

# Personvern, forskningsetikk og forskningsintegritet med utgangspunkt i EU Horison 2020 (og NFR 2019)

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NARMA, 05.03.2019



The Norwegian National  
**RESEARCH ETHICS  
COMMITTEES**

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Date: 13 December 2018

### Statement on ethical evaluation in EU-projects

Based on various inquiries recently concerning challenges related to ethics evaluation in EU-projects, NESH has decided to give a general advice which might be applicable for others. The aim is to clarify, translate and harmonize the different approaches to ethical evaluation in the Norwegian system and H2020s Ethics Appraisal Procedure respectively. Hopefully, the statement will be helpful for the administration of the Participant Portal for H2020, when processing applications from Norway.

#### Regulation in the Norwegian system

In Norway, research ethics in general is regulated in The Research Ethics Act of 2017, originally introduced in 2007. The act provides a legal basis for three independent National Research Ethics Committees, initially established as advisory bodies in 1990, covering all fields of research in both private and public sector:

- a) The National Committee for Medical and Health Research Ethics (NEM)
- b) The National Committee for Research Ethics in Science and Technology (NENT)
- c) The National Committee for Research Ethics in the Social Sciences and the Humanities (NESH)

Since 2007, with The Research Ethics Act, we also have a fourth national body:

- d) The National Commission for the Investigation of Research Misconduct (GRU)



# RESEARCH & INNOVATION

## Participant Portal H2020 Online Manual



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> H2020 Online Manual > Cross-cutting issues >

- International cooperation
- Social Sciences & Humanities
- Open access & Data management
- Climate action & Sustainable development
- Ethics**
- Gender
- SMEs
- ERA-NETs
- Links to regional policy
- Intellectual property
- Innovation procurement

## Ethics



For all activities funded by the European Union, ethics is an integral part of research from beginning to end, and ethical compliance is seen as pivotal to achieve real research excellence. There is clear need to make a thorough ethical evaluation from the conceptual stage of the proposal not only to respect the legal framework but also to enhance the quality of the research. Ethical research conduct implies the application of fundamental ethical principles and legislation to scientific research in all possible domains of research. The process to assess and address the ethical dimension of activities funded under Horizon 2020 is called the **Ethics Appraisal Procedure**.

### Objectives

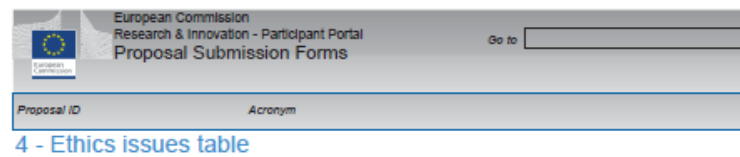
In addition to the scientific evaluation focusing on the scientific merit, the quality of the management and the potential impact, the Ethics Appraisal ensures that all research activities carried out under the Horizon 2020 Framework Programme are conducted in compliance with fundamental ethical principles.

### Ethics Appraisal Procedure

The Ethics Appraisal Procedure concerns all activities funded in Horizon 2020 and includes the Ethics Review Procedure, conducted before the start of the project, as well as the Ethics Checks and Audits.

When preparing a proposal, it is required to conduct an Ethics Self-assessment starting with the completion of an **Ethics Issues Table**. You can read further practicalities in [How to complete your ethics self-assessment](#) guide.

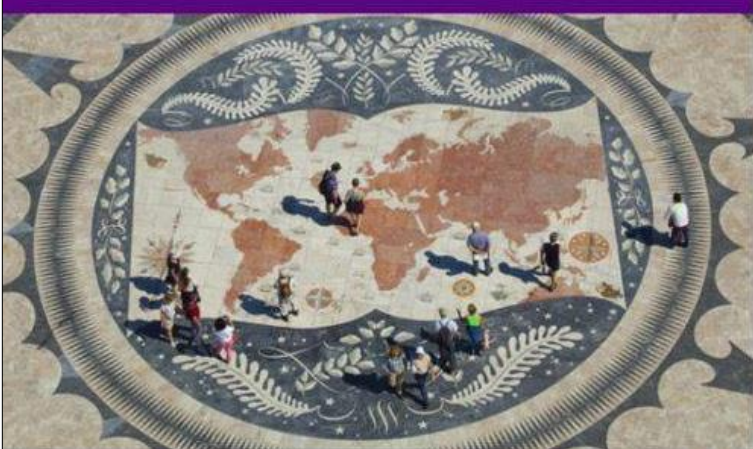
# Ethics Appraisal Procedure



## ETHICS APPRAISAL STEPS

Activity	Who?	When?	How?
Ethics Self-assessment	Applicant	Application phase	Consideration of ethical issues of the proposal
Ethics Pre-screening/Screening	Ethics experts and/or qualified staff	Evaluation phase	Review of application material
Ethics Assessment (for proposals involving hESC or raising serious ethical issues: severe intervention on humans)	Ethics experts	Evaluation/ Grant preparation phase	Review of application material
Ethics Check/Audit	Ethics experts	Implementation phase	Review of project deliverables/interview with applicants

## Forskningsetiske retningslinjer for samfunnsvitenskap, humaniora, juss og teologi



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5.0	18.10.2017	<ul style="list-style-type: none"><li>▪ The main changes compared to version 4.0 of the model grant agreement are under:<ul style="list-style-type: none"><li>– Article 6.2 'Specific conditions for costs to be eligible'</li><li>– Article 32.1 'Obligations towards the recruited researcher'</li><li>– Article 34 'Ethics and research integrity'</li><li>– Article 55.1 'Amendments to the Agreement – Conditions'</li><li>– Annexes 2a 'Additional information on the estimated budget' and 4 'Model for the financial statements'</li></ul></li><li>▪ Other minor drafting changes and corrections of clerical mistakes can be viewed in a <a href="#">version with tracked changes</a>.</li></ul>
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## ARTICLE 33 — GENDER EQUALITY

### 33.1 Obligation to aim for gender equality

The beneficiary must take all measures to promote equal opportunities between men and women in the implementation of the action. It must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

### 33.2 Consequences of non-compliance

If the beneficiary breaches its obligations under this Article, the Agency may apply any of the measures described in Chapter 6.

## ARTICLE 34 — ETHICS AND RESEARCH INTEGRITY

### 34.1 Obligation to comply with ethical and research integrity principles

The beneficiary must carry out the action in compliance with:

- (a) ethical principles (including the highest standards of research integrity)
- and
- (b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States or for activities which destroy human embryos (for example, for obtaining stem cells).

The beneficiary must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiary must ensure that the activities under the action do not:

- (a) aim at human cloning for reproductive purposes;
- (b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or
- (c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

In addition, the beneficiary must respect the fundamental principle of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity<sup>13</sup>.

This implies compliance with the following fundamental principles:

- reliability in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources;
- honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way;
- respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment;
- accountability for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts

and means that the beneficiary must ensure that persons carrying out research tasks follow the good research practices and refrain from the research integrity violations described in this Code.

This does not change the other obligations under this Agreement or obligations under applicable international, EU or national law, all of which still apply.

### 34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the 'ethics requirements' set out as deliverables in Annex 1.

Before the beginning of an activity raising an ethical issue, the beneficiary must have obtained:

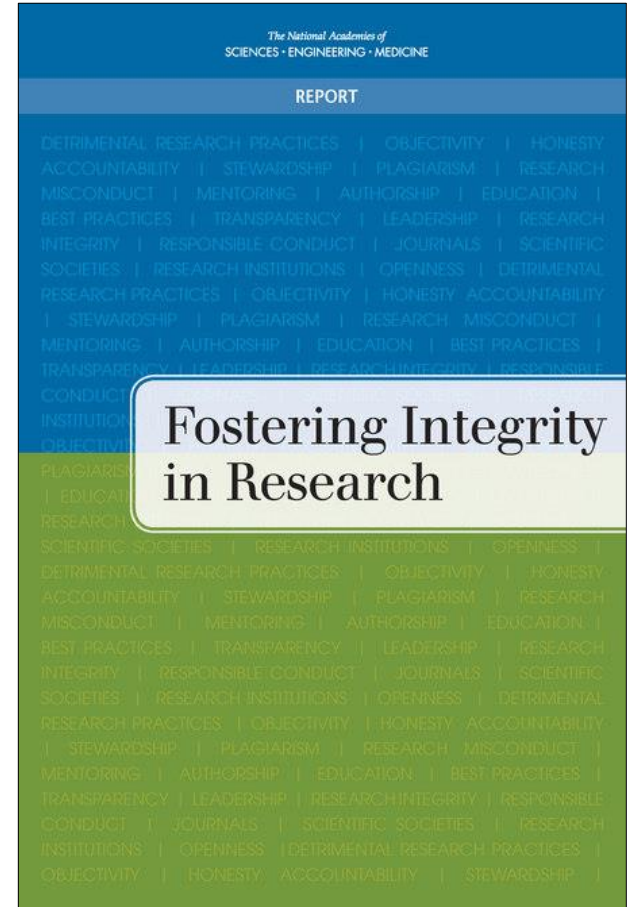
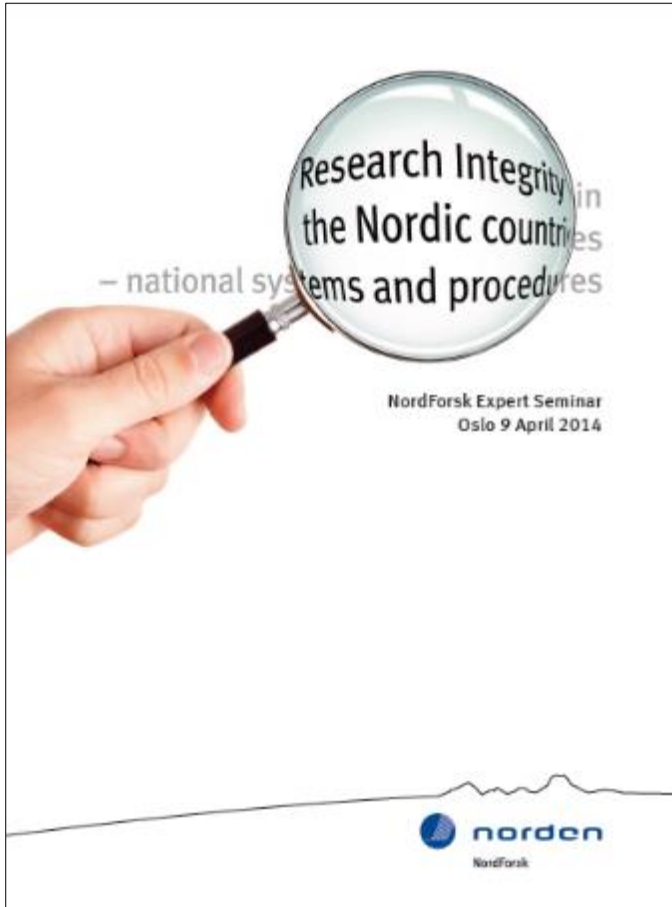
- (a) any ethics committee opinion required under national law and
  - (b) any notification or authorisation for activities raising ethical issues required under national and/or European law
- needed for implementing the action tasks in question.

The documents must be kept on file and be submitted upon request by the beneficiary to the Agency (see Article 52). If they are not in English, they must be submitted together with an English summary, which shows that the action tasks in question are covered and includes the conclusions of the committee or authority concerned (if available).

### 34.3 Activities involving human embryos or human embryonic stem cells

<sup>13</sup> European Code of Conduct for Research Integrity of ALLEA (All European Academies)  
[http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics\\_code-of-conduct\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf)







Home ALLEA News ALLEA publishes revised edition of The European Code of Conduct for Research Integrity

## ALLEA publishes revised edition of The European Code of Conduct for Research Integrity

24 March 2017

ALLEA, the European Federation of Academies of Sciences and Humanities, published today the revised edition of *The European Code of Conduct for Research Integrity*, a document that serves the European research community as a framework for self-regulation across all scientific and scholarly disciplines and for all research settings. Particularly the revised Code addresses recent and emerging challenges emanating from technological developments, open science, citizen science and social media, among other areas. The publication was presented to the European Commissioner for Research, Science and Innovation, Carlos Moedas, in Brussels, who recognised the relevance of the ALLEA Code as a model for organisations and researchers across Europe.



ALLEA President presents European Code of Conduct for Research Integrity to European Commissioner for Science, Research and Innovation, Carlos Moedas. Credit: European Commission

The Code sets out principles of research integrity, criteria for good research practice, and describes how to prevent violations of research integrity. The present revision is motivated by current developments in the European research funding and regulatory landscape, changing institutional responsibilities, and evolving review procedures. In addition, the Code is applicable to expanding open access publishing, and the use of digital repositories, and takes into account new ways of communicating science and involving citizens in research. The Code seeks to empower individual researchers and a variety of research bodies, funding agencies and publishers by creating a common understanding of how research should be conducted.

### Archives

- ▶ 2018
- ▶ 2017
- ▶ 2016
- ▶ 2015
- ▶ 2014

### Latest News

- ALLEA publishes statement on the inappropriate political infringement on academic curricula in Hungary
- European Academies call for a clear and inclusive definition of 'associated countries' in Horizon Europe
- European Code of Conduct for Research Integrity - New set of translations available
- ALLEA Publishes Open Letter in support of the Hungarian Academy of Sciences



## The European Code of Conduct for Research Integrity

REVISED EDITION



Home Publications Reports & Publications The European Code of Conduct for Research Integrity

## The European Code of Conduct for Research Integrity

*The European Code of Conduct for Research Integrity* serves the European research community as a framework for self-regulation across all scientific and scholarly disciplines and for all research settings.

The 2017 revised edition of the Code addresses emerging challenges emanating from technological developments, open science, citizen science and social media, among other areas. The European Commission recognises the Code as the reference document for research integrity for all EU-funded research projects and as a model for organisations and researchers across Europe.

The Code was published originally in English on 24 March 2017 and was translated to all official EU languages by the European Commission's Translational Services and with the support of ALLEA Member Academies.



### The European Code of Conduct for Research Integrity

Original version in English  
Published in 2017



### Kodi Europian i Shtjtes për Integritet në Kërkimin Shkencor

Albanian translation  
Published in 2018



### Европейски кодекс за честност на научните изследвания

Bulgarian translation  
Published in 2018



### Europese gedragscode voor wetenschappelijke integriteit

Dutch translation  
Published in 2018



RESEAR

Research and I

European Commission > Research & Innovation > RIO

Country analysis ▾

Policy Support

## MLE on Resea

Research integrity is a foundation of ex  
research integrity across Europe is of t  
ensure a fruitful relationship between s

The MLE will focus on the exchange of  
positive incentives, spreading research  
the research careers and stimulating p  
different perspectives: institutional, nat

Date 📅

Exercise type ↗

Geo coverage ↗

🔍 Search "Market..."



## Europeiske retningslinjer for forskningsintegritet

REVIDERT VERSJON



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Search



search institutions. Advancing  
ducibility of research results, and to

ch integrity field, namely, promoting  
ue, enhancing training in all stages of  
areas will be analysed from three

land Lithuania



## Etiske retningslinjer og god forskningsskikk

Prosjekter finansiert av Forskningsrådet skal holde høy forskningsetisk standard og følge grunnleggende prinsipper for forsker-, forskningsetikk og forskningsskikk.

Forskningsorganisasjonene skal sikre at forskningen deres skjer i henhold til anerkjente forskningsetiske normer. I søknader til Forskningsrådet skal søkeren i prosjektbeskrivelsen gjøre rede for eventuelle etiske problemstillinger knyttet til gjennomføring av prosjektet, og beskrive hvordan de vil bli håndtert. Denne redegjørelsen inngår i grunnlaget for søknadsvurderingen vår.

Prosjektbeskrivelsen skal utformes i tråd med god forskningsskikk og være skrevet spesielt for dette formålet. Alle sitater skal være korrekte og ha tydelig kildeangivelse. Hvis stoff fra andres tekster og/eller resultater blir benyttet i prosjektbeskrivelsen, gjelder samme krav til kildeangivelse

[De nasjonale forskningsetiske komiteene](#) har laget en [oversikt over generelle og fag-/temaspesifikke forskningsetiske retningslinjer](#).

Forskere kan ta kontakt med [De nasjonale forskningsetiske komiteene](#) om de ønsker råd ved vurdering av konkrete forskningsetiske utfordringer i sitt prosjekt. [Hvem er De nasjonale forskningsetiske komiteene og hva gjør de?](#)

Hovedansvaret for god forsker-, forskningsetikk og forskningsskikk ligger hos forskerne og organisasjonen eller virksomheten som er ansvarlig for prosjektet. I følge norsk lovgivning skal alle prosjekter som krever forhåndsgodkjenning av den regionale forskningsetiske komiteen, være godkjent før prosjektet kan settes i gang. Prosjekter som behandler personopplysninger skal også meldes til personvernombudet for forskning.

### Andre nettsider

- [Generelle forskningsetiske retningslinjer](#)
- [The European Code of Conduct for Research Integrity](#)

### Del



### FORSIDEN

Om Horisont 2020

Kunstfribud og søknadshjelp

Støtte til våre søkere

EU-nettverkene

Ofte stilte spørsmål

➤ Immaterielle rettigheter

➤ Hvem kan delta?

➤ Startpakke

➤ [Etikk](#)

Kontaktpersoner - (NCP)

Kalender

Nyheter

Suksesshistorier

Brusselkontoret

Norske resultater

## Derfor bør du inkludere etikk i ditt Horisont 2020-prosjektforslag

Når EU vurderer Horisont 2020-søknader kommer alltid etikk opp som vurderingskriterie. Vurder derfor mulige etiske problemstillinger så tidlig som mulig i søknadsprosessen og integrer disse i søknaden på lik linje med andre faktorer.

Når det gjennomføres aktiviteter i Horisont 2020, forventer EU at man lever opp til etiske prinsipper, og relevant nasjonal fellesskaps- og internasjonal lovgivning. Den etiske vurderingen fokuserer på disse hovedemnene:

- beskyttelse av mennesker (herunder deltagere i studier og forskerne selv)
- dyrebeskyttelse og -velferd
- databeskyttelse og privatliv
- miljøbeskyttelse
- tredjeland
- dual use (militær anvendelse)
- misbruk av forskningsresultater

Med det økende fokus på blant annet behandling av personopplysninger og brukarinvolvering, og fordi Norge har status som tredjeland i etikk-sammenheng, vil etikk komme opp som relevant problemstilling i svært mange prosjekter med norsk delaktelse.

### Hvordan håndteres etikk i Horisont 2020?

Når du søker EU om støtte til Horisont 2020-prosjekter, skal du alltid fylle ut et skjema vedrørende mulige etiske problemstillinger. Det er en del av det elektroniske søknadsskjemaet Part A som kalles for Ethics Self-Assessment. Det er prosjektkoordinatør eller den prosjektansvarlige, som skal fylle ut skjemaet. Hvis det er noe i skjemaet, som er relevant for forskningsprosjektet, skal det i søknadsteksten i Part B beskrives hvordan emnet håndteres ut fra nasjonale retningslinjer i de land hvor aktivitetene gjennomføres. Det betyr at etiske problemstillinger må integreres i søknadsteksten for hver arbeidspakke. Dersom etikk er en stor del av prosjektet bør det derimot være en egen arbeidspakke.

Vi anbefaler at du eventuelt legger ved allerede mottatte godkjenninger/etiske vurderinger. Hvis etiske godkjenninger ennå ikke er oppnådd ved søknadstidspunkt, må du beskrive hvilke godkjenninger som skal innhentes og når de forventes godkjent.

Gjør dessuten rede for, hvordan de markerte etiske emner er relatert til forskningsmålene, metoden og den mulige effekt (impact), som forskningen kan få.

Når det inngås en tilkuddsavtale (Grant Agreement) gjennomfører EU-kommisjonen en etikk-screening og muligens en etikk-vurdering. Dersom ekspertene mener at søknaden ikke godt nok beskriver hvordan etiske problemstillinger skal håndteres, kan prosjektet bli pålagt ekstra krav. Disse kravene kan enten komme som betingelse for inngåelse av tilkuddsavtalen eller i form av ekstra aktiviteter som må gjennomføres. I noen tilfeller kreves det at man lager en ekstra arbeidspakke på etikk. Fordi maks støttelep ikke kan økes i grant forberedingsfasen, får prosjektet ikke tildele ekstra midler for aktiviteter som blir pålagt etter søknaden er sendt inn.

I noen prosjekter gjennomføres en etikk-sjekk og revisjon etter at tilkuddsavtalen er underskrevet.

[Les anbefalingen fra Den nasjonale forskningsetiske komité for samfunnsvitenskap og humaniora \(NESH\) om vurderingen av forskningsetikk i EU-søknader.](#)

### Våre anbefalinger

- Vurder nøyaktig mulige etiske problemstillinger så tidlig som mulig i søknadsprosessen og integrer disse i søknaden på lik linje med andre faktorer
- Aktiviteter for å håndtere etiske problemstillinger og kostnader knyttet til disse skal helst integreres i de arbeidspakkene der relevante forskningsaktiviteter gjennomføres. I prosjekter med svært omfattende etiske problemstillinger kan det utformes en egen arbeidspakke (samt budsjett til det).

Publisert: 30.11.2018

Sist oppdatert: 14.02.2019

[Skriv ut siden](#)

### Kontaktpersoner

Anja Wiesbrock  
Carina Hundhammer

### Del



## Project description template for Researcher Projects, Young Research Talents, Mobility Grants

This project description template consists of

**A:** overview of the chapters and sections to be used as the structure of the project description

**B:** guidance on the content in each chapter and sections

### A. Chapters and sections to be used

#### 1. Excellence

1.1. State of the art, knowledge needs and project objectives

1.2. Novelty and ambition

1.3. Research questions and hypotheses, theoretical approach and methodology

#### 2. Impact

2.1. Potential impact of the project

2.2. Measures for communication

#### 3. Implementation

3.1. Project manager and project

3.2. Project organisation and management

### B. Guidance

#### Please note:

Complete all chapters and sections in part A, and delete the guidance (part B) and the evaluation criteria. Nevertheless, read the evaluation criteria carefully.

The project period, the progress plan, budget, the dissemination plan and risk management form. The project description is to provide background for the project and how it will be implemented.

The proposed research should be presented to individuals with a general scientific background.

The project description is not to exceed 10 pages. It is possible to upload an attachment. The project description should have 2 cm margins, single spacing and Arial font. It is permitted to use 9-point font for the project description will not be included in the evaluation.

### 1. Excellence

This chapter should provide a description of the planned project to enable an assessment of its excellence, i.e. the novelty/originality and quality/solidity of the proposed work.

#### 1.1. State of the art, knowledge needs and project objectives

- Summarise the state of the art of the research area/field and describe the knowledge needs and challenges that justify the initiation of the project.
- State the overall project objectives and aims in the context of the state of the art and knowledge needs.

#### 1.2. Novelty and ambition

- Describe the potential for development of new knowledge beyond the current state of the art, including significant theoretical, methodological, experimental and/or empirical advancements.
- Highlight any particularly novel, original or ambitious aspects of the project, e.g. in the objectives, research questions/hypotheses, approaches and/or methodology.

### 2. Impact

This chapter should describe the importance of the anticipated results in terms of the potential scientific impact, and, if relevant, the potential societal impact of the research. The potential impact can be in the short or longer term. The chapter should also specify the planned measures for exploitation, communication and dissemination of the project results.

#### 2.1. Potential impact of the proposed research

- Building on the description of project objectives and novelty in chapter 1, describe clearly why and how the project outputs may address important present and/or future scientific challenges and have an impact on the research area/field, if successful.
- If relevant, building on the description of knowledge needs and challenges in section 1.1., describe why and how the project outputs, if successful, have the potential to meet the mentioned societal challenge(s).
- If relevant, describe how new knowledge and project outputs have the potential to address one or more of the UN sustainable development goals.

## Excellence - please note:

Make sure that the theoretical approach and/or choice of methods is well accounted for and described, and that it is clear how the methods are adequate for addressing the research questions, hypotheses, and project objectives.

The ethical guidelines of the Research Council may be used when preparing the grant application:

[https://www.forskningsradet.no/no/Artikkel/Etiske\\_retningslinjer\\_og\\_god\\_forskningssett/1182736867344](https://www.forskningsradet.no/no/Artikkel/Etiske_retningslinjer_og_god_forskningssett/1182736867344) (Norwegian)

[https://www.forskningsradet.no/en/Article/Research\\_Ethics\\_checklist/1182736871270](https://www.forskningsradet.no/en/Article/Research_Ethics_checklist/1182736871270) (English)

of the project results and outputs

and engagement activities.

It contribute to the realisation of societal goals (in or beyond the scientific

and related to the planned wider context should be

challenge, please describe how the project is not a relevant context for the project. This description will be used by the Research Council to assess the quality of the project. In addition, it will be used by the Research Council to call for references to the call.

national roadmap for a better future. Knowledge and outputs generated in the project on important issues related to the wider context for the project in