FOUR QUICK POINTS:

- Please do not add your Data Management Plan and/or Informed Consent Materials at the bottom of the checklist but rather submit as separate documents
- Please do not re-format the checklist template
- Note that incomplete submissions (either in terms of documentation or the information provided therein) will be returned for completion prior to any assessment
- If you have any feedback on any aspect of the HREC approval tools and/or process you can leave your comments here

ACRONYMS USED:

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCMO</td>
<td>Centrale Commissie Mensgebonden Onderzoek</td>
</tr>
<tr>
<td>DMP</td>
<td>Data Management Plan</td>
</tr>
<tr>
<td>GDPR</td>
<td>General Data Protection Regulation (2016)</td>
</tr>
<tr>
<td>HREC</td>
<td>Human Research Ethics Committee</td>
</tr>
<tr>
<td>HSE</td>
<td>Health, Safety and Environment</td>
</tr>
<tr>
<td>IC/ICF</td>
<td>Informed Consent/ Informed Consent Form</td>
</tr>
<tr>
<td>OS</td>
<td>Opening Statement</td>
</tr>
<tr>
<td>PII</td>
<td>Personally Identifiable Information (collected for administrative purposes)</td>
</tr>
<tr>
<td>PIRD</td>
<td>Personally Identifiable Research Data (research data collected from Research Subjects)</td>
</tr>
<tr>
<td>WMO</td>
<td>Wet Maatschappelijke Ondersteuning</td>
</tr>
</tbody>
</table>

SOURCE MATERIALS:

The guidance for completing the checklist (see sections A to G below) is largely extracted from and/or based on materials produced by the European Commission to guide researchers applying for Horizon Europe funding. For each issue covered you will find links to the original sources – where you can also find more detail on each topic.
I. Applicant Information

**Note 1:** You only need to include the names of the Corresponding Researcher and Responsible Researcher – we don’t need a full list of names where larger teams are involved.

II. Research Overview

**Note 2:** The easier it is for us to understand what you’re trying to do, the easier (and quicker) it will be for us to assess your application. Equally, the summary in your Participant Information and/or Informed Consent forms should also be easy for your participants to understand.

a) Please summarise your research very briefly (100-200 words)
What are you looking into, who is involved, how many participants there will be, how they will be recruited and what are they expected to do?

**Note 3:** What we’re looking for here is a very brief summary of the various components of your research that might have the potential to expose your “human subjects” to risks of different types. For example, consider what the following two scenarios suggest about the possible risks to participants:
- For the purposes of designing a new type of domestic iron, we will be surveying 1000 anonymous participants recruited through a crowd-sourcing platform which will not collect IP addresses. The survey explores what shapes of handles participants prefer. The research is funded internally and there are no research partners.
- We will be asking 10 experts from a very small specialist sector to test a prototype tool that assesses their performance in a task relevant to their professional role. The research is funded by one of the biggest employers in this sector, and their Head of Operations will also have access to the raw data.

There is no need, in this summary, to go into details of any issues that will be covered in your Risk Assessment and Mitigation Plan (see below).

b) If your application is an additional project related to an existing approved HREC submission, please provide a brief explanation including the existing relevant HREC submission number/s.

**Note 4:** In addition to providing the project’s HREC submission number, please provide a line or two which summarise in what way the studies are related and what is the same – or different – regarding the benefits of the research versus risks to participants.

c) If your application is a simple extension of, or amendment to, an existing approved HREC submission, you can simply submit an [HREC Amendment Form](#) as a submission through LabServant.

III. Risk Assessment and Mitigation Plan
Please complete the following table in full for all points to which your answer is “yes”. Bear in mind that the vast majority of projects involving human participants as Research Subjects also involve the collection of [Personally Identifiable Information (PII)](http://example.com) and/or [Personally Identifiable Research Data (PIRD)](http://example.com) which may pose potential risks to participants as detailed in [Section G: Data Processing and Privacy](#) below.

To ensure alignment between your risk assessment, data management and what you agree with your Research Subjects you can use the last two columns in the table below to refer to specific points in your Data Management Plan (DMP) and Informed Consent Form (ICF) – but this is not compulsory.
Note 5: Completing the Risk Assessment and Mitigation Plan

The HREC Risk Assessment/Mitigation Plan will prompt you to consider potential risks and the appropriate legal, professional and ethical actions that can help to mitigate those risks. The guidance below provides examples of some of the most frequently arising risks and mitigating steps we see in HREC applications. For each issue (A to G) you can also find the source materials behind this guidance, and some specific examples of particular kinds of risk.

It’s worth noting that you’re much more likely to need to resubmit your application if you neglect to identify potential risks, than if you identify a potential risk and demonstrate how you will mitigate it. If necessary, the HREC will always work with you and colleagues in the Privacy Team and Data Management Services to see how, if at all possible, your research can be conducted.

To complete the risk assessment:
1) Go through the whole checklist and select “yes” or “no” as appropriate for each issue
2) Complete the Risk Assessment and Mitigation Plan columns for each issue for which you’ve selected “yes”
3) Make sure you include all the risks and mitigating steps you’ll take, but keep your responses brief and clear
4) You can find more information on each kind of issue in sections A to G below:
   (You can scroll downwards to browse, or else click on these links to go to the appropriate guidance below)
   - A: Partners and collaboration
   - B: Location
   - C: Participants
   - D: Recruiting participants
   - E: Subject matter
   - F: Research methods
   - G: Data processing and privacy

You can also find out more about the roles of Informed Consent and Data Management in HREC applications.

H: More on Informed Consent and Data Management

5) Where you explicitly refer to your Data Management Plan or Informed Consent to explain the mitigating steps you will take, please make sure that you clarify which specific (numbered) point/s in which document/s you are referring to.

6) In all applications it’s important that the risks and mitigating steps you identify in the checklist are consistent with the agreements you make with your participants. It’s equally important that this agreement is in line with how you will manage your data in practice. You can, if you wish to double-check, use the DMP (Data Management Plan) and IC (Informed Consent) columns to cross-check your application by referring to specific (numbered) points in your accompanying documents.
### A: Partners and collaboration – Issues 1-3

<table>
<thead>
<tr>
<th>RISK ASSESSMENT</th>
<th>MITIGATION PLAN</th>
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<tbody>
<tr>
<td>• Different kinds of partnerships can expose research participants (Research Subjects) to different kinds of risks. Consider, for example, an internship provider who wants to survey their employees; a research collaborator with whom you want to share data outside of the EU; a third party supplier who has agreed their own terms and conditions with their platform users; an external research partner who is funding or part-funding the research etc.</td>
<td>• Be clear that specific responsibilities – particularly regarding ethical approval, legal compliance, liability &amp; insurance, or quality control – are clearly agreed. Be clear also how these agreements will be properly actioned and monitored.</td>
</tr>
<tr>
<td>• Be clear about who you are partnering with. What is their role or interest in the research? And are there any relevant issues such as their relationship with your Research Subjects and/or what raw data they might access?</td>
<td>• Be clear on who is responsible for key steps such deleting any special or sensitive data before it is to be shared.</td>
</tr>
<tr>
<td>• Be clear that specific responsibilities – particularly regarding ethical approval, legal compliance, liability &amp; insurance, or quality control – are clearly agreed. Be clear also how these agreements will be properly actioned and monitored.</td>
<td>• Make sure you have clear agreements on issues such as: data ownership, (international) data transfer, potential use (or misuse) of data for commercial or other (eg: military) purposes.</td>
</tr>
<tr>
<td>• Addressing the points above, ensure you have the appropriate contractual arrangements in place, including project consortium, joint controller and/or internship agreements.</td>
<td>• When using datasets from collaborators or third parties, demonstrate how you’ll check the data’s legal and ethical pedigree. For example, this could be through setting up explicit Data Processing or Data Transfer Agreements, or by referring to existing ethical approvals and/or published Informed Consent processes.</td>
</tr>
</tbody>
</table>

### CONTACTS:
- Faculty Contract Manager
- TU Delft Policy Advisor on Medical (Devices) Research
- TU Delft Privacy Team [privacy-tud@tudelft.nl](mailto:privacy-tud@tudelft.nl)
- TU Delft Innovation and Impact Center

### EXAMPLES:
- **Third-party datasets**

[Back to menu](#)
## RISK ASSESSMENT

- Research in different countries will bring different legislative requirements – including, for example, the need for research permits in particular areas or involving particular participants. Similarly the age at which one can legally give informed consent will differ from place to place.

- Some research contexts and geographical areas can pose specific risks to the safety of both participants and researchers, for example:
  - Countries or regions where economic, political, environmental or health conditions pose particular risks to research “subjects” and/or research staff
  - Research in troubled neighbourhoods in any country

- Consider the safety of participants and staff, especially if you plan to involve marginalized, vulnerable or hard-to-reach groups, and/or address sensitive topics, such as political views, sexual orientation, religion, trade union membership.

- TU Delft policy is to observe advice from the Dutch Ministry for Foreign Affairs on the latest travel advice. Research requiring travelling to a red or an orange area will require approval from the Dean of your faculty.

- Consider the ethical acceptability of your research with respect to the customs, standards and practices at your study site.

- Bear in mind that obtaining informed consent does not in itself guarantee ethical research. In some research settings, the very act of obtaining informed consent, while aiming to safeguard participants' rights and well-being, may in fact place them at risk of harm in their social context.

## MITIGATION PLAN

- Demonstrate that you have consulted, notified and gained approval where required, from the relevant bodies in the country where you are to conduct your research.

- Consider very carefully what you are asking from whom, and, in cases where potential risks to participants may be high, make sure that you have expert advice on all aspects surrounding data collection, storage, transport and access.

- Ensure you have the right (local) expertise on your project team and/or advisory group to consider the relevant risks and address the local legal and ethical needs, which might include:
  - Applying for formal ethics approval locally
  - Applying for local authorisation

- If your research is to take place in resource-poor location/s, make sure that it is responsive to the needs of the country where it is carried out (e.g. the study has value for the welfare of the intended participants, their community, and/or their country). This issue is of critical relevance for emerging and developing countries and could include:
  - Showing how the results of your research can be applied in low and/or lower middle-income countries
  - Showing how your research activities will build local capacities and/or other benefits of the research will be shared.

- Any country can have more dangerous locations depending on the object of your study. If there are serious risks, make sure these are cleared by your Dean and that you have consulted the Integrated Safety team where appropriate.

- Where your research does involve significant security risks, provide a clear risk analysis and mitigation strategy.

## CONTACTS:

- Integrated Safety - Safety, Insurance and Vaccinations - TU-IV@tudelft.nl
- TU Delft Privacy Team privacy-tud@tudelft.nl
- Appropriate subject/local experts

## SOURCES:

- Ethics in Social Science and Humanities (European Commission DGR&I 2021)
- Research Ethics in Ethnography/Anthropology (European Commission DGR&I 2021)
- Refugees, asylum seekers and migrants (European Commission DGR&I 2021)
- Global Code of Conduct for Research in Resource Poor Settings (globalcodeofconduct.org)
- Identifying serious and complex ethics issues in EU-funded research (European Commission DGR&I 2021)

## EXAMPLES:

- Global Witness records the highest number of land and environmental activists murdered in one year – with the link to accelerating climate change of increasing concern
### RISK ASSESSMENT

- Certain kinds of participants may be exposed to particular kinds of risks. For example:
  - because they may be vulnerable – such as children or adults who cannot (legally) give IC;
  - because they may be vulnerable under specific circumstances or in a specific context (such as refugees of victims of violence or abuse);
  - because there is a higher likelihood of reidentification; or
  - because they are in a subordinate relationship with (one or more of) the researchers (such as students, children or employees).

- The key thing to consider here is what specific risks might arise for your participants as a consequence of participating in your research. For example, is there a risk of stigmatization, loss of reputation or livelihood, increased risk of investigation by authorities or potential danger of physical or mental harm.

- Consider also the possible longer-term impact of participation, not just at the moment of giving consent or the duration of the study. For example, a participant’s political observations may pose a different level of risk under changed circumstances (such as a new governing regime).

- Make clear why any participants who may be vulnerable to risk are important to your research

### MITIGATION PLAN

- Ensure that you provide your participants (and/or the gatekeepers who legally or customarily control access to them) with sufficient information to make an informed decision on whether or not to participate

- Note that consent cannot be given by power of attorney, but that parents/legal guardians give consent for PIRD use of a child based on their legal authority

- Your Opening Statement/Participant Information and Informed Consent form should include clear information on your research goals, what you expect from participants, what risks could arise both during and after the research, and what steps you will take to limit those risks

- Your Data Management Plan can be used to record data processing decisions and as such serve to demonstrate GDPR compliance.

- It’s important to ensure that you have the right expertise in your group, and that you fulfil any specific legal or ethical requirements towards your participants given your specific physical research location and/or disciplinary field. For example, take care to provide details of both what informed consent will be obtained and how this will be done. Be clear also on whether there are specific types of certification required to work with (gatekeepers to) your target participant group

### CONTACTS:

- TU Delft Privacy Team privacy-tud@tudelft.nl
- TU Delft Policy Advisor on Medical (Devices) Research
- Appropriate subject/local experts

### SOURCES:

- Ethics in Social Science and Humanities (European Commission DGR&I 2021)
- Research Ethics in Ethnography/Anthropology (European Commission DGR&I 2021)
- Refugees, asylum seekers and migrants (European Commission DGR&I 2021)
- Identifying serious and complex ethics issues in EU-funded research (European Commission DGR&I 2021)

### EXAMPLES:

- Anonymisation and Pseudoanonymisation UCL (UK)
- Seeking consent for research with indigenous communities: a systematic review (Fitzpatrick et al 2016)
- On our terms: obtaining Aboriginal community consent for social research: A literature review and case study (Tony Dreise 2018)
### D: Recruiting participants – Issues 11-14

#### RISK ASSESSMENT

- Different recruitment methods also bring the possibility of different kinds of risk, and may need careful consideration and explanation. Specific points can include:
  - Compensating participants
  - Recontacting lists of previous participants or using other (e.g.: conference participant) lists
  - Participants who are TU Delft Students or employees, or employees in a partner company (including internship providers)
- Consider that the (manner of) selecting participants may lead to collecting unintended personal data and/or possible reidentification
- Make sure that you clarify how participants in potentially subordinate relationships (e.g.: students and employees) are being recruited – and that they are not required or somehow induced to participate
- Also be clear on your criteria for inclusion/exclusion based on, for example, the outcomes of an initial questionnaire.

#### MITIGATION PLAN

- It is essential to include in your Informed Consent both that participation is voluntary and that participants can withdraw at any point without adverse consequence.
- In the case that participants are TU Delft students (especially if they are in a subordinate position to the researcher), state clearly in the Informed Consent that (lack of) participation does not influence grading. Ideally, ensure that the researchers are not in a position of grading/evaluating the students and/or do not know who has or has not participated in the study.
- In general be sure to reflect on any potential risk of stigmatisation resulting from how you select and communicate with, or about, your participants, and be clear in your application on how you will avoid this

#### CONTACTS:

- TU Delft Privacy Team privacy-tud@tudelft.nl
- TU Delft Policy Advisor on Medical (Devices) Research
- Appropriate subject/local experts

#### SOURCES:

- Ethics in Social Science and Humanities (European Commission DGR&I 2021)
- Research Ethics in Ethnography/Anthropology (European Commission DGR&I 2021)
- Refugees, asylum seekers and migrants (European Commission DGR&I 2021)
- Identifying serious and complex ethics issues in EU-funded research (European Commission DGR&I 2021)
<table>
<thead>
<tr>
<th>RISK ASSESSMENT</th>
<th>MITIGATION PLAN</th>
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<tbody>
<tr>
<td>• Failure to protect personal data (PII and/or PIRD) against loss or misuse can have devastating consequences for the data subjects, such as loss of employment, exposure to physical or online abuse, refusal of insurance cover, or loss of reputation</td>
<td>• Ensure that your research is GDPR compliant by consulting your Faculty Data Steward and/or TU Delft Privacy Team</td>
</tr>
<tr>
<td>• It may also have serious legal, reputational and financial consequences for the researcher (i.e.: the data controller and/or processor)</td>
<td>• Ensure that your research is HSE compliant by consulting your Faculty HSE advisor</td>
</tr>
<tr>
<td>• Equally, failure to address health and safety hazards, and subjecting participants to such hazards, may result in civic liability</td>
<td>• Consider any unintended/unexpected/incidental findings you might discover by chance and explain how you intend to deal with such findings.</td>
</tr>
<tr>
<td>• Research related to medical questions/health may require special attention. See also the website of the CCMO before contacting the HREC</td>
<td>• Where your own teaching experience is also the subject matter of your research, make sure that you deal adequately with the fact that your participants may potentially be considered as in a subordinate relationship, and that processing of Personal Data for that research may still require Informed Consent. It’s also important to provide a meaningful possibility for your students not to participate.</td>
</tr>
<tr>
<td>• Incidental/Unexpected findings - may include indications of, for example, criminal activity, human trafficking, abuse, domestic violence or bullying that may require the researcher to take some form of action.</td>
<td>• If appropriate, consider conducting a Human Rights Impact Assessment and/or involving human rights experts in the research (see Ethics in Social Science and Humanities – misuse of research)</td>
</tr>
</tbody>
</table>

**CONTACTS:**
- TU Delft Privacy Team privacy-tud@tudelft.nl
- TU Delft Policy Advisor on Medical (Devices) Research
- Appropriate subject/local experts
- TU Delft Legal Services
- Faculty HSE advisor

**SOURCES:**
- CCMO website
- Ethics and Data Protection (European Commission 2021)
- Ethics in Social Science and Humanities (European Commission 2021)
- Identifying serious and complex ethics issues in EU-funded research (European Commission DGR&I 2021)
- Guidance note on potential misuse of research results
- Guidance note on research focusing exclusively on civil applications

For medical-related research see:
- Uw onderzoek: WMO-plichtig of niet?
- Wet medisch-wetenschappelijk onderzoek met mensen
- Clinical investigations with medical devices
- EU Medical Device Regulation (EU no 2017/745, MDR)
RISK ASSESSMENT

- Failure to flag health and safety risks, and/or to explain how these risks will be mitigated, are two of the most common things missing from HREC applications. Where you seek Informed Consent from your participants it is important that all such risks and steps are clear to your participants in your Informed Consent materials.

- In general, all scientists must consider whether their research methods tally with their objectives and whether the expected benefits outweigh the potential risks.

- Research methods that need particular attention from the perspective of research ethics include:
  - covert research
  - use of deception in research
  - internet research and social media data in research

- Where informed consent is sought, it must be made clear to prospective research participants that they are free to decide whether or not to take part in the research, and whether any data collected from and about them is included in analysis.

- Where informed consent is not an option – e.g.: research is either covert, involves deception or uses social media data – steps to mitigate risks to participants remain important.

- Surveys, interviews and expert consultation may expose participants to different kinds of risks depending on who is participating, what kinds of questions they are answering and how the information they give you will be used.

- Note that expert consultation – where responses do not form part of your research dataset – does not require HREC approval, but may still require measures to comply with GDPR.

MITIGATION PLAN

- Research must comply with ethical principles and relevant European, national and international legislation, including the EU’s Charter of Fundamental Rights and the European Convention on Human Rights and its Supplementary Protocols, specifically as it relates to:
  - Medical and/or clinical trials
  - Medical Devices Research/In vitro Devices Research
  - Psychological Research
  - Research where there is the potential for injury, infection or stress to participants
  - Research with potential legal, financial, reputational or other consequences for participants

- Informed consent will almost always be required for participation in the project – regardless of whether PII (Personally Identifiable Information) and/or PIRD (Personally Identifiable Research Data) are to be collected.

- Where your own teaching is part of the methodology of your research, make sure that you deal adequately with the fact that your students could be either your participants (and potentially in a subordinate relationship) and/or your research collaborators.

CONTACTS:

- Faculty/Dean
- TU Delft Privacy Team privacy-tud@tudelft.nl
- Faculty HSE advisor
- Faculty Data Steward
- TU Delft Policy Advisor on Medical (Devices) Research
- Appropriate subject/local experts

SOURCES:

- Ethics and Data Protection (European Commission DGR&I 2021)
- Ethics in Social Science and Humanities (European Commission DGR&I 2021)
- Identifying serious and complex ethics issues in EU-funded research (European Commission DGR&I 2021)
### RISK ASSESSMENT

- **NOTE:** For practical purposes the HREC distinguishes between two distinct types of personal data:
  - Personally Identifiable Information (PII) (used for administrative purposes); and
  - Personally Identifiable Research Data (PIRD) (research data collected from Research Subjects)

- Where you are collecting, storing, analyzing, accessing, publishing or re-using PIRD it is imperative to identify and substantiate the legal ground for your data processing. In the context of scientific research this is often, but not always, through informed consent.

- A project which involves any data about identifiable persons, even if they are not directly participating in the research, most likely involves “processing” of “personal data” and must comply with EU and national law. Only data that have been fully and irreversibly anonymised may be exempt from these requirements. However, where multiple anonymous datasets (including public datasets) are to be combined, the possibilities for unintended re-identification should be carefully considered.

- Bear in mind, also, that datasets which are legally compliant, may not necessarily be ethically acceptable

- Failure to protect personal data against loss or misuse can result in enforcement action by regulators.

- Unauthorised collection and/or (mis)use of personal data, examples of unethical research practices have involved the organisations (data controller and/or processor). Recent consequences for researchers and research performing organisations (including professional reputation), increasing the risk of adverse reputational effects (for the researcher/s and/or the organization); and

- It is critically important to demonstrate clear and informed thinking on the potential risks to research participants as a result of re-identification. Such risks might include exposing participants to threats and intimidation, damaging reputation (including professional reputation), increasing the risk of investigation by authorities, loss of livelihood or being refused insurance, financial or other services.

- A Research Subject may complain to the Dutch Supervisory Authority concerning a data breach of personal data, with the possibility of a penalty being imposed. A civil action may be pursued by the data subject for damages incurred. While such actions are not common, both are possible.

- Failure either to obtain appropriate consent, or to act according to the consent terms agreed, may give rise to adverse reputational effects (for the researcher/s and/or the Research Performing Organisation).

### MITIGATION PLAN

**Researcher responsibilities**

- If the legal ground for data processing is informed / explicit consent you must document the consent, ensure that a participant can revoke consent and demonstrate that revocation can be executed in practice (including data deletion).

- The GDPR emphasizes the need of data minimization: processing as little personal data as possible. Aim to collected as little PII/PIRD as possible. For example, don’t use video recordings if audio recordings suffice. Either way, justify why gathering your data is necessary.

- Note that in all cases where there are special categories of PIRD, such as health information or political views, this requires the data subjects’ explicit consent.

- Make use of, and reference to, professional standards, best practices and (funding) organisations’ requirements.

- Use tools and platforms that are considered secure from an IT perspective. Consult your Data Steward regarding the accepted tooling list or when considering untested or insecure tools and platforms.

- Ask explicitly for consent if personal data will be published as open data.

- Each personal data process needs to be entered in the processing register. The person responsible for the processing is also responsible for keeping the register entry up to date.

**Working with partners**

- Describe and document the entire data processing activity and clearly allocate responsibilities for GDPR compliance.

- Include a provision on personal data sharing between partners in the collaboration or consortium agreement (transfer of data to research partners requires a contractual basis).

- Sign a processor agreement with the appropriate entities for any tool, platform, SaaS-solution used when processing personal data.

- Ensure that any agreements in data sharing agreements, data transfer agreements and processor agreements are in line with the project agreement signed with the funding organization.

**Anonymisation, pseudo-anonymisation, minimization and identification**

- Anonymisation is the process of removing personal identifiers (both direct and indirect) that may lead to an individual being identified.

- Pseudonymisation is defined within the GDPR as “the processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information, as long as such additional information is kept separately and subject to technical and organizational measures to ensure non-attribution to an identified or identifiable individual.”

- Importantly, while pseudonymisation can provide individual data subjects with a degree of protection and anonymity, pseudonymised data still fall within the scope of personal data because it is possible to re-identify the data subject.
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<tr>
<th>CONTACTS:</th>
<th>SOURCES: General (EU) Guidance – Data Protection</th>
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<tr>
<td>• Faculty TU Delft Privacy Team</td>
<td>• Ethics and Data Protection (European Commission</td>
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<tr>
<td><a href="mailto:privacy-tud@tudelft.nl">privacy-tud@tudelft.nl</a></td>
<td>DGR&amp;I 2021)</td>
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<tr>
<td>• Faculty Data Steward</td>
<td>• Ethics Guidelines for Trustworthy AI (EC – Independent</td>
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<td></td>
<td>High-Level Expert Group on Artificial Intelligence 2019)</td>
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<td>• Ethics by design/operational use for Artificial Intelligence</td>
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<td>• Identifying serious and complex ethics issues in EU-funded research (European Commission DGR&amp;I 2021)</td>
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<td>Anonymisation and Pseudo-anonymisation</td>
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<tr>
<td>• UCL (UK) Data Protection Guidance</td>
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<td>EXAMPLES:</td>
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<tr>
<td>Legal but not ethical</td>
<td>• Can unethically produced data be used ethically? RW Halpin (2010) PubMed</td>
</tr>
<tr>
<td>Risks associated with identification can be life-changing</td>
<td>• Global Witness records the highest number of land and environmental activists murdered in one year – with the link to accelerating climate change of increasing concern</td>
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<td></td>
<td>• Spat at, abused, attacked: healthcare staff face rising violence during Covid</td>
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</table>
H: More on Informed Consent and Data Management

Your research involves human participants as Research Subjects if you are recruiting them or actively involving or influencing, manipulating or directing them in any way in your research activities. This means you must seek informed consent and agree/implement appropriate safeguards regardless of whether you are collecting any PIRD.

Where you are also collecting PIRD, and using Informed Consent as the legal basis for your research, you need to also make sure that your IC materials are clear on any related risks and the mitigating measures you will take – including through responsible data management.

| Informed Consent Process | The informed consent process seeks to gain your participants’ (Research Subjects’) consent to participate in your research. In order to allow potential participants to make proper informed choices, your informed consent materials need to include:
|                       | o Any physical, emotional or privacy-related risks your research could potentially expose them to. These should include risks arising both directly during the research and subsequently due either to the repercussions of your research findings and/or in the event of participants’ re-identification as the consequence of any kind of data breach.
|                       | o The mitigating measures you will take to minimize these risks
|                       | o Any realistic potential benefits of the research (and to whom)
|                       | o Assurances that their participation is voluntary, that they can stop at any point, and that their data can be deleted if they request this

| Informed Consent Materials | Depending on your Informed Consent process your materials could comprise Participant Information + Informed Consent Form OR Opening Statement:
|                           | o Participant Information – describes the goals of the research and what is expected of the participant
|                           | o Informed Consent Form – itemizes exactly what participants are agreeing to in terms of risks and their mitigation. These points need to include your commitments to data management, including publication and re-use
|                           | o Opening Statement – summarizes the relevant points found in Participation and Informed Consent, and generally allows participants to consent by clicking through to an (anonymous) online survey. It is unlikely, in such cases, that itemized Informed Consent points can be used, since participants must generally either agree or not agree to the full terms.

| Data Management Plan | Your Data Management Plan allows you to comply with GDPR by documenting how you will manage your participants’ personal data. It’s important that your DMP is consistent with your HREC checklist and Informed Consent materials. Equally, it is vital that your plan is executed in practice.

RESOURCES

**SOURCES:**
- Ethics in Social Science and Humanities (European Commission DGR&I 2021)
- Ethics and Data Protection (European Commission DGR&I 2021)
- Ethics Guidelines for Trustworthy AI (EC - Independent High-Level Expert Group on Artificial Intelligence 2019)
- Ethics by design/operational use for Artificial Intelligence

**EXAMPLES:**
- Seeking consent for research with indigenous communities: a systematic review (Fitzpatrick et al 2016)
- On our terms: obtaining Aboriginal community consent for social research: A literature review and case study (Tony Dreise 2018)
- Informed Consent in Social Sciences Research: Ethical Challenges (Ferreira and Serpa 2018)
- A Modern History of Informed Consent and the Role of Key Information (Bazzano et al 2021)
- Informed consent in anthropological research: we are not exempt (Fluehr-Lobban 1994)

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