Informed Consent and Information Letter Checklist for the GDPR

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 document summarizes the requirements described in 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. Many of these requirements are already ingrained in our informed consent standards and practices; new requirements will be highlighted and explained further in this checklist. 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 cases where consent is not feasible, contact the FGB Privacy Champion as early as possible in your project planning.

- 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 his or her participation
  - 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 data collection and use need to be described
  - There must be a clear description of all of the purposes for which the data will be used
    - 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 reuse of research data for future research purposes (with the intent to inform participants as those purposes become clearer)
    - If you plan to publish the data in a data repository, request consent for this. Inform participants as to whether or not the data will be openly available or only accessible upon request. Also inform participants that published data cannot be erased, barring exceptional circumstances.
  - 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 all necessary for participation, then requesting consent for these purposes should not be asked separately; it should instead 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 deliberate action by the participant, i.e. consent cannot be given passively or via an opt-out system
  - Explicit consent is best obtained with a signed, written statement
    - Research under the purview of the WMO must utilize written, paper statements. Non-WMO research may use 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 of the best ways 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).

- For consent to be informed, specific information must be provided to participants
  - The informed consent form must include:
    - The name of the controller (the 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 (NB: don’t forget to mention contact information, if applicable!)
    - The specific research purposes for each data type collected
    - The right to withdraw consent without consequence and information on how to do so
If applicable, risks of data transfers to countries outside the EEA if no safeguards are utilized

- The information letter must include:
  - The name of the controller and a contact person from the research project
  - The contact information for the data protection officer (functionarisgegevensbescherming@vu.nl)
  - The specific research purposes and an explanation that processing is legally allowed because of the participant’s consent
  - If applicable, the recipients of the data (i.e. co-controllers and processors)
  - 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, while the requirement to publish data indefinitely 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 their data are published indefinitely or not
  - Information that participants have rights under the GDPR, but with a disclaimer that research is often exempt from the application of these rights; if a participant wishes to exercise his/her rights, he/she should contact the data protection officer for the VU or the contact person for the study.
  - The right to withdraw consent without 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)

- 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

- 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
  - For longitudinal studies that maintain contact information for participants, a new information letter can be provided (or a link to the webpage where this information is available)
  - If no contact information has been maintained, but there is a study website, the new information should be published on the website
  - If there is neither contact information nor a study website, and therefore it would require excessive effort to inform the participants, the research team should document the new purposes in their data processing registry or data management plan

- For research with children, once a child is 16 years of age he or she has the right to confirm, modify or withdraw the consent given by his/her parents
  - 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 he/she reaches 16 years of age so that the child has the option to confirm, change or withdraw consent
  - If the child does nothing (e.g. 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

Consent forms must be maintained for as long as the researchers are responsible for the data under the GDPR

- The FGB is working on a solution with regards to indefinitely published data; with regards to archiving, consent forms must be archived for the same duration as the archived data
- Currently all consent forms must be maintained in their original format, meaning that paper consent forms cannot be destroyed 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.