Participant Information and Consent Form

1. Evaluation of low-cost techniques for detecting sickle cell disease and sickle cell trait

2. Study personnel

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Sponsor(s) / Funder:	UBC Public Scholars Initiative
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If you are a parent or legal guardian of a child who may take part in this study, permission from you and the assent (agreement) of your child may be required. When we say “you” or “your” in this consent form, we mean you and/or your child; “we” means the doctors and other staff.

3. Invitation

You are being invited to take part in this research study. You are invited because you either have sickle cell disease, sickle cell trait or are a healthy volunteer.

4. Your participation is voluntary

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving.

Please review the consent document carefully when deciding whether or not you wish to be part of the research and sign this consent only if you accept being a research participant.

5. Who is conducting this study?

This study is being run by:

- Researchers at University of British Columbia
- Doctors at BC Children's Hospital
- Doctors at St. Paul's Hospital

The doctors specialize in diseases of blood. Many of them work at the hospitals to help patients with blood disorders. The doctors' involvement in the study will not affect patient care.

6. Background

Sickle cell disease (SCD) is a disease that can cause serious illness and organ damage. SCD is caused by receiving variant or abnormal genes from both parents. If people get a variant gene from only 1 parent, it is called "sickle cell trait" (SCT). People with SCT do not have symptoms of SCD. But, people with SCT can also pass the variant gene on to their children.

Early screening and treatment improve the quality of life of patients with SCD. This is the case in developed countries, like Canada. But, many low-income countries do not have screening and treatment options. Sadly, in these cases most of the children born with SCD die early. Low-cost tests to detect SCD and SCT can improve the lives of patients in remote and rural communities of low-income countries.

We plan to assess 5 low-cost tests to detect SCD and SCT. We will compare the 5 tests with the "gold-standard" test in Vancouver. We will recruit 30 people with SCD, 30 people with SCT, and 30 people without SCD or SCT. We will recruit people from the University of British Columbia, BC Children's Hospital and St. Paul's Hospital.

After this study in Vancouver, we will run a similar study in Nepal. In rural and remote parts of Nepal, there are few or no options to detect SCD. We want to find which low-cost tests are suitable for Nepal. The studies planned in Vancouver and Nepal will help us choose a suitable low-cost test for Nepal and other low-income countries. We will also take images of blood samples from both Vancouver and Nepal for a low-cost test used in both studies.

7. What is the purpose of the study?

The purpose of this study is to find how accurate the 5 low-cost tests are to detect SCD and SCT. We also want to know which low-cost tests can be applied in rural and remote communities. "Gold-standard" tests are costly and hard to access in rural and remote communities. We hope that the low-cost tests can be used to screen many people in these communities.

8. Who can participate in this study?

You may be able to participate in this study if*:*

- You are 6 months and older
- You have been diagnosed with SCT, SCD or are suitable for participating in the study as someone who does not have SCT or SCD

9. Who should not participate in this study?

You will not be eligible to participate in this study if:

- You are pregnant
- You have had blood transfusion in the last 3 months

10. What does the study involve?

- **If You Decide to Join This Study: Specific Procedures**

  If you agree to take part in this study, the procedures and visits you can expect will include the following:

- **Study Visits**
  The study visit only includes drawing blood from your arm. The blood draw is similar to that done during routine blood tests. Around 3-4 mL (or less than a teaspoon) of blood will be drawn for the study. The total time for the study visit is approximately 30 minutes for the blood draw and the wait time. The study visit will either be part of your routine standard-of-care visit, or be a separate visit exclusively for this study. Blood will be drawn at BC Children's Hospital or St. Paul's Hospital.

- **Expected Follow-up**
  There are no expected follow-up visits.

Details of the use of the blood samples are provided below:

a) **Intended use**: The blood samples will be used for 5 low-cost tests and a "gold-standard" test to check for sickle cell disease and sickle cell trait. For one of the tests, images of blood cells will be taken under a microscope.
b) **Storage of blood samples**: The blood will be stored at BC Children's Hospital. Blood collected at St. Paul's Hospital will be transferred to BC Children's Hospital. Standard protocols for transferring blood will be followed.
c) **People in charge of blood samples**: Doctors at the hospitals will be in charge of the blood samples. These doctors specialize in diseases of blood.
d) **Privacy of participants:** The blood samples and test results will only be referred to using unique codes. These codes do not have any information that can identify you. An example of a participant code is "BCCH-20211012-001". The first part of the code is the location of blood collection (BCCH or BC Children's Hospital). The second part is the date (12 October 2021). The last part is the serial number of the sample (001 or the first sample collected that day). The study team members will be provided with

only the codes. Data will be analyzed using the code as the main label or reference. Blood samples labels, images, test results, etc. will all be associated only with the unique codes, and not contain identifiable information.

e) **Time of storage:** The microscope slides of blood samples will be stored until the results of the study are published. This is in case additional images are required. The microscope slides will be disposed properly after the study completes.
f) **Linking blood samples to your information:** Only the doctors at the hospitals involved in the study will have access to the reference list of personal identifiers. Personal identifiers include details like name, date of birth, and Provincial Health number. The list will be stored in encrypted files in password protected computers. This list will not be shared with the other study team members and the list is not required for analysis. Any data used for the study, such as test results and images of blood cells, will not have any information that can be linked back to you. One low-cost test requires images of blood cells. Images of red blood cells do not have any information that can be linked to you.
g) **Results and findings:** We might publish or present the results of this study in journal articles and conferences. Health workers and researchers might use results from this study to implement some of the low-cost tests. The published results will have no identifiable information. The images of the blood cells will be used to help automatically detect SCD using machine learning. Your de-identified images will be deposited into an open research data repository, and the images will be publicly available online.

11. What are the possible harms and discomforts?

During blood draws, some people experience pain or discomfort. Other less common effects include bruising and fainting. Infection is possible, but is rare.

12. What are the potential benefits of participating?

There will not be direct benefit to you from taking part in this study.
We hope that this study can help other people in the future. These people include those with sickle cell disease in low-income countries.

13. After the study is finished

The overall results of the study will be shared with you. The results will not contain any identifiable information. The results will be shared in the form of a link to a scientific article or a media briefing.

14. What happens if I decide to withdraw my consent to participate?

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, you have the right to request the withdrawal of your information and/or your samples collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn for example where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data and/or samples, please let the principal investigator of the study know.

15. How will my taking part in this study be kept confidential?

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or designate and by representatives of UBC Providence Health Care Research Ethics Board, for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. You also have the legal right of access to the information about you and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to the study team.

If data is being transferred out of Canada

Any study related data, sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries, dealing with protection of information may not be as strict as in Canada. However, all study related data, that might be transferred outside of Canada will be coded (this means it will not contain your name or personal identifying information) before leaving the study site. By signing this consent form, you are consenting to the transfer of your de-identified information, to organizations located outside of Canada.

- De-identified data (or data without any identifiable information) can be used in a following study in Nepal (e.g. images of your blood cells, with no identifiable link to you, may be used to test a detection software for detecting SCD/SCT in rural communities in Nepal)

Disclosure of Race/Ethnicity

Studies involving humans now routinely collect information on race and ethnic origin as well as other characteristics of individuals because these characteristics may influence how people respond to different medications. You should be aware that providing this information is not mandatory.

Demographic data such as age, sex and race will be collected in this study only to properly identify the population represented by the study. You will be asked to answer some questions about your age, sex and race in a separate questionnaire, which will be stored without personal identifiers. At the end of the study, the demographic data will be reported with the results as overall averages or in aggregate form to indicate the population represented by the study.

Open Access

There is an increasing trend in research requiring researchers to make their data publicly available at the time of publication. This is mostly done to increase the transparency in scientific communication. We will only publish data that is de-identified and cannot be linked back to you. Examples of data that will be published include accuracy of low-cost tests (using test results from all participants in the study), and images of blood cells, with no identifiable information. The images of blood cells will be published online in an open access research data repository. The images will be publicly available online, and may be downloaded and used for future research.

Needed Consent Form Disclosures:

- The de-identified data may be used in the future by researchers. It is likely that this future use of data aims at improving the quality of screening tools for sickle cell disease, but the images may be used for reasons other than those disclosed in this consent form.
- Only data that does not include identifiable information, such as images of blood cells, will be made publicly available.
- The risk of you being identified through public data is unknown, but appears to be low.
- Once the data is made publicly available, you will not be able to withdraw their data.

16. What happens if something goes wrong?

By signing this form, you do not give up any of your legal rights and you do not release the principal investigator, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan.

17. What will the study cost me?

All research-related procedures that you will receive during your participation in this study will be provided at no cost to you.

Remuneration

You will be remunerated for your participation and provided with a gift card of $10.

18. If I have questions about the study procedures during my participation, who should I speak to?

If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact Pranav Shrestha at 250-858-3404 or Dr. Hayley Merkeley at 236-479-0498.

19. Who do I contact if I have any questions or concerns about my rights as a participant?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598). Please reference the study number (H21-01929) when calling so the Complaint Line staff can better assist you.

20. Signatures

Evaluation of low-cost techniques for detecting sickle cell disease and sickle cell trait

Participant Consent

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me.
- I understand that de-identified data, like images of blood cells, will be publicly available.

I will receive a signed and dated copy of this consent form for my own records.
I consent to participate in this study.

______________________	______________________	______________
Participant's Signature	Printed name	Date

______________________	______________	____________	______________
Signature of Person Obtaining Consent	Printed name	Study Role	Date

Verbal Consent

Was verbal consent provided at an earlier time, before the in-person visit?

☐ Yes, Time: ___________________ Date: ___________________

☐ No

Initials ___________

Future Contact

Are you interested in learning about other studies conducted by Dr. Hayley Merkeley in the future?

☐ Yes ☐ No Initials___________

Note that for any future studies, a separate consent form will be provided to you for review.

Parent/Guardian Consent:

This consent form was read by the parent(s)/guardian(s), and both the person reading this consent form and the investigator are satisfied that:

- The study information was accurately explained to, and apparently understood by, the child/participant.
- The child/participant was given an opportunity to ask questions, and all questions have been answered.
- The child/participant assents to participating in the research.

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Participant Name

_______________________________ ____________ __________________
Parent/Guardian's Signature Printed name Date

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Relationship of Parent / Guardian / Substitute Decision Maker to Participant

______________________ ________________ ____________ ________________
Signature of Person Obtaining Consent Printed name Study Role Date