Low-High risk assessment – scientific research

Admissibilty for ethical approval	
1	
Does your research involve human participants?	
❑ Yes ❑ No = no ethical assessment is required	
2	
Is your research performed only to evaluate and improve the quality of the education at the Open Universiteit?	
❑ Yes = no ethical assessment is required ❑ No	
3	
Is your research already ethically assessed by another research ethics committee (in the Netherlands) and carried out under the responsibility of an institute other than the OU? ***Please note*** *that research given a no-WMO advice by a MREC is not yet ethically approved.*	
❑ Yes = no second ethical assessment is required ❑ No	
4	
In case you use secondary data, do you use secondary data in combination with additional data collection?	
❑ Yes ❑ No = no ethical assessment is required. Make sure that you document some clear agreements about sharing, storage, publishing and responsibilities concerning the data, to avoid conflict or discussion afterwards. The advice is to ask the data steward for consultation. ❑ Not applicable	
5	
Has your recruitment procedure already started?	
❑ Yes = no ethical assessment is possible anymore. If the recruitment has only just started, please contact cETO as soon as possible to discuss possible solutions. ❑ No	
One of the answers showed 'no ethical assessment is required/possible': You don't need to apply an ethical assessment by the cETO. Please ensure that ethical and legal guidelines are safeguarded within the research. Also make sure that you comply to the data management guidelines of the Open Universiteit. You can consult the data steward for advice. **None of the answers showed 'no ethical assessment is required or possible':** Your research is admissible for ethical assessment. Please continue to the risk assessment (question 6) to determine if the research is low or high risk.	

Risk assessment	
WMO	
6	

Does your research fall under the scope of the WMO (WMO - Open Universiteit - Open Universiteit)?

This type of research must be assessed by an accredited Medical Research Ethical Committee (MREC). If you are unsure whether your research is in the scope of WMO, you can ask the cETO for a WMO check before the start of the research. You can submit an online full track application, which includes a WMO check. If the cETO concludes that the research falls under the scope of the WMO, you still need to go to a MREC.

- ❑ Yes = high risk, ask for ethical assessment by a MREC
- ❑ Unsure = high risk, please apply a full track
- ❑ No

Vulnerable participants	
7	

Does your research involve children below the age of 16?

- ❑ Yes = high risk, please apply a full track
- ❑ No

8	

Traditionally, research including participants who belong to a *vulnerable group* was considered as high risk research. However, recent ethical views[1] simply belonging to a vulnerable group, does not always imply that a person is indeed vulnerable in the context of the research that needs to be conducted. A woman early in her pregnancy is for example not vulnerable in the context of research that aims to examine attitudes towards prenatal vitamins, but can be considered vulnerable in the context of research studying the psychological effects of prenatal screening, as this can be a very stressful research context.

Participants are vulnerable and therefore at higher risk, when there is an intrinsic or situational condition present that puts them at greater risk of being used in ethically inappropriate ways of research (= contextual vulnerability)[1]. There are several categories of contextual vulnerability. Carefully consider each type of vulnerability in your research. Look at who your participants are, what your research context is, and how this possibly influences their vulnerability. Please estimate each type of vulnerability on a scale of 1 to 4 (1= not vulnerable; 2= little vulnerable; 3= vulnerable; 4=very vulnerable)

- ***Cognitive or communicative vulnerability***:
  People who have difficulty comprehending information and making decisions about participation. *Examples: children under the age of 16 years, adults with cognitive impairments, people with linguistic barriers*.
  ❑ 1 ❑ 2 ❑ 3 ❑ 4
- ***Institutional vulnerability:***
  Persons who are under formal authority of others, who might have different values, goals, and priorities than those of the potential participant. *Examples: prisoners, military, and any person whose relationship with a superior might make it difficult to*

[1] B. Gordon, 2020. Vulnerability in research: basic ethical concepts and general approach to review. Ochsner Journal, 20, p. 34-38.

say 'no', such as managers and their employees matched in the research, students in the researcher's own course or classroom.

❑ 1 ❑ 2 ❑ 3 ❑ 4

- ***Deferential vulnerability:***
  Persons who are under informal authority based on gender, race, class, inequalities or inequalities of power and knowledge. Feelings of fear of offending the authority and incurring retribution or a genuine sense to please the respected other.
  Examples: *patient-doctor relationship*
  ❑ 1 ❑ 2 ❑ 3 ❑ 4
- **Medical vulnerability**:
  People with serious health conditions for which no satisfactory standard treatment options are available.
  ❑ 1 ❑ 2 ❑ 3 ❑ 4
- **Economic vulnerability**:
  People who are disadvantages in distribution of social goods and services as income, housing or healthcare. *Examples: impoverished mother trying to feed her children receives 20 euro for a 30-minute survey, making it difficult for her to say no*.
  ❑ 1 ❑ 2 ❑ 3 ❑ 4
- **Social vulnerability**:
  People who belong to undervalued social groups, which includes stereotyping and can lead to discrimination. *Examples: ethnic minorities, transgenders*.
  ❑ 1 ❑ 2 ❑ 3 ❑ 4

Looking at your indicated scores on each of the six types of vulnerability, do you consider the participants in your research to be vulnerable (any indication of scale 3 or 4 will be considered as vulnerable and requires a fast track procedure)?
In case of doubt, please contact the cETO for advice.

❑ Yes = high risk, please apply a full track
❑ No

Burden

9

Will the research be conducted in Belgium **and** does it concern medical research or clinical psychology, psychotherapy or an invasive intervention?

❑ Yes = high risk. Apply for local ethical assessment in Belgium and do not forget to obtain a No-Fault insurance at the OU.
❑ No

10

Do you employ deception in your research?

❑ Yes = high risk, please apply a full track
❑ No

11

Do you collect sensitive/risky data (such as questions depression, sexual arousal, bullying or suicide), that can be invasive and/or provoke negative emotions?

❑ Yes = high risk, please apply a full track
❑ No

12

Do you collect sensitive information about third persons, who are not participating in the research?

❑ Yes = high risk, please apply a full track
❑ No

13	

In case you collect personal data, will you anonymize or pseudonymize the personal data?

Personal data means that data is traceable to an individual person. Data can be direct identifiers like name and email address, but can also be indirectly identifying. For example: zip code and date of birth are in itself not directly traceable, but can identify a person when they are combined.

Factors such as available (supplementary) information, user and access, and technology also determine whether identification is possible. In an environment where other datasets are available, the combination of different data can enhance traceability. Who has access to the data is important. A random person may not be able to do any deduction, while an organization with access to additional data can. New analytical techniques and data aggregation methods may change the reducibility of previously non-reducible data.

Examples:

- *An anonymous survey on job satisfaction may not seem traceable, but if the answers contain unique details about the job or team, an employer can still identify the person.*
- *An IP address on its own is not always directly traceable, but when combined with login details at a website, it can be.*
- *In a small town, a combination of gender, age and occupation may be enough to trace someone, while the same combination in a big city may not be traceable.*

Thus, whether data is traceable depends not only on the data itself, but also on the context in which it is used. You should always take into account the possibilities of deduction and take appropriate measures to protect privacy.

❑ Yes / not applicable
❑ No = high risk, please apply full track

14	

Will new data to be collected linked to other already existing data?

❑ Yes = high risk, please apply a full track
❑ No

Final assessment:

One of the answers showed 'high risk':
Your research is considered as **high risk**. Your research is:

- Student research with high risk with or without publication
- Scientific research with high risk

You can either adjust the research accordingly to make it compliant to low risk research and redo the risk assessment, or submit your current application in the cETO app for **full track** ethical assessment by the cETO (unless otherwise indicated).

None of the answers showed 'high risk':
Your research is considered as **low risk**. Your research is:

- Student research with low risk but with the intention to publish.
- Scientific research with low risk

You can submit your current application in the cETO app for **fast track** ethical assessment by the cETO.