

**APPROVED BY  
INTEGREVIEW IRB  
JULY 1, 2020**

**Informed Consent Form**

**Protocol Number and Title of Study:** C-SCD-001; “Research study collecting longitudinal data of patients with sickle cell disease”

**Sponsor:** PicnicHealth

**Investigator:** Noga Leviner

**Daytime & After Hours telephone number:** (415) 801-0572

**Introduction**

You (“you” refers to you or your child throughout this consent form) are invited to take part in research using your medical data. Because you have sickle cell disease, you are uniquely positioned to help advance disease understanding and care. This document describes the purpose of this research study and how your data will be used, so that you can make an informed decision about participating in the study. Please take your time to read the following information carefully.

The investigator is being paid by the sponsor (the company paying for this study) to conduct this research study.

**What is the purpose of this research study?**

At PicnicHealth, we believe that every patient should have control of their medical data. In the hands of researchers, this data can be incredibly valuable for understanding disease and improving care.

The purpose of this study is to help researchers and organizations working in the sickle cell disease space to better understand sickle cell disease so that we can improve how it is diagnosed and treated.

**How many people will participate in this study?**

Up to 5000 boys, girls, men, and women with sickle cell disease will participate in this study.

**How much time will this study require of me?**

Time will be required to set up an account and review this document.

**What will happen if I join the study?**

If you agree to join you’ll be asked to:

- List information about your healthcare providers (doctors, hospitals, and/or clinics) and insurance provider
- Authorize PicnicHealth to collect your medical records on your behalf

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You will receive a free subscription to PicnicHealth - an online service that helps patients collect and manage their medical records - for free as long as you participate in the study. Neither you nor your insurance company will be billed for PicnicHealth's services. As part of these services, PicnicHealth will:

- Collect your medical records on your behalf from the healthcare providers that you authorize
- Digitize your medical records so that you can access them online through your PicnicHealth timeline
- Collect your ongoing medical records on your behalf from the doctors who continue to provide care for you

PicnicHealth may contact you in the future with survey questions related to this study or may reach out with new information about this study. Additionally, PicnicHealth may contact you about other similar IRB-approved studies like this one in the future to determine if you would like to participate in future studies.

Data collected from this study may be made available to qualified researchers or companies working to advance sickle cell disease research. Any personally identifying information, such as your name, will be removed before your data is used for this study or any study in the future by any party other than PicnicHealth. We'll refer to data, with your personally identifying information removed, as "de-identified data."

**Who will conduct the research?**

PicnicHealth partners with select third party organizations specializing in conducting scientific research or analysis on this type of medical data. These third parties might include government, academic, or commercial organizations. Data access for these institutions will be controlled through an application process managed by PicnicHealth, where partners will be evaluated based on their commitment to advance science for the public good. While PicnicHealth may be compensated for providing access to this data, we will always grant free access for non-commercial research - meaning, research that is not intended to make money but rather to contribute to science and the public good.

Your de-identified health information and data will be analyzed in order to advance sickle cell disease research. The study data may be recorded, analyzed, and published. No names or personally identifying information will be disclosed to any researchers or research organizations. No patient will be identified in any report or publication from this study.

You may at any point contact PicnicHealth to get more information about how your de-identified data is being used.

**What data will be collected?**

This study will look at medical data that has already been recorded in your medical records during your normal medical care. You will not need to make any special doctors' visits as part of the study. The following information will be extracted from your medical records when available:

- Demographics (gender, date of birth, etc.)
- Visits to healthcare providers (date, care site, etc.)
- Data about sickle cell disease (diagnosis date, severity, etc.)
- Medical history (other diseases you may have or have had)
- Vital signs (heart rate, body temperature, etc.)

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- Results of physical examinations
- Blood tests and other laboratory tests
- Procedures (imaging, surgeries, etc.)
- Medications
- Doctor's notes

**What type of analysis will be done with my data?**

It's hard for us to know every research question that your data may help answer. Since science is continually evolving, new questions may arise that we can't predict yet.

Some research objectives that your data may help answer could include but are not limited to:

- Understanding effectiveness of treatments on different patients
- Understanding unmet needs in the patient population
- Understanding patient and physician behavior

Additionally, we may link the data collected here to other existing healthcare data sets (e.g., patient registries) to help answer key research questions. Any data you contribute will be de-identified before using it in any study regardless of whether it is linked to other healthcare data sets.

**How will my personal and health information be kept private?**

As part of this study, data will be extracted from your medical records in a way to ensure that your medical and personal information is kept confidential. Your medical and personal information and copies of your medical records will be held by PicnicHealth.

You will be assigned a unique patient identification number. The medical data used for this study will be labeled with this identification number; the data will not be labeled with your name, picture, or any other personally identifying information.

Applicable national laws and regulations to protect the personalized data in your medical records will be strictly followed. The confidentiality of your personal information will be protected throughout the study and afterwards. It will be kept confidential; your medical and personal information may be revealed only if required by law. National health authorities, regulatory bodies, or other overseeing agencies may want to examine your data within the scope of an inspection according to national law to ensure that this study is done properly.

In certain situations, to make sure that the study is being done properly or to check the quality of the data, the following people and groups of people might be granted direct access to copies of your medical records (i.e. they may see your medical and personal information) without violating the confidentiality of your data:

- The investigator
- PicnicHealth personnel directly involved with the medical data retrieval processes
- If applicable, study auditors from organizations who have had access to the database
- The Institutional Review Board responsible for protecting the rights and safety of the patients who take part in research studies
- Regulatory health authorities (government agencies involved in keeping research safe for people)

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The Institutional Review Board (IRB), IntegReview, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

You have the right to see and get a copy of your medical records kept by PicnicHealth. Your authorization (permission) to use and disclose (share) your health information does not have an expiration date, but that use and sharing will only be for the purposes described in this consent form.

You are free at any time to limit PicnicHealth's use and sharing of your health information, without penalty or other consequence. However, you may not be allowed to take part or continue to take part in this study if at any time you choose to limit PicnicHealth's use and sharing of your health information that is necessary for the completion of this study.

You may change your mind and revoke (take back) this authorization at any time. If you revoke this authorization, no additional health information will be retrieved nor shared about you. However, any data that has already been shared with a partner, up until the time you notify PicnicHealth to revoke your authorization, cannot be modified or deleted. This data will not include your name or personally identifying information.

**Are there possible benefits to agreeing that my personal and health data can be used in the study?**

There is no direct medical benefit to you from being in this study. The information gained from this study may help scientists and doctors learn more about sickle cell disease. You and other patients with sickle cell disease or a similar condition could benefit from the results of this study in the future.

You will benefit from free access to PicnicHealth's medical record collection and management services as long as you participate in this study. With these services, you will be able to view your medical records data (e.g., lab results, prescriptions, and imaging files), download copies of records, and share your records with your doctors. You will not receive any other financial compensation.

**Are there any possible risks if I agree that my personal and health data can be used in the study?**

There are no physical risks from participating in this study, but there may be privacy and confidentiality risks. Despite making our best efforts, it's never possible to fully guarantee that your personally identifiable information (e.g., name, date of birth) will never become known. For example, data may be vulnerable in transit or servers may be accessed by unauthorized individuals. The risk for such a confidentiality breach is considered low. If at any point your identifiable information does become known by unauthorized individuals, the PicnicHealth Legal Team or Privacy Officer will notify the relevant parties as required by government regulation.

**What alternative do I have if I do not want my data to be used in the study?**

Your alternative is not to participate in this study. If you choose not to give consent and not be part of this study, you will not receive PicnicHealth's services free of charge. You can always choose to pay to use PicnicHealth's medical record collection and management services, independent of the study. If you use PicnicHealth independent of the study, you can authorize PicnicHealth to collect your medical records for your personal use and care coordination.

To learn more about PicnicHealth's services, you can visit <https://picnichealth.com/>.

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**Can I withdraw from the study?**

Your participation in this research study is completely voluntary and you can withdraw at any time.

If you choose to stop participating in the study, you can continue to access your existing medical records through your PicnicHealth account but no new records will be added unless you choose to subscribe to the PicnicHealth service at your own expense.

You can request that your data be deleted from the PicnicHealth service at the time you withdraw from the study, or at any time before or after. However, any data that has already been shared with a partner, up until the time you notify PicnicHealth to stop participating in the study, cannot be modified or deleted. This data will not include your name or personally identifying information.

**Will I receive the results of this study?**

We believe it's important for you to see the results of research produced using your data and we'll make every effort to share published results back with you.

**Who is financing this research?**

This research study is being financed and conducted by PicnicHealth.

**Will I be paid for participating in the study?**

You will be compensated up to \$100.00 through a Visa gift card for your participation in this study. You will receive the gift card within 5-7 business days once your diagnosis is verified if you agree to participate in the study and sign the consent. Please note that the timeframe may vary depending on how responsive your doctor's office is when requesting records.

**Who can answer my questions about this study?**

You can contact PicnicHealth for any questions.

Email: [SCD@picnichealth.com](mailto:SCD@picnichealth.com)

Phone: 1-415-801-0572

If you do not want to talk to PicnicHealth, or if you have concerns or complaints about the research, or if you want to ask about your rights, you may contact IntegReview. IntegReview is a group of people that has reviewed this research study. The main goal of this review is to protect the rights and well-being of the human subjects participating in research studies. IntegReview's policy indicates that all concerns/complaints are to be submitted in writing for review to:

**Email and Mailing Address:** [integreview@integreview.com](mailto:integreview@integreview.com)

Chairperson

IntegReview IRB

3815 S. Capital of Texas Highway

Suite 320

Austin, Texas 78704

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If you are unable to provide your concerns/complaints in writing or if this is an emergency situation regarding subject safety, contact IntegReview's office at:

**Phone:** 1-512-326-3001  
or toll free at 1-877-562-1589  
(between 8 a.m. and 5 p.m. Central Time)

IntegReview has approved the information in this consent form and has given approval for the investigator to do the study. This does not mean IntegReview has approved your being in the study. You must consider the information in this consent form for yourself and decide if you want to be in this study.

**Volunteering to be in the study**

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled. If you want to stop participating in this study, you should email PicnicHealth at [SCD@picnichealth.com](mailto:SCD@picnichealth.com).

PicnicHealth or IntegReview may take you out of the study without your permission, at any time, for the following reasons:

- If you do not meet the study's eligibility criteria
- If you do not follow the investigator's instructions
- If the study is stopped

You will not lose any of your legal rights by signing this consent form.

**Subject's Bill of Rights**

You will be given a separate copy of the California Experimental Research Subject's Bill of Rights. If you have not received a copy of this document, please notify study staff.

I understand that I will be able to access an electronic copy of this entire form. I have read it, or it has been read to me. I understand the information and have had my questions answered. I voluntarily agree to the use of my personal and health data for this observational study as described above and authorize PicnicHealth to disclose (share) my health information as described in this Informed Consent Form.

You will be given a signed and dated copy of this consent form.

IntegReview approves the use of electronic signatures.

Your signature will be electronically captured if you agree to participate.

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**ASSENT FORM FOR MINOR STUDY SUBJECTS**

[Note: this form will only appear for participants 7 - 17 years of age]

You are being asked to be in a research study to better understand the health of people living with sickle cell disease in the U.S.

If you decide that you want to be a part of this study, you will be asked to give PicnicHealth permission to collect your past medical records, remove your personal information (such as your name), and give your medical records to science. You will not need to go to any doctor's visits outside of your routine care.

We will collect your information until you are no longer in the study. You can decide not to be or PicnicHealth can take you out of the study.

By being in the study, you will have the benefit of having all your past medical records collected by PicnicHealth, and available for you to view online.

When we are finished with this study we will write a report about what was learned. This report will not include your name or that you were in the study.

You do not have to be in this study if you do not want to be. You can say no and no one will be mad at you. If you decide to stop after you begin, that's okay too.

**Statement of Assent:**

You have read or someone has read to you this assent form. Your parent(s) or legally authorized representative (if applicable) have explained the study to you. You have had your questions answered.

By clicking on the agree button below you are indicating that you agree to participate in this study.

You (and/or your legally acceptable representative) will be given a signed and dated copy of this assent form.

IntegReview approves the use of electronic signatures.

Your signature will be electronically captured if you agree to participate.

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