**Delft University of Technology**

**HUMAN RESEARCH ETHICS**

**INFORMED CONSENT TEMPLATES AND GUIDE**

**(English Version: January 2022)**

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| The following templates have been developed by the Human Research Ethics Committee (HREC) to assist you in the design of your Informed Consent materials for non-medical research involving human Research Subjects. **It is important to adapt this template to the outline and requirements of your particular study, using the notes and suggestions provided.**  For additional information or specific expertise on preparing your Informed Consent materials you can consult the following:   * The TU Delft [Research Ethics webpages](https://www.tudelft.nl/en/about-tu-delft/strategy/integrity-policy/human-research-ethics), * Your faculty Data Steward, the TU Delft Privacy Team * Our brief guide on Completing the HREC checklist * Our [Risk-Planning tool, Managing Risk in Human Research](https://filelist.tudelft.nl/user_upload/6_RPT-Risk-planning%20tool.pdf)   If you have any questions about applying for HREC approval which are not dealt with on the [Research Ethics webpages](https://www.tudelft.nl/en/about-tu-delft/strategy/integrity-policy/human-research-ethics), please contact [HREC@tudelft.nl](mailto:HREC@tudelft.nl)  You can find **Dutch versions** of the Informed Consent templates in the Informed Consent section of the [Research Ethics webpages](https://www.tudelft.nl/en/about-tu-delft/strategy/integrity-policy/human-research-ethics). |

**Informed Consent as a legal and ethical agreement**

The key function of the Informed Consent (IC) process is that this is where you (the Responsible Researcher) come to an agreement with your participants about what they will do for your research and what you will do, both legally and ethically, to ensure their physical, emotional and reputational security. It is key that they know exactly what – and particularly what potential risks – they are agreeing to, and that this is clear in your agreement, and executed in practice.

***Two types of Informed Consent***

“Informed Consent” covers two distinct, if overlapping, elements of a participant’s agreement to participate in scientific research. These are essentially: consent to participate in the research and consent to the way in which any personal data will be processed and managed.

* **Research Participation** – obtaining a participant’s consent to participate is essential for any research involving human “subjects”. It requires researchers to flag the potential physical, emotional or other risks they might be exposed do by virtue of the research process or its findings.
* **Data Processing and Privacy** – at the same time, under the European General Data Protection Regulation (2016) Informed Consent is the most common (but not only) legal basis for collecting Personal Data (including both Personally Identifiable Information and/or Personally Identifiable Research Data) from “human subjects”.  Within the context of scientific research specifically it is important that research participants (“human subjects”) understand what potential risks they might face as a consequence of the collection of any Personal Data, as well as what steps will be taken to mitigate those risks. The development and execution of a robust **Data Management Plan** constitutes one of those mitigating steps.

**Structure and content of your Informed Consent materials**

Your Informed Consent materials can be considered as a legal and ethical contract between you and the people who will be providing you with your research data. In most cases this agreement will comprise of Participant Information and Explicit Consent points. The Participant Information is normally a short, clear summary that informs your participant of anything that might affect their willingness to participate in your research. The specific Explicit Consent points list specific points with which your participants can choose to agree or disagree. Bear in mind, when you are giving participants particular choices, that you will need to execute these agreements with precision.

**Standard structure of Informed Consent materials**

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| **Participant Information** | * Your **Participant Information** should clearly summarise what your research aims to do, what participants are asked to do, what risks might arise – including identification – and what steps you will take to mitigate them. Remember to include not just the personally identifiable research data (PIRD) you collect, but also how you will store the Informed Consent forms and any personally identifiable information (PII) therein. * See [TEMPLATE 1](#template1) |
| **Explicit Consent points** | * In addition to the Participant Information it is best practice (and sometimes a legal requirement) to include a list of specific **Consent Points** with which your participants can agree or disagree. * Bear in mind that where your participants disagree, you will need to have **practical plans** in place to comply with these specific points. * See [TEMPLATE 2](#template2) |

**Alternative approaches to Informed Consent**

Depending on your research methods and goals, the standard approach outlined above may not appropriate or possible. For example, if you are gathering your research data using an anonymous online survey, the option of removing specific datasets may not be possible – and so this is not something you can offer in your Informed Consent process. In such cases, the Participant Information and Explicit Consent points are replaced by an **Opening Statement** with which participants demonstrate their agreement by clicking the link to the survey (see [TEMPLATE 1](#template1)).

**Alternative Informed Consent materials**

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| **Opening Statement** | * Where your participants are asked to, for example, complete an anonymous online survey, a signed Informed Consent form is not an option. Instead, the Participant Information and Explicit Consent points might be replaced by an **Opening Statement**. In this case a participant’s agreement with the terms and conditions of your research can be signified by clicking through to the survey. * Your Opening Statement should ensure that your participants are aware of what your research is about, and what is expected of them before they click through to the survey. * Make sure that your participants can leave the survey or skip questions in line with your Opening Statement – and that your Opening Statement is clear on this. * Make it clear that by clicking through to the survey participants are agreeing to conditions. |
| **Verbal Consent** | * In some circumstances it might be necessary to use other Informed Consent approaches – such as verbal consent and/or consent of a Gatekeeper. |
| **Debriefing Information** | * Where deception is required for your research, Informed Consent has technically not been given. In such cases you are advised to debrief your participants, explaining why they were deceived and how, and seek Informed Consent again after the debrief. |

Where it is not possible to seek Informed Consent at all – e.g.: because your method involves covert observation, relies on existing datasets, or is collected from the public domain – steps to ensure the safety of your participants are nevertheless required. For example, you can make sure that the party or parties providing your data are permitted to do so, collect information on the original informed consent process, or demonstrate that you understand how combining multiple datasets might lead to unintended consequences and the steps you will take to avoid this.

Please contact your Faculty Data Steward or the TU Delft Privacy Team, or consult our Guidance Notes on [completing the HREC checklist](https://filelist.tudelft.nl/TUDelft/Over_TU_Delft/Strategie/Integriteitsbeleid/Research%20ethics/2_CHC-completing%20the%20HREC%20checklist_2022.pdf) for more information.

**Executing Informed Consent agreements**

Like any contract between parties, your Informed Consent agreement needs to be managed and executed in perpetuity, so make sure that you have plans in place to honour the agreements you have made – including what happens if you or another member of the research team moves elsewhere. Bear in mind also what is and is not executable in practical terms. For example, if you are seeking approval to use personal names with quotes in any publications, then it is unlikely that you can assure anonymity of stored data. Equally, if you agree with participants to use actual names in any kind of publication, it is best practice to obtain additional, specific approval from named participants prior to publication.

It is critical here that the risks and mitigating steps you identify in your HREC checklist and Data Management Plan are consistent with the agreement you make with your participants. It is your job as the (Responsible) Researcher to ensure that your participants are made aware of any potential risks which they may not themselves foresee. In relation to any Personal Data you may be gathering for administrative purposes and/or as research data, it’s equally important that this agreement is in line with how you will manage your data in practice.

***To this end, you must make sure that the information across your HREC application documents is consistent and aligned.***

**TEMPLATE 1: Participant Information/Opening Statement**

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| --- | --- |
| **Key points to include** | **Suggested text** |
| 1. Level (eg: Masters, PhD, research) purpose, potential outcomes and implications of the study 2. The role of TU Delft and any third parties including funding body 3. Who participants are (eg: children, experts, students in a dependent role to the researcher) 4. What exactly what they are being asked to do 5. What if any Personal Data (Personally Identifiable Information and/or Personally Identifiable Research Data) will be collected, and how it will be used, published and managed. This should include clarity on:    * how the data you collect will be used during the research    * safeguarding personal information, maintaining confidentiality    * de-identifying (pseudo/anonymising) data    * controlling access to data, data archiving and reuse    * (possible) data publication and dissemination, and    * data archiving and the retention period for research data or criteria used to determine that 6. What physical, emotional or reputational risks might arise from participation either during or after the study, and what steps will be used to mitigate these risks 7. Participants’ right to refuse to answer/withdraw from the study at any time 8. The right (or otherwise) of participants to request access to and rectify or erase personal data 9. Any remuneration for time/compensation for travel 10. Contact details of the Responsible Researcher and procedure for making complaints.   **Note: the TUD Human Research Ethics Committee should not be included as a contact and does not deal with participant complaints.** | You are being invited to participate in a research study titled [*Name of your research*]. This study is being done by [*Name of Researcher(s)*] from the TU Delft [*include also any collaborating partners including internship provider and/or funding body*].  The purpose of this research study is [*provide participants with a short statement about the research*], and will take you approximately *[XX*] minutes to complete. The data will be used for [*provide list of intended uses, including publication, application and teaching*]. We will be asking you to [*provide summary of what kinds of questions or tasks participants will be faced with*].  As with any online activity the risk of a breach is always possible. To the best of our ability your answers in this study will remain confidential. We will minimize any risks by [*be clear on whether the survey is completely anonymous, and/or whether IP addresses or other Personal Data will be collected. If so* *describe how you will safely store data, how confidentiality will be secured and how it will be anonymised*].  [*mention Open data specifically if applicable*]  Your participation in this study is entirely voluntary and you can withdraw at any time. You are free to omit any questions. [*Include also clarification on whether data can be removed within a given timescale. This will not be possible where surveys are completely anonymous*]  [*Provide contact details for corresponding and Responsible Researcher*]  [*If participants are agreeing to this Opening Statement by clicking through to an (anonymous) online survey, this should also be clear in the Opening Statement.*] |

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**TEMPLATE 2: Explicit Consent points**

*Please make sure that you select (and amend as necessary) any Explicit Consent points which are relevant to your study and exclude those which do not apply. You should also add further points and necessary to address your specific research situation.*

| **PLEASE TICK THE APPROPRIATE BOXES** | **Yes** | **No** |
| --- | --- | --- |
| **A: GENERAL AGREEMENT – RESEARCH GOALS, PARTICPANT TASKS AND VOLUNTARY PARTICIPATION** |  |  |
| 1. I have read and understood the study information dated [*DD/MM/YYYY*], or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction. |  |  |
| *Separate ‘yes/no’ tick boxes allow you to make sure that your participant is actively affirming their consent. If the participant wants to tick the no box this allows you to clarify any points the participant is unsure about.* ***If this is not applicable for your study, then remove the ‘no’ box.*** |  |  |
| 2. I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason. |  |  |
| *This point should be modified accordingly where a legal guardian will be giving consent, and/or where a participant, outside the context of the research is in a dependent or subordinate position to the researcher.* |  |  |
| 3. I understand that taking part in the study involves: [*see points below*] |  |  |
| *Provide briefly what is relevant from the following:*   * *Describe in a few words how information is captured, using the same terms as you used in the Opening Statement, for example: an audio-recorded interview, a video-recorded focus group, a survey questionnaire completed by the enumerator…* * *For interviews, focus groups and observations, specify how the information is recorded (audio, video, written notes)* * *For questionnaires, specify whether participant or enumerator completes the form* * *For audio or video recordings, indicate whether these will be transcribed as text, and whether the recording will be destroyed. NB: Please consider whether audio or video recording is essential to your research.* ***As far as possible you should aim to minimise the Personal Data (PII and/or PIRD) you collect.*** |  |  |
| 4. I understand that I will be compensated for my participation by [*…*] |  |  |
| *Include reasonable compensation for time or travel (if any) and how this will be disbursed* |  |  |
| 5. I understand that the study will end [*…*] |  |  |
| *Please add the anticipated timing or how the date will be determined* |  |  |
| **B: POTENTIAL RISKS OF PARTICIPATING (INCLUDING DATA PROTECTION)** |  |  |
| 6. I understand that taking part in the study involves the following risks [*…*]. I understand that these will be mitigated by [*…*] |  |  |
| * *Describe in a few words any risks associated with participating in the study,* ***other than those relating to Personal Data and the potential for re-identification****, for example: physical or mental discomfort; risks for participants in a surbordinate position to the researcher* * *Describe also what steps you will take to mitigate these risks – such as device certification, or the ability to ask for the experiment to stop at any point* |  |  |
| 7. I understand that taking part in the study also involves collecting specific personally identifiable information (PII) […] and associated personally identifiable research data (PIRD) […] with the potential risk of my identity being revealed […] |  |  |
| * *Please list which PII and/or PIRD will be collected and summarise (if) any potential risks of re-identification (eg: public/professional reputation)* |  |  |
| 8. I understand that some of this PIRD is considered as sensitive data within GDPR legislation, specifically [*see points below*] |  |  |
| *List the relevant issues: eg:*   * *religion, political views* * *Data concerning criminal activities will/may be collected and processed* * *Research has a Data Processing Impact Assessment (DPIA) in place* |  |  |
| 9. I understand that the following steps will be taken to minimise the threat of a data breach, and protect my identity in the event of such a breach […] |  |  |
| *Provide brief summaries of the mitigating measures to be taken (eg: anonymous data collection, (pseudo-) anonymisation or aggregation, secure data storage/limited access, transcription, blurring, voice modification etc)* |  |  |
| 10. I understand that personal information collected about me that can identify me, such as [*e.g. my name or where I live*], will not be shared beyond the study team. |  |  |
| 11. I understand that the (identifiable) personal data I provide will be destroyed […] |  |  |
| *Please add the anticipated timing or how the date will be determined* |  |  |
| **C: RESEARCH PUBLICATION, DISSEMINATION AND APPLICATION** |  |  |
| 12. I understand that after the research study the de-identified information I provide will be used for [*see points below*] |  |  |
| * *Please list any planned or possible outputs, e.g. reports, publications, website, video channel. This should also include any planned application (such as decision-making, policy- service- or product development. Consider any secondary use and whether knowledge sharing and benefits sharing needs to be considered, e.g. for indigenous knowledge.* * *Please be explicit if the publication of recognisable images, quotes or other PIRD are anticipated and ensure specific agreement on this* |  |  |
| 13. *If you want to use quotes in research outputs then add extra question:* I agree that my responses, views or other input can be quoted anonymously in research outputs |  |  |
| 14. *If you want to use named quotes, then add extra question:* I agree that my real name can be used for quotes in research outputs |  |  |
| 15. *If written information or other works are provided by the participants (e.g. in a reflection or other diary, or as images etc.) please check* [*https://www.tudelft.nl/library/support/copyright*](https://www.tudelft.nl/library/support/copyright) *for information on copyright, and/or contact the Copyright Team for further information at* [copyright-lib@tudelft.nl](mailto:copyright-lib@tudelft.nl) *and insert appropriate consent questions accordingly.* |  |  |
| **D: (LONGTERM) DATA STORAGE, ACCESS AND REUSE** |  |  |
| 16. I give permission for the de-identified [*specify the data*] that I provide to be archived in [*name of data repository/ies*] repository so it can be used for future research and learning. |  |  |
| 17. *If relevant please add:* I understand that access to this repository is [*open/ unrestricted/ restricted only to ……… according to the access status to be conferred*.] |  |  |
| ***If different from Explicit Consent points 8 and 9 above:***   * *Specify in which form the data to be stored will be deposited, e.g. anonymised transcripts, audio recording, survey database, etc.; and if needed repeat the statement for each form of data you plan to deposit.* * *Specify whether deposited data will be anonymised, and how. Make sure to describe this in detail in your Opening Statement* * *Specify whether use or access restrictions will apply to the data in future, e.g. exclude commercial use, apply safeguarded access, etc.; and discuss these restrictions with the repository in advance.* * *Include when the data will be deleted – or provide criteria for when and how that decision will be made* |  |  |

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| |  | | --- | | **Signatures** | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_  Name of participant [printed] Signature Date  *[Add legal representative, and/or amend text for assent where participants cannot give consent as applicable]* | | I, as legal representative, have witnessed the accurate reading of the consent form with the potential participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_  Name of witness [printed] Signature Date | | I, as researcher, have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_  Researcher name [printed] Signature Date | | Study contact details for further information: [*Name, phone number, email address*] | |

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