

NARMA

Kort om evalueringen av etikk i EU-søknaden og krav til dokumentasjon og rapport.

mona.Bekkhus@psykologi.uio.no

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Hva er gangen
fra vurdering til
advisory board
og rapport?

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Etikkpanelets vurdering

Vurderer aller først
søknaden deretter

...

Utfylling av *self-
assessment*

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11 March 2024
[Go to task list](#)

ERC HE Ethics Screening - Individual Report

Help ⓘ
Status: Ethics clearance
Total score: 1.00 Evaluation progress: 100.00%
[Expand / Collapse all criteria](#)

- + Section 1: Human embryos/foetus
Current status: None
- + Section 2: Humans
Current status: Ethics issues
- + Section 3: Human cells/tissues
Current status: Ethics issues
- + Section 4: Personal data
Current status: Ethics issues
- + Section 5: Animals
Current status: None
- + Section 6: Non-EU countries
Current status: Ethics issues
- + Section 7: Environment, Health and Safety
Current status: None
- + Section 8: Artificial Intelligence
Current status: None
- + Section 9: Other ethics issues
Current status: None
- + Activities excluded from funding
Current status: No
- + Exclusive focus on civil applications
Current status: No
- + Analysis of the ethical dimension
- + Ethics recommendations

2024 07 26

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ERC HE Ethics Screening - Consensus

Statu

Total score: 1 00 Evali

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Etikkpanelets vurdering

- *Humans*
- *Biological tissue*
- *Personal data*
- *Non-EU countries*
- *AI*

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2024 07 26

ERC HE Ethics Screening - Individual Report

11 March 2024

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Help

Status: Ethics clearance

Total score: 1.00 Evaluation progress: 100.00%

Expand / Collapse all criteria

+

Section 1: Human embryos/foetus

Current status: None

+

Section 2: Humans

Current status: Ethics issues

+

Section 3: Human cells/tissues

Current status: Ethics issues

+

Section 4: Personal data

Current status: Ethics issues

+

Section 5: Animals

Current status: None

+

Section 6: Non-EU countries

Current status: Ethics issues

+

Section 7: Environment, Health and Safety

Current status: None

+

Section 8: Artificial Intelligence

Current status: None

+

Section 9: Other ethics issues

Current status: None

+

Activities excluded from funding

Current status: No

+

Exclusive focus on civil applications

Current status: No

+

Analysis of the ethical dimension

+

Ethics recommendations

Eksempel:

AI: The applicant has not provided any measures to prevent potential biases in the input data and has not secured the robustness of machine learning methods.

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ERC HE Ethics Screening - Individual Report

11 March 2024
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Help

Status: Ethics clearance
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2024 07 26

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- ✦ Section 8: Artificial Intelligence
Current status: None
- ✦ Section 9: Other ethics issues
Current status: None
- ✦ Activities excluded from funding
Current status: No
- ✦ Exclusive focus on civil applications
Current status: No
- ✦ Analysis of the ethical dimension
- ✦ Public communication

Eksempel:
AI: The applicant has not **provided any measures** to prevent potential biases in the input data and has not **secured the robustness** of machine learning methods.

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HUMANS

- 1) Detailed information on the procedures and criteria to identify/recruit research participants for each type of participation.
- 2) Detailed information on the informed consent procedures for the research participants tailored to each type of participation to the research and the Photovoice.
- 3) Detailed information on the informed consent procedures related to the processing of personal data including on the linkage of data
- 4) Project-specific templates of the information sheets and informed consent/assent forms (in language and terms understandable to the participants) with all relevant information regarding the unexpected findings disclosure policy and protection of personal data, including the DPO contact details for host institutions required to appoint a DPO under the General Data Protection Regulation 2016/679 and the disclosure policy in case of unexpected findings
- 5) A detailed risks assessment and corresponding detailed information on adequate measures to protect all vulnerable participants involved in the research, prevent coercion and undue inducement, exacerbation of their vulnerability, and minimise the risk of harm and/or stigmatisation including more detailed information on referral pathways.
- 6) A detailed description of unexpected findings procedures and disclosure policy.
- 7) More details of the ethical advisory board e.g. no-disclosure agreement 9) Detailed information on compliance of the activities undertaken in non-EU countries with respective legal framework(s) in at least one EU Member State and with the Horizon Europe ethical standards
- 8) Details on the local resources to be used and modalities for their use, and provide details on whether the project will collect genetic data.
- 9) More detailed information on the fair benefit sharing arrangements with stakeholders from Bangladesh and how it will align with the Trust code

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Eksempel: etikkpanelets vurdering

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Eksempel: etikkpanelets vurdering

HUMANS

- 1) Detailed information on the procedures and criteria to identify/recruit research participants for each type of participation

- 2) Detailed information on the informed consent procedures for the research participants

- 3) Detailed information on the informed consent procedures related to the processing of personal data

- 4) Project-specific templates of the information sheets and informed consent/assent forms (in language and terms understandable to the participants) with all relevant information regarding the unexpected findings disclosure policy and protection of personal data, including the DPO contact details for host institutions required to appoint a DPO under the General Data Protection Regulation 2016/679 and the disclosure policy in case of unexpected findings

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Ethics Clearance:

- Har ingen etiske utfordringer.
- Har noen utfordringer, men de er adressert.
- Har ikke diskutert utfordringerne, men de er ikke komplekse eller alvorlig.

Additional ethics panel: varierer med grad av sensitivitet og kompleksitet.

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SECTION 03: ETHICAL ASSESSMENT

Please select below the appropriate ethics opinion for this proposal (only one can be selected).

PLEASE NOTE

If there are no ethics issues, the opinion must be "Ethics Clear".

Based on the proposal, including the ethics self-assessment.

- If yes, please select "Additional Ethics Panel" and the proposal must undergo an ethics assessment.

- If you select "Additional Ethics Panel", please summarise your justification for the next step.

Additional Ethics Panel

Justification mandatory for the next step

Ethics issues are complex and serious. The research will involve a large number of highly vulnerable participants involving risks of exacerbation of vulnerabilities and reprisals, as well as significant issues related to the management of unexpected findings. It involves the large-scale processing of personal data including special categories of data and the secondary use of special categories of data with a lack of information on safeguards in place; as well as fieldwork in [redacted] with risks for the safety and security of researchers and participants and insufficient information on local resources to be used and benefit-sharing measures.

Går videre til ny etikk vurdering:

"It involves the large-scale processing of personal data including special categories of data and the secondary use of special categories of data with a lack of information on safeguards in place"

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De aller fleste søknader vil gå gjennom

- men ekstra dokumentasjon og beskrivelser er vanlig

• 'Ethical clearance with or without observations'

Complex and high sensitivity:

• Sendes til neste runde/panel.

• Aktuelt med Etikk råd (Ethical advisory Board).



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Etisk rådgivergruppe og Rapport

Note that proposals which are not so contractual deliverables. It is however Ethics Advisor or Ethics Advisory Board appointment of the Independent Ethics reports will become contractual obligations.

De vil på den ene siden hjelpe forskerne med å oppnå god etisk håndtering, og på den andre siden gi en grad av forsikring til ERCEA.



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Rådgivende etikk gruppe/Ethical advisory board

Rapporten:

- En *Ethical advisor* må være **uavhengig**, men ha kompetanse i fagfeltet
- Rapporten struktureres etter punktene som er fremhevet i *ethical assessment* delen.
- Oppsummere forskningen så lang og om det har oppstått problemer, og hvordan det ble håndtert.



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Eksempel: Rådgivende etikk gruppe/Ethical advisory board

[Roles and Functions of Ethics Advisors/Ethics Advisory Groups
in EC-funded Projects \(europa.eu\)](#)

[Roles and Functions of Ethics Advisors/Ethics Advisory Groups
in EC-funded Projects \(europa.eu\)](#)



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Takk for meg!

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