. when providing treatment to a patient, participation in any related research must still be voluntary)*
  - **There must be no negative consequences for the participant if they withdraw**
    - *Complex issues related to withdrawal of consent are addressed in Annex 1 of the FGB Research Data Management Policy*
- ✓ Specific purposes for how the data will be used need to be described
  - **There must be a clear and specific description of all of the purposes for which each type of data will be used**
  - **If it is possible for a participant to agree to only some research purposes and still participate in the study, they should have the option to consent to each purpose separately**
    - *It is important to consider which purposes are essential to your research and which purposes are optional. If all purposes are necessary for participation, then consent should not be separately obtained for each purpose, but it should be clear that by consenting to participate in the study, the individual consents to ALL of the purposes described.*
- ✓ Consent must be unambiguous and when special types of data are collected, it must be explicit
  - **"Unambiguous" means consent must be obtained via a clearly affirmative (i.e. deliberate) action by the participant. Consent cannot be given passively or via an opt-out system; they must opt-in.**
  - **"Explicit" means that the participant is fully informed about the collection of special data and how this data will be used.**
- ✓ For consent to be informed, specific information must be provided to participants
  - **The informed consent form must include, at a minimum:**
    - *The name of the controller (Stichting VU) and any other co-controllers (e.g. collaborating Universities that will also work directly with the data)*
    - *The type(s) of data that will be collected. It is important to mention special categories of personal data, such as data concerning health. (NB: don't forget to mention the collection of contact information, if applicable!)*
    - *The specific purposes for which each type of data will be used*
    - *The right to withdraw consent without negative consequences and information on how to do so. (NB: withdrawing consent should be as easy as providing consent)*
    - *If applicable, risks of data transfers to countries outside the EEA if no adequacy decision or appropriate safeguards are utilized*
  - **The information letter must include, at a minimum:**
    - *The name of the controller (Stichting VU) and a contact person from the research project*
    - *The contact information for the data protection officer (functionarisgegevensbescherming@vu.nl)*
    - *The type(s) of data that will be collected. It is important to mention special categories of personal data, such as data concerning health. (NB: don't forget to mention the collection of name and contact information!)*
    - *If data are not collected directly from the participant, the source(s) of the data, such as data repositories or publicly accessible sources, must be provided.*
    - *The specific purposes for which the data will be used and an explanation that processing is legally allowed because of the participant's consent (NB: If you are working with data not on the basis of consent, contact the FGB privacy champion for advice)*
    - *If applicable, the recipients of the data (i.e. co-controllers and processors); in the case of future data sharing, describe the types of parties that could be given access to the data (e.g. only researchers vs. researchers, NGOs and businesses etc.)*

        - *If applicable, the plan to transfer data outside the EEA, what safeguards are in place and where the participant can obtain a copy of/information on these safeguards*
        - *How long the data will be stored → NB: it is a requirement that researchers archive data at least 10 years post publication (or 15 years after the last treatment for WMO- applicable research), while the requirement to publish data indefinitely so that it can be shared depends on the research funder. It is not possible for participants to opt-out of having their data archived, whereas, in most cases, participants should be free to choose whether or not their data are published indefinitely for data sharing purposes*
        - *Explain that participants have rights under the GDPR that are described here, but explain that scientific research is often exempt from the application of these rights; if a participant wishes to exercise their rights, they should contact the data protection officer for the VU.*
        - *The right to withdraw consent without negative consequence and information on how to do so*
        - *The right to lodge a complaint with a supervisory authority (in The Netherlands this is the Autoriteit Persoonsgegevens)*
    - **Participants should be informed if there are changes to the purposes described in the original information letter or if data will be used in a different way than originally described**
        - *When data are being used in research, it is often not possible to know ahead of time ALL of the possible future uses. At a minimum, request consent for the specific purposes that are already planned at the outset. If over the course of the research, new specific purposes are defined, participants must be informed about these changes and be given the opportunity to update their consent. If you are unable to contact the participants, but you have a study website, the new information should be published on the website. If you have neither contact information nor a study website, and it would require **excessive** effort to inform the participants, contact the FGB Privacy Champion for advice.*
        - *If you plan to share the data with other parties after your research, you should request consent for this in the original consent form. How you inform participants about the details of data sharing depends on what data you plan to share and with whom you plan to share the data. Review the Do's and Don'ts in this document for best practices and aim to describe as much as possible what the future uses of the data will be. If you still have questions, contact the FGB Privacy Champion for advice.*
    - **The language and media used to inform participants about the research project should be appropriate for participants' language skills and mental capacities**
        - *Young children or mentally impaired individuals who cannot consent for themselves should still receive information, for example through pictures that show what participation will entail*
    - **For research with children, once a child is 16 years of age they have the right to confirm, modify or withdraw the consent given by their parents**
        - *For research with children below 16 years of age, consent from a parent (or legal representative) is required. Such consent may be withdrawn by the parent at any time*
        - *The information about a child's rights as of 16 years of age should be included in the original information letter and the researcher should attempt to contact the child once they reach 16 years of age so that the child has the option to confirm, change or withdraw consent*
        - *If the child does nothing (i.e. no response), the consent obtained from the parents is still valid for the **specific purposes** described in the original information letter*
        - *NB: Rules regarding consent and children can vary per EU member state*
- ✓ Depending on the nature of your research, consent can be obtained digitally or on paper
    - Research under the purview of the WMO must utilize paper consent forms.
    - For Non-WMO research, digital consent can be obtained through online consent forms, scanned and uploaded written consent forms, or electronic signatures. Ideally, you should ensure that digitally obtained consent is valid and obtained from the correct person, especially when dealing with vulnerable groups; one way to do so is with two-step verification (i.e. a participant fills in an online form, receives an e-mail after submission and confirms their participation by clicking on a link in the e-mail).
- ✓ Consent forms must be maintained for as long as the researchers are responsible for the data under the GDPR
    - Consent forms must be archived for the same duration as the archived data; for data published for sharing purposes, the consent forms should be kept indefinitely.
    - Currently all consent forms must be maintained in their original format, meaning that paper consent forms cannot be destroyed, even if they are digitalized. The VU is working on this issue and it may be possible to digitalize paper consent forms in mid-2020, however, all WMO-applicable research must continue to maintain the original paper consent forms.