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D2.2 – Ethics procedures for user engagement

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Abstract:	This document provides information on the ethics procedures for user engagement for the co-design of the SmartCHANGE tools. It contains practical guidelines for ethical interaction with users, including healthcare professionals, families (parents and their children) and adolescents. Additionally, it provides a template for ethical approval for the user engagement in the co-design.
Keyword List:	User engagement, participation, co-design, participatory design, ethical approval, ethical interactions, healthcare professionals, families, children, adolescents.
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Executive summary

In pursuit of the overall aim of the SmartCHANGE project, which is to develop trustworthy AI-based decision support tools to help health professionals and citizens reduce long-term risks of non-communicable diseases, participatory research methods will be applied. These participatory methods, which will engage users (health professionals, families (parents and their children) and adolescents) require the creation of collaborative, equitable and ethical partnerships. This document presents key information for partners involved in this participatory research for navigating the significant ethical aspects of the research. General ethical considerations as should be considered for the relevant local ethical approval processes are addressed first, followed by a specific section focused on relevant ethical aspects to consider when conducting research with children and adolescents. The first section includes relevant input with regards to five common subsections of ethical approval forms: rationale and study design; study population and recruitment; study procedures; risks and benefits for participants; data privacy and administrative aspects; and informed consent. This section highlights the importance of defining participatory research methods and participatory design, the need for representation and diversity in recruitment strategies and study populations, awareness of the time costs of the project and the need for stakeholder-specific informed consent forms and information letters. The second section contains seven sub-sections regarding research with children and adolescents: unanticipated psycho/social harm; investment of time and reciprocity, protocols for child safety concerns; shared expectations and transparency; diversity and inclusion; and finally power dynamics and tokenism. This section highlights the importance of in-depth exploration of the place of children in research, for instance by reflecting on how the lack of guaranteed confidentiality among participants could result in or be linked to bullying or the need for clear protocols in the event of child safety concerns. The key take-away from the full documents is that ethical considerations in research require an elaborate and ongoing reflection on the research project, its stakeholder groups and its methods. Preparing to continually return to the question of ethical participation will ensure a project that meets the ethical standards of scientific research and represents the underlying ethical and rights-based approach within participatory research methods.

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List of abbreviations

Abbreviation	*Definition*
NCD	Non-communicable disease
ICPHR	International Collaboration for Participatory Health Research

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1 Introduction

The overall aim of the SmartCHANGE project is to is to develop trustworthy, AI-based decision-support tools that will help health professionals and citizens reduce long-term risk of non-communicable diseases (NCDs), by accurately assessing the risk of children and adolescents, including those with difficult-to-detect risks, and promoting delivery of optimised risk-lowering strategies.

Engage users – health professionals, educators, children, and families – will be engaged in requirements elicitation and participatory design from the start. End-users – health professionals, families (parents and their children) and adolescents – will be engaged from the start of the project in four countries. End-users will be engaged in exploration of the use, benefits and risks of AI, co-creation of risk-prediction models, their explanations and visualisations, as well as co-design of the SmartCHANGE tools.

During participatory design meetings, in a process of co-learning and shared-decision making, the SmartCHANGE tools will be designed. A key principle of participatory design is that "users" become central to the design process, as "experts" of their own lived experiences. To facilitate their contributions, we will train all stakeholders in design skills in tailored capacity building workshops. These workshops will also include essential education about AI and privacy, as these are critical components of SmartCHANGE. Special attention will be paid to explaining the risk-prediction models to obtain expert feedback and use it to improve the models. We will also make sure that the tools for health professionals, families (parents and their children) and adolescents use these models in a transparent manner, explaining their predictions as clearly as possible. Participatory design meetings will be organized with a core group of key stakeholders in the four countries, in the family, community, primary health care and school setting. The diversity of the participants in terms of age, gender and cultural background will be emphasized in the recruitment approaches. We strive to include samples that are representative of the proportions of the local community, though it is important to note that if minority voices often need to be given a place beyond direct proportions, as existing power imbalances may otherwise be reproduced. A participatory design approach is particularly suitable to gain the input, insights and contributions of a diversity of stakeholders.

To ensure a collaborative, equitable partnership with the users throughout the participatory design meetings, training of facilitators as well as a practical guideline for ethical interaction with users is key. This deliverable provides ethics approval procedures, practical guidelines

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for ethical interaction with users, and a template for ethical approval. Further reading regarding ethical research involving children can be found via this link:

Ethical Research Involving Children | Save the Children's Resource Centre

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1 Ethics Approval

Ethics approval procedures are unique to each study setting and should be well researched and considered by relevant partners. The section below contains topics that will likely be a part of the research protocol to be submitted to the ethics committee. Appendix I presents an example of an ethics application form, from the ethics committee of Amsterdam UMC, the Netherlands.

1.1 Rationale and study design

Given the considerable time investment for the participants in the participatory design approach, including children and adolescents, explaining the rationale and research question is important. Additionally, given that ethics committees might not be familiar with participatory research methods, it is important to clearly explain the need for the participatory design approach, as well as the study design.

1.2 Study population and recruitment

The study population and recruitment section clearly needs to justify the choice of the population of interest, i.e. healthcare practitioners and families with children or adolescents, and how they will be recruited. We acknowledge and underscore that research must address the needs and variations in gender and cultural backgrounds. Stigmatisation or creation of situations of vulnerability will be prevented through engaging participants in a democratic design process, which will contribute to participants' skills and personal growth. Inclusion/exclusion criteria will be established and justified. To increase inclusivity, it is recommended to limit exclusion criteria to minor practical concerns such as the geographic area under consideration. The recruitment strategies should be made explicit in terms of where and how potential participants will be contacted. Recruitment strategies should not impact the voluntary nature of participation, for instance if participants may fear their continued treatment at a facility is affected by their unwillingness to participate.

1.3 Study procedures

The study procedures section should clearly describe what participation entails and what is expected from the participants., including the number of sessions, duration of the sessions, other participants/collaborators in the research/sessions, data that will be collected and methods used to collect the data. A detailed description of the study procedures for the user

engagement in SmartCHANGE is described in deliverable 3.1: Participatory design research protocol.

1.4 Risks and benefits for participants

Although participants will not be subjected to an intervention, consideration of the indirect effects of participation in the participatory design is important. This includes aspects related to the time-investment, which can impose stress or time pressure regarding other (school, work) tasks, sports or hobbies. Some of the topics discussed in the participatory sessions may result in some emotional distress, for instance if parents perceive judgement on their parenting or if adolescents realise that they don't meet recommendations for physical activity. Participation can also have benefits, including having a say in the development of an app, workshops and skills training (e.g., presentation skills, collaboration skills, design skills), and getting incentives such as vouchers.

1.5 Data, privacy and administrative aspects

Ethics approval also involves explicit plans for how and what kind of data will be collected and how it will be stored and processed. In particular, it should be addressed how the privacy of their participants will be assured, for instance by pseudo/anonymizing of the data, by storing it on a secure server and by considering at what point after the completion of the study these data will be destroyed.

1.6 Informed consent

Before the start of the participatory design process, all participants need to sign informed consent. The question of whether consent is 'informed' requires an age appropriate explanation of the project and what participation would entail. An information letter includes all relevant information about the project and contains an informed consent form, that can be completed by the participants. Information letters need to be specified for the different stakeholder groups, i.e. healthcare practitioners, families with children, and adolescents. It is essential that these documents make it clear that participation is voluntary and that participants can withdraw at any time without providing an explanation (though they must inform the researcher of their decision to withdraw). In the case of children and adolescents below the age of 15 or 16 (depending on the country), consent from one of their legal guardian is also required (depending on the local definitions regarding age limits).

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2 Further Ethical Considerations for Children/Adolescents

Ethics in research goes beyond requirements for ethical approval. It involves ongoing reflection and consideration of the process and impacts of the research and the needs, preferences and safety of participants. This is especially relevant when working with children and adolescents. Preparing for particular issues well in advance, as well as consistently revisiting the question of ethical conduct and potential harm is essential to carrying out ethical research.

2.1 Ethical issues involved in participatory forms of health research

In the participatory design process we will follow the guidelines developed by the International Collaboration for Participatory Health Research (ICPHR; International Collaboration For Participatory Research - Home (icphr.org)), which addresses the specific ethical issues involved in participatory forms of health research. These guidelines focus on eight key areas: mutual respect, democratic participation, active learning, making a difference, collective action, personal integrity, equality and inclusion. All academic researchers and stakeholders engaged in the co-creation groups will be expected to engage in ethical reflexivity throughout the research process to ensure adherence to the principles. All academic researchers, teenage researchers and stakeholders will receive training regarding the ethical issues in participatory heath research, including an explanation of the principles and methods to adhere to them. Feedback sessions will take place regularly and facilitators will discuss together during their meetings to discuss and resolve barriers and issues in participation. Unanticipated psycho/social harm

2.1.1 Distress from conversations

Given the discussions involved in this research may concern their wellbeing, health and environment, there is a chance that difficult, personal and emotionally charged subjects may come up during sessions. Imagine for instance that the subject of the inability to pay for sports equipment were to come up. This could be distressing for the participants. A number of steps can be taken to prepare for such occurrences. Firstly, facilitators should continually work on shaping a safe environment for discussions, for instance through the creation of session guidelines and the encouraging of supportive communication and active listening among participants. Secondly, facilitators should continually remind their participants that they do

not have to discuss subjects or answer questions that make them uncomfortable, as well as that they can leave the sessions at any time. Thirdly, plans should be made for how to tackle debriefing if a particularly tense conversation does take place.

2.1.2 Confidentiality and bullying

When intensively working with a group of participants, it is important to ensure that participants can speak freely, without the thought that the conversation might be shared with others and cause distress. Attention should therefore be paid to mutual respect, accountability and confidentiality, already in the first session, for example, by drafting 'collaboration rules' in and with the group. Additionally, a plan should be in place for mediation and support in the event of bullying linked to participation.

2.2 Investment of time and reciprocity

To participate in this research, participants invest time that might otherwise be spent on beneficial activities such as sports, hobbies, work or study. As such it is important that the participation also produces benefits for them, and not just the long-term future benefits to be anticipated from the final products of the research. Benefits can include skills and knowledge gained during participation. This requires consistent engagement with researchers as well as follow up, where findings and developments should be shared with participants in an appropriate language level and style. Simply working on making sure participation is fun/joyful or ensuring that children's voices are heard is also a benefit. An important way to ensure reciprocity in research is to discuss with (potential) participants what they would find a good/fair benefit to balance out participation.

2.3 Protocols for child safety concerns

2.3.1 Suspected abuse

During research participation, there is a chance children or adolescents may reveal harm or safety issues or that a researcher may come to suspect a child is at risk. This could include for instance concerns about a child who is being abused, harmed or neglected, or is threatening harm to themselves/another person. An immediate and sensitive response from the researcher as well as follow-up support and referral to appropriate services is essential. As such, establishing a protocol for such situations, including knowledge of relevant referral and reporting institutions is essential. It may be worth establishing contact with an organization involved in child protection and safety, as well as to invest in some training or targeted supervision for facilitators.

2.3.2 Researcher misconduct

As researchers we must consider the reality that the conduct of researchers, both intentionally and unintentionally, cannot be beyond reproach if we wish to conduct ethical research. Incompetence, lack of research integrity and abusive intentions can all occur within research with damaging effects for participants. Preparing a code of conduct for facilitators prior to research is one important step that can be taken. This should include guidance, for instance on what misconduct can mean (i.e. accepting gifts from participants, meeting one on one outside the research context). Protocols for reporting misconduct should also be made clear and available to all participants.

2.4 Shared Expectations and transparency

A form of harm that is often overlooked in research with children and adolescents is the disappointment that can occur if their expectations for participation are not met. It is therefore important to have transparency about the outcomes of the research project and the degree of input and control they have over it. For instance, the production of one final product for all four countries, where each country will have multiple participatory groups in their sample implies that not every thought or idea they have may be fully reflected in the final product. Ongoing communication about the incorporation of their ideas and how these are weighed against other perspectives included in the study is essential.

2.5 Diversity and Inclusion

Research that aims to represent the voices of children should consider that in order to do so it must represent and include children across intersecting categories of gender, ethnicity, disability and language (among others). The underlying principles of fairness and justice mean that the wider sociopolitical context within which research occurs cannot be set aside. It implies that children should be treated equally and with respect for their dignity and human rights. For this reason good ethical practice would involve consideration of the nature of sampling practices, who gets to have a voice and what can be done to include those who might otherwise be dismissed (e.g. children with special needs).

2.6 Power dynamics and tokenism

One of the most frequently recognized ethical issues in research with children and adolescents is the risk of tokenistic participation because of a lack of awareness or action regarding power dynamics at play between children and adults. Sociocultural expectations

regarding adulthood and expertise as a research and compliance/respect on the part of children (falling into the role of students) can result in research that does not represent children's voices. Other issues can include: a lack of adjustment of activities and techniques to participant's age, limiting their ability for meaningful participation; (unintentionally) belittling or undermining perspectives or opinions voiced by participants; and imposing perceptions of vulnerability or a lack of capacity on participants, and thus limiting the questions and issues they are allowed to engage with. Active reflection on the role of the facilitator and how children's voices can be amplified and respected is required.

Power dynamics do also exist between children, where social dynamics between participants can also limit the extent to which all voices are heard. Considerations of both who has access to spaces of participation and how participants interact should be raised continually and efforts should be made to address any issues.

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3 Appendix I

Research protocol

General Information

Title	
Date	
Version number	
Author	
Coordinating researcher	<>
Principal researcher	< >
Organizer/Funder	< >

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Onderzoekgegevens

Rationale	<Describe the background and hypotheses of the research>
Goal	<Indicate primary and secondary research goals>
Study design	<Describe the study design (i.e. longitudinal, exploratory etc.)>
Studie population	<Describe the characteristics of the study population (e.g., healthy volunteers aged 18-55 who are gynecology patients)>
Inclusion criteria	<List inclusion criteria>
Exclusion criteria	<List exclusion criteria>
Sample size	<Describe target sample size and how this was decided>
Recruitment of participants	<Describe the who/what/when and where of recruitment as well as how informed consent will be obtained>
Intervention	<Describe the types of intervention that will take place e.g. questionnaires, filling in a weekly diary etc. >
Study end goal/ products	<Indicate the primary end goals, indicators or products>

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Study parameters	<Indicate which variables and parameters are under consideration>
Statistical analysis	
Requirements for participants	<Indicate what the requirements are for participants and how much time these will cost. E.g. coming to the university once a month and filling in three questionnaires>
Risks for participants	<Indicate what health risks participants may incur>
Benefits for participants	<Indicate any potential benefits of participation >
Potential harm for participants	<Indicate any potential harm for participants >
Reimbursement of participants	<Indicate how participants may be reimbursed. E.g. free lunch, a gift card>
Administrative aspects	<Indicate how data will be collected and stored and for what duration they will be stored>
Publication plans	<Describe the publication policy of the project>
Other concerns	

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