1. They are asked to fill in their age (date of birth), country of residence and preferred language. Based on this, they receive an information "brochure" from one of the target groups.

Model for informed consent (3 target groups)

There are a number of mandatory components that such an information sheet and consent form must meet: The idea is that for each target group the headings are the same, but the level of information is age-appropriate.

By having them indicate immediately after each topic whether they have understood it, you can build in an extra check (still thinking about how to check that the parent is also authorized to sign)

Icons (developed by Erasmus MC, free to use; <https://surfdrive.surf.nl/files/index.php/s/sP6Og3hDRIni5jj>

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | |  | | m.b.v. tick box (convert to smart contract)? |
|  | **16 years and older** | **12-16 years** | **children up to 12 years** | **\*Read and understood? Yes/No**  **Read and understood by parents? Yes/no** |
| **Title of the study** | **Daily burden of patients with sickle cell disease** | **Study about your health and how you deal with your sickle cell disease.** | **You and your sickle cell disease** |  |
| **Introduction** | Dear Sir/Madam,  Are you interested to take part in a study about the daily burden of living with Sickle cell disease?  If you are interested, please go on reading the information about what kind of research it is, what it means for you, and what the advantages and disadvantages are.  It's a lot of information, you can take your time to think about it.  If you decide you want to participate, you can fill in the form at the end | Dear Cheyenne,  Would you like to take part in a study about your health and living with sickle cell disease?  Before you say yes take some time to read about the research and your rights.  Read this carefully, because then you will know what you are deciding about. You can take your time before you decide.  Your parents will also have to read this information with you, because they have to make a decision together with you. | Dear Oscar,  We would like to ask you to participate in a study about your sickle cell disease and how you feel about your health and about yourself.  You can decide for yourself whether you want to participate. But your parents have to sign for you |  |
| **Why this study?**  **(Er kan evt. naar en website worden verwezen met meer info-website hoeft niet te bestaan)** | Patients with sickle cell disease experience many physical and emotional complaints daily. The way that the disease impacts their life is not the same for every patient. There are also differences in how patients experience the disease, depending on which country they live in and on their living circumstances. Most studies about the burden of SCD have been performed in the US and these are not always representative of how patients living in Europe experience their disease. It is important to have more knowledge about how the disease affects patients in Europe, so that when new treatments become available, we can find out much quicker if it improves the quality of life of patients in Europe | Most information about how teenagers with sickle cell disease their daily life is affected comes from the US. But teenagers living in Europe have different experiences, and it’s even different between countries. It is important to learn about these differences because when new treatments become available, we can find out faster if it also improves the lives of patients in Europe. | We would like to know which symptoms you experience and how much you suffer from them. We also would like to know how you feel about school, friends and family. |  |
| **Where do I go with my questions**  **(hier kan eventueel een link naar een website met info)** | Ask the researcher. by using the chat function in the app  You can also email the researcher at: vraagdeonderzoeker@ziekenhuis.nl  Do you want to talk about the research with your own doctor? That is perfectly fine.  When you decide to take part in the study, your doctor will also be asked to give some information about your health status, but we do this only with your permission.  During the study you are allowed to share all the information about yourself that is stored in the app with your own doctor or with whomever you like. | Discuss your questions with your parents.  Or ask the researcher. by using the chat function in the app  You can also email the researcher at: vraagdeonderzoeker@ziekenhuis.nl  Do you want to talk about the research with your own doctor? That is perfectly fine.  When you decide to take part in the study, your doctor will also be asked to give some information about your health status, but we do this only with your permission.  During the study you are allowed to share all the information about yourself that is stored in the app with your own doctor or with whomever you like. | You can discuss questions with your parents.  Or you can ask the researcher by using the chat together.  You can also email the researcher at: vraagdeonderzoeker@ziekenhuis.nl.  And If you like you can even ask your parents to discuss the study with your doctor |  |
| **About the study** | This is what we call an observational study. This means that there will be no need to take additional medication, or additional treatment, no drawing of blood or taking tests other than what you would normally do as part of your regular treatment. | For this study you don’t have to undergo any additional tests, e.g. like drawing blood. You don’t have to pay additional visits to the hospital. You will receive your regular treatment. We will just ask you to answer some questions about your health, your feelings and how you are functioning daily. | You don’t have to take any extra treatment or medicine. You don’t have to take extra tests |  |
| **How long will the study take?** | 2 years | 2 years | 2 years |  |
| **How does it work when I participate?** | Every month you will receive a questionnaire to be filled in your app. You will receive a notification via WhatsApp/sms/email.  The questionnaires will not be the same every time.  Your doctor will also be asked to provide some information about your medical situation on your behalf, e.g. after your regular visits or when you have had a crisis, but only if you have given this permission | Every month you and your parents receive a message via WhatsApp/sms/ email that you have a new list of questions in your app ready to be answered.  Sometimes it will be a long list, and other times it may be shorter.  Your doctor will also be asked to provide some information about your medical situation on your behalf, e.g. after your regular visits or when you have had a crisis, but only if you have given this permission | Every month you will receive in your app a list of question that you and your parents can fulfill.  We will also ask your doctor to provide some information about you |  |
| **Will I get any discomfort?** | Taking part in the study will require a time investment of about 40-60 minutes each month. | It will take you some time (about 40-60 minutes) to answer the list of questions, but it is almost like playing a game. | It will take you and your parents some time, but it will be like playing a game on an ipad, or phone |  |
| **Are there any benefits for me?** | By participating you help us to better understand the disease.  As a personal benefit you will have your own dashboard in the app, in which you can keep score of your own outcomes during the study.  You will be able to discuss them with your doctor or other healthcare providers, if you feel like it. | By participating you help us to better understand the disease.  You can also follow your own progression in the app. You can use the information to discuss with your doctor or your parents to help them better understand how you are feeling | You are helping the researchers to better understand sickle cell disease  You will also learn about your own health because you can always see your own results back. You can also discuss it with your doctor, so he/she understands better how you are feeling. |  |
| **What will I get for participating**  **v.b. Wavydata?)** | Each time you have finished the survey, you receive points in your wallet, that you may trade for perks | Each time you have finished the questions, you receive points in your wallet, that you may trade for perks | Every time that you finish the list with questions, you are collecting points. You can use the points that you collect to buy things in the “game store” |  |
| **What are my rights?** | Your participation is completely voluntary. We will ask your doctor to provide information only when you decide to take part in the study and when you consent to include your doctor.  You have the right to stop taking part of the study at any time you choose, without any negative consequences, and without providing any explanation | You do not have to participate if you don’t want to. It is your decision.  You don't have to participate, even if your parents would want it.  If you change your mind, you can always stop. Just send a message via the chat to the researcher. You don't have to explain why you're quitting. | You can always stop and you don’t have to tell why  You can always ask questions |  |
| **And how do I make it known if I don’t want to take part anymore?** | If you want to withdraw you consent, just send a message via the chat to the researcher | If you want to stop, just send a message via the chat to the researcher. This is called: withdrawing your consent. | Tell your parents that you want to stop, they will tell the researcher. |  |
| **What happens with my data if I withdraw my consent?** | Your consent will be valid for an indefinite period and applies only to the use of your data for specific analysis. The study sponsor will only have access to the outcomes of these analysis and never will your identity or personal data be disclosed to them. | We will still use information that has already been collected for the research. The sponsor of this study will never have access to your personal information | We use the information that you gave us first, but no-one will know who you are |  |
| **What information do I need to provide about myself?** | We will collect two types of information about you.  • Personal data = information about who you are, for example your date of birth and where you live.  • Medical data = (also a type of personal data) information about which type of sickle cell disease your health, for example if you had a crisis or whether you are taking medication.  These two things are necessary when doing the research.  Would you like to know more about what we do with your data? Then ask the researcher via the chat, or visit the website. | We will collect two types of information about you.  • Personal data = information about who you are, for example your date of birth and where you live.  • Medical data = (also a type of personal data) information about which type of sickle cell disease your health, for example if you had a crisis or whether you are taking medication.  These two things are necessary when doing the research. Your parents must give permission so that we may use these things.  Would you like to know more about what we do with your data? Then ask your parents, it's in their information letter.  You can also ask the researcher via the chat, or visit the website | We will ask some questions about you and questions about the results from your tests at the doctor’s office  Would you like to know more about what we do with your data? Then ask your parents, it's in their information letter.  You can also ask the researcher via the chat, or visit the website |  |
| **How will my information be protected**  **(Hier moet een GDPR statement komen)** | Your data will be encrypted stored in your own personal cloud during an indefinite time. | Your data will be encrypted stored in your own personal cloud during an indefinite time. | The parent letter says this |  |
| **Who will have access to my information?** | Your data remains under your control. You will have access to the data and you will have insights into your own results.  At at all times you will have the possibility to rectification or removal your data. You may give restrictions to the use of your data or object to the processing of your personal data.  The researcher or study sponsor will not have access to your personal information. They will only receive the results of analysis that have been made with your data, and these results will be completely anonymized | Your data remains under your control. You will have access to the data and you will have insights into your own results.  At at all times you will have the possibility to rectification or removal your data. You may give restrictions to the use of your data or object to the processing of your personal data.  The researcher or study sponsor will not have access to your personal information. They will only receive the results of analysis that have been made with your information, and they will never be able to see that is was you |  |  |
| **How long will my data be stored?** | Your data will be stored indefinitely, but can only be accessed by you. | Your data will be stored indefinitely, but can only be accessed by you. | The parent letter says this |  |
| **And how will it be used?** | If there is an interest to re-use your data to make additional analysis for other studies, you will be offered the possibility to opt out for the use of your data, if you have indicated that you want to be contacted for this purpose. | If there is an interest to re-use your data to make additional analysis for other studies, you will be offered the possibility to opt out for the use of your data, if you have indicated that you want to be contacted for this purpose. |  |  |
| **If I have remarks or complaints** | If you have any remarks or complaints regarding this research, or if you have questions or additional information you may use the chat | If you have any remarks or complaints regarding this research, or if you have questions or additional information you may use the chat |  |  |
| **Do you want to participate?** | Then put your signature on the consent form. | Then put your signature on the consent form. We also need a signature from your parents/guardian. | If your parents also agree they have to sign the consent form |  |
| **DECLARATION OF CONSENT** | | | | |
| I understood the information. | Y/N | Y/N | Parent answer | Smart contract |
| I could also ask questions. | Y/N | Y/N |  |  |
| My questions have been answered | Y/N | Y/N |  |  |
| I had plenty of time to decide if I would participate | Y/N | Y/N |  |  |
| I know I'm not obligated to participate | Y/N | Y/N |  |  |
| I understand that I can always stop if I don't want to participate anymore | Y/N | Y/N |  |  |
| I give permission that my data will processed and used as mentioned in the information letter. | Y/N | Y/N |  |  |
| I give permission that my data will be stored indefinetely | Y/N | Y/N |  |  |
| \*\* I give permission that during the study my doctor will provide some medical information on my behalf | Y/N | Y/N |  |  |
| \*\*I give permission to ask me for a follow-up study later | Y/N | Y/N |  |  |
| I want to participate in this research. | Y/N | Y/N |  |  |
| **Signature**  **Date** | adult signature | Child & parent signature | Parent signature |  |

\*Toestemmingsformulier: we kunnen ook bij de verschillende onderdelen uit het informatie formulier de controle vragen laten beantwoorden

\*\* Alle vragen moeten met ja beantwoord worden alleen deze vraag mag met nee om door te kunnen gaan met het onderzoek.

1. Nadat de informed consent is doorlopen wordt een smart contract gegenereerd en wordt het consent op de blockchain vastgelegd
2. Nu kan de onderzoeksdeelnemer het persoonlijke dashboard openen en personaliseren.
3. Vervolgens worden meer details over de patient en de ziekte uitgevraagd: ook de naam van de arts en het ziekenhuis (of vraag om toestemming om de arts te benaderen) – we kunnen misschien ook een dropdown lijst maken met alle in SCZ gespecialiseerde artsen
4. Vervolgens wordt er een email gegenereerd die naar de arts gaat zodat deze **gelinked** kan worden aan de patient en ontvang de arts ook een download van zijn dashboard (later kunnen evt ook andere patienten die in hetzelfde ziekenhuis o.v.v. dezelfde arts aan dit dashboard toegevoegd worden