Risk-Planning Tool

Managing Risk in Human Research

Produced by the TU Delft Integrity Office

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Managing Risk in Human Research

MINIMISE RISKS

- Build risk management into your research planning
- Organise a risk-planning session
- Role play different stakeholders, including funders and participants, in the session

COMMUNICATE RISKS

- Check that your Informed Consent and Data Management Plan are aligned
- Check that any risks and mitigating measures are clear in your Informed Consent

MANAGE RISKS

- Execute your Informed Consent as a contract between you and your participants

Click to Begin

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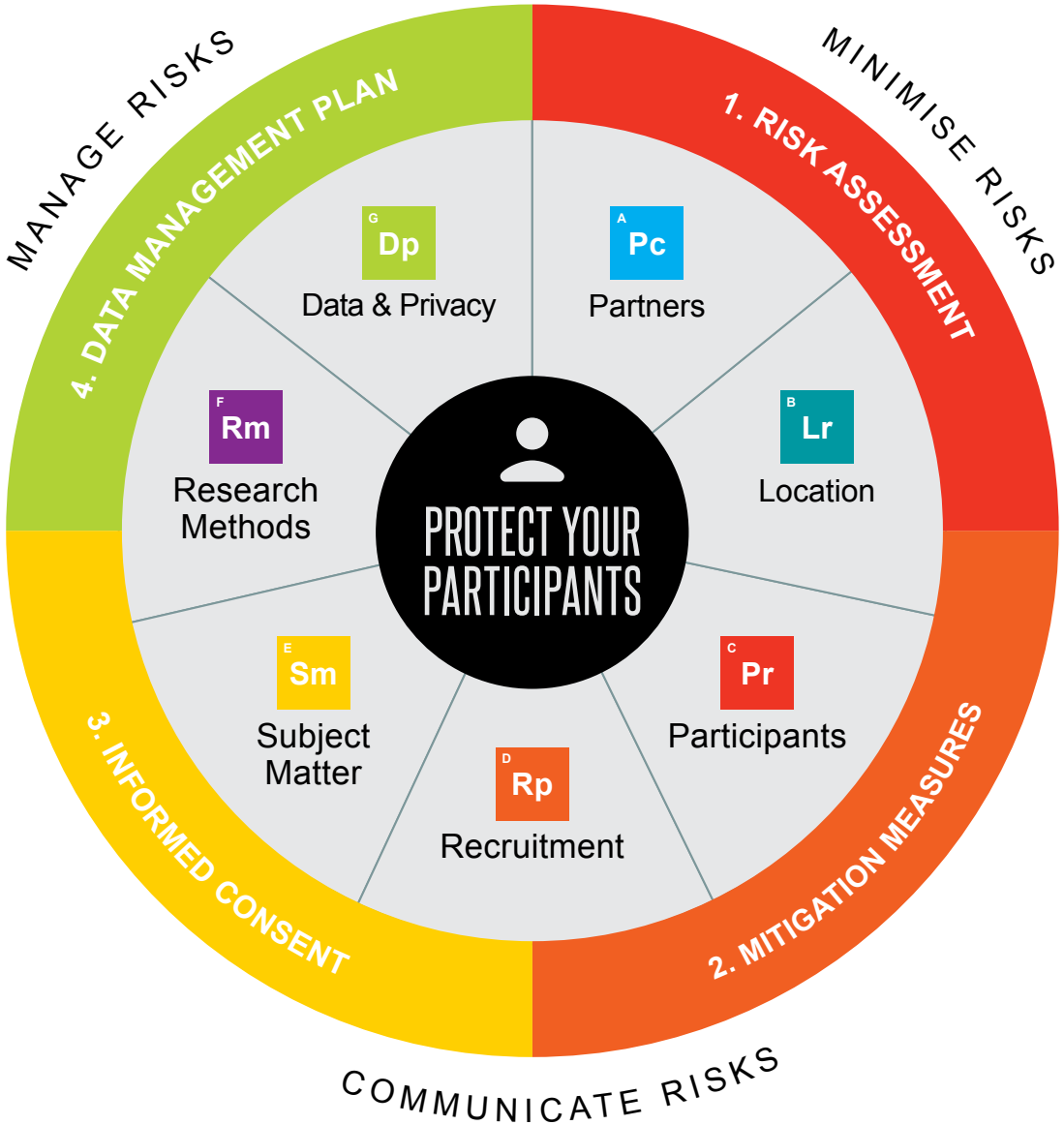
Research Design 1:

Planning for risk

Click on any **Risk Factor** for help with your risk planning session



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Research Design 2:

Risk-planning session

0A **Pc**

Partners & collaboration

Is there anything about my funder, internship provider or research partner that participants should be aware of? For example, might there be repercussions if my partners see the raw data?

0B **Lr**

Location risks

Does the location of my research (whether it's physical or online) bring any potential risks? For example might my research put participants at risk from a non-democratic regime? Or does it influence what might be considered "reasonable compensation"?

0C **Pr**

Participant risks

Are there any possible risks specific to my participants? For example, are they legally able to provide informed consent? Or might my research run the risk of triggering an investigation of them by an authority?

0D **Rp**

Recruiting participants

Is it OK for me to use that old conference attendance list to recruit participants? Or is there some legal or customary entity I have to go through to contact my participants?

0E **Sm**

Subject matter

Does my research need Medical Ethics approval? Could the research potentially put my participants in physical or emotional danger?

0F **Rm**

Research methods

Might my participants object to something that I'm doing? For example am I observing them without them knowing – either physically or online? Or what about that dataset I want to use – did the participants agree for it to be reused?

0G **Dp**

Data and Privacy

What kinds of problems could participants face if their identity was somehow linked to the data they are providing? Am I potentially putting them in danger – even after the research has been published?

MINIMISE RISKS	Can I do this research while collecting less personally identifiable research data?
Which colleagues should I discuss these issues with? Do I have the required expertise in my research team?	Am I sure that my participants fully understand what they will do, what the potential risks are and how their physical, emotional and reputational security will be ensured?
What long-term effects can the research and its outcomes have on the participants and their communities?	Do I have the right insurances, licences and safety certification – the right or expertise – in place?
What difference is there between what is legal and what is ethical?	**MANAGE RISKS**
Putting myself in the participant's shoes: is it possible a lay person may experience participating differently than I am anticipating?	How do I ensure that I legally and responsibly execute the agreement I've made with my participants in the Informed Consent?
Are there any unnecessary risks in the study design?	What is the plan if I or someone else moves to another organisation? What happens if there is a data breach?
Can I do this research with a less vulnerable group of participants?	When and how do I evaluate the decisions I made?

Click on any Risk Factor for a list of prompting questions

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0A Partners & Collaboration	0B Location	0C Participants	0D Recruiting Participants	0E Subject Matter		0F Research Methods	0G Data and Privacy
1. Will the research be carried out in collaboration with additional organisational partners (including internship providers)?	**4.** Will the research take place in a country or countries, other than the Netherlands, within the EU?	**7.** Will the study involve participants, such as children or people living in nursing homes, who **may** be vulnerable and (legally) unable to give informed consent?	**11.** Will your participants be recruited through specific network/s and particularly through specialist or self-help groups?	**15.** Will your research involve clinical trials, medical devices, invasive sampling or medical imaging?	**20.** Will the study involve disclosing commercially or professionally sensitive, or confidential information?	**24.** Will it be necessary for participants to take part in the study without their knowledge and consent at the time?	**30.** Will the research involve collecting any directly identifiable personal information (e.g. name or email address) that will be used for administrative purposes only?
2. Is this research dependent on (non-public) data provided by, or copied from, a third party?	**5.** Will the research take place in a country or countries outside the EU?	**8.** Will the study involve participants, such as sex workers or dissidents, who **may** be vulnerable under specific circumstances?	**12.** Will the participants be recruited or accessed by a gatekeeper – such as an adult professional working with children or a community leader who has this customary role?	**16.** Will drugs, placebos, or other substances (e.g. drinks, foods, or dietary supplements) be administered to the study participants?	**21.** Has your study been identified by the TU Delft Privacy Team as requiring a Data Processing Impact Assessment (DPIA)?	**25.** Will the study involve actively deceiving the participants?	**31.** Will the research involve collecting any directly or indirectly identifiable Personal Research Data (e.g. video or audio recordings, IP address, gender, age)?
3. Has this research been approved by another ethics committee (including Medical Ethics Committees)?	**6.** Will the research take place in a place/ region or of higher risk – e.g. dangerous locations (in any country) or regions with non-democratic regimes?	**9.** Are the participants in a dependent or subordinate position to any of the investigators (such as own children, own students or employees)?	**13.** Will you be recruiting your participants through a crowd-sourcing service and/or involve a third party in data-gathering service (e.g. via a survey platform)?	**17.** Will blood or tissue samples be obtained from participants?	**22.** Does your research investigate causes or areas of conflict?	**26.** Are either pain (more than mild discomfort), or possible accidents likely to result from the study?	**32.** Will this research involve collecting data from the internet, social media and/ or publicly available datasets?
		10. Is there, for any reason, a high possibility of re-identification for your participants?	**14.** Will you be offering any financial, or other, remuneration to participants, and might this induce or bias participation?	**18.** Does the study risk causing psychological stress or anxiety beyond that normally encountered by the participants research?	**23.** Does your research involve observing illegal activities or data processed or provided by those authorities concerned with criminal offences?	**27.** Will the experiment involve the use of devices that are not 'CE' certified?	**33.** Will your research findings be published in one or more forms in the public domain, as e.g. Masters thesis, journal publication, conference presentation or wider public dissemination?
				19. Will the study involve discussing personal sensitive data which could put participants at increased legal, financial, reputational, security or other risk?	**29.** Will your research involve either data-gathering and/or data-merging techniques which might lead to re-identification and/ or artificial intelligence where, e.g. biased datasets could lead to biased outcomes?	**28.** Will your research involve face-to-face encounters with your participants and if so how will you assess and address Covid considerations?	**34.** Will your research data be archived for re-use and/or teaching in an open, private or semi-open archive?

Research Design 3:

Prompting Questions

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