

# Project and research related risks

In projects with user involvement, it is crucial that the project management and staff carefully consider ethical issues that may arise. We suggest preventive solutions and list suggestions for the case that the risk does occur and needs to be solved.

The risks are assessed with the help of a matrix with two four-graded scales. The vertical scale assesses how likely it is that the risk occurs. The horizontal scale tells us how serious the impact is, if it does occur. The matrix then gives us a score for each combination. Those scores can be labeled in five steps from very low to very high.

		Impact			
		How severe would the impact be if risk event occurred?			
		1 Insignificant	2 Minor	3 Significant	4 Major
Likelihood	4 Likely	Medium 4	High 8	Very high 12	Very high 16
What is the chance of the risk occurring?	3 Moderate	Low 3	Medium 6	High 9	Very high 12
	2 Unlikely	Very low 2	Low 4	Medium 6	High 8
	1 Rare	Very low 1	Very low 2	Low 3	Medium 4

## Recruitment and information to participants

Risks	Likelihood	Impact	Risk score	Proposed prevention	Proposed solution
Information on pilot procedure is not clear to participants	2	1	Very low 2	Strive to be as clear as possible.	Give more time and try to explain in another way. Use pictures, videos and demonstrate. Suggest to meet again, understanding may also come over time.
Participant expects different outcomes from pilot procedure	3	1	Low 3	Be clear from the start about the possibilities with participation	Inform about the possibility to withdraw and give the person a opportunity to come back.
Participants are not sufficiently made aware of how services function or their weaknesses	1	2	Very low 2	Be sure to inform clearly about limitations	Explain that this is a test situation. Make sure to tell them that it is not their fault and that their input is very important for the project
Participants are not sufficiently informed of the ombudsman or other contact persons and their role	2	3	Medium 6	Make this a task in the routine presentation for participants	If researchers observe that the test person not seems to be comfortable, explain about the ombudsman and give contact information
Recruitment process excludes certain users	1	2	Very low 2	Make efforts to have various ages, disabilities, sexes and ethnicities represented	Complete with more test persons if needed.
Recruitment process did not allow room for participant to say no	2	3	Medium 6	Make sure to ask explicitly and give time to think about it	Inform about the possibility to withdraw or adjust the participation to tasks suitable

## Testing with participants

Risks	Likelihood	Impact	Risk score	Proposed prevention	Proposed solution
Informed consent is not understood by participant	2	4	High 8	Make sure that the consent forms are accessible. If needed, use pictorial support and explain orally.	Make sure that the consent is thoroughly explained in a way that the participant can understand
Participants cannot use the systems due to lack of suitable tools	1	3	Low 3	Make sure to know in advance any needs for adaptations or access and adapt the test situation	If this occur during a test session, try to solve the situation and if not possible, offer time for a new test day.
Participants' opinions are not taken into consideration during testing	1	4	Medium 4	Make sure all the researchers know it is important to listen to the test persons' view	Have necessary equipment to document all information
Materials are not presented in an accessible way (e.g. with pictures, easy text)	2	3	Medium 6	Researchers prepare materials beforehand in accessible formats	If this occurs during a test session, try to solve the situation otherwise, offer time for a new test day and prepare suitable materials
Participants' views and validations are not taken into account in the software development process	2	2	Low 4	Researchers are responsible for conveying all opinions and developers to do their best to incorporate them	Developers have to update the tool with functions needed
Peer researchers don't feel equal to the rest of the research team	2	3	Medium 6	Researchers must treat and respect the peer researchers in accordance with IPAR-UCD	Try to find out the problem and how the peer researchers want to be treated. Inform about the ombudsman.
The regulation regarding compensation for participation is not followed	1	1	Very low 2	Researchers are careful to inform about the conditions for participation before they consent	

## Participants' comfort

Risks	Likelihood	Impact	Risk score	Proposed prevention	Proposed solution
Participants are stressed or frustrated in the test situation	2	3	Medium 6	Researchers are well prepared before the test situation and have considered options to try if something doesn't go as planned	Researchers adapt the test situation, e.g. take a pause or try a new task
Participants don't feel valued	1	4	Medium 4	Researchers are well prepared before the test situation and have considered optional ways of posing questions and adapting to the participant	Researchers are attentive to the participants' opinions and mood and are prepared to change the way they interact with the participant
Testing environment cannot be suited to participants' needs	1	2	Very low 2	Researchers responsible for testing are flexible to changes	If this occurs during a test session, try to solve the situation and if not possible, offer time for a new test day and prepare suitable materials
Testing situation intrudes too much on the participants' lives	1	1	Very low 1	Participants must be informed of their rights to revoke their consent	Participants must be informed of their rights to revoke their consent
Participants are not allowed to leave a test situation	1	2	Very low 2	All researchers must be informed about and aware about the participants' rights	Researchers must make sure that no one pressures participants

## Privacy and data protection

Risks	Likelihood	Impact	Risk score	Proposed prevention	Proposed solution
Unnecessary data is collected from participants	2	2	Low 4	Researchers must think through what data is absolutely necessary	Researchers have to delete unnecessary data and if needed contact a Data Protection Officer
Participant data is kept too long	2	2	Low 4	Researchers are responsible for keeping data stored securely in accordance with regulations	
Participant data is not stored safely	1	4	Medium 4		
Unauthorized staff has access to participant data	2	4	High 8		Take necessary steps to make it right and contact a Data Protection officer in your organization
Participant data is not deleted when requested	1	4	Medium 4	All participant data needs to be stored so that it is easy to delete participant data on request	Researchers must comply with such requests immediately
Data is not given to participant when requested	1	4	Medium 4	A designated person must be responsible for dealing with user requests	
Data is collected without permission or consent	1	4	Medium 4	Researchers must make sure that no participant is photographed or filmed without consent	Researchers have to delete this data or collect a consent from the participant and if needed contact a Data Protection Officer
Data is published without consent	1	4	Medium 4	Researchers must make sure that all data that is published has consent	
Sensitive data is collected	1	4	Medium 4	Researchers must make sure that this will not be collected in accordance with regulations, or make sure to have an explicit consent	Researchers have to delete unnecessary data, if needed contact a Data Protection Officer

## Stability

Risks	Likelihood	Impact	Risk score	Proposed prevention	Proposed solution
Systems are not tested sufficiently before released to the participants	2	3	Medium 6	Developers must make sure the systems are ready for testing and researchers must be prepared and know the system	If this occurs during a test session, try to solve the situation and if not possible, offer time for a new test day and give feedback to developers
Insufficient access to technical support during testing sessions	2	2	Low 4	Developers must be available for questions when the testings are underway	

## Accessibility

Risks	Likelihood	Impact	Risk score	Proposed prevention	Proposed solution
Participation is restricted due to economic reasons	1	3	Low 3	Researchers are flexible and coordinate so that it suits the participant. Project partners must offer test persons compensation for expenses	
Participation is restricted due to physical limitations	2	4	High 8	Researchers make premises, material and test procedure accessible to suit persons with motor, visual and hearing impairments	Researchers responsible for testing are flexible and try to coordinate tests so that it suits the participant
Participation is restricted due to communicative/cognitive limitations	2	4	High 8	Researchers make sure that there are communicative and cognitive support available. Inform test persons to bring their personal aids	Researchers responsible for testing are flexible and try to coordinate tests so that it suits the participant

## Advisory expertise

Risks	Likelihood	Impact	Risk score	Proposed prevention	Proposed solution
Advisory committee does not fairly represent the target group	1	3	Low 3	The project partners who are responsible for the advisory committee make sure to invite a diverse group	Try to invite additional representatives

## Ethical regulations

Risks	Likelihood	Impact	Risk score	Proposed prevention	Proposed solution
Researchers do not follow their set research and ethics guidelines	1	3	Low 3	The ethical guidelines for the project are sufficient and available	Take contact with the local ethical management
Researchers do not have a Data Protection Officer to contact about data processing	1	3	Low 3	Researchers make a plan for an alternative contact	Try to find an external contact to discuss with. Ask for advice from other project partners
Researchers do not have an Ombudsman	1	3	Low 4	Researchers need to make sure there is an Ombudsman for participants to contact	Try to find an external contact to discuss with. Ask for advice from other project partners
Ombudsman is not suitable for the task	1	3	Low 3	Researchers need to follow the guidelines on the Ombudsman selection in D8.2	Find a new person for this task, or complement with additional expertise