

**D11.1. H - Requirement No. 2**

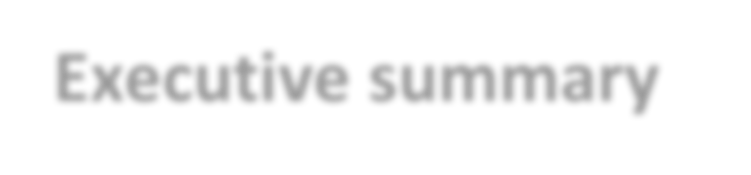
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| 0.1 | 02.02.2018 | Claudia Fabian (ZSI) | Proposal |
| 0.2 | X |  | Peer review and detailed feedback on overall structure and specific content |
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**Executive summary**

This document is part of the ethics requirements of the REINFORCE project. As human participants are involved in the project as volunteers the project has elaborated a set of consent/assent forms and information sheets. These inform the volunteers in advance about all relevant aspects of their engagement in any project activities. Especially children, senior or 'vulnerable' individuals such as for instance visually impaired people need to be 'able' to consent to any engagement in the project.

The document describes the importance of obtaining informed consent, establishes a procedure to generate consent forms specific for individual REINFORCE activities and provides first templates. The EU’s General Data Protection Regulation is referred to as regulatory framework for REINFORCE’s data collection.

The document includes the following:

* informed consent for adult participants
* parental consent
* informed assent for children and minors

The forms provided in this document are all in English. For the activities taking place in participating countries, the partners will translate the forms into their respective languages.

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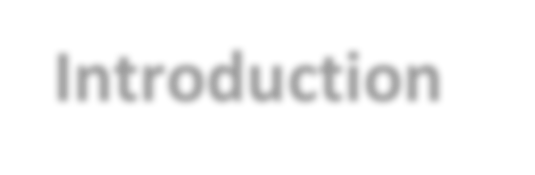
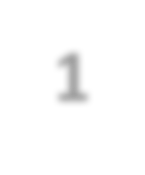
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**1 Introduction**

The REINFORCE project is committed to a high quality output and responsible research and innovation (RRI) as defined by the European Commission (Jacob et al., 2013)1. Ethical procedures are a core element of RRI. Thus, this document defines a set of procedures that the consortium is committed to with regards to the consenting process of project participants.

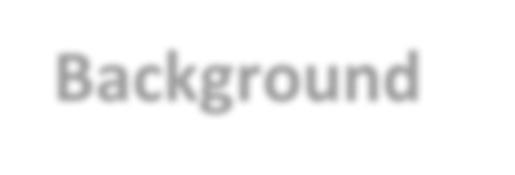
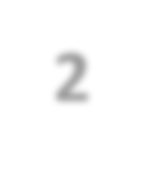
The main objective of this deliverable is to summarize the requirements for informed consent procedures in the REINFORCE project’s research and innovation activities and to establish a process, which helps to acquire the consent of all individuals, adult or children, participating in REINFORCE actions, such as co-design sessions. Informing participants and getting their or their parents’ consent is not only a legal obligation, but also the expression of an ethical principle, which the European Commission has started to promote more forcefully over the last years as a component of Responsible Research and Innovation (RRI).

The European Commission defines ethics as key dimension of RRI as follows: “*European society is based on shared values. In order to adequately respond to societal challenges, research and innovation must respect fundamental rights and the highest ethical standards. Beyond the mandatory legal aspects, this aims to ensure increased societal relevance and acceptability of research and innovation outcomes. Ethics should not be perceived as a constraint to research and innovation, but rather as a way of ensuring high quality results*.” (p.4)*2*

Especially the last point of the Commission’s definition highlights the value we want to provide in this deliverable. Beyond simply providing the two documents promised in the title of this deliverable, i.e. an information sheet and a consent form, informed consent is a step in a process, in which researchers, practitioners (e.g. designers, makers, healthcare professionals) and participants enter a dialogue about the purpose of the research as well as their specific role. This urges researchers and stakeholders to question themselves if they comply with high moral standards and if they ensure increased societal relevance and acceptability of research and innovation outcomes.

More details on ethics in REINFORCE will also be given in the Ethics Handbook and Data Management Plan (deliverable D1.2 due on the 8Th month of the project). The following section are structured along these aspects:

* + ‘Giving consent’ as a component of RRI, ensuring socially relevant research;
  + A procedure to obtain consent based on REINFORCE specific data collection needs;
  + The EU’s General Data Protection Regulation (GDPR) as the foundation for obtaining consent;
  + Templates, which combines project information and the consent/assent forms.



**2 Background**

According to the European Union’s definition of RRI ethics comprises three main aspects3:

* + Research integrity and good research practice.

1 Jacob, K., Van Den Hoven, J., Nielsen, L., Roure, F., Rudze, L., Stilgoe, J., … Riera, C. M. (2013). Options for strengthening responsible research and innovation: Report of the expert group on the state of the art in Europe on responsible research and innovation. *European Commission: Brussels*.

2 <http://ec.europa.eu/research/science-society/document_library/pdf_06/responsible-research-and-> innovation-leaflet\_en.pdf

3 <http://ec.europa.eu/research/science-society/document_library/pdf_06/responsible-research-and->

innovation-leaflet\_en.pdf

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* + Research ethics for the protection of research objects (people, animals, and environment).
  + Societal relevance and ethical acceptability of research and innovation outcomes.

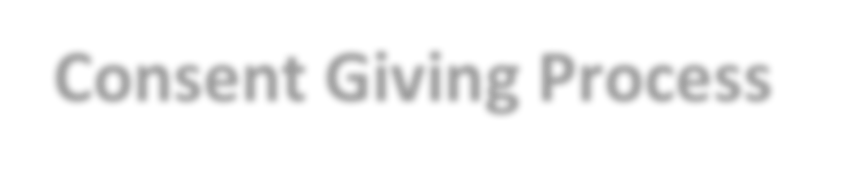
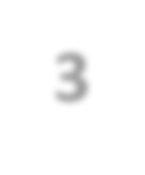
The first point mostly relates to the fact that scientific misconduct and questionable research practices shall be avoided. The second aspect is often taken up by institutional guidelines as well as national and international laws and policies. The aim of this deliverable is to define research ethics for research participants in REINFORCE. Thus, in this document we mostly related to this aspect of RRI.

In order to define appropriate processes, tools and protocol, we need to think about the different target groups involved in our actions. This is outlined in the following table.

*Table 1: REINFORCE Target groups possibly involved in REINFORCE actions*

|  |  |
| --- | --- |
| **Target Group** | **Envisioned involved in REINFORCE activities** |
| Adults | Participating in co-design sessions, workshops, etc. |
| Children | Participating, together with their parents/legal guardians in co-design sessions |
| Fragile adults (senior, visually or otherwise impaired,….) | Participating in co-design sessions, workshops, etc. |
| High School teachers | Participating in co-design sessions, workshops, etc. |
| Makers | Participating in co-design sessions, workshops, etc. |
| Policy makers | Possibly involved in survey or interview, workshop, etc. |

As we can see in Table 1, there is a considerable variety of participants that may be taking part in evaluation activities of the project. At this point, it becomes important to think about ‘obtaining consent from research participants’ at a project level. At the project level, we suggest a process that starts with comprehensive templates and proceeds through a fine-tuning process in order to obtain information sheets and consent forms that match best planned co-design activities.



**3 Consent Giving Process**

As outlined in the previous section, we have different target groups that are involved in different REINFORCE activities. Since these activities are taking place in different countries on a global scale, some general procedures need to be defined to make sure that consent is obtained from the different target groups in an appropriate manner. The following main principles apply:

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* + partners engaged in the organisation of virtual (web) and in person (local events, workshops, co-design sessions) participation will reflect on the level of engagement of participants in the action and define in the planning phase what contributions are expected from the participants.
  + All partners have access to the informed consent templates and will adapt these according to the specific needs of the action, including the information sheet, the language, etc.

Figure 1 below gives a general overview of how the consent process works and how the templates are adapted according to the action particularities. It also relates to the objectives of specific actions with the general evaluation and impact assessment data gathering process. A more detailed discussion of possible data collection instruments will be integrated in the deliverable D1.2.

The tools at hand, as well as the size of the group and the shape of the activity will suggest some data collection methods as more effective than others. Put differently, the objectives on the left side of Figure 1 need to be specified under the concrete action to be performed, which in turn will suggest the most adequate methods of data collection so that we can clearly say what the data will contain (e.g. transcripts of interviews, survey data etc.). In a first step, the concrete information about the REINFORCE project will be merged with the REINFORCE specific templates for an ‘Information sheet’ and a ‘Consent form’. These forms are included in this deliverable in a later chapter. In a second step, these merged documents are then translated into the local languages where the action is taking place.



**Adaption of Forms**

**Action Information sheet**

Local language

**Action Consent form** Local language

*Figure 1: Consent obtaining process in REINFORCE*

An important step in the process illustrated above, is the merging of the REINFORCE specific templates with the action specific details. The implications of that merging are presented in Table 2.

**REINFORCE participation, co-design**

* Web participation
* Hangouts
* Live sessions
* Co-design sessions

**Template Information Sheet** English

**REINFORCE Evaluation**

* Survey
* Interviews
* Reflections
* Platform data

**Template Consent Form** English

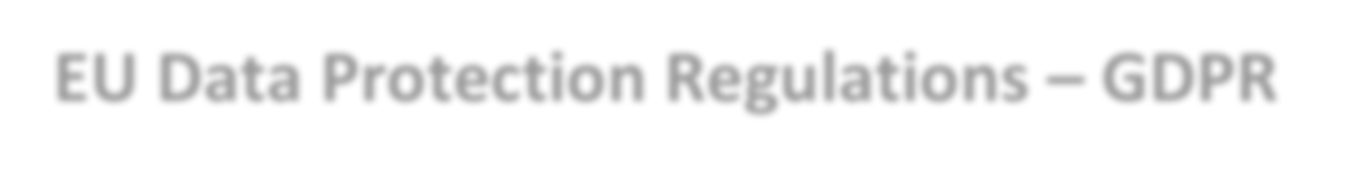
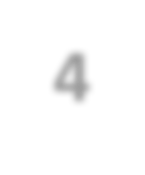
*Table 2: The merging of REINFORCE and action specific information*

|  |  |  |
| --- | --- | --- |
| **Information sheet Consent form** | | |
| REINFORCE specific | * General project objectives * The project’s benefits * Project description (duration, coordinator) | * Rights of participants according to the GDPR (e.g. withdrawal from study, deletion of personal data) * Data storage and handling,   anonymizing of data |

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|  |  |  |
| --- | --- | --- |
| Action specific | * Specific action’s objective * The action’s benefits * Action description (duration, lead- responsible,…) | * Active assent to data collection activities * Specification of what data can be extracted and / or deleted upon request |



**4 EU Data Protection Regulations – GDPR**

The EU’s General Data Protection Regulation (GDPR) is a framework regulating the storage and handling of personal data. Main changes w.r.t previous scheme (Data Protection Directive) include4:

1. Research institutions must keep a thorough record of how and when an individual gives consent to store and use their personal data.
2. Consent needs to be granted by active agreement. Consent giving needs to be backed up by a clear audit trail of consent, including information sheets and other materials of informing participants.
3. Participants also have the right to withdraw consent at any time, easily and swiftly. When somebody does withdraw consent, their details must be permanently erased, it would not be sufficient to simply delete them from the contact list and still keep their data. GDPR gives individuals the right to be forgotten.
4. Moreover, GDPR requires organisations to know exactly what personal data they hold and where it is located and have procedures in place to ensure its complete removal when a request to do so is made.
5. Monitoring protocols must be able to recognise and act on access breaches as soon as they happen, and participants must be informed about any unauthorized access within 72 hours.

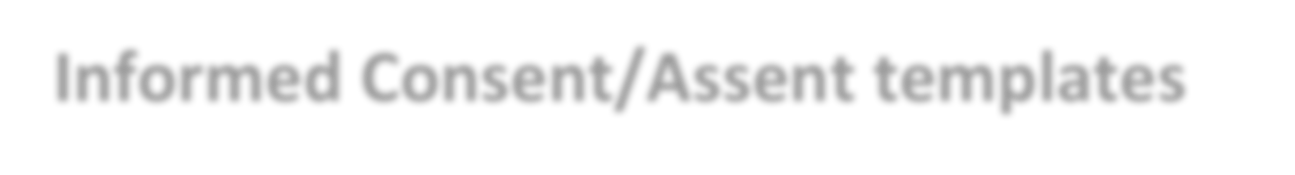
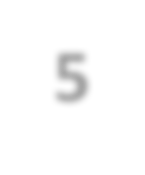
Particularly, items 1 – 3 need to be taken care of by lead-researchers. Points 4 and 5 should rarely apply as most data should be stored in an anonymized format. The recommended age limit by the GDPR to join an online-information service (without verifiable parental/ custodian consent) is 16 years, however, individual EU countries can determine a different age, starting with 13 years. For example, in Austria youths needs to have completed 14 years before they can legally consent to participate in online services5.

4 https://[www.eugdpr.org/key-changes.html](http://www.eugdpr.org/key-changes.html)

5 https://www.wko.at/service/wirtschaftsrecht-gewerberecht/EU-Datenschutz-Grundverordnung:-Wichtige- Begriffsbestimmu.html#Kind

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**5 Informed Consent/Assent templates**

We reviewed various project information sheets 7 and adjusted their structure and content to the needs of the REINFORCE project. To avoid the impression of a primarily bureaucratic process we aimed to use a clear and accessible language without oversimplifying the form. The forms are provided in English here, but version in different languages will be produced by the partners.

The templates consist of two parts:

* *Part I:* Project and pilot information – which should be the same for all participants
* *Part II:* Consent form for adults or consent form to be presented to the parents (on behalf of the children); assent form in case of children

6 E.g. the Made4you project sheets

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## Informed Consent Form for adults

### This informed consent form is for adults participating in the REINFORCE citizen’s science program:

#### [REINFORCE partner: Stavros Katsanevas

#### [REINFORCE partner: EGO

***This project has received funding from the European H2020 research and innovation programme under grant agreement No 872859***

**This Informed Consent Form has two parts:**

* **Information Sheet (to share information about the study with you)**
* **Certificate of Consent (for signatures if you agree that your child may participate) You will be given a copy of the full Informed Consent Form**

**Information Sheet**

**Introduction**

I am \_\_\_\_\_\_\_\_\_\_\_, and I work at \_\_\_\_\_\_\_\_\_\_ organization in \_. I am working on some

research and innovation actions which might help you and others to get access to customized healthcare solutions caused by physical limitations.

#### Purpose

There are many patients with physical limitations that need personalized devices to support their everyday lives. While public healthcare is taking care of providing support, their offers are not always ready to have, not personalized or you have to wait a long time. In this project we want to develop personalized solutions together and share their designs on an open platform, called “Careables” (www.careables.org). Patients, like you, are experts in their lives and in their personal needs. So we want to ask you to share your knowledge and understanding with us so that we can together find ways of meeting their needs when facing their physical disablements.

#### Type of Intervention

**(please select)** Questionnaire Focus group

Co-design workshop Interview

#### Selection of Participants

We want to include as many patients with physical limitations as possible in order to have a large number of open healthcare solutions available and shareable on the Careables platform (careables.org). Therefore, we would like to ask you to participate because you may be able to contribute to designing an open solution for you than can be shared with others.

#### Voluntary Participation

Your participation is completely voluntarily and you can stop your participation at any time.

#### Procedure

(chose from the examples, depending on what activity you involve the child in)

1) the following applies only to co-design sessions:

You will take part in a co-design session with a mix of other patients, makers, healthcare professionals and intermediaries. This design process will be guided by [give name of moderator]. The whole co-design process will be documented by [give name of person documenting] and the documentation material will be shared on the open health platform Careables (careables.org). Personal information about you will not be shared on the platform unless explicitly agreed in advance.

The co-design session will take place in [location of the group discussion] for an expected period of [indication of how many co-design sessions or a time period].

1. the following applies only to focus group discussions:

You will take part in a discussion with other patients, parents/guardians and healthcare professionals from the local community. This discussion will be guided by [ give name of moderator] or me.

The discussion will take place in [location of the group discussion], and no one else but the people who take part in the discussion and the guide or I will be present during this discussion. The entire discussion might be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s) with access to the tapes] will be allowed to listen to the tapes. [The tapes will be destroyed after period of time.]

1. the following applies only to interviews:

You will participate in an interview with [name of interviewer] or myself.

If you do not wish to answer any of the questions during the interview, you may say so and we will move on to the next question. The information recorded is confidential, and no one else except [name of person(s) with access to the information] will have access to the information documented during your interview.) [The tapes will be destroyed after period of time.]

1. the following applies only to questionnaire surveys:

You will fill out a questionnaire which will be provided by [name of distributor of blank questionnaires] and collected by [name of collector of completed questionnaires].

If you do not wish to answer some of the questions included in the questionnaire, you may skip them and move on to the next question. The information recorded is confidential, and no one else except [name of person(s) with access to the information] will have access to her questionnaire. [The questionnaires will be destroyed after period of time.]

#### Benefits

[adapt the text below if necessary]

We expect a direct benefit for you in providing personalised healthcare solution. In addition, others may benefit from your contribution if you agree to sharing the documented design process (without any personal/private information) on the Careables platform (careables.org) under different creative commons licences options to select from.

#### Reimbursements

You will not be provided with any payment to take part in the project activities. Material for the co-design sessions will be provided by the project as far as this is within our budgetary limits. If material that cannot be covered by the project budget is needed, we will inform your beforehand. Snacks are also provided by the project.

#### Confidentiality:

We will not be sharing information about you outside of the project team. The information that we collect from this project will be kept confidential. Information about you that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about you will be stored anonymously.

The following applies to focus groups:

We will ask you and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each participant to keep what was said in the group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.

#### Sharing of Research Findings

We will be sharing what we have learnt with the participants and with the community. We will do this by providing a written report. Nothing that you will tell us today will be shared with anybody outside the research team, and nothing will be attributed to you by name. We might also publish the results in academic outlets in order that other interested people may learn from our research. Data will only be included in these publications in aggregated and anonymized form.

#### Right to refuse or withdraw

You may choose to opt out and stop your participation at any time.

#### Who to Contact

If you have any questions you may ask them now or later, even after the participation. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e- mail]

This proposal has been reviewed and approved by the European Union’s research and innovation programme Horizon 2020, including an ethical screening to make sure that participants are protected from harm and their privacy is respected at all times.



# Certificate of Consent

#### I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction.

**I hereby give consent for my data to be conveyed and documented for the purpose stated above. I confirm that I have been informed of the nature of REINFORCE and that my participation is voluntary. I am aware that I may withdraw my consent at any time.**

**Print Name of Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Participant\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Day/month/year**

**Statement by the project team member/person taking consent**

**I have accurately read out the information sheet to the participant, and to the best of my ability made sure that the person understands the process.**

**I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.**

**Print Name of project team member/person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of project team member/person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Day/month/year**

**A copy of this Informed Consent Form has been provided to the participant**



**Informed Consent Form for parents/legal guardians**

This informed consent form is for parents/legal guardians of adolescent girls and boys participating in the research and innovation activities titled: "Open and Inclusive Healthcare for Citizens Based on Digital Fabrication"

**[REINFORCE partner: insert name of principle contact person] [REINFORCE partner: insert the name of your organization]**

***This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 020120***

**This Informed Consent Form has two parts:**

* **Information Sheet (to share information about the study with you)**
* **Certificate of Consent (for signatures if you agree that your child may participate) You will be given a copy of the full Informed Consent Form**

**Introduction**

**Information Sheet**

I am \_\_\_\_\_\_\_\_\_\_\_, and I work at \_\_\_\_\_\_\_\_\_\_ organization in \_. I am working on some

research and innovation actions which might help your child to get access to customized healthcare solutions caused by their physical limitations. In our project we will talk to children and teenagers, both girls and boys, and ask them a number of questions. Whenever researchers study children, we talk to the parents and ask them for their permission. After you have heard more about the study,

and if you agree, then the next thing I will do is ask your daughter/son for their agreement as well. Both of you have to agree independently before we can begin.

You do not have to decide today whether or not you agree to have your child participate in this project. Before you decide, you can talk to anyone you feel comfortable with.

There may be some words that you do not understand. Please ask the contact person, who handed you over this consent sheet and they will take time to explain. If you have questions later, you can ask them or any another person working in the project to answer them.

#### Purpose

There are many patients, including children and teenagers, with physical limitations that need personalized devices to support their everyday lives. While public healthcare is taking care of providing support, their offers are not always ready to have, non-personalized or you have to wait a long time. In this project we want to develop personalized solutions together and share the designs on an open platform. Patients are experts in their lives and their personal needs. We want to ask them to share their knowledge and understanding with us so that we can together find ways of meeting their needs when facing their physical disablements.

#### Type of Research Intervention (please select)

Questionnaire Focus group

Co-design workshop Interview

#### Selection of Participants

We want to include as many patients (including children) with physical limitations as possible in order to have a large number of open healthcare solutions available and shareable on the Careables platform (careables.org). We would like to ask your daughter/son to participate because she/he is a patient with special physical limitation and may be able to contribute to designing an open solution for herself/himself than can be shared with others.

#### Voluntary Participation

You do not have to agree that your daughter/son can talk to us. You can choose to say no and any services that you and your family receive at this centre will not change. We know that the decision can be difficult when it involves your children. You can ask as many questions as you like and we take the time to answer them. You don't have to decide today. You can think about it and tell me what you have decided later.

#### Procedure

(chose from the examples, depending on what activity you involve the child in)

1) the following applies only to co-design sessions:

Your daughter/son will take part in a co-design session with a mix of other patients, makers, healthcare professionals and intermediaries. This design process will be guided by [give name of moderator]. The whole co-design process will be documented by [give name of person documenting] and the documentation material will be shared on the open health platform Careables (careables.org). Personal information about your daughter/son will not be shared on the platform unless explicitly agreed.

The co-design session will take place in [location of the group discussion].

1. the following applies only to focus group discussions:

Your daughter/son will take part in a discussion with other patients, parents/guardians and healthcare professionals from the local community. This discussion will be guided by [ give name of moderator] or me.

The discussion will take place in [location of the group discussion], and no one else but the people who take part in the discussion and the guide or I will be present during this discussion. The entire discussion will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s) with access to the tapes] will be allowed to listen to the tapes. [The tapes will be destroyed after period of time.]

1. the following applies only to interviews:

Your daughter/son will participate in an interview with [name of interviewer] or myself.

If your daughter/son does not wish to answer any of the questions during the interview, she/he may say so and the interviewer will move on to the next question. The interview will take place in [location of the interview], and no one else but the interviewer will be present unless your child asks for someone else to be there. The information recorded is confidential, and no one else except [name of person(s) with access to the information] will have access to the information documented during your interview.) [The tapes will be destroyed after period of time.]

1. the following applies only to questionnaire surveys:

Your daughter/son will fill out a questionnaire which will be provided by [name of distributor of blank questionnaires] and collected by [name of collector of completed questionnaires]. **OR** The questionnaire can be read aloud and she/he can give you the answer which she/he wants you to write.)

If your daughter/son does not wish to answer some of the questions included in the questionnaire, she/he may skip them and move on to the next question. The information recorded is confidential, and no one else except [name of person(s) with access to the information] will have access to her questionnaire. [The questionnaires will be destroyed after period of time.]

#### Duration

Include a statement about the time commitments of the study for the child and any time commitments on the part of the parent(s). Include both the duration of the study and follow-up, if relevant.

#### Benefits

[adapt the text below if necessary]

We expect a direct benefit for your child in providing personalised healthcare solution for her/him. In addition, others may benefit from the contribution of your child if you and your child agree to sharing the documented design process (without any personal/private information) on the Careables platform.

#### Reimbursements

Your daughter/son will not be provided with any payment to take part in the project activities. Material for the co-design sessions will be provided by the project as far as this is within our budgetary limits. If material that cannot be covered by the project budget is needed, we will inform you beforehand. Snacks are also provided by the project.

#### Confidentiality:

We will not be sharing information about your son or daughter outside of the project team. The information that we collect from this project will be kept confidential. Information about your child that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about your child will be stored anonymously.

The following applies to focus groups:

We will ask your child and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each participant to keep what was said in the group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.

#### Sharing of Research Findings

We will be sharing what we have learnt with the participants and with the community. We will do this by providing a written report. Nothing that your child will tell us today will be shared with anybody outside the research team, and nothing will be attributed to him/her by name. We might also publish the results in academic outlets in order that other interested people may learn from our research. Data will only be included in these publications in aggregated and anonymized form.

#### Right to refuse or withdraw

You may choose not to have your child participate in this study and your child does not have to take part in this research if she/he does not wish to do so. Your child may stop participating in the discussion/interview/workshop at any time that you or she/he wish without either of you losing any of your rights here.

#### Who to Contact

If you have any questions you may ask them now or later, even after the participation. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e- mail]

This proposal has been reviewed and approved by the European Union’s research and innovation programme Horizon 2020, including an ethical screening to make sure that participants are protected from harm and their privacy is respected at all times.



# Certificate of Consent

#### I have been asked to give consent for my daughter/son to participate in this research study which will involve her/him completing one interview and one questionnaire

**I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study.**

**Print Name of Parent or Guardian**

**Signature of Parent of Guardian\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Day/month/year**

**Statement by the project team member/person taking consent**

**I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands the process.**

**I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.**

**A copy of this Informed Consent Form has been provided to the parent or guardian of the**

**participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Print Name of project team member/person taking the consent**

**Signature of project team member/person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Day/month/year**

**An Informed Assent Form will \_\_\_\_ OR will not be completed.**



**Informed Assent Form for children/adolescent girls and boys**

This form is for parents/legal guardians of children and adolescent girls and boys participating in the research and innovation activities titled: "Open and Inclusive Healthcare for Citizens Based on Digital Fabrication"

**[REINFORCE partner: insert name of principle contact person] [REINFORCE partner: insert the name of your organization]**

**This Informed Assent Form has two parts:**

* **Information Sheet (gives you information about the study)**
* **Certificate of Assent (this is where you sign if you agree to participate) You will be given a copy of the full Informed Assent Form**

**Information Sheet**

**Introduction**

My name is and I work in the project REINFORCE, where we want to design and build

together things that support your or other people’s daily life.

I am going to give you information and invite you to be part of our project activities. You can choose whether or not you want to participate. We have discussed this with your parent(s)/guardian and they know that we are also asking you for your agreement. If you are going to participate, your parent(s)/guardian also have to agree. But if you do not wish to take part in our activities, you do not have to, even if your parents have agreed.

You may discuss anything in this form with your parents or friends or anyone else you feel comfortable talking to. You can decide whether to participate or not after you have talked it over. You do not have to decide immediately.

There may be some words you don't understand or things that you want me to explain more about because you are interested or concerned. Please ask me to stop at anytime and I will take time to explain.

#### Why are we doing this project and why do we want to involve you?

In this project we want to support people who have some difficulties in their daily lives by making devices together and share the instructions on how to make similar devices with others.

We do want to help adults and children alike and that’s why we are involving you.

#### Do I have to do this?

You can participate in our project activities if you want to. If you do not want to continue you can tell us anytime. It’s up to you. If you decide not to be in the project, it’s okay and nothing changes. Even if you say "yes" now, you can change your mind later and it’s still okay.

#### I have checked with the child and they understand that participation is voluntary \_\_(initial)

**What is going to happen to me?**

Explain the procedures in simple language. Focus on what is expected of the child. E.g. if it is a co- design workshop briefly outline how the workshop is going to take place. Explain also how long it will take and if it is over various sessions.

#### I have checked with the child and they understand the procedures (initial)

**Can I take something home afterwards?**

Describe if the child can take a design or device home.

#### I have checked with the child and they understand the benefits (initial)

**Is everybody going to know about this?**

We will not tell other people that you are participating in this project and we won't share information about you to anyone who does not work in the project.

Information about you that will be collected will be put away and no-one but the researchers will be able to see it.

If you decide to share the information with others on our platform called “Careables” (careables.org) it will be your decision and you will have to agree on the sharing on the platform itself.

If picture are taken during the activities we will ask you and your parents in case we would like to use them for our promotional material. We will not use it without your agreement.

#### Will you keep me informed about the project?

We do inform more people, other patients with specific healthcare issues, scientists, designers and others, about our project. We will do this by writing and sharing reports and by going to meetings with people who are interested in the work we do.

#### Can I choose not to participate later and can I change my mind?

You do not have to be in this project. No one will be mad or disappointed with you if you say no. It’s your choice. You can think about it and tell us later if you want. You can say "yes" now and change your mind later and it will still be okay.

#### Who can I talk to or ask questions to?

You can ask me questions now or later. You can also ask my colleagues involved in the project.

#### If you choose to be part of this research I will also give you a copy of this paper to keep for yourself. You can ask your parents to look after it if you want.



**Certificate of Assent**

The REINFORCE project is supporting the building and sharing of open and inclusive healthcare devices.

#### I understand my involvement in the REINFORCE project.

**I have read this information (or had the information read to me). I have had my questions answered and know that I can ask questions later if I have them.**

**I agree to take part in the research.**

***OR***

**I do not wish to take part in the research and I have not signed the assent below (initialled by child/minor)**

**Only if child assents:**

**Print name of child**

**Signature of child: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**day/month/year**

***If illiterate:***

A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the project team).

#### I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

**Print name of witness (not a parent) Signature of witness**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Day/month/year**

**I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.**

**Print name of researcher/project team member**

**Signature of researcher/project team member\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Day/month/year**

**Statement by the researcher/person taking consent**

**I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the child understands the process it is being involved.**

**I confirm that the child was given an opportunity to ask questions about the project, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.**

**A copy of this assent form has been provided to the participant.**

**Print Name of project team member/person taking the consent**

**Signature of project team member/person taking the consent**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Day/month/year**

**Copy provided to the participant (initialed by researcher/project team member)**

**Parent/Guardian has signed an informed consent Yes No (initialed by researcher/assistant)**