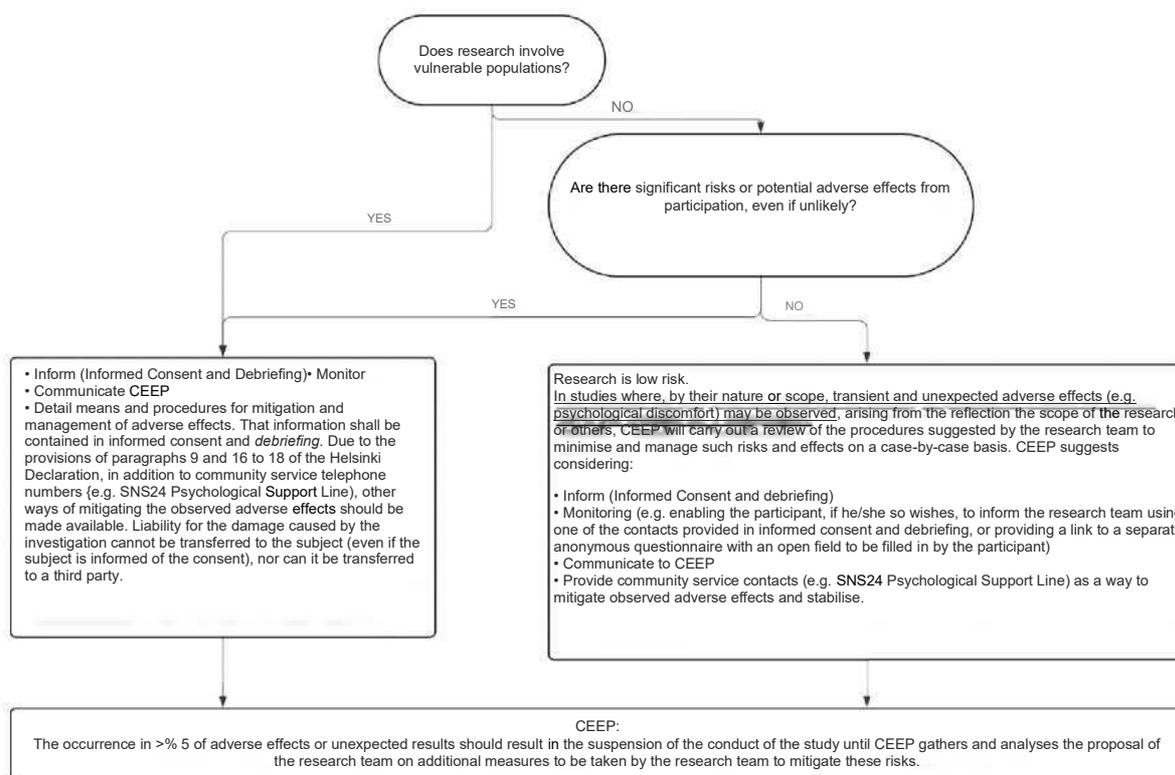


Flowchart: Monitoring and risk management, and adverse effects and outcomes unexpected

*Translation into English: EU eTranslation tool



Step 1.

Does research involve vulnerable populations? Yes/No

IF YES,

Step 2.

Regardless of whether significant adverse effects or unexpected results are likely to occur, the research team should develop a monitoring and mitigation plan for these risks, which should always be referred to in informed consent and *debriefing*.

Step 1.

Does research involve vulnerable populations? Yes/No

IF NOT,

Step 2.

Are there any significant risks or potential adverse effects from participation (e.g. collection of sensitive data, induction of physical/psychological discomfort, attribution of labels impacting self-concept, invasive activities, collection of biological materials), even unlikely? Yes/No

IF NOT,

Step 3.

Research is low risk.

There are no significant risks or potential adverse effects arising from participation, or they are unlikely to arise. There are studies which, by their nature or scope, may give rise to transitory and unexpected adverse effects (e.g. psychological discomfort), arising from reflection on the scope of research or others, or even unexpected results. In these cases, CEEP will carry out a case-by-case analysis of the procedures foreseen by the research team to mitigate and manage such potential risks, adverse effects and unexpected outcomes.

CEEP suggests that in such cases consideration should be given to: put this information in informed consent and debriefing, indicating the procedure for monitoring these risks, even if they are unlikely.

For example, the participant could be suggested to inform the research team using one of the contacts provided in informed consent and debriefing, or a link to a separate anonymous questionnaire with open question indicating adverse effects occurred.

Step 4.

Have any adverse effects or unexpected results been reported to the investigation team? Yes/No

IF YES,

The investigation team shall report to the Psychology Ethics Committee as part of the process of monitoring risks and adverse effects. The occurrence in >% 5 of adverse effects or unexpected results should result in the suspension of the conduct of the study until CEEP gathers and analyses the proposal of the research team on additional measures to be taken by the research team to mitigate these risks.

Step 1.

Does research involve vulnerable populations? Yes/No

IF NOT,

Step 2.

Are there significant risks or potential adverse effects from participation (e.g. collection of sensitive data, induction of physical/psychological discomfort, attribution of labels impacting self-concept, invasive activities, collection of biological materials) or are they unlikely? Yes/No

IF YES,

Step 3.

Research carries moderate to high risks.

Information about potential risks, significant adverse effects and unexpected outcomes should be included in informed consent and debriefing, indicating the procedure for monitoring and mitigating these risks and adverse effects, even if these are unlikely.

A way of contacting or notifying the investigation team about the observed effects or results should be made available. All reports of adverse effects or unexpected results shall be reported to the Specialised Ethics Committee on Psychology.

Means and procedures to mitigate such adverse effects shall be made available. That information shall be contained in informed consent and *debriefing*. Due to the provisions of paragraphs 9 and 16 to 18 of the Helsinki Declaration, in addition to community service telephone numbers (e.g. SNS24 Psychological Support Line), other ways of mitigating the observed adverse effects should be made available. Liability for the damage caused may not be transferred to the subject, even if he or she is informed of the consent, or to a third party.

Step 4.

Have any adverse effects or unexpected results been reported to the investigation team? Yes/No

IF YES,

The investigation team shall report to the Psychology Ethics Committee as part of the process of monitoring risks and adverse effects. The occurrence in >% 5 of adverse effects or unexpected results should result in the suspension of the conduct of the study until CEEP gathers and analyses the proposal of the research team on additional measures to be taken by the research team to mitigate these risks.