Project title	Artificial intelligence and the personalized prevention and management of chronic conditions		
Project acronym	WARIFA		
Project number	101017385		
Call	Digital transformation in Health and Care	**Call ID**	H2020-SC1-DTH-2020-1
Topic	Personalised early risk prediction, prevention and intervention based on Artificial Intelligence and Big Data technologies	**Topic ID**	SC1-DTH-02-2020
Funding scheme	Research and Innovation Action		
Project start date	01/01/2021	**Duration**	48 months

D1.10 – PARTICIPANT IDENTIFICATION AND RECRUITMENT PLAN

Due date	30.06.2021	**Delivery date**	30.06.2021
Work package	WP1 Project Management		
Responsible Author(s)	Conceição Granja Bartnæs		
Contributor(s)	Eva Henriksen, Thomas Schopf, Merethe Drivdal		
Version	1.0		

DISSEMINATION LEVEL

Please select only one option according to the GA			
☒	PU: Public	☐	PP: Restricted to other program participants
☐	RE: Restricted to a group specified by the consortium	☐	CO: Confidential, only for members of the consortium

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017385

VERSION AND AMENDMENTS HISTORY

Version	Date (MM/DD/YYYY)	Created/Amended by	Changes
0.0	22.04.2021	Merethe Drivdal	Creation of document
0.1	05.05.2021	Merethe Drivdal	Update on all chapters
0.2	08.05.2021	Conceição Bartnæs	Update
0.3	27.05.2021	Eva Henriksen	DSPM Input
0.4	07.06.2021	Conceição Bartnæs	Update
0.5	27.06.2021	Thomas Schopf	Update and Review
0.6	28.06.2021	Eva Henriksen	Review
1.0	28.06.2021	Conceição Bartnæs	Final version

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017385

TABLE OF CONTENTS

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017385

LIST OF ABBREVIATIONS

Abbreviation	Meaning
AI	Artificial Intelligence
DMP	Data Management Plan
EAB	Ethical Advisory Board
EA	Ethical Advisor
REA	Research Executive Agency
REC	Regional Committee for Medical and Health Research Ethics
WP	Work Package

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017385

1 INTRODUCTION

WARIFA's main aim is to develop a prototype of a combined early risk assessment tool that will provide individual citizens with personalised recommendations for the management of non-communicable diseases - such as cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes. This will be studied by identifying medical, social and behavioural risk factors and evaluating their contribution to the management and development of non-communicable diseases. In this way, WARIFA will contribute to a better (scientific) understanding of how citizens social environment and behaviour influences their risk of developing a non-communicable disease.

Based on these findings, a second aim of WARIFA is to develop innovative artificial intelligence (AI) algorithms to provide a combined early risk assessment. To achieve this aim, the project will collect and analyse user-generated data, and community registries, to provide a personalized set of recommendations on lifestyle factors according to the risk score of each individual. The collected data will be used to generate big data from which the AI algorithms will learn from. During the project pilots, user-generated data and results (i.e., risk score and a set of personalized recommendations) will be made available to project participants via a user-friendly app on their smartphone.

The Participant Identification and Recruitment Plan provides the ethical guidelines and procedures that will govern the WARIFA project activities. This deliverable describes the procedures and tools of the project to ensure good research practices when involving end-users and stakeholders, and it serves as a reference to which all the WARIFA project members have to comply in their participation in project activities.

The Participant Identification and Recruitment Plan shall be updated, as necessary, during the duration of the project, and is kept available for all WARIFA project members on the chosen platform for project interaction, Microsoft Teams.

2 ETHICAL ISSUES MANAGEMENT

The Horizon 2020 Regulation of Establishment states, in Article 19 (Ethical principles): "All the research and innovation activities carried out under Horizon 2020 shall comply with ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols. Particular attention shall be paid to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection."

2.1 APPOINTMENT OF ETHICAL COMMITTEE

To guarantee ethical compliance of all activities undertaken during the WARIFA project, Ernst Nordtveit (University of Bergen), has been appointed as chair of the Ethical Advisory Board (EAB). Additionally, WARIFA will consult with Regional Committee for Medical and Health Research Ethics (REC). Together, the EAB and REC will:

- Ensure proper management of all ethical procedures;
- Review all WARIFA activities for ethical compliance;

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017385

- Give advice and assistance on ethics to the consortium.

2.2 PROCEDURE IN CASE OF SCIENTIFIC MISCONDUCT

All WARIFA partners are fully aware of the ethical issues that may arise during the project activities. They are committed to follow the fundamental principles of research integrity outlined in the revised version of the European Code of Conduct for Research Integrity:

- **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, full 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 organization, for training, supervision and mentoring, and for its wider impacts.

Violations of research integrity should be avoided at all cost. Research misconduct can consist of fabrication of results, falsification of data or records, plagiarism, or piracy, failing to acknowledge authorship, misleading reporting of study results, sabotaging the work of other scientists, etc. Should misconduct related to WARIFA activities occur, then the misconduct will be handled locally according to the local regulations, following the principle of subsidiarity. However, project partners are obliged to inform the EAB and the Project Coordinator if such misconducts occur, and shall maintain them updated on the development of the process on the matter.

2.3 ETHICAL CLEARANCE

WARIFA will implement different methodological approaches, such as focus groups, workshops, interviews, surveys, pilots, etc. Since the project will collect sensitive data in different countries for different purposes, the consortium has decided to submit the research protocol for each project activity for review by the national ethical entity of each country.

WARIFA has submitted an application to the REC North-Norway. The Committee has reviewed the application (ref.no. 229092 2.3.2021) and concluded that the Warifa project is exempt of ethics approval possibly with exception of the clinical validation study in the final year of the project (see Annex 1). The committee has advised to submit a separate proposal for the validation study.

2.4 ETHICAL GUIDELINES AND PROCEDURES

The objective of the ethical guidelines is to ensure that all WARIFA partners work in an ethically sound way with respect to involving participants in all project activities, as well as creating ethically sound technology. The guidelines specify how the consortium will maintain security, privacy, and confidentiality norms. Furthermore, it will advise all partners in the consortium, both EU and non-EU, on how to work with participants, respecting the combined ethical standards of the consortium members, as well as the national regulations and pilot-specific guidelines.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017385

2.4.1 Participant Identifications - End-users

The identification of end-users for the WARIFA project is performed in WP2 with assistance from WP7. The leader of WP2 administrates this work. The medical doctors in WP2 and WP7 define the inclusion criteria for study participants. These criteria are reached in a consensus process which is mainly based on the results of deliverable D2.1 and D7.1 as well as the doctors` clinical and research experience. The decision-making process might also be further supported by looking at the latest cohort studies within epidemiology and preventive medicine.

Study participants may be classified into 3 groups:

- Patients that have been diagnosed with at least one of the chronic conditions target by WARIFA;
- Citizens at high risk of developing at least one of the chronic conditions target by WARIFA;
- Citizens not at high risk for developing a chronic condition (control group).

Information about the WARIFA project is distributed among the members of patient organizations and patients at the outpatient clinics. Individuals willing to participate in WARIFA are asked to answer an online survey. Based on the answers to the survey, participants who fulfil the inclusion criteria are asked to consent to participate in the study by completing an informed consent form (see 2.4.2.3). A random selection of individuals who do not fulfil the inclusion criteria, are asked if they consent to be included in the control group.

2.4.2 Participant Identification - Stakeholders

WP8 will identify the most important stakeholders of the WARIFA tool and assess their position towards the project's results in order to set up engagement strategies. The partners will jointly brainstorm about relevant stakeholder groups for WARIFA. A thorough mapping of the relevant stakeholders for WARIFA will be made, starting from the networks of contacts of the partners and enlarging to other networks or specific groups at EU level. Also recently funded EU-projects will be assessed to find similarities with WARIFA, with the aim to: 1) Establish links and develop synergies with on-going projects for mutual benefit and maximisation of EU-funding results; 2) Map relevant stakeholders with an active role in the European innovation ecosystem, as privileged interlocutors for the WARIFA results. All stakeholders will be invited to participate in an online survey, which will be designed to measure stakeholder characteristics, e.g., their interest, attitude, influence and knowledge relevant for the project.

2.4.3 Participant Recruitment - End-users

In general, human subjects are recruited from within the populations with the highest prevalence of the chronic conditions targeted by WARIFA, and the exclusion criteria is designed to prevent the participation of subjects that do not own the required equipment or are unable to use it in their area of residence (i.e., someone that does not own a smartphone or that lives in an area without mobile network coverage is not a suitable participant for the studies within WARIFA). For most project activities, participants will mainly be recruited from the user organizations, health app vendors and outpatient clinics at the University Hospitals, represented in the WARIFA consortium.

In all the activities, it will be ensured an even male/female ratio. In some of the studies, age criteria will be used to maintain homogeneity of the sample being studied. For each activity, details of their

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017385

specific recruitment procedures and inclusion/exclusion criteria are detailed as part of the submission to the ethics review committee. The WARIFA EAB will review these procedures and ethical statements prepared by researchers for their local institutional ethics committees and keep copies of granted approvals that will be submitted to Research Executive Agency (REA) upon request.

2.4.4 Participant Recruitment - Stakeholders

In WP8, an online survey will be distributed to WARIFA stakeholders in Norway, Spain and Romania. The sampling procedure that will be used is convenience sampling. All consortium partners will distribute the survey through the channels available to them.

2.4.5 Informed consent

Written informed consent (based on the Norwegian Regional Ethics Committee for Medical and Health Research example information and consent sheet, see Annex 2) will be obtained from participants before fieldwork begins. The information and consent sheet will be made available to the Consortium in the relevant languages, i.e., English, Norwegian, Spanish and Romanian. At the start of each study, it will be made clear to participants that they participate voluntarily and that they have the right to withdraw from the research at any time without providing a reason, and that their data will, as far as possible, be eliminated from the study.

All Partners ensure that the participants understand the considerations involved in informed consent. In general, information about the fieldwork, its risks and exclusion criteria will be given to the potential participants 24 hours before informed consent can be given and again at the beginning of the fieldwork. By allowing a waiting period between receiving the information and giving informed consent, participants can carefully consider, without pressure, if they want to participate.

For each study details of their specific informed consent procedures are detailed as part of the submission to the institutional ethics review committee. The WARIFA EAB will review these procedures and ethical statements prepared by researchers for their local institutional ethics committees and keep copies of granted approvals that will be submitted to REA upon request. Templates for informed consent forms and detailed information sheets will be prepared for each study and approved by the appropriate institutional ethics committees and reviewed by the WARIFA EAB. Templates of the informed consent forms and information sheets will be kept in file by the WARIFA Ethical Committee and submitted to REA upon request.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017385

ANNEX 1 ETHICAL CLEARANCE

REK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK nord	Monika Rydland	77620756	02.03.2021	229092
			Deres referanse:	

Thomas Roger Schopf

229092 Warifa - Kunstig intelligens og forebygging av kroniske tilstander

Forskningsansvarlig: Nasjonalt senter for e-helseforskning

Søker: Thomas Roger Schopf

Søkers beskrivelse av formål:

Warifa er et EU-finansiert forskningsprosjekt. Et internasjonalt konsortium med 12 partnere skal gjennomføre prosjektet i perioden 1.1.2021 - 31.12.2024. Målet er å utvikle et dataprogram som ved bruk av kunstig intelligens kan hjelpe enkeltindivider ("brukere") til å bedømme egen fremtidig risiko for å få kroniske livsstilssykdommer samt å gi tilpassede råd angående forebygging av disse sykdommene.
Programvaren vil bli installert på en sentral server. Brukeren vil kunne styre programvaren via Internett gjennom en app som installeres på brukerens mobiltelefon. Appen vil be brukeren legge inn opplysninger om helserelaterte forhold. Bakgrunnen for prosjektet er en generelt økende forekomst av kroniske sykdommer. I tillegg ser man at flere kroniske sykdommer utvikles samtidig hos en og samme person. Målgruppen med prosjektet er både friske individer og pasienter som allerede har fått diagnostisert en kronisk sykdom. Prosjektet tar for seg diabetes, hjertekarsykdommer, luftveissykdommer og hudkreft. Rådene som programmet gir er rettet mot viktige livsstilsfaktorer som fysisk aktivitet, ernæring, vekt og solvaner. Utviklingen av dataprogrammet bygger i all hovedsak på kunnskap om maskinlæring, bayesiansk statistikk, kontekstbasert datamodellering og simulering. Målet er å bruke anerkjente og validerte kliniske risikomodeller som tilpasses ved å ta inn så mye kontekstrelatert informasjon om brukeren som mulig slik at risikomodellen blir mer presis. En slik individualisert tilnærming vil i tillegg gjøre det mulig å gi råd som er optimalt tilpasset brukerens behov. Spesielt ønsker man å harmonisere rådene når det kan være økt risiko for flere kroniske sykdommer samtidig. Dataprogrammet vil få helserelatert informasjon både ved at brukeren selv legger inn slik informasjon i appen, men også ved at brukeren kan tillate programmet å samle inn informasjon automatisk fra mobiltelefonen.
I prosjektets første fase (ca frem til 2023) vil man utvikle selve dataprogrammet og appen. I denne fasen benyttes allerede eksisterende data fra tidligere prosjekter. Disse dataene består til dels av helseopplysninger, men som utleveres anonymisert til prosjektet. Dataene utgjør f.eks. blodsukkerverdier, antall kalorier inntatt ila et døgn og data om fysisk aktivitet. Datasettene er innsamlet ifm med flere tidligere forskningsprosjekter. I prosjektets andre fase, ca fra 2023, vil dataprogrammet prøves ut i en mindre pilotstudie. Man ønsker da å rekruttere både friske individer samt pasienter som allerede har fått diagnostisert en kronisk sykdom. Det vil da etter informert samtykke samles inn nye data fra brukerne. Hensikten med studien er å undersøke om dataprogrammets risikovurdering og forebyggende livsstilsråd er gyldig for den enkelte brukeren. Man skal rekruttere ca 20-30 frivillige testpersoner som skal bruke appen og programmet i en begrenset periode på ca 8 uker. I denne fasen vil testpersonene få råd fra appen om en sunn livsstil. Appen vil også ha en "dagbokfunksjon" som tillater brukeren å følge utviklingen av sin livsstil over

REK nord
Besøksadresse: MH-2, 12. etasje, UiT Norges arktiske universitet, Tromsø
Telefon: 77 64 61 40 | **E-post:** rek-nord@sesp.uit.no
Web: https://helseforskning.no

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017385

tid og med tilbakemeldinger fra dataprogrammet om evt endringer av sykdomsrisiko. Man forventer da en læringseffekt som kan motivere brukeren til å opprettholde en positiv livsstilsendring. Kvaliteten på livsstilsrådene gitt av appen i forsøksperioden blir så vitenskapelig vurdert. Dette gjøres ved at leger vurderer hver enkelt bruker individuelt og ser på dataene som programmet har tatt utgangspunkt i. Det gjøres en nøye vurdering av hvorvidt sykdomsrisiko ble korrekt vurdert samt om det ble gitt riktige råd basert på denne vurderingen. På grunn av den korte studieperioden på 8 uker, vil det ikke være mulig å si noe sikkert om sykdomsrisikoen faktisk har endret seg. Hensikten med pilotforsøket er hovedsakelig å vurdere brukervennlighet og om rådene som gis er i samsvar med gjeldende kliniske retningslinjer. Det vil spesielt bli lagt vekt på å undersøke om rådene for ulike kroniske sykdommer kan være motstridende.

REKs vurdering

Vi viser til forespørsel om fremleggingsplikt for ovennevnte forskningsprosjekt. Forespørselen er behandlet av sekretariatet i REK nord på delegert fullmakt fra komiteen, med hjemmel i forskningsetikkforskriften § 7, første ledd, tredje punktum. Forespørselen er vurdert med hjemmel i helseforskningsloven § 10.

De prosjektene som skal framlegges for REK er prosjekt som dreier seg om *«medisinsk og helsefaglig forskning på mennesker, humant biologisk materiale eller helseopplysninger»*, jf. helseforskningsloven § 2. *«Medisinsk og helsefaglig forskning»* er i § 4 a), definert som *«virksomhet som utføres med vitenskapelig metodikk for å skaffe til veie ny kunnskap om helse og sykdom»*. Det er altså formålet med studien som avgjør om et prosjekt skal anses som framleggelsespliktig for REK eller ikke.

I dette prosjektet er formålet i første del å utvikle et dataprogram og en app, og i neste fase å teste ut appen ved å undersøke om dataprogrammets risikovurdering og forebyggende livsstilsråd er gyldig for den enkelte brukeren.

Det er lagt ved en prosjektbeskrivelse som er altfor omfattende til at REK kan sette seg inn i dette i forbindelse med en fremleggingsvurdering, men

det er nok på det rene at første del av prosjektet ikke er fremleggingspliktig. Når det gjelder del to heller sekretariatet til at selv om prosjektet har noen helsemessige endepunkt og funnene i studien på sikt vil kunne gi helsemessig gevinst faller ikke prosjektet inn under definisjonen av de prosjekt som skal vurderes etter helseforskningsloven.

Prosjekter som faller utenfor helseforskningslovens virkeområde kan gjennomføres uten godkjenning av REK. Det er institusjonens ansvar å sørge for at prosjektet gjennomføres på en forsvarlig måte med hensyn til for eksempel regler om taushetsplikt og personvern.

Vi gjør oppmerksom på at dette kun er en veiledende uttalelse som har tatt utgangspunkt i de opplysninger søker har fremkommet med i fremleggingsvurderingen. Dersom søker har behov for en nærmere avklaring må det sendes inn en fullstendig søknad for del to.

Vedtak

Ikke fremleggspliktig

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017385

Prosjektet er ikke framleggingspliktig, jf. helseforskningsloven § 2.

Vi gjør oppmerksom på at etter personopplysningsloven må det foreligge et behandlingsgrunnlag etter personvernforordningen. Dette må forankres i egen institusjon.

Med vennlig hilsen

May Britt Rossvoll
sekretariatsleder

Monika Rydland
rådgiver

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017385

ANNEX 2 PARTICIPANT INFORMATION AND CONSENT SHEET TEMPLATE

PARTICIPANT INFORMATION SHEET TEMPLATE FOR ADULTS

[*Place your logo here*]

INVITATION TO PARTICIPATE IN A RESEARCH PROJECT

[TITLE OF YOUR PROJECT]

You are invited to participate in a research project [*insert information regarding the purpose of the project, why the person has been selected for possible participation, and information about how the project manager or institution has identified the person.*]

WHAT IS THE PROJECT ABOUT?

[*Describe the main features of what the project entails, if the participant will need to take any tests or examinations, if they will be interviewed, filmed, etc. Describe how participation in the project may deviate from regular treatment. Give an approximate timeframe of the project. The information you give here will need to be short and concise.*]

The project will collect and record personal information about you. [*Explain what type of information will be collected/recorded. If the information will be compiled (linked to other personal data or registers), the data source (e.g. records* concerning health data*, data from questionnaires, blood-test results) and register will need to be specified.*]

FORESEEABLE BENEFITS AND PREDICTABLE RISKS AND BURDENS OF TAKING PART

[*Insert information regarding the expected advantages and risks, disadvantages, side effects and discomfort from participating in the project. If the research will be combined with treatment a clear explanation will need to be given, detailing the advantages and disadvantages in relation to the treatment received if they take part in the research project in comparison to the treatment one normally receives.*]

VOLUNTARY PARTICIPATION AND THE POSSIBILITY TO WITHDRAW CONSENT

Participation in the project is voluntary. If you wish to take part, you will need to sign the declaration of consent on the last page. You can, at any given time and without reason withdraw your consent. This will not have any consequences for any future treatment [*You can delete this last sentence if the participant is not recruited by virtue of being a patient.*] If you decide to withdraw participation in the project, you can demand that your tests and personal data concerning health be deleted, unless however, the personal data concerning health and tests have already been analysed or used in scientific publications. If you at a later point, wish to withdraw consent or have questions regarding the project, you can contact [*Insert name, telephone number and project managers e-mail address, and if necessary another permanent project member/contact person.*] (A participant should be able to both participate in a project and withdraw their consent with equal ease.)

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017385

WHAT WILL HAPPEN TO YOUR PERSONAL DATA CONCERNING HEALTH?

Any personal data concerning health that has been recorded about you will only be used as described in the purpose of the project. You have the right to access information that has been recorded about you and the right to stipulate that any error(s) in the information that is recorded is/are corrected. You also have the right to know which security measures have been/will be taken when your personal data concerning health is processed.

All information will be processed and used without your name or personal identification number, or any other information that is directly identifiable to you. A code links you and your personal data concerning health via an identifier list. [*Any deviations from this process will need to be specified here*.] Only [*insert the name of the project manager, and possibly others that are involved in the project*] will have access to this list.

(If you are planning to reuse the personal data, a further explanation will need to be given).

Information about you will be anonymised or deleted five years after the project has ended. [*Any deviations from this must be reflected in the text*]

SHARING OF PERSONAL DATA AND TRANSFER OF PERSONAL DATA ABROAD [***ONLY*** *INCLUDE THIS SECTION IF IT IS APPLICABLE TO THE PROJECT*]

By agreeing to participate in the study, you are also consenting to that your information [*state which information (including genetic data if applicable)*] can be transferred to another country as a part of research collaboration and publication. [*If de-identified personal data will be sent to a country that is outside of the EU/EEC, you will need to state the country and include the following sentence:*] This can be a country where the laws do not meet the requirements of the European Data Protection Law. The project manager will therefore ensure that your personal data concerning health is kept safe.

The code that connects you and your personal data concerning health will not be released.

[If you are planning to transfer personal data concerning health to any international databases, you will need to provide further information about which database(s) the personal data will be transferred to as well as the purpose for the transfer]

WHAT WILL HAPPEN TO THE TESTS YOU HAVE TAKEN?

[***only*** *include this section if it is applicable to the project*]

The tests taken from you will be stored in a Research Biobank connected to Research Project. [*Describe which tests will be stored, the name of the Research Biobank, its location, and the person in charge of the Research Biobank.*]

The Research Biobank will terminate once the research project has ended. [*If the tests are going to be sent out of the country for analysis in relation to the aforementioned research project, you will need to state which country they will be sent to. You will also need to provide further information about whether the material will be destroyed or returned once the project has ended.*]

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017385

as a part of the main consent form. You will need to state within which areas the research will take place, when the material will be stored and for how long. You will need to make it clear for the participant that REC does not have the authority to review later use of biological material abroad.]

GENETIC TESTING [***ONLY*** *INCLUDE THIS SECTION IF IT IS APPLICABLE TO THE PROJECT*]

[*Explain in lay terms which type of genetic analysis (analysis of one or several genes vs. more comprehensive mapping of the genome) will be performed, as well as a short summary of what it entails. You will need to specify whether the participant will be contacted concerning any findings made, if relevant*]

- Genetic Counselling
  [*Specify if counselling will be given verbally and/or in written form, and by whom. Give information outlining what kind of counselling will be given, before, during and after the genetic analyses are completed.*]
- Incidental findings
  [*If incidental findings are made - you will need to inform the participant as to whether they will be contacted and be given a referral - should you coincidentally uncover a genetic defect where the participant has a high chance of developing a serious illness which can be prevented or treated.*]
- Possible re-identification
  [*You will need to inform the participant that, even though their name and personal identification number is removed, the genome sequencing is so unique that it can in theory never be regarded as completely anonymous.*]

INSURANCE [*DESCRIBE AS APPLICABLE*]

[*You will need to provide information regarding what type of insurance cover is applicable, for instance the Patient Injuries Act (pasientskadeloven), the Product Liability Act (produktansvarsloven), etc.*]

FOLLOW-UP PROJECT [***ONLY*** *INCLUDE THIS SECTION IF IT IS APPLICABLE TO THE PROJECT*]

[*You will need to inform the participant if they will be contacted in the future regarding follow-up projects.*]

FINANCE [***ONLY*** *INCLUDE THIS SECTION IF IT IS APPLICABLE TO THE PROJECT*]

[*You will need to explain any possible ethical and/or other challenges in relation to financing of the Project (for example, the participant will receive an honorarium/fee, compensation, etc.). If the Research Project or Biobank receives any financial support from a sponsor, you will need to inform the participant about the sponsor's role, possible financial benefits for the Institution/project manager, as well as any conflicts of interest.*]

APPROVAL

The Regional Committee for Medical and Health Research Ethics has reviewed and approved the Research Project [*insert reference number from REC (20xx/yyyy)*].

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017385

In accordance with the General Data Protection Regulation the controller [*insert the name of the institution that is responsible for processing*] and the project manager [*insert the name of the project manager*] is independently responsible to ensure that the processing of your personal data concerning health has a legal basis.

The processing of personal data is in accordance with [insert legal basis for processing, according to the institutions' Data Protection Officer].

You have the right to submit a complaint on the processing of your personal health data concerning health to the Norwegian Data Inspectorate (Datatilsynet).

CONTACT INFORMATION

If you have any questions regarding the research project, you can get in touch with [*insert name, telephone number and email address of the project manager, and possibly another permanent member of the project team*].

You can also get in touch with the Institution's Data Protection Officer (personvernombud) if you have any questions related to the use of your personal health data concerning health in the research project [*email address of the Data Protection Officer*].

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017385

I CONSENT TO PARTICIPATING IN THE RESEARCH PROJECT AND THAT MY PERSONAL DATA CONCERING HEALTH AND BIOLOGICAL MATERIAL CAN BE USED AS DESCRIBED ABOVE

[*Remove the alternative(s) that are not applicable*]

City/Town and date

Participant's Signature

Participant's Name (in BLOCK LETTERS)

[*If a project includes a child or adolescent under the age of 16 years, initially both parents/guardians will need to sign the*] [*Remove any text/sentences that are not applicable.*]

As parents/guardians of_ (Full name), we consent for him/her to participate in the Research Project

---

City/Town and date

Parent's/Guardian's Signature

Parent's/Guardian's (in BLOCK LETTERS)

City/Town and date

Parent's/Guardian's Signature

Parent's/Guardian's (in BLOCK LETTERS)

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017385

Consent on behalf of a representative [*Delete the following sentences if it has not been applied for or if it is not required/applicable*]

As next of kin for _ (Full name) I hereby consent to that he/she can participate in the research project.

Place and date

Next of kin signature

Next of kin name (IN BLOCK LETTERS)

I confirm that I have given information about the research project [*You can include this sentence if you wish, only in the instances where the information is given face to face.*]

Place and date

Signature

Role in the research project

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101017385