*Version 13 / 202103*

**TISEM IRB SUBMISSION FORM STANDARD RESEARCH PROTOCOL**

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| --- |
| Application id: <IRB: enter code of application> |

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| --- |
| **GUIDE** The TiSEM Institutional Review Board (IRB) evaluates proposals for research conducted by TiSEM faculty. Research proposals are evaluated on ethics of data collection and data management, including participant privacy protection, and the quality of data management, including data accessibility. The TiSEM submission form for a Standard Research Protocol (SRP), like the regular submission form, has four parts to be completed by the Principal Investigator (PI):* Part 1. General information
* Part 2. Research Proposal
	+ Part 2A. Data collection
	+ Part 2B. Data management
	+ Part 2C. Compliance
* Part 3. Signatures and declarations
* Part 4. Supporting documents

The submission form needs to be completed fully.The submission form is completed in English.The appendices are in language in which the proposed research is executed (stimuli, informed consent, debriefing, surveys, and so forth). If the language is not Dutch or English than the researcher is responsible for a translation into English.More information: <https://www.tilburguniversity.edu/research/economics-and-management/institutional-review-board> For questions contact the IRB manager: 4887, irb-tisem@tilburguniversity.edu. |

**1. GENERAL INFORMATION**

**1.1 TITLE**

|  |
| --- |
| What is the title of the SRP? |
|  |

**1.2 APPLICANTS**

|  |
| --- |
| Main applicant (coordinator) of the SRP? |
| Department | <add name> |
| Name | <add name> |
| Email | <add address> |

|  |
| --- |
| Co-Applicant 1 |
| Department | <add name> |
| Name | <add name> |
| Email | <add address> |

|  |
| --- |
| Co-Applicant 2 *(expand if needed)* |
| Department | <add name> |
| Name | <add name> |
| Email | <add address> |

**1.3 TYPE OF DATA**

|  |
| --- |
| Which types of data are used in this SRP?(check all that apply, and at least one) |
| O | Data are to be collected from identifiable, natural persons or groups consisting of these. Examples: data from experiments, surveys, focus group interviews, or observational studies. |
| O | Data are available from identifiable, living, natural personsor groups consisting of these. Examples: data collected by survey organizations ….. |
| O | Data are available from anonymous, natural, living persons OR from identifiable, natural, deceased persons. Examples: archival, historical data… |
| O | No data from identifiable, natural persons are used in the proposed research. Examples: simulated data, analytical or theoretical research. |

**1.4 BACKGROUND**

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| 1. What are the key themes, problem statements, and/or research question(s) of this SRP? *(maximum 500 words)* |
| <add information> |

|  |
| --- |
| 1. What are the typical research designs?

*Summarize in sufficient detail the data collection methodology and procedures to enable a balanced IRB review. (maximum 500 words).* |
| <add information> |

**2. PROPOSAL**

**PART A.**

**DATA COLLECTION**

**A1. SAMPLE**

|  |
| --- |
| 1. Who are the sample members?(check all categories that apply, and at least one) |
| O | Tilburg University students |
| O | Volunteers from the general population |
| O | Children or minors (under 16 years of age) |
| O | Other, namely <add information> |

|  |
| --- |
| 1. What are the typical target sample sizes?

(if sample sizes vary substantially, provide further detail on the determinants) |
| <add information> |

|  |
| --- |
| 1. What are the sampling procedures?

(if sampling procedures vary substantially, provide further detail) |
| <add information> |

|  |
| --- |
| 1. Where does data collections take place

(check all that apply, and at least one) |
| O | CentERLab at Tilburg University |
| O | Other location(s) at Tilburg University, namely <add information> |
| O | Other location(s) or institution(s) outside of Tilburg University, namely <add information> |
| O | On-line, via a research organization or platform, namely <add information> |
| O | Other, namely <add information> |
| O | Not applicable |

|  |
| --- |
| 1. Are prospective participants asked to provide informed consent prior to participating?
 |
| O | Yes |
| O | No |
|  | If **No**, indicate why participants are **not** asked to provide informed consent prior to participating:<add information> |

|  |
| --- |
| 1. What is the total time investment (on average is varying) for a participant in studies within this SRP?
 |
| <add information> |

|  |
| --- |
| 1. Do participants receive a compensation for their participation or reimbursement of costs?
 |
| O | No |
| O | Yes, ECTS credits, namely <add information> |
| O | Yes, financial compensation, namely <add information> |
| O | Yes, other, namely <add information> |

**A2. CONTENT: SENSITIVITY**

|  |
| --- |
| Are studies within the SRP about one or more sensitive topics?*Sensitive topics include personal, intimate, illegal or socially unacceptable attitudes/preferences/characteristics/behaviors of participants. Examples include, but are not limited to, racial or gender stereotyping, sexual activity, drug use, and illegal activities. Research about such sensitive topics may pose a risk to the well-being and/or health of participants, for instance, by activating a negative mood or reducing self-esteem.* |
| O | No |
| O | Yes, studies within this SRP involve one or more sensitive topics |
|  |  If **Yes**, indicate what the topic(s) is/are and what the potential risk to participants is:<add information> |
|  | If **Yes**, indicate how the sensitivity of the topic and/or the potential risk to participants is minimized: <add information> |

**A3. PROCEDURE: INTERVENTION**

|  |
| --- |
| Do studies within the SRP have one or more interventions? *An intervention is any treatment of, contextual change to, or manipulated difference to a participant or between participants intended to induce psychological, physiological, and/or behavioral changes in the participants.* *There is no intervention in case of a single survey which asks participants to report on the same pre-existing states, traits, and/or behaviors with the same instruction or in case of observation of participants.*  |
| O | No, studies within the SRP do **not** have one or more interventions |
| O | Yes, studies within the SRP have one or more interventions |
|  | If **Yes**, indicate what the interventions are and how they are imposed:<add information> |

**A4. PROCEDURE: DECEPTION**

|  |
| --- |
| Do studies within the SRP involve deception?*Deception occurs when researchers purposely mislead participants by providing them false information about the true purpose and/or procedures of the research.* |
| O | No, studies within the SRP do **not** involve any deception  |
| O | Yes, studies within the SRP involve deception.  |
|  | If **Yes**, indicate which false information is provided to the participants:<add information> |
|  | If **Yes**, indicate why deception in this research is necessary.<add information> |

**A5. PROCEDURE: INCOMPLETE DISCLOSURE**

|  |
| --- |
| Does the research involve incomplete disclosure?*Incomplete disclosure occurs when researchers deliberately withhold information about the true nature and or procedures of the research. Example 1: participants are not informed about the experimental condition they are in and about other experimental conditions. Example 2: Participants are not informed about data that are collected from them during the research, such as facial expressions, response times, or body positions.* |
| O | No, this research does **not** involve incomplete disclosure. |
| O | Yes, this research involves incomplete disclosure, but this does **not** increase the risk of harm for the participants.  |
|  | If **Yes**, which information is withheld from the participants?<add information> |
| O | Yes, and this can increase the risk of harm for the participants. |
|  | If **Yes**, which information is withheld from the participants?<add information> |
|  | If **Yes**, why is incomplete disclosure necessary and how will you try to minimize the potential harm for participants as much as possible?<add information> |

**A6. DEBRIEFING**

|  |
| --- |
| Do studies within the SRP include a debriefing after data collection that fully informs the participants about the true purpose and procedures of the research? *Debriefing occurs after data collection. It is not mandatory.* *Debriefing provides participants information about: (1) the true purpose and procedures of the research, in case this information was not provided before data collection, and/or (2) how and where to obtain more information about the research or to obtain support if needed.*  |
| O | Yes, studies within the SRP include a debriefing with information about (1) and/or (2) as above.If **Yes**, upload debriefing material in section 4 |
| O | No, studies within the SRP do **not** include a debriefing because participants received information about (1) and/or (2) as above before data collection. |
|  |  |
| O | No, the studies within the SRP do **not** include a debriefing: Information about (1) and/or (2) as above is withheld from the participants.  |
|  | If **No**, indicate **which** information is not provided to the participants.<add information> |
|  | If **No**, indicate **why** this information is not provided to the participants.<add information> |

**A7. DATA**

|  |
| --- |
| Which data are obtained from or become available of participants?(check all that apply; at least one) |
| O | Self-reports (states, traits, behaviors of participants using a questionnaire or check-list) |
| O | Choices |
| O | Audio or video recordings |
| O | Online behavior (e.g., via web scraping) |
| O | Biomarkers (e.g., eye tracking, EMG, fMRI, hair, saliva) |
| O | Archival data (e.g., purchase, financial, tax or criminal records) |
| O | Other, namely<add information> |

**A8. RISK ASSESSMENT**

|  |
| --- |
| Can studies within the SRP in any way potentially pose **more** than minimal risk to the well-being and/or health of participants? |
| O | This studies within the SRP do **not** pose more than minimal risk to the participants |
| O | Yes, studies within the SRP pose more than minimal risk to the well-being and/or health of participants |
|  | If **Yes**, indicate what the potential risk is:<add information> |
|  | If **Yes**, indicate if and how participants are compensated and/or treated in case their well-being and/or health is harmed:<add information> |

**A9. POST-EVALUATION**

|  |
| --- |
| Do studies within the SRP include a post-evaluation survey of the study among participants ? *Post-evaluation occurs after data collection.**It may include (1) whether participants guessed the true purpose and/or procedures of the research in case of deception, or in other ways had knowledge that threatens the validity of their data, and/or (2) how participants evaluated the research (intervention, material, procedures, measures), and/or (3) their current well-being and/or health.**Post-evaluation may be included to exclude certain participants from data analysis (e.g., in case of correct hypothesis guessing), and/or to treat participants whose well-being and/or health was negatively affected by their participation in the research and/or to improve future research.**Including post-evaluation is essential in case the research topics(s), intervention(s), procedure, and/or measure(s) could pose more than a minimal risk to the well-being and/or health of the participants.* *Post-evaluation is typically in the form of a brief self-report questionnaire but may include other procedures. It can include information on how to contact a member of the research team or another person or organization to obtain more information about the research or to obtain follow-up care.* |
| O | No, studies within the SRP do not include a post-evaluation survey. |
| O | Yes, studies within the SRP include a post-evaluation survey.if **Yes**, upload the post-evaluation questionnaire or other documents in section 4. |

**PART B.**

**DATA MANAGEMENT**

This part is about how the research data are handled during and after the research has been conducted. Part 1 (General Information) and Part 2B (Data Management) of the submission form constitute the Data Management Plan (DMP). For more information, see [Tips for writing a data management plan](https://www.tilburguniversity.edu/sites/default/files/download/Tips%20for%20writing%20a%20Data%20Management%20Plan%20%28DMP%29%20Sep2020.pdf).

Data can be in digital form (electronic; e.g., numbers, text, image, audio, video files, other) or non-digital form (e.g., paper, artifacts, hair samples, other). Sections B1-B3 are about digital data. B4 is about non-digital data.

**B1. STORAGE OF DIGITAL DATA**

Indicate (1) the location where the data will be stored, (2) the format in which the data are stored, and (3) who has access to the data, during (A) Data Collection and Analysis, and (B) Data Archiving.

Tilburg University has approved various data storage locations and formats, specifically

* [Data storage during research](https://www.tilburguniversity.edu/intranet/research-support-portal/rdm/data-storage)
* [Data archiving](https://www.tilburguniversity.edu/intranet/research-support-portal/rdm/publishing-and-sharing/dataverse)

Indicate whether the research relies on TiU approved (“TiU-a”) and/or “other” locations and formats, and indicate which ones.

List of storage formats: Approved and standard data formats are csv, txt, dat, xls, xlsx, (SPSS) sav, (STATA) dta, SAS XPORT, RDATA, and for video/audio recordings AVI or MP4 (video) and WAV, or M4A (audio).

|  |  |  |  |
| --- | --- | --- | --- |
| **Which phase of the research?** | 1. **Storage Location:**

Where are the data stored? | 1. **Storage Format:**

Is the storage format in the list above | 1. **Access to Data:**

Can others than members of the research team access the data in this phase of the research? |
| A. Data Collection and Analysis | O | TiU-a: <add information> | O | No, <add information> | O | No |
| O | Other: <add information> | O | Yes | O | Yes, <add information> |
|  |
| B. Data Archiving(min. period: ten years) | O | TiU-a: <add information> | O | No, <add information> | O | No |
| O | Other: <add information> | O | Yes | O | Yes, <add information> |

**B2.** **META DATA**

Metadata describe your data set/package during “B. Data Archiving”. There are three types:

1. Descriptive (common fields such as title, author, abstract, keywords that help users to discover online sources through searching and browsing),
2. Administrative (preservation, rights management, and technical metadata about formats),
3. Structural (how different components of a set of associated data relate to one another, such as a diagram describing relations between tables in a database).

Repositories often use an existing Metadata standard to describe a data set/package. For TiU Dataverse this is the DDI (Data Documentation Initiative) standard.

|  |
| --- |
| What will be included in the metadata, and how it will be documented?If you use a metadata standard, indicate which one. |
| <add information> |

**B3. SHARING DATA**

|  |
| --- |
| Will (part of) the data be made available for re-analysis or re-use by others after completing the project?  |
| O | Yes, (part of) the data will be made available in an **anonymized** form. |
| O | Yes, (part of) the data will be made available in a **pseudonymized** form. |
| O | Yes, (part of) the data will be made available in **another** form, namely <add information> |
| O | No, data will **not** be made available to others after completing the project. |
|  | If **No**, indicate why (e.g., violates the informed consent agreement with participants, or intellectual property rights, or a non-disclosure agreement (NDA): <add information> |

**B4. STORAGE OF NON-DIGITAL DATA**

|  |
| --- |
| Will data in non-digital form (e.g., paper, pictures, hair samples, saliva, artifacts, other) need to be stored? |
| O | No, no data in non-digital form need to be stored. |
| O | Yes, data in non-digital form need to be stored. |
|  | If **Yes**, add information below |
|  | 1. Storage Location

Where are the data stored? | 1. Form of the data

Which data storage formats are used? | 1. Access to Data

Can others than members of the research team access the data? |
|  | <add information> | <add information> | <add information> |

**PART C.**

**COMPLIANCE WITH THE GDPR/Data Processing Register**

By filling out this part of the form you are complying with the GDPR, which requires a completed data processing register when processing personal data. This includes a pre-DPIA (Data Protection Impact Assessment), which identifies risks and determines if a DPIA is required.

For more information see: <https://www.tilburguniversity.edu/about/conduct-and-integrity/privacy-and-security> or contact the TiSEM Data Representative: gdpr.tisem@tilburguniversity.edu.

**C1. Will personal data[[1]](#footnote-1) be processed?**

[ ]  No personal data will be processed. This is the end of the questionnaire; you can skip questions C.2 until C.10.
[ ]  Yes, namely (multiple answers possible):

[ ]  **General**[ ] Contact data (for example: name, email address, phone)
[ ] Gender
[ ] Age, birthdate
[ ] Nationality, birth place, birth country
[ ] Student number/employee number
[ ] Experience (work, education)
[ ] Finances
[ ] Visual materials (pictures, video)

[ ] IP address

[ ]  **Special data**[ ] Racial or ethnic origin[ ] Religious or philosophical beliefs[ ] Political opinions[ ] Health data (e.g., stamina, eating habits, exercise regimen)[ ] Sex life or sexual orientation[ ] Trade union membership[ ] Genetic data[ ] Medical data (e.g., illness, blood values, mental disorder, side effects)
[ ] Biometric data[ ] Criminal records

[ ]  **Sensitive data**[ ] Data relating to criminal convictions and offences

[ ] **Other personal data not covered by the above-mentioned categories, for example household composition, product preferences, personality traits.**

[ ] Namely, Click here to enter text.

**C2. Will data be anonymized or pseudonymized after collection and, in case of pseudonymization, who will have access to the identifying file?**

|  |
| --- |
| <add information> |

**C3. What is the legal base for which the processing activity takes place?**

According to the GDPR, personal data cannot be processed unless there is a legal basis for processing. Check the one(s) that apply:

[ ]  (1) Consent (participants sign a consent form to process their personal data);

[ ]  (2) Legitimate interest as scientific researcher (*gerechtvaardigd belang*) (for example, this applies to the use of public data from social media for which consent is not needed);

[ ]  (3) Permission (when an external party provides the applicant with personal data and the external party has obtained consent to use these data)

**C4. Does the applicant receive personal data from or provide personal data to a third party?**

This question isrelevant to determine responsibilities regarding the processing of the personal data, for example, in case of collaboration with other researchers or organizations. If both applicant and third party determine the processing of personal data (both parties are controller), a joint controller agreement, a collaboration agreement, or a data sharing agreement must be concluded. Contact the Data Representative for support.

[ ] No

[ ] Yes, data will be received from or provided to:

[ ]  The project group, including Click here to enter text.
[ ]  Co-researcher from other universities or institutions. Please state their names, contact details and countries: Click here to enter text.
[ ]  Other persons/organizations responsible for processing the data. Please state their names, contact details, and countries: Click here to enter text.

**C5. Is the applicant receiving personal data from a third party to conduct contract research and the third party determines the purposes and means of the processing?** If so, the applicant is a processor and a data processor agreement is needed. The model processor agreement and procedure is available via [intranet](https://www.tilburguniversity.edu/about/conduct-and-integrity/privacy-and-security/careful-handling-personal-data/settlement-agreement) or can be requested from the Data Representative.

[ ] No

[ ] Yes

**C6. Are there any external parties (processors) involved in this research regarding data collection, data storage, archiving and/or other data-related activities? If so, please describe and mention them here and state the website(s) of the processor(s).**

The applicant must ensure that there is a contract and a data processor agreement to confirm correct processing by the external party. This party must take appropriate technical and organizational measures to protect personal data against loss or any form of unlawful processing (e.g. unnecessary collection of data or further processing). With, for example, Surfdrive and Qualtrics Tilburg University has signed a data processing agreement.

The model processor agreement and procedure is available via [intranet](https://www.tilburguniversity.edu/about/conduct-and-integrity/privacy-and-security/careful-handling-personal-data/settlement-agreement) or can be requested from the Data Representative.

**Data collection**[ ] Not applicable
[ ]  Yes: Click here to enter text.

**Data storage**[ ] Not applicable
[ ]  Yes: Click here to enter text.

**Data archiving**[ ] Not applicable
[ ]  Yes: Click here to enter text.

**Other data-related activities (e.g. analyses)**[ ] Not applicable
[ ]  Yes:

**C7. Have you agreed upon and centrally archived the data processor agreement(s)? Please specify. (This question is only applicable if answers to questions C5 – C6 require a processor agreement)**

|  |
| --- |
|  |

**C8. If applicable, to which third parties (controllers and processors) are the data provided by default? What is the purpose and the basis of this provision?**

Examples are tax authorities, pension funds, health insurers etc. Third parties with an independent processing responsibility are always external and determine their own purpose and resources for the processing. If the data are provided to another controller, then an agreement should be concluded about privacy and security guarantees. This can be done in the agreement that already exists with that other party or in a data exchange agreement for the research for which this clearance is required.

|  |
| --- |
|  |

**C9. Data Protection Impact Assessment (DPIA) needed?**

A DPIA is an estimate of the impact of data processing on the data protection of the persons concerned. Such an assessment is required if the intended processing of personal data poses a high privacy risk to the persons concerned, for example if the applicant intends to collect a huge data set or an extremely sensitive data set. Such processing warrants a separate analysis of the risks of the project. Based on this estimate, recommendations can be made to minimize this impact as much as possible or even eliminate it completely.

**Tick all categories[[2]](#footnote-2) that apply to the research. If a DPIA is required, the Data Representative will contact you to schedule this.[[3]](#footnote-3)**

[ ]  **Assessing people on the basis of personal characteristics**: this includes profiling and predicting, particularly on the basis of characteristics such as a person's professional performance, economic situation, health, personal preferences or interests, reliability or behavior, location, or movements. Examples include a bank that determines the creditworthiness of customers (credit scoring), a company that provides DNA tests to consumers to test health risks, and a company that follows visitors to its website and uses this to create profiles of these people.[[4]](#footnote-4)

[ ]  **Automated decisions**: this concerns making decisions with technological means and without human intervention. In order to fall within this category, the decisions have legal effects or comparable significant effects on the person concerned. Such data processing may, for example, lead to exclusion or discrimination. Data processing with little or no impact on individuals is not covered by this criterion.

[ ]  **Systematic and large-scale monitoring**: this concerns the monitoring of publicly accessible spaces, for example with camera surveillance, but also systematically following data subjects online. Personal data can be collected without those involved knowing who is collecting their data and what happens to it. Additionally, it may be impossible for people to withdraw from this data processing in public places.

[ ]  **Sensitive data**: this concerns special categories of personal data, as laid down in Article 9 of the GDPR: personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person’s sex life or sexual orientation. Moreover, this category also includes data that are generally regarded as privacy sensitive, such as data about electronic communication, location data and financial data.

[ ]  **Large-scale data processing**: there is no specific definition of this category, but the following criteria should be used to determine whether this is applicable: a. very large datasets concerning many thousands or millions of people; b. the volume of data and/or the range of different data items being processed; c. the duration of the data processing activity; d. the geographical extent of the processing activity.[[5]](#footnote-5)

[ ]  **Combining databases**: Datasets that have been matched or combined, for example originating from two or more data processing operations performed for different purposes and/or by different data controllers in a way that would make it possible to deduce the personal identities of subjects.

[ ]  **Data concerning vulnerable data subjects**: this applies when there is an unequal balance of power between the data subject and the data controller for example minors, mentally ill persons, asylum seekers, or the elderly, patients, etc.

[ ]  **Use of new technologies**: e.g., combining use of fingerprint and face recognition for improved physical access control, etc. The reason is that this use may involve new ways of collecting and using data, with potentially high privacy risks. The personal and social consequences of using a new technology may even be unknown, a DPIA then helps to understand and remedy the risks.

[ ]  **Data transfer across borders outside the European Union**: taking into consideration, the potential risks of data transfers to such countries.

[ ]  **Blocking of a right, service, or contract**: this concerns data processing that result in data subjects not being able to exercise a right, use a service, or enter into a contract. [[6]](#footnote-6)

**3. DECLARATION BY APPLICANT(S)**

**3.1 Additional information**

|  |
| --- |
| Q. Please use this space to add information that is important to the SRP and de review procedure but was not asked about in the form. |
| <add information> |

**3.2 Declaration**

|  |
| --- |
| Declaration by the applicants:We, the applicants agree to have provided a complete and correct application. |
| Signed by Coordinator |  |
| Print Name |  |
| Date |  |
|  |  |
| Signed by Co-applicant 1 |  |
| Print Name |  |
| Date |  |
| Signed by Co-applicant 2 *(expand if needed)* |  |
| Print Name |  |
| Date |  |

1. **SUPPORTING DOCUMENTS** *(if applicable)*
* Format Information letter (see appendix 1 for checklist)
* Format Informed consent form (see appendix 2 for checklist)
* Format Debriefing material
* Format Surveys/questionnaires/interview questions (written or online)
* Format Post-evaluation survey
* Other documents, specify <add information>

**APPENDIX 1 CHECKLIST INFORMATION LETTER**

Possible items to add to an information letter. It is not required to add all of the items mentioned.

[ ]  Title (Title of the research, if necessary simplified, abbreviated, or translated)

[ ]  Introduction

**A. What does the research entail?**

[ ]  Purpose

[ ]  Background

[ ]  Nature

[ ]  Duration

**B. What does participating in the research entail?**

[ ]  Procedures

[ ]  Expected duration

[ ]  Disadvantages/consequences/risks

[ ]  Possible advantage for the participant

**C. Information about the participation**

[ ]  Voluntariness of the participation.

[ ]  Right to decline to participate and withdraw from the research once participation has begun, without any negative consequences and without providing any explanation.

[ ]  Information regarding privacy in research and the rights of participants as stated in the Tilburg University privacy statement: www.tilburguniversity.edu/privacy.

[ ]  Confidentiality protection and limitations

[ ]  Applicable insurance guarantees (only if there is additional insurance to the standard insurance)

[ ]  Period of time to which the consent applies (normally the length of the research)

[ ]  Re-use of specified data in the current, future or other research, where applicable

[ ]  Deliberation time (if applicable)

[ ]  How the data will be processed

[ ]  Period of time that data will be stored and encrypted

[ ]  Incentives for participation (traveling expense, pp hours)

[ ]  Approval Institutional Review Board (IRB)

[ ]  Request for participation

[ ]  The following text should be included:

If you have any remarks or complaints regarding this research, you can also contact the Institutional Review Board of Tilburg School of Economics and Management via irb-tisem@uvt.nl.

[ ]  Closing/whom to contact in case of question or additional information (name and telephone number/email address researchers)

[ ]  Appendices: Informed Consent

**APPENDIX 2 CHECKLIST INFORMED CONSENT FORM**

* *In case of a mentally incompetent participant, informed consent is obtained from the legal representative(s). It is good practice to also ask the participant where possible.*
* *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.*
* *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).*
* *From 16 years of age, consent is only obtained from the participant. For some types of research, it may nevertheless be good practice to inform the parents or legal representatives.*

*Please check each applicable box to confirm that the informed consent contains the required elements.*

**A. Mentally competent participants and minors 12-16 year**

[ ]  Title (Title of the research, if necessary simplified, abbreviated or translated)

[ ]  Confirmation that the information is read

[ ]  Confirmation that there was room for questions

[ ]  Reminder on voluntariness of participation. Right to decline to participate and withdraw from the research once participation has begun, without any negative consequences, and without providing any explanation

[ ]  Confirmation that the Tilburg University privacy statement was referred to

[ ]  Permission for processing anonymous/coded data as mentioned in the information letter

[ ]  Permission for storing the research data for a period of at least ten years

[ ]  Permission for participation in the research

[ ]  Date, name, signature participant

**B. Addition/correction for mentally incompetent adults**

[ ]  Date, name, signature legal representative, relation to participant

**C. Addition/correction for minors**

[ ]  Date of birth participant

[ ]  Date, name, signature (if possible both) parents/guardians

1. Personal data: any information relating to an identified or identifiable living natural person (directly or indirectly) [↑](#footnote-ref-1)
2. The European Working Party 29 (WP29) has indicated nine criteria for which, if there are at least two applicable, a DPIA must be carried out. These criteria are endorsed by the European Data Protection Board and the Dutch Data Protection Agency (“Autoriteit Persoonsgegevens”). Tilburg University has added the criterion about data transfer across borders of the EU due to special regulations that apply in that situation. The criteria are written mostly for large corporations processing personal data and do not take the specifics of scientific research into account. An additional explanation by Tilburg University is given for some of the criteria for scientific research. [↑](#footnote-ref-2)
3. Please note that as a rule of thumb a DPIA is required when two or more categories apply. However, it is possible that a DPIA is required if one or even none of the criteria are applicable. [↑](#footnote-ref-3)
4. At Tilburg University research is conducted in which characteristics of individuals might be used to segment individuals into different groups to explain for example their behavior. This can be seen as profiling. If the processing is done for research purposes and it does not affect the individuals directly, this does not present a high level of privacy risk, which is why in those cases, the criterion **will not** be applicable. However, if the research is conducted as for example contract research and the results directly affect individuals, this criterion **will be** applicable. [↑](#footnote-ref-4)
5. The Dutch Data Protection Agency has determined that for the health care industry 10,000+ individuals make up a large dataset. For other industries, no number has been provided. However, depending on the type of data and the number of data points per individual, a smaller number of individuals might make up a large dataset because the processing of the data will likely present a **high level of privacy risk**. When in doubt, check with your data representative. [↑](#footnote-ref-5)
6. This criterion is applicable for example when covert research is conducted since data subjects are not aware they are being part of scientific research and can therefore not claim their right to information, to object to the processing of their information, etc. [↑](#footnote-ref-6)