Informed Consent Guidelines

version June 2020

Consent from participants is the key to ethical research practice. According to the GDPR, consent 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 a clear affirmative action, signifies agreement to the processing of personal data relating to him or her. Research with participants should comply with European and Dutch privacy laws (i.e. GDPR/UAVG) and with the ethics guidelines provided by the ERB (FMG-UvA). The ERB distinguishes between the following categories for establishing the appropriate consent procedure.

1. Before collecting personal information, you inform and require consent from participants

An FMG researcher who collects or processes personal identifiers (e.g., names, birthdays) informs the participant and asks for consent. Participants, or their legal representatives, receive an information letter. They must be given ample opportunity to understand the nature, purpose and anticipated consequences of research participation, so that they are fully informed. Consent can be given by signing a consent form. Standard participant information letters and consent forms are available at http://ethiek.fmg.uva.nl. Participants in online research are presented with a digital version of the information letter. For offline access or storage of the information letter, participants might be offered the option to download a copy of the information document of be prompted to take a screen shot to retain the information. Participants provide online consent by marking a check box to state that they are fully informed and agree to participate. After completing the online study, participants are again given the option to indicate that they would like to withdraw their data.

a. Research involving participants of 16 years or older, requires his or her consent.
b. Research involving minors older than 11 and younger than 16 years requires consent from both the minor and the parent(s) / legal representative(s).
c. Research involving minors younger than 12 years, requires consent from the parent or legal representative.

2. Before collecting anonymous data, you inform participants

An FMG-researcher collects data that are fully anonymous. This means that there is no way for anyone (including the researcher) to personally identify participants in the study.

a. *Face-to-face data collection.* An FMG researcher administers a short survey or questionnaire that is simple, effortless, and does not involve the collection of personally identifying information. The research setting could be a school, involving participants who are 16 years or older. During face-to-face contact, the FMG researcher verbally explains all relevant ethical information, including the purpose and duration of the study, who uses the anonymous data, the right to stop at any point (see the standard information documents available at http://ethiek.fmg.uva.nl). Consenting participants mark a check box to state that they are fully informed and agree to participate. A signature is not required. After the brief survey, participants are handed the information document, including the contact details of the researcher(s) and the ERB-member to be contacted for formal complaints. The procedure should be submitted to the ERB for ethical evaluation.

b. *Internet-based data collection*. An FMG researcher collects anonymous data using an online platform, such as the internet. Before data collection starts, the participant is presented with a

(web)page containing all relevant ethical information, including the purpose and duration of the study, who uses the anonymous data, the right to stop at any point (see the standard information and consent documents available at http://ethiek.fmg.uva.nl). For offline access or storage of the information letter, participants might be offered the option to download a copy of the information document or be prompted to take a screen shot to retain the information. Participants provide online consent by marking a check box to state that they are fully informed and agree to participate. After completion, participants are again informed that, by proceeding, they agree with participation and that once they submit their data, this cannot be undone. The procedure should be submitted to the ERB for ethical evaluation.

3. Processing data collected by an external party and shared with you

The FMG researcher was not responsible for the data collection involved in the original study.

a. *Sharing anonymous data*. An external party shares an anonymous dataset with an FMG researcher. The original data file may contain personal identifiers but a person who has legal access to the data has removed these personal identifiers before sharing the data file with the FMG researcher. The FMG researcher cannot in any way access personal identifiers, not by secondary recognition (a combination of variable values revealing someone's identity) and not by means of a key (no pseudonymization). The FMG-researcher should submit the original consent procedure used by the external party to the ERB to verify (i) that the original dataset was collected in an ethical way, and (ii) that the interests of the participants in the original study are respected if their data were to be used in another study.
b. *Sharing personal data*. An external party can only share their dataset with personal identifiers with an FMG-researcher if (i) participants have been informed and have agreed that their personal data might be shared with other researchers, (ii) the research goal of the FMG-research matches the research goal of the original study for which participants gave their consent, (iii) both parties sign a data processing agreement. The original consent procedure used by the external party should be submitted to the ERB for ethical evaluation of the current FMG study to verify that conditions (i) and (ii) are met.

4. Collecting anonymous data in observational research

Observation of people in public spaces may occur without consent. Such research must be conducted with respect for privacy. Data collection occurs fully anonymously (no personal data can be registered) and unobtrusively, in accordance with local cultural values, and restricted to situations where people being studied can reasonably expect to be observed by strangers. By law, the collection of any personal data requires informed consent. Observation of specific groups or organizations (not necessarily in public spaces), including participant observation, occurs with informed consent from either the group members, or from an appropriate representative – a person who can be demonstrably or reasonably considered to represent the interests of the group (e.g. a teacher, a village elder, a team leader, a coach, or a chosen representative). Here too, observation must occur with respect for privacy, and local cultural values. The research project should be submitted to the ERB for ethical evaluation.

5. Before collecting anonymous data from minors in a school setting, you need to inform parents

An FMG-researcher collects fully anonymous data from minors in a school setting. This means that the FMG-researcher cannot personally identify participants in the study. Although the AVG does not require parental consent, the ERB (FMG-UvA) requires that parents are timely and fully informed about the intention to approach children for behavioral research in a school-setting. The following conditions should all be met:

i. Before data collection, participating minors are fully informed in an age-appropriate way to ensure dissemination. The information letters and consent forms presented to minor participants (older than 11 and younger than 16) should be uploaded as part of the ERB application.

ii. The dataset is fully anonymous for the FMG-researcher. Personal identifiers are removed before the data is transferred to the FMG-researcher. Secondary recognition therefore is not possible. A code is used to link different sources of research data (e.g., test scores previously collected by the school and newly obtained data from questionnaires). The key is stored separate from all types of data, never transferred to the FMG researcher, and destroyed as soon as possible. The FMG researcher should explain the procedure as part of the ERB application.

iii. The research centers on a broadly school-related topic. The load for the minor participant is mild For example, it entails completing a short (typically less than one hour) classroom survey or a brief individual administration of a school-related computer task. Use of stimuli or items that may be associated with negative affect (such as administering anxiety questionnaires or presenting negative IAPS pictures) or intervention studies are not permitted (the consent guidelines of category 1 apply).

iv. Parents are informed by means of a parental information letter drafted together with the school (see the standard forms available at http://ethiek.fmg.uva.nl). It is important that the information letters reach the parents, at the latest two weeks before data collection is planned. School (i.e. the organization that has access to parental email addresses) sends the information letter to the personal email address of the parent(s). These documents may be sent by regular mail, handed to minors with the instruction to pass it on to their parents or sent by a (digital) newsletter, on the condition that the school also sends the information letter to the parents by a personally addressed email.

v. If a parent objects to participation of their child, it is easy to opt out, for example by calling a phone number or by sending an email to the designated contact person at school (e.g., a familiar teacher).