Informed Consent Documents
PI: L Lauren Brown
Title of the study: Implementation of Trauma-informed HIV Care in Memphis, TN
Meharry Medical College
Clinical Trials registry: 22-08-1234
August 15, 2025

Implementation of Trauma Informed Care for Youth Living with HIV in Memphis, TN

Note: When we say "you" in this informed consent document, we mean "you or your child." When we talk about research, it can be called a clinical trial, research study (study), or research protocol.

Key Information

To start, we highlight here the risks, benefits, and study requirements that we think you should know before deciding if you want to take part in this research study. If you're still interested, we'll then get into more details.

A. Why are you being asked to voluntarily take part in this study?
You are being asked to take part in this research study because you are a patient of the St. Jude ID Clinic.

B. Why is this study being done?
The purpose of this study is to implement trauma-informed care in the St. Jude ID clinic.

C. What will happen if you decide to take part in this study?
You are being invited to participate in focus groups. The groups include open-ended questions to promote group discussions. Discussions will concentrate on patient feedback for changing patient treatment for psychological trauma. You may be asked to participate in a series of focus group discussions, with each taking approximately 1-1.5 hours to complete.

D. What are the research risks and benefits of taking part in this study?
There are no expected risks in participating in this study beyond experiencing minor discomfort in answering some of the questions. You may directly benefit by having the possibility to discuss some of your experiences receiving care from the clinic.

E. How many people will take part in this study?
Around 10 patients from the St. Jude ID Clinic will take part in this portion of the study.

F. What are your options?
    1) Taking part in this research study is completely your choice.
    2) If you decide to take part in this study, you can change your mind and stop at any time.

If you are still interested in taking part in this research study, TICID1, more detail is provided below in the following pages.

Study Contact Details and Further Inform

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your doctor, who will be able to provide you with up-to-date information about the drug(s)/procedure(s) involved. If there is anything that you do not understand, or if you have any other questions, please contact any of the people below.

Who to talk to for…	**You can contact…**	**At…**
• Any new or unexpected symptoms, side effects or discomforts • General study questions • Any research concerns or complaints	**Megan Wilkins, PhD** 262 Danny Thomas Place Memphis, TN 38105	901-595-3300 (Main Hospital Number)
• Your rights as a research participant • Any research concerns or complaints	**Institutional Review Board (IRB)/Research Participant Advocate** * IRB is a group of scientists and community members who make sure research meets legal and ethical standards. * Research Participant Advocates are individuals who are not part of the research study team and are available to you to discuss problems, concerns, and questions. The Advocate can help you obtain information and can relay any input you may have concerning the research to the research study team and the IRB.	901-595-4644 or 901-595-1139 Meharry 615-557-3499 or 615-327-6735

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1. Why are you being asked to voluntarily take part in this research study?

You are being asked to participate in a research study because you are a patient of the St. Jude ID Clinic. Taking part in this study is completely your choice. Please take your time in deciding and feel free to discuss it with your family, friends, and St. Jude staff. Before agreeing, it is important that you read this informed consent document (consent form) that describes the study. After you understand the study and if you agree to take part, you will be asked to sign this consent form. You will be given a copy to

2. Who is sponsoring this study?

This study is sponsored by the National Institutes of Health who are providing funding for the study. Meharry Medical Center is serving as the IRB of record. Questions regarding the study should be directed to St. Jude at 901-595-3300 or Dr. Lauren Brown with Meharry Medical College at 615-327-

3. What is the purpose of this study?

The purpose of this study is to implement trauma-informed care in the St. Jude ID Clinic. Trauma informed care recognizes the presence of trauma symptoms and acknowledges the role trauma may play in your life.

4. What will be done in this study?

approached by a member of the research team who has informed you about the study. For anyone agreeing to participate, you will sign this informed consent form and then be invited to participate in focus groups. The groups include open-ended questions to promote group discussions. Discussions will concentrate on patient feedback for changing patient treatment for psychological trauma. You may be asked to participate in a series of focus group discussions, with each taking approximately 1-1.5 hours to complete. Should any of the questions make you feel uncomfortable, you may choose not to answer them. This will not affect your status as a patient in the St. Jude ID clinic.

5. What are the risks and benefits of taking part in this study?

a. Risks

Beyond experiencing minor discomfort in answering some of the questions, there are no expected risks in participating in this study. Should unforeseeable risks occur, you are encouraged to speak with a member of the research team to discuss the risks so that actions may be taken to assist you.

b. Benefits

You may or may not directly benefit from this study. You will have the possibility to discuss some of your experiences receiving care in the clinic. Additionally, information from this study might be used to improve the nature of services in the St. Jude ID clinic as well as other HIV care systems.

6. Can you stop taking part in this study?

You may change your mind about taking part in this research study and stop at any time. This decision will not affect your relationship with St. Jude or your status as a patient with the St. Jude HIV clinic.

If you change your mind about participating in this study, related information that has already been used by researchers will not be removed.

What are your other options?

No treatment will be provided as part of this phase of the study. The other option is to not take part in this study.

8. How much will it cost you to take part in this study?

If you have health care coverage, we will bill your health care insurer for all standard of care services, tests, and procedures, as applicable. Billing your health care insurer impacts your annual deductible and life-time maximum, if any. This may affect your health care coverage to some extent if you go to another health care provider or institution in the future.

At St. Jude, you will not be responsible for or receive bills for co-pays, co-insurance, deductibles, or similar patient-liability amounts, or for the cost of medical care related to your disease or this study not covered by your health insurer. This includes research-only costs. Research-only tests and procedures will not be billed to you or your health care insurer.

9. Will you be paid for your time or expenses while taking part in this study?

in each focus group.

If you receive $600 dollars or more for taking part in the study, the payment may be taxable and will be reported to the Internal Revenue Service (IRS).

10. What if there is a problem while taking part in this study?

If you are injured from being in this research study, please notify your St. Jude Doctor or the study doctor, Mehan Wilkins, PhD. Any personnel needing treatment for anything related to the discussions in this study please consult with a member of the research team. St. Jude will offer you reasonable and necessary medical treatment for that injury. If you need more care than St. Jude can provide or if you prefer to seek treatment elsewhere, we will help you find medical care somewhere else. St. Jude may bill your insurance company or other third parties, if appropriate.

It is not the hospital's policy to provide payment for other types of costs, such as lost wages, disability, or discomfort if you are injured from being in this study. You are not giving up any of your rights by signing this consent form.

11. How will new findings related to your participation in this study be shared with you?

The researcher will tell you of any new information learned during your study participation which might cause you to change your mind about continuing the study.

12. How will you find out the results of this study?

St. Jude researchers share information with people in studies in many ways including:

- Articles on www.stjude.org
- In newsletters
- In medical or scientific journals
- In the media

Published research results will only describe groups of people who took part in the study. Information that points out a single person will not be in research journals or other reports.

13. What about identifiable private information obtained from you during the study?

If you choose to take part in this study, your data will be used to answer the research question(s) and to publish the findings of this study. Published research results will only describe groups of people who took part in the study. Information that points out a single person will not be in research journals or other reports. You will not own your research data. If researchers use your data to create a new product or idea, including those that may have commercial value, you will not benefit financially. There is no plan to share any money with you.

St. Jude's researchers and their collaborators will store the data collected in this study in electronic databases and other locations. They may use the data collected in this study for future research purposes and may share some of the data with others without seeking further consent from you. You may not receive results from that future research.

Sharing data is part of research. It may increase what can be learned from this study and future studies. Often data sharing is required as a condition of funding or for publishing study results. It is also needed to allow other researchers to validate study findings and to come up with new ideas.

Your data may be shared with government agencies, research collaborators, and other researchers and organizations conducting research that may not be related to this study.

Because science constantly advances, we do not yet know what other future uses of research data may include. There is no time-limit on the sharing of information.

This future research may be unrelated to the current study and may include outside researchers and organizations from around the world. These organizations may include for-profit companies conducting medical research. We or others who distribute data may be paid for data or samples, including yours. You will not receive payment if this happens.

St. Jude will do its best to protect and maintain your data in a safe way. One of the ways we protect your data is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data sharing agreements and review by oversight groups within St Jude. Often the data may be coded to protect your identity before they are shared, and we will keep the key to the code in a secure way.

If data are used or shared with any information that may be likely to identify you, such as your name, address, or medical record number, further institutional review and approval would be required. In these cases, we will review whether additional consent from you is required.

Generally, if your data are used and shared without any personal identifiers or only with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed, and you will not be contacted.

By signing this consent form, you allow the Sponsor, Meharry Medical College, to use study data for commercial purposes, and to use and share data from this study in the future for this and other studies. St. Jude may also use and share study data for patient care, academic uses, and publication, and when required by law. St. Jude and Meharry Medical College will take precautions to remove any information that could identify you (like your name or medical record number) before sharing.

Data sharing could change over time and may continue after the study ends.

The use and sharing of your data is required for participation in this research study. The purpose of research is to learn and discover new information to make improvements to patient care and/or treatments. To make these improvements, research results must be shared with others. By agreeing to take part in research studies, you are agreeing for your information or data to be used and shared with others. If you are generally not comfortable with the use and sharing of your data in future research as explained this consent, you should talk with your doctor before agreeing to take part in this study.

14. What about permission to use your data/information (HIPAA Privacy Rule), privacy and confidentiality?

Permission to Use Your Data/Information- HIPAA Privacy Rule and Privacy

All efforts, within reason, will be made to keep your personal information confidential. Confidentiality in focus groups cannot be guaranteed due to other group members. Your privacy will be protected to the extent permitted by law. If the results from this study are published, your name will not be made public. Your participation in this study will remain confidential, that is members of the research team collecting data will know who has agreed to participate but your answers to study questions will remain anonymous and will only be shared as aggregate data or summaries as part of published research and will not be connected with any names or other identifying information. No identifying information will be shared with St. Jude HIV Clinic from this study.

While unlikely, the following may look at the study records:

- Meharry Medical College Institutional Review Board
- St. Jude Children's Research Hospital Institutional Review Board
- St. Jude Children's Research Hospital ID Clinic Staff
- Office for Human Research Protections (OHRP)
- Ending the Epidemic Program Committee Human Research Protection Program (HRPP)

Focus group sessions for this study will be audio recorded to retain the most accurate documentation of your statements and experiences. Data (or information from this study) will be stored electronically by the research team on the password protected computer of the study coordinator or interviewer. Once the study has been completed, study information (data) will be sent by email to the primary investigator of this study. Access to the computer will be password protected, and the computer will be HIPAA compliant (follow privacy guidelines of the Health Insurance Portability and Accountability Act).

SUBJECT RIGHTS

Any questions you have involving the research and your rights may be addressed to Dr. Lauren Brown at 615-557-3499 or the chair of the Meharry Institutional Review Board, at 615-327-6735. Your participation in this study is voluntary and you are free to withdraw at anytime without penalty or loss of benefits that you are otherwise entitled to. You will be given a copy of this form to keep.

The HIPAA Privacy Rule defines the situations in which PHI (protected health information) may be used or given to someone outside of the hospital to be used or released for research and other purposes. PHI includes information such as your name, MRN, date of birth, or other identifying information, including research information placed in your medical record.

To do this research, St. Jude Children's Research Hospital (St. Jude) will need to collect, use, and share your private health information. St. Jude is required by law to protect your health information. By signing this consent form, you give St. Jude permission to use and/or release (share) your private health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

If you sign this consent form, you give permission to all researchers and their staff involved in the study at St. Jude to use or release (share) your health information that identifies you for the research study described in this document.

If you sign this consent form, you give St. Jude permission to share your information for future research studies about disease or advancing science and for future unspecified research. You also give permission for us to place this information on databases as described below under Privacy and Confidentiality.

Any information placed in the medical record becomes a permanent part of your record, is kept indefinitely, and is not protected by a Certificate of Confidentiality (Certificate of Confidentiality, if included with this study, is described below under Privacy and Confidentiality). It is protected like any other part of your medical record as described in the Notice of Privacy Practices. You have the right to see, copy, and ask for changes to your PHI that will be used or shared. However, research information may not be available until after the end of the study.

When you first registered at St. Jude, you received a copy of the St. Jude Notice of Privacy Practices. It tells how your PHI, including research information placed in your medical record, may be used or given to someone outside of St. Jude. You have the right to read the Notice of Privacy Practices before you sign this consent form. It may have changes since you first registered at St. Jude. You can find it at the bottom of every page on the St. Jude internet website: www.stjude.org

The people who may view, request, receive, or use your private health information include St. Jude researchers and their staff, and other doctors, nurses, and staff members. Additionally, St. Jude may share your information with other people or groups of people. These include:

- Office of Human Research Protections (OHRP)
- National Institutes of Health (NIH)
- Accrediting agencies like the Joint Commission

- St. Jude Children's Research Hospital Institutional Review Board (IRB) and other committees or people involved in overseeing research studies
- Others who have access to your medical record by authorization or law
- Other approved health care providers
- Meharry Medical College Institutional Review Board and Medical College staff involved in the study

You do not have to sign this consent form which gives your permission, but if you do not, you may not receive research-related treatment.

Please note that you may change your mind and take back (revoke) this permission at any time. Even if you take back this permission, St. Jude Children's Research Hospital may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To take back this consent form/permission, you must write to:

HIPAA Privacy Officer
St. Jude Children's Research Hospital
262 Danny Thomas Place, Mail Stop 280
Memphis, TN 38105

This permission does not have an expiration date.

Confidentiality

We will protect the confidentiality of your information to the extent reasonably possible.

Researchers and study staff are required by law to report suspected child abuse, threat of harm to self or others, and certain diseases that spread from person to person.

Research data obtained from this study from standard of care tests and procedures and research tests and procedures such as tumor and normal specimens and genetic data, are often shared with the research community using various databases, including those maintained by St. Jude, the federal government, and international collaborative databases. This is to advance scientific discovery, and to satisfy requirements of organizations that fund research, and journals that publish the results of research.

There are two types of databases used for sharing research data. One is a public, unrestricted access database and the other is a controlled access database. Each is described below.

Unrestricted access databases:

The information from research studies using your samples, genetic information, and some health information may be freely available in a public, unrestricted database that anyone can use. A public database could include information on hundreds of thousands of genetic variations in your DNA code, as well as your ethnic group and sex. Summary-level information about all participants included in a dataset, including you, but not genetic data for each individual, may be shared.

Some examples of information that may be shared includes how different genes are associated with different traits or diseases across the many participants in the dataset, or how often certain gene changes are seen across participants from many studies. However, the risk of anyone identifying you with this information is very low. This public information will not be labeled with your name or other information that could be used to easily identify you.

Controlled access databases:

Your individual genomic data and health information may be put in a controlled-access database. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to easily identify you.

Researchers approved to access information in the database must agree to protect the information and not to try to identify you. Examples are the St Jude Cloud, which is run by St. Jude, the database of Genotypes and Phenotypes which is run by the Federal Government, and the European Genome-Phenome archive. These are databases available to researchers to use genomic information from tumor and non-tumor samples to study genetic changes in pediatric diseases.

All efforts, within reason, will be made to keep your personal information confidential. Confidentiality in focus groups cannot be guaranteed due to other group members. Your privacy will be protected to the extent permitted by law. If the results from this study are published, your name will not be made public. Your participation in this study will remain confidential, that is members of the research team collecting data will know who has agreed to participate but your answers to study questions will remain anonymous and will only be shared as aggregate data or summaries as part of published research and will not be connected with any names or other identifying information. We have provided a HIPAA waiver form for you to sign so that we may request basic information from St. Jude HIV clinic on your past year's viral load, CD4 cell count, and appointment adherence. By signing this form, you are consenting that they share this information with us for the purpose of this research only. No identifying information will be shared with St. Jude HIV Clinic from this study.

While unlikely, the following may look at the study records:

- Meharry Medical College Institutional Review Board
- Office for Human Research Protections (OHRP)
- Ending the Epidemic Program Committee Human Research Protection Program (HRPP)

Therapeutic treatment sessions for this study will be audio recorded to retain the most accurate documentation of your statements and experiences. Data (or information from this study) will be stored electronically by the research team on the password protected computer of the study coordinator or interviewer. Once the study has been completed, study information (data) will be sent by email to the primary investigator of this study. Access to the computer will be password protected, and the computer will be HIPAA compliant (follow privacy guidelines of the Health Insurance Portability and Accountability Act).

[redacted]

If you decide you would like to take part in this research study, please ask any questions you have, and read and sign this consent form. You will be given a copy of it to keep. A copy of this consent form will also be put in your patient notes, one will be put with the study records, and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this informed consent document and to consider taking part in this study.

RESEARCH PARTICIPANT STATEMENT (Age 18 years and older):

I have read this consent form or it was read to me. I have been encouraged to ask questions and all of my questions were answered. I agree to take part in this research study.

_____	_____	_____AM/PM	
Research Participant Signature	Date	Time	(circle one)

RESEARCHER/DESIGNEE STATEMENT:

I have explained the research to the participant and his/her parent(s) or legal guardian(s). The research participant and parent(s)/guardian(s) were encouraged to ask questions and all questions were answered to their satisfaction. A copy of this consent form has been given to the participant or his/her representative.

		_____AM/PM	
Researcher/Designee Signature	Date	Time	(circle one)

_____

Researcher/Designee Print Name

		_____AM/PM	
Interpreter (if needed) Signature	Date	Time	(circle one)

PLEASE UPLOAD COMPLETED CONSENT FORM TO EPIC.

Patient Surveys Informed Consent Document PI: L
Lauren Brown
Meharry Medical College
Clinical Trials registry: 22-08-1234

Implementation of Trauma Informed Care for Youth Living with HIV in Memphis, TN

Note: When we say "you" in this informed consent document, we mean "you or your child." When we talk about research, it can be called a clinical trial, research study (study), or research protocol.

Key Information

To start, we highlight here the risks, benefits, and study requirements that we think you should know before deciding if you want to take part in this research study. If you're still interested, we'll then get into more details.

A. Why are you being asked to voluntarily take part in this study?
You are being asked to take part in this research study because you are a patient in the St. Jude ID clinic.

B. Why is this study being done?
The purpose of this portion of the study is to develop a new instrument to measure patient experiences of organizational trauma resilience and gain information on patient experiences in the ID clinic.

C. What will happen if you decide to take part in this study?
If you agree to participate, you will be directed to a one-time, self-administered survey. Survey items, or questions, will prompt you to answer multiple choice questions about several of your experiences. The survey will take approximately 30-45 minutes to complete. You may also be asked to participate in a one-on-one survey.

D. What are the research risks and benefits of taking part in this study?
There are no expected risks in participating in this study beyond experiencing minor discomfort in responding to some of the questions. This study may not benefit you directly. However, information from this study might be used to improve the services at St. Jude as well as similar institutions in the future.

E. How many people will take part in this study?
Around 75 participants will take part in this portion of the study.

F. What are your options?
    1) Taking part in this research study is completely your choice.
    2) If you decide to take part in this study, you can change your mind and stop at any time.

If you are still interested in taking part in this research study, TICID1, more detail is provided below in the following pages.

Study Contact Details and Further Information

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your doctor, who will be able to provide you with up-to-date information about the drug(s)/procedure(s) involved. If there is anything that you do not understand, or if you have any other questions, please contact any of the people below.

Who to talk to for…	You can contact…	At…
• Any new or unexpected symptoms, side effects or discomforts • General study questions • Any research concerns or complaints	**Megan Wilkins, PhD** 262 Danny Thomas Place Memphis, TN 38105	901-595-3300 (Main Hospital Number)
• Your rights as a research participant • Any research concerns or complaints	**Institutional Review Board (IRB)/Research Participant Advocate** * IRB is a group of scientists and community members who make sure research meets legal and ethical standards. * Research Participant Advocates are individuals who are not part of the research study team and are available to you to discuss problems, concerns, and questions. The Advocate can help you obtain information and can relay any input you may have concerning the research to the research study team and the IRB.	St. Jude 901-595-4644 or 901-595-1139 Meharry 615-557-3499 or 615-327-6735

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1. Why are you being asked to voluntarily take part in this research study?

You are being asked to participate in a research study because you are a patient in the St. Jude ID clinic. Taking part in this study is completely your choice. Please take your time in deciding and feel free to discuss it with your family, friends, and St. Jude staff. Before agreeing, it is important that you read this informed consent document (consent form) that describes the study. After you understand the study and if you agree to take part, you will be asked to sign this consent form. You will be given a copy to keep.

2. Who is sponsoring this study?

directed to St. Jude at 901-595-3300 or Dr. Lauren Brown with Meharry Medical College at 615-327-6735.

3. What is the purpose of this study?

The purpose of this portion of the study is to develop a new instrument to measure patient experiences of organizational trauma resilience. The purpose of the overall study is to implement trauma-informed care at the St. Jude ID Clinic. Trauma informed care recognizes the presence of trauma symptoms and

4. What will be done in this study?

If you agree to participate, you will sign this informed consent form and then be directed to a one-time, self-administered survey. Survey items, or questions, will prompt you to answer multiple choice questions about several of your experiences. Topic areas will include questions to assess your experiences with your healthcare provider, experiences of psychological trauma and their effects, resilience (otherwise known as strengths and resources), discrimination, social determinants of health (or conditions where you live, work, or socialize), and medication adherence. The survey will take approximately 30-45 minutes to complete, and you will have the option of using an audio service in case you would prefer to have the questions read aloud to you. Should any of the questions make you feel uncomfortable, you may choose not to answer them. This will not affect your status as a patient in the St. Jude ID clinic.

You may also be asked to participate in one-on-one interviews that occur once a year for two years. We will approach participants for the one-on-one interviews until 10 individuals have agreed to participate. If approached, you may refuse to participate in the one-on-one interviews and still participate in the survey portion of the study.

5. What are the risks and benefits of taking part in this study?

a. Risks

Risks in participating in this study are expected to be minimal. You may experience minor discomfort in answering some of the questions. Another potential risk of this study is loss of confidentiality about information you provide during the study. However, all possible protections have been put in place to prevent this from happening, as described below. Should any unforeseeable risks occur, you are encouraged to speak with a member of the research team to discuss the risks so that actions may be taken to assist you.

b. Benefits

This study may not benefit you directly. However, information from this study might be used to improve the services in the St. Jude ID clinic as well as similar institutions in the future.

6. Can you stop taking part in this study?

You may change your mind about taking part in this research study and stop at any time. This decision will not affect your relationship with St. Jude or your status as a patient in the St. Jude HIV clinic.

If you change your mind about participating in this study, related information that has already been used by researchers will not be removed.

7. What are your other options?

8. How much will it cost you to take part in this study?

If you have health care coverage, we will bill your health care insurer for all standard of care services, tests, and procedures, as applicable. Billing your health care insurer impacts your annual deductible and

life-time maximum, if any. This may affect your health care coverage to some extent if you go to another health care provider or institution in the future.

At St. Jude, you will not be responsible for or receive bills for co-pays, co-insurance, deductibles, or similar patient-liability amounts, or for the cost of medical care related to your disease or this study not covered by your health insurer. This includes research-only costs. Research-only tests and procedures

9. Will you be paid for your time or expenses while taking part in this study?

You will be paid for your time or expenses. You will receive a $25 gift card for completing the survey. If you are selected for the one-on-one interviews, you will receive $50 for each completed interview.

If you receive $600 dollars or more for taking part in the study, the payment may be taxable and will be

10. How will new findings related to your participation in this study be shared with you?

The researcher will tell you of any new information learned during your study participation which might cause you to change your mind about continuing the study.

11. What if there is a problem while taking part in this study?

If you are injured from being in this research study, please notify your St. Jude Doctor or the study doctor, Megan Wilkins, PhD. Any personnel needing treatment for anything related to the discussions in this study please consult with a member of the research team. St. Jude will offer you reasonable and necessary medical treatment for that injury. If you need more care than St. Jude can provide or if you prefer to seek treatment elsewhere, we will help you find medical care somewhere else. St. Jude may bill your insurance company or other third parties, if appropriate.

It is not the hospital's policy to provide payment for other types of costs, such as lost wages, disability, or discomfort if you are injured from being in this study. You are not giving up any of your rights by signing this consent form.

12. How will you find out the results of this study?

St. Jude researchers share information with people in studies in many ways including:

- Articles on www.stjude.org
- In newsletters
- In medical or scientific journals
- In the media

Published research results will only describe groups of people who took part in the study. Information that points out a single person will not be in research journals or other reports.

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If you choose to take part in this study, your data will be used to answer the research question(s) and to publish the findings of this study. Published research results will only describe groups of people who took part in the study. Information that points out a single person will not be in research journals or other reports. You will not own your research data. If researchers use your data to create a new product or idea, including those that may have commercial value, you will not benefit financially. There is no plan to share any money with you.

St. Jude's researchers and their collaborators will store the data collected in this study in electronic databases and other locations. They may use the data collected in this study for future research purposes and may share some of the data with others without seeking further consent from you. You may not receive results from that future research.

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Your data may be shared with government agencies, research collaborators, and other researchers and organizations conducting research that may not be related to this study.

Because science constantly advances, we do not yet know what other future uses of research data may include. There is no time-limit on the sharing of information.

This future research may be unrelated to the current study and may include outside researchers and organizations from around the world. These organizations may include for-profit companies conducting medical research. We or others who distribute data may be paid for data or samples, including yours. You will not receive payment if this happens.

St. Jude will do its best to protect and maintain your data in a safe way. One of the ways we protect your data is by limiting the uses of the information and the type of information that is shared, especially your

personal information. This may occur through data sharing agreements and review by oversight groups within St Jude. Often the data may be coded to protect your identity before they are shared, and we will keep the key to the code in a secure way.

If data are used or shared with any information that may be likely to identify you, such as your name, address, or medical record number, further institutional review and approval would be required. In these cases, we will review whether additional consent from you is required.

Generally, if your data are used and shared without any personal identifiers or only with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed, and you will not be contacted.

By signing this consent form, you allow the Sponsor, Meharry Medical College, to use study data for commercial purposes, and to use and share data from this study in the future for this and other studies. St. Jude may also use and share study data for patient care, academic uses, and publication, and when required by law. St. Jude and Meharry Medical College will take precautions to remove any information that could identify you (like your name or medical record number) before sharing.

Data sharing could change over time and may continue after the study ends.

The use and sharing of your data is required for participation in this research study. The purpose of research is to learn and discover new information to make improvements to patient care and/or treatments. To make these improvements, research results must be shared with others. By agreeing to take part in research studies, you are agreeing for your information or data to be used and shared with others. If you are generally not comfortable with the use and sharing of your data in future research as explained this consent, you should talk with your doctor before agreeing to take part in this study.

14. What about permission to use your data/information (HIPAA Privacy Rule), privacy and confidentiality?

All efforts, within reason, will be made to keep your personal information in your research record confidential. Your privacy will be protected to the extent permitted by law. If the results from this study are published, your name will not be made public. Your participation in this study will remain confidential, that is members of the research team collecting data will know who has agreed to participate but your answers to study questions will remain anonymous and will only be shared as aggregate data or as summaries as part of research and will not be connected with any names or other identifying information. While unlikely, the following may look at the study records:

- Meharry Medical College Institutional Review Board
- Office for Human Research Protections (OHRP)
- St. Jude Children's Research Hospital Institutional Review Board
- St. Jude Children's Research Hospital ID Clinic Staff

Data (or information from this study) will be stored electronically by the research team on the password protected computer of the study coordinator or interviewer. Once the study has been completed, study information (data) will be sent by email to the primary investigator of this study. Access to the computer will be password protected, and the computer will be HIPAA compliant (follow privacy guidelines of the Health Insurance Portability and Accountability Act).

We will work with St. Jude to request electronic medical records for you as a participant in this study for the year prior to your participation date in the areas of viral load, CD4 cell count, and appointment adherence. By signing this form, you are consenting to the medical providers' release of this information only to our study team for the purposes of research.

When you complete this survey, your answers will be recorded with a case identification number so that your name is not used to identify your information. Data (or information from this study) will be stored electronically by the research team on a secure server. Once the study has been completed, study information, (data) in the form of case identification numbers and not names, will be downloaded from REDCap (a secure online data collection system used for research purposes) by the primary investigator of this study. The study information (data) will be stored on the computer of the primary investigator. Access to the computer will be password protected, and the computer will be HIPAA compliant (follow privacy guidelines of the Health Insurance Portability and Accountability Act).

Any questions you have involving the research and your rights may be addressed to Dr. Lauren Brown at 615-557-3499 or the chair of the Meharry Institutional Review Board, at 615-327-6735. Your participation in this study is voluntary and you are free to withdraw at any time without penalty or loss of benefits that you are otherwise entitled to. You will be given a copy of this form to keep.

The study results will be kept as a research record for an unknown length of time. Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Wilkins in writing and let her know that you withdraw your consent. Her email address is megan.wilkins@stjude.org. At that time, we will stop getting any more data about you, but the health data we stored before you withdrew your consent may still be used for reporting and research quality.

You have the right to see and copy the PHI we gather on you for as long as the study investigators or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished. If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

The HIPAA Privacy Rule defines the situations in which PHI (protected health information) may be used or given to someone outside of the hospital to be used or released for research and other purposes. PHI includes information such as your name, MRN, date of birth, or other identifying information, including research information placed in your medical record.

To do this research, St. Jude Children's Research Hospital (St. Jude) will need to collect, use, and share your private health information. St. Jude is required by law to protect your health information. By signing this consent form, you give St. Jude permission to use and/or release (share) your private health

information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

If you sign this consent form, you give permission to all researchers and their staff involved in the study at St. Jude to use or release (share) your health information that identifies you for the research study described in this document.

If you sign this consent form, you give St. Jude permission to share your information for future research studies about disease or advancing science and for future unspecified research. You also give permission for us to place this information on databases as described below under Privacy and Confidentiality.

Any information placed in the medical record becomes a permanent part of your record, is kept indefinitely, and is not protected by a Certificate of Confidentiality (Certificate of Confidentiality, if included with this study, is described below under Privacy and Confidentiality). It is protected like any other part of your medical record as described in the Notice of Privacy Practices. You have the right to see, copy, and ask for changes to your PHI that will be used or shared. However, research information may not be available until after the end of the study.

When you first registered at St. Jude, you received a copy of the St. Jude Notice of Privacy Practices. It tells how your PHI, including research information placed in your medical record, may be used, or given to someone outside of St. Jude. You have the right to read the Notice of Privacy Practices before you sign this consent form. It may have changes since you first registered at St. Jude. You can find it at the bottom of every page on the St. Jude internet website: www.stjude.org

The people who may view, request, receive, or use your private health information include St. Jude researchers and their staff, and other doctors, nurses, and staff members. Additionally, St. Jude may share your information with other people or groups of people. These include:

- Office of Human Research Protections (OHRP)
- National Institutes of Health (NIH)
- Accrediting agencies like the Joint Commission
- St. Jude Children's Research Hospital Institutional Review Board (IRB) and other committees or people involved in overseeing research studies
- Others who have access to your medical record by authorization or law
- Other approved health care providers
- Meharry Medical College Institutional Review Board and Medical College staff involved in the study

You do not have to sign this consent form which gives your permission, but if you do not, you may not receive research-related treatment.

Please note that you may change your mind and take back (revoke) this permission at any time. Even if you take back this permission, St. Jude Children's Research Hospital may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To take back this consent form/permission, you must write to:

HIPAA Privacy Officer
St. Jude Children's Research Hospital
262 Danny Thomas Place, Mail Stop 280
Memphis, TN 38105

This permission does not have an expiration date.

Confidentiality

We will protect the confidentiality of your information to the extent reasonably possible.

Researchers and study staff are required by law to report suspected child abuse, threat of harm to self or others, and certain diseases that spread from person to person.

Research data obtained from this study from standard of care tests and procedures and research tests and procedures such as tumor and normal specimens and genetic data, are often shared with the research community using various databases, including those maintained by St. Jude, the federal government, and international collaborative databases. This is to advance scientific discovery, and to satisfy requirements of organizations that fund research, and journals that publish the results of research.

There are two types of databases used for sharing research data. One is a public, unrestricted access database and the other is a controlled access database. Each is described below.

Unrestricted access databases:

The information from research studies using your samples, genetic information, and some health information may be freely available in a public, unrestricted database that anyone can use. A public database could include information on hundreds of thousands of genetic variations in your DNA code, as well as your ethnic group and sex. Summary-level information about all participants included in a dataset, including you, but not genetic data for each individual, may be shared.

Some examples of information that may be shared includes how different genes are associated with different traits or diseases across the many participants in the dataset, or how often certain gene changes are seen across participants from many studies. However, the risk of anyone identifying you with this information is very low. This public information will not be labeled with your name or other information that could be used to easily identify you.

Controlled access databases:

Your individual genomic data and health information may be put in a controlled-access database. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to easily identify you.

Researchers approved to access information in the database must agree to protect the information and not to try to identify you. Examples are the St Jude Cloud, which is run by St. Jude, the database of Genotypes and Phenotypes which is run by the Federal Government, and the European Genome-

Phenome archive. These are databases available to researchers to use genomic information from tumor and non-tumor samples to study genetic changes in pediatric diseases.

All efforts, within reason, will be made to keep your personal information confidential. Confidentiality in focus groups cannot be guaranteed due to other group members. Your privacy will be protected to the extent permitted by law. If the results from this study are published, your name will not be made public. Your participation in this study will remain confidential, that is members of the research team collecting data will know who has agreed to participate but your answers to study questions will remain anonymous and will only be shared as aggregate data or summaries as part of published research and will not be connected with any names or other identifying information. We have provided a HIPAA waiver form for you to sign so that we may request basic information from St. Jude HIV clinic on your past year's viral load, CD4 cell count, and appointment adherence. By signing this form, you are consenting that they share this information with us for the purpose of this research only. No identifying information will be shared with St. Jude HIV Clinic from this study.

While unlikely, the following may look at the study records:

- Meharry Medical College Institutional Review Board
- Office for Human Research Protections (OHRP)
- Ending the Epidemic Program Committee Human Research Protection Program (HRPP)

Therapeutic treatment sessions for this study will be audio recorded to retain the most accurate documentation of your statements and experiences. Data (or information from this study) will be stored electronically by the research team on the password protected computer of the study coordinator or interviewer. Once the study has been completed, study information (data) will be sent by email to the primary investigator of this study. Access to the computer will be password protected, and the computer will be HIPAA compliant (follow privacy guidelines of the Health Insurance Portability and Accountability Act).

This section is about optional interviews you may be invited to take part in if you participate in the main research study.

You will not get health benefits from the optional one-on-one interviews. There are no costs to you or your insurance or other payors. You will receive $50 for each completed interview. If any of the research leads to new tests, drugs, or other commercial products, there is no plan to share any money with you.

By signing this consent form, you are voluntarily and freely donating your information to Meharry Medical College and St. Jude Children's Research Hospital.

The researchers leading the optional studies believe the results will help other people in the future.

The results from these optional research studies will not be added to your medical record.

You can still take part in the main study even if you say "no" to the optional interviews. If you sign up for but cannot complete any of the optional interviews for any reason, you can still take part in the main study.

What will happen in this Optional Interviews?

If you agree to take part in the optional interviews, here is what will happen next:

You may be contacted to take part in a one-on-one interview to discuss your experiences in the ID clinic. If you complete that interview, you will be contacted again about one year later for another interview about your experiences.

The purpose of these interviews is to help develop later parts of this study.

How will information about me be kept confidential for Future Optional Studies?

Your privacy is very important to the researchers and they will make every effort to protect it as discussed in section 13 above.

What if I Change my Mind?

If you decide you no longer want to participate in the interviews, you can call the St. Jude study doctor, Megan Wilkins at 901-595-3300 who will let the researchers know. Information that has already been given to or used by researchers will not be removed.

• One-on-One Interviews	One time per year for 2 years	• To learn more about patient experiences in tl ID clinic
ease initial your choice: I agree to participate in the additional one-on-one interviews		**s: _____ Initials** **): _____ Initials**

If you decide you would like to take part in this research study, please ask any questions you have, and read and sign this consent form. You will be given a copy of it to keep. A copy of this consent form will also be put in your patient notes, one will be put with the study records, and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this informed consent document and to consider taking part in this study.

RESEARCH PARTICIPANT STATEMENT (Age 18 years and older):

I have read this consent form or it was read to me. I have been encouraged to ask questions and all of my questions were answered. I agree to take part in this research study.

_____	_____	_____AM/PM	
Research Participant Signature	Date	Time	(circle one)

RESEARCHER/DESIGNEE STATEMENT:

I have explained the research to the participant and his/her parent(s) or legal guardian(s). The research participant and parent(s)/guardian(s) were encouraged to ask questions and all questions were answered to their satisfaction. A copy of this consent form has been given to the participant or his/her representative.

		_____AM/PM	
Researcher/Designee Signature	Date	Time	(circle one)

_____

Researcher/Designee Print Name

		_____AM/PM	
Interpreter (if needed) Signature	Date	Time	(circle one)

PLEASE UPLOAD COMPLETED CONSENT FORM TO EPIC.

Personnel focus groups Informed Consent Document
PI: L Lauren Brown
Meharry Medical College
Clinical Trials registry: 22-08-1234

Implementation of Trauma Informed Care for Youth Living with HIV in Memphis, TN

Note: When we say "you" in this informed consent document, we mean "you or your child." When we talk about research, it can be called a clinical trial, research study (study), or research protocol.

Key Information

To start, we highlight here the risks, benefits, and study requirements that we think you should know before deciding if you want to take part in this research study. If you're still interested, we'll then get into more details.

A. Why are you being asked to voluntarily take part in this study?
   You are being asked to take part in this research study because you are personnel of the St. Jude ID clinic or an ancillary staff member to the clinic.
B. Why is this study being done?
   The purpose of this study is to implement trauma-informed care in the St. Jude ID clinic.
C. What will happen if you decide to take part in this study?
   For this portion of the study, you are being asked to participate in staff focus group discussions. There will be about 4 focus group discussions and they will last around 1.5 hours each.
D. What are the research risks and benefits of taking part in this study?
   There are no expected risks in participating in this study beyond experiencing minor discomfort in responding to some of the focus group topics. You may directly benefit by having the possibility to discuss some of your experiences personally or as personnel of the ID clinic.
E. How many people will take part in this study?
   We expect around 40 clinic and ancillary staff to take part in this portion of the study.
F. What are your options?
   1) Taking part in this research study is completely your choice.
   2) If you decide to take part in this study, you can change your mind and stop at any time.

If you are still interested in taking part in this research study, TICID1, more detail is provided below in the following pages.

Study Contact Details and Further Information

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your doctor, who will be able to provide you with up-to-date information about the drug(s)/procedure(s) involved. If there is anything that you do not understand, or if you have any other questions, please contact any of the people below.

Who to talk to for…	You can contact…	At…
• Any new or unexpected symptoms, side effects or discomforts • General study questions • Any research concerns or complaints	**Megan Wilkins, PhD** 262 Danny Thomas Place Memphis, TN 38105	901-595-3300 (Main Hospital Number)
• Your rights as a research participant • Any research concerns or complaints	**Institutional Review Board (IRB)/Research Participant Advocate** * IRB is a group of scientists and community members who make sure research meets legal and ethical standards. * Research Participant Advocates are individuals who are not part of the research study team and are available to you to discuss problems, concerns, and questions. The Advocate can help you obtain information and can relay any input you may have concerning the research to the research study team and the IRB.	901-595-4644 or 901-595-1139 Meharry 615-557-3499 or 615-327-6735

Table of Contents

1. Why are you being asked to voluntarily take part in this research study?

You are being asked to participate in a research study because you are personnel of St. Jude ID clinic or an ancillary staff member to the clinic. Taking part in this study is completely your choice. Please take your time in deciding and feel free to discuss it with your family, friends, and St. Jude staff. Before agreeing, it is important that you read this informed consent document (consent form) that describes the study. After you understand the study and if you agree to take part, you will be asked to sign this

2. Who is sponsoring this study?

This study is sponsored by the National Institutes of Health who are providing funding for the study. Meharry Medical Center is serving as the IRB of record. Questions regarding the study should be directed to St. Jude at 901-595-3300 or Dr. Lauren Brown with Meharry Medical College at 615-327-

3. What is the purpose of this study?

The purpose of this study is to implement trauma-informed care at St. Jude ID Clinic. Trauma informed care recognizes the presence of trauma symptoms and acknowledges the role trauma may play in your life.

What will be done in this study?

As a St. Jude ID clinic personnel or ancillary staff member, you have been asked if you would like to participate in the study. You have been approached by a member of the research team who has informed you about the study. For anyone agreeing to participate, you will sign this informed consent form and then be invited to participate in an experimental study which seeks to improve knowledge, attitudes, practices, culture, and quality of life of St. Jude ID clinic personnel. For this portion of the study, you are being asked to participate in staff focus group discussions. Focus groups will take about 1.5 hours to complete and will be administered by research staff. Should any of the focus group discussions make you feel uncomfortable, you may choose to not response to the discussion topic. Taking part or not taking part in this study will have no impact on your employment status favorably or unfavorably, directly or indirectly.

5. What are the risks and benefits of taking part in this study?

a. Risks

Beyond experiencing minor discomfort in responding to some of the focus group topics, there are no expected risks in participating in this study. Should unforeseeable risks occur, you are encouraged to speak with a member of the research team to discuss the risks so that actions may be taken to assist you.

b. Benefits

You may or may not directly benefit from this study. You will have the opportunity to discuss some of your experiences personally or as personnel of the ID clinic. Additionally, information from this study

s.

[redacted]**an you stop taking part in this study?**

You may change your mind about taking part in this research study and stop at any time. This decision will not affect your relationship with St. Jude or your status as personnel with the St. Jude ID clinic.

If you change your mind about participating in this study, related information that has already been

7. What are your other options?

No treatment is being provided as part of this study. The other option is not to take part in this study.

8. How much will it cost you to take part in this study?

If you have health care coverage, we will bill your health care insurer for all standard of care services, tests, and procedures, as applicable. Billing your health care insurer impacts your annual deductible and life-time maximum, if any. This may affect your health care coverage to some extent if you go to another health care provider or institution in the future.

At St. Jude, you will not be responsible for or receive bills for co-pays, co-insurance, deductibles, or similar patient-liability amounts, or for the cost of medical care related to your disease or this study not covered by your health insurer. This includes research-only costs. Research-only tests and procedures will not be billed to you or your health care insurer.

9. Will you be paid for your time or expenses while taking part in this study?

You will be paid for your time or expenses. You will receive a $25 gift card for each focus group you participate in.

If you receive $600 dollars or more for taking part in the study, the payment may be taxable and will be reported to the Internal Revenue Service (IRS).

[redacted]. What if there is a problem while taking part in this study?

If you are injured from being in this research study, please notify your St. Jude Doctor or the study doctor, Mehan Wilkins, PhD. Any personnel needing treatment for anything related to the discussions in this study please consult with a member of the research team. St. Jude will offer you reasonable and necessary medical treatment for that injury. If you need more care than St. Jude can provide or if you prefer to seek treatment elsewhere, we will help you find medical care somewhere else. St. Jude may bill your insurance company or other third parties, if appropriate.

It is not the hospital's policy to provide payment for other types of costs, such as lost wages, disability, or discomfort if you are injured from being in this study. You are not giving up any of your rights by signing this consent form.

11. How will new findings related to your participation in this study be shared with you?

The researcher will tell you of any new information learned during your study participation which might cause you to change your mind about continuing the study.

[redacted]. How will you find out the results of this study?

St. Jude researchers share information with people in studies in many ways including:

- Articles on www.stjude.org
- In newsletters
- In medical or scientific journals
- In the media

Published research results will only describe groups of people who took part in the study. Information that points out a single person will not be in research journals or other reports.

13. What about identifiable private information and identifiable biospecimens (blood, tissue, urine, cells, and any type of data and/or samples) obtained from you during the study?

If you choose to take part in this study, your data will be used to answer the research question(s) and to publish the findings of this study. Published research results will only describe groups of people who took part in the study. Information that points out a single person will not be in research journals or other reports. You will not own your research data. If researchers use your data to create a new product or idea, including those that may have commercial value, you will not benefit financially. There is no plan to share any money with you.

St. Jude's researchers and their collaborators will store the data collected in this study in electronic databases and other locations. They may use the data collected in this study for future research purposes and may share some of the data with others without seeking further consent from you. You may not receive results from that future research.

Sharing data is part of research. It may increase what can be learned from this study and future studies. Often data sharing is required as a condition of funding or for publishing study results. It is also needed to allow other researchers to validate study findings and to come up with new ideas.

Your data may be shared with government agencies, research collaborators, and other researchers and organizations conducting research that may not be related to this study.

Because science constantly advances, we do not yet know what other future uses of research data may include. There is no time-limit on the sharing of information.

This future research may be unrelated to the current study and may include outside researchers and organizations from around the world. These organizations may include for-profit companies conducting medical research. We or others who distribute data may be paid for data or samples, including yours. You will not receive payment if this happens.

St. Jude will do its best to protect and maintain your data in a safe way. One of the ways we protect your data is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data sharing agreements and review by oversight groups within St Jude. Often the data may be coded to protect your identity before they are shared, and we will keep the key to the code in a secure way.

If data are used or shared with any information that may be likely to identify you, such as your name, address, or medical record number, further institutional review and approval would be required. In these cases, we will review whether additional consent from you is required.

Generally, if your data are used and shared without any personal identifiers or only with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed, and you will not be contacted.

By signing this consent form, you allow the Sponsor, Meharry Medical College, to use study data for commercial purposes, and to use and share data from this study in the future for this and other studies. St. Jude may also use and share study data for patient care, academic uses, and publication, and when required by law. St. Jude and Meharry Medical College will take precautions to remove any information that could identify you (like your name or medical record number) before sharing.

Data sharing could change over time and may continue after the study ends.

The use and sharing of your data is required for participation in this research study. The purpose of research is to learn and discover new information to make improvements to patient care and/or treatments. To make these improvements, research results must be shared with others. By agreeing to take part in research studies, you are agreeing for your information or data to be used and shared with others. If you are generally not comfortable with the use and sharing of your data in future research as explained this consent, you should talk with your doctor before agreeing to take part in this study.

14. What about permission to use your data/information (HIPAA Privacy Rule), privacy and confidentiality?

Permission to Use Your Data/Information- HIPAA Privacy Rule and Privacy

All efforts, within reason, will be made to keep your personal information confidential. Confidentiality in focus groups cannot be guaranteed due to other group members. Your privacy will be protected to the extent permitted by law. If the results from this study are published, your name will not be made public. Your participation in this study will remain confidential, that is members of the research team collecting data will know who has agreed to participate but your answers to study questions will remain anonymous and will only be shared as aggregate data or summaries as part of published research and will not be connected with any names or other identifying information. No identifying information will be shared with St. Jude ID Clinic from this study.

While unlikely, the following may look at the study records:

- Meharry Medical College Institutional Review Board
- St. Jude Children's Research Hospital Institutional Review Board
- St. Jude Children's Research Hospital ID Clinic Staff
- Office for Human Research Protections (OHRP)
- Ending the Epidemic Program Committee Human Research Protection Program (HRPP)

Focus group sessions for this study will be audio recorded to retain the most accurate documentation of your statements and experiences. Data (or information from this study) will be stored electronically by the research team on the password protected computer of the study coordinator or interviewer. Once the study has been completed, study information (data) will be sent by email to the primary investigator

of this study. Access to the computer will be password protected, and the computer will be HIPAA compliant (follow privacy guidelines of the Health Insurance Portability and Accountability Act).

SUBJECT RIGHTS

Any questions you have involving the research and your rights may be addressed to Dr. Lauren Brown at 615-557-3499 or the chair of the Meharry Institutional Review Board, at 615-327-6735. Your participation in this study is voluntary and you are free to withdraw at any time without penalty or loss of benefits that you are otherwise entitled to. You will be given a copy of this form to keep.

The HIPAA Privacy Rule defines the situations in which PHI (protected health information) may be used or given to someone outside of the hospital to be used or released for research and other purposes. PHI includes information such as your name, MRN, date of birth, or other identifying information, including research information placed in your medical record.

To do this research, St. Jude Children's Research Hospital (St. Jude) will need to collect, use, and share your private health information. St. Jude is required by law to protect your health information. By signing this consent form, you give St. Jude permission to use and/or release (share) your private health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

If you sign this consent form, you give permission to all researchers and their staff involved in the study at St. Jude to use or release (share) your health information that identifies you for the research study described in this document.

If you sign this consent form, you give St. Jude permission to share your information for future research studies about disease or advancing science and for future unspecified research. You also give permission for us to place this information on databases as described below under Privacy and Confidentiality.

Any information placed in the medical record becomes a permanent part of your record, is kept indefinitely, and is not protected by a Certificate of Confidentiality (Certificate of Confidentiality, if included with this study, is described below under Privacy and Confidentiality). It is protected like any other part of your medical record as described in the Notice of Privacy Practices. You have the right to see, copy, and ask for changes to your PHI that will be used or shared. However, research information may not be available until after the end of the study.

When you first registered, or became an employee, at St. Jude, you received a copy of the St. Jude Notice of Privacy Practices. It tells how your PHI, including research information placed in your medical record, may be used or given to someone outside of St. Jude. You have the right to read the Notice of Privacy Practices before you sign this consent form. It may have changed since you first registered or became an employee at St. Jude. You can find it at the bottom of every page on the St. Jude internet website: www.stjude.org

The people who may view, request, receive, or use your private health information include St. Jude researchers and their staff, and other doctors, nurses, and staff members. Additionally, St. Jude may share your information with other people or groups of people. These include:

- Office of Human Research Protections (OHRP)
- National Institutes of Health (NIH)
- Accrediting agencies like the Joint Commission
- St. Jude Children's Research Hospital Institutional Review Board (IRB) and other committees or people involved in overseeing research studies
- Others who have access to your medical record by authorization or law
- Other approved health care providers
- Meharry Medical College Institutional Review Board and Medical College staff involved in the study

You do not have to sign this consent form which gives your permission, but if you do not, you may not receive research-related treatment.

Please note that you may change your mind and take back (revoke) this permission at any time. Even if you take back this permission, St. Jude Children's Research Hospital may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To take back this consent form/permission, you must write to:

HIPAA Privacy Officer
St. Jude Children's Research Hospital
262 Danny Thomas Place, Mail Stop 280
Memphis, TN 38105

This permission does not have an expiration date.

Confidentiality

We will protect the confidentiality of your information to the extent reasonably possible.

Researchers and study staff are required by law to report suspected child abuse, threat of harm to self or others, and certain diseases that spread from person to person.

Research data obtained from this study from standard of care tests and procedures and research tests and procedures such as tumor and normal specimens and genetic data, are often shared with the research community using various databases, including those maintained by St. Jude, the federal government, and international collaborative databases. This is to advance scientific discovery, and to satisfy requirements of organizations that fund research, and journals that publish the results of research.

There are two types of databases used for sharing research data. One is a public, unrestricted access database and the other is a controlled access database. Each is described below.

<u>Unrestricted access databases:</u>

The information from research studies using your samples, genetic information, and some health information may be freely available in a public, unrestricted database that anyone can use. A public database could include information on hundreds of thousands of genetic variations in your DNA code, as

well as your ethnic group and sex. Summary-level information about all participants included in a dataset, including you, but not genetic data for each individual, may be shared.

Some examples of information that may be shared includes how different genes are associated with different traits or diseases across the many participants in the dataset, or how often certain gene changes are seen across participants from many studies. However, the risk of anyone identifying you with this information is very low. This public information will not be labeled with your name or other information that could be used to easily identify you.

Controlled access databases:

Your individual genomic data and health information may be put in a controlled-access database. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to easily identify you.

Researchers approved to access information in the database must agree to protect the information and not to try to identify you. Examples are the St Jude Cloud, which is run by St. Jude, the database of Genotypes and Phenotypes which is run by the Federal Government, and the European Genome-Phenome archive. These are databases available to researchers to use genomic information from tumor and non-tumor samples to study genetic changes in pediatric diseases.

All efforts, within reason, will be made to keep your personal information confidential. Confidentiality in focus groups cannot be guaranteed due to other group members. Your privacy will be protected to the extent permitted by law. If the results from this study are published, your name will not be made public. Your participation in this study will remain confidential, that is members of the research team collecting data will know who has agreed to participate but your answers to study questions will remain anonymous and will only be shared as aggregate data or summaries as part of published research and will not be connected with any names or other identifying information. We have provided a HIPAA waiver form for you to sign so that we may request basic information from St. Jude HIV clinic on your past year's viral load, CD4 cell count, and appointment adherence. By signing this form, you are consenting that they share this information with us for the purpose of this research only. No identifying information will be shared with St. Jude HIV Clinic from this study.

While unlikely, the following may look at the study records:

- Meharry Medical College Institutional Review Board
- Office for Human Research Protections (OHRP)
- Ending the Epidemic Program Committee Human Research Protection Program (HRPP)

Therapeutic treatment sessions for this study will be audio recorded to retain the most accurate documentation of your statements and experiences. Data (or information from this study) will be stored electronically by the research team on the password protected computer of the study coordinator or interviewer. Once the study has been completed, study information (data) will be sent by email to the primary investigator of this study. Access to the computer will be password protected, and the

computer will be HIPAA compliant (follow privacy guidelines of the Health Insurance Portability and Accountability Act).

If you decide you would like to take part in this research study, please ask any questions you have, and read and sign this consent form. You will be given a copy of it to keep. A copy of this consent form will also be put in your patient notes, one will be put with the study records, and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this informed consent document and to consider taking part in this study.

RESEARCH PARTICIPANT STATEMENT (Age 18 years and older):

I have read this consent form or it was read to me. I have been encouraged to ask questions and all of my questions were answered. I agree to take part in this research study.

_____	_____	_____AM/PM	
Research Participant Signature	Date	Time	(circle one)

RESEARCHER/DESIGNEE STATEMENT:

I have explained the research to the participant and his/her parent(s) or legal guardian(s). The research participant and parent(s)/guardian(s) were encouraged to ask questions and all questions were answered to their satisfaction. A copy of this consent form has been given to the participant or his/her representative.

		_____AM/PM	
Researcher/Designee Signature	Date	Time	(circle one)

_____

Researcher/Designee Print Name

		_____AM/PM	
Interpreter (if needed) Signature	Date	Time	(circle one)

Personnel survey Informed Consent Document
PI: L Lauren Brown
Meharry Medical College
Clinical Trials registry: 22-08-1234

Implementation of Trauma Informed Care for Youth Living with HIV in Memphis, TN

Note: When we say "you" in this informed consent document, we mean "you or your child." When we talk about research, it can be called a clinical trial, research study (study), or research protocol.

Key Information

To start, we highlight here the risks, benefits, and study requirements that we think you should know before deciding if you want to take part in this research study. If you're still interested, we'll then get into more details.

A. Why are you being asked to voluntarily take part in this study?
   You are being asked to take part in this research study because you are personnel of the St. Jude ID clinic or an ancillary staff member to the clinic.
B. Why is this study being done?
   The purpose of this study is to implement trauma-informed care in the St. Jude ID clinic.
C. What will happen if you decide to take part in this study?
   For this portion of the study, you are being asked to participate in personnel surveys. There will be up to 7 surveys. Each survey will take about 30-45 minutes to complete.
D. What are the research risks and benefits of taking part in this study?
   There are no expected risks in participating in this study beyond experiencing minor discomfort in responding to some of the survey questions. You may or may not directly benefit by having the possibility to discuss some of your experiences personally or as personnel of the ID clinic.
E. How many people will take part in this study?
   Around 70 ID Clinic personnel will take part in this portion of the study.
F. What are your options?
   1) Taking part in this research study is completely your choice.
   2) If you decide to take part in this study, you can change your mind and stop at any time.

If you are still interested in taking part in this research study, TICID1, more detail is provided below in the following pages.

Study Contact Details and Further Information

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your doctor, who will be able to provide you with up-to-date information about the drug(s)/procedure(s) involved. If there is anything that you do not understand, or if you have any other questions, please contact any of the people below.

Who to talk to for…	You can contact…	At…
• Any new or unexpected symptoms, side effects or discomforts • General study questions • Any research concerns or complaints	**Megan Wilkins, PhD** 262 Danny Thomas Place Memphis, TN 38105	901-595-3300 (Main Hospital Number)
• Your rights as a research participant • Any research concerns or complaints	**Institutional Review Board (IRB)/Research Participant Advocate** * IRB is a group of scientists and community members who make sure research meets legal and ethical standards. * Research Participant Advocates are individuals who are not part of the research study team and are available to you to discuss problems, concerns, and questions. The Advocate can help you obtain information and can relay any input you may have concerning the research to the research study team and the IRB.	St. Jude 901-595-4644 or 901-595-1139 Meharry 615-557-3499 or 615-327-6735

Table of Contents

1. Why are you being asked to voluntarily take part in this research study?

You are being asked to participate in a research study because you are personnel of St. Jude ID clinic or an ancillary staff member to the clinic. Taking part in this study is completely your choice. Please take your time in deciding and feel free to discuss it with your family, friends, and St. Jude staff. Before agreeing, it is important that you read this informed consent document (consent form) that describes the study. After you understand the study and if you agree to take part, you will be asked to sign this

2. Who is sponsoring this study?

This study is sponsored by the National Institutes of Health who are providing funding for the study. Meharry Medical Center is serving as the IRB of record. Questions regarding the study should be directed to St. Jude at 901-595-3300 or Dr. Lauren Brown with Meharry Medical College at 615-327-

3. What is the purpose of this study?

The purpose of this study is to implement trauma-informed care at St. Jude ID Clinic. Trauma informed care recognizes the presence of trauma symptoms and acknowledges the role trauma may play in your life.

What will be done in this study?

As a St. Jude ID clinic personnel or ancillary staff member, you have been asked if you would like to participate in the study. You have been approached by a member of the research team who has informed you about the study. For anyone agreeing to participate, you will sign this informed consent form and then be invited to participate in an experimental study which seeks to improve knowledge, attitudes, practices, culture, and quality of life of St. Jude ID clinic personnel. For this portion of the study, you are being asked to participate in personnel surveys. Surveys will take about 30-45 minutes to complete. We anticipate survey responses will be requested every six months for two years, totaling around seven different surveys. Should any of the survey questions make you feel uncomfortable, you may choose to not respond to the questions. This will not affect your status as personnel of St. Jude ID clinic.

[redacted] **What are the risks and benefits of taking part in this study?**

a. Risks

Beyond experiencing minor discomfort in responding to some of the survey questions, there are no expected risks in participating in this study. Should unforeseeable risks occur, you are encouraged to speak with a member of the research team to discuss the risks so that actions may be taken to assist you.

b. Benefits

You may or may not directly benefit from this study because you have the possibility to discuss some of your experiences personally or as personnel of the ID clinic. Additionally, information from this study might be used to improve the nature of services at St. Jude ID clinic as well as other HIV care systems.

[redacted]

If you change your mind about participating in this study, related information that has already been used by researchers will not be removed.

7. What are your other options?

8. How much will it cost you to take part in this study?

If you have health care coverage, we will bill your health care insurer for all standard of care services, tests, and procedures, as applicable. Billing your health care insurer impacts your annual deductible and life-time maximum, if any. This may affect your health care coverage to some extent if you go to another health care provider or institution in the future.

At St. Jude, you will not be responsible for or receive bills for co-pays, co-insurance, deductibles, or similar patient-liability amounts, or for the cost of medical care related to your disease or this study not

covered by your health insurer. This includes research only costs. Research only tests and procedures s

9. Will you be paid for your time or expenses while taking part in this study?

You will be paid for your time or expenses. You will receive a $25 gift card for each survey you complete.

If you receive $600 dollars or more for taking part in the study, the payment may be taxable and will be

10. What if there is a problem while taking part in this study?

If you are injured from being in this research study, please notify your St. Jude Doctor or the study doctor, Mehan Wilkins, PhD. Any personnel needing treatment for anything related to the discussions in this study please consult with a member of the research team. St. Jude will offer you reasonable and necessary medical treatment for that injury. If you need more care than St. Jude can provide or if you prefer to seek treatment elsewhere, we will help you find medical care somewhere else. St. Jude may bill your insurance company or other third parties, if appropriate.

It is not the hospital's policy to provide payment for other types of costs, such as lost wages, disability, or discomfort if you are injured from being in this study. You are not giving up any of your rights by signing this consent form.

11. How will new findings related to your participation in this study be shared with you?

The researcher will tell you of any new information learned during your study participation which might cause you to change your mind about continuing the study.

[redacted]. How will you find out the results of this study?

St. Jude researchers share information with people in studies in many ways including:

- Articles on www.stjude.org
- In newsletters
- In medical or scientific journals
- In the media

Published research results will only describe groups of people who took part in the study. Information that points out a single person will not be in research journals or other reports.

13. What about identifiable private information obtained from you during the study?

If you choose to take part in this study, your data will be used to answer the research question(s) and to publish the findings of this study. Published research results will only describe groups of people who took part in the study. Information that points out a single person will not be in research journals or other reports. You will not own your research data. If researchers use your data to create a new product or idea, including those that may have commercial value, you will not benefit financially. There is no plan to share any money with you.

St. Jude's researchers and their collaborators will store the data collected in this study in electronic databases and other locations. They may use the data collected in this study for future research purposes and may share some of the data with others without seeking further consent from you. You may not receive results from that future research.

Sharing data is part of research. It may increase what can be learned from this study and future studies. Often data sharing is required as a condition of funding or for publishing study results. It is also needed to allow other researchers to validate study findings and to come up with new ideas.

Your data may be shared with government agencies, research collaborators, and other researchers and organizations conducting research that may not be related to this study.

Because science constantly advances, we do not yet know what other future uses of research data may include. There is no time-limit on the sharing of information.

This future research may be unrelated to the current study and may include outside researchers and organizations from around the world. These organizations may include for-profit companies conducting medical research. We or others who distribute data may be paid for data or samples, including yours. You will not receive payment if this happens.

St. Jude will do its best to protect and maintain your data in a safe way. One of the ways we protect your data is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data sharing agreements and review by oversight groups within St Jude. Often the data may be coded to protect your identity before they are shared, and we will keep the key to the code in a secure way.

If data are used or shared with any information that may be likely to identify you, such as your name, address, or medical record number, further institutional review and approval would be required. In these cases, we will review whether additional consent from you is required.

Generally, if your data are used and shared without any personal identifiers or only with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed, and you will not be contacted.

By signing this consent form, you allow the Sponsor, Meharry Medical College, to use study data for commercial purposes, and to use and share data from this study in the future for this and other studies. St. Jude may also use and share study data for patient care, academic uses, and publication, and when required by law. St. Jude and Meharry Medical College will take precautions to remove any information that could identify you (like your name or medical record number) before sharing.

Data sharing could change over time and may continue after the study ends.

The use and sharing of your data is required for participation in this research study. The purpose of research is to learn and discover new information to make improvements to patient care and/or treatments. To make these improvements, research results must be shared with others. By agreeing to take part in research studies, you are agreeing for your information or data to be used and shared with others. If you are generally not comfortable with the use and sharing of your data in future research as explained this consent, you should talk with your doctor before agreeing to take part in this study.

14. What about permission to use your data/information (HIPAA Privacy Rule), privacy and confidentiality?

Permission to Use Your Data/Information- HIPAA Privacy Rule and Privacy

All efforts, within reason, will be made to keep your personal information confidential. Your privacy will be protected to the extent permitted by law. If the results from this study are published, your name will not be made public. Your participation in this study will remain confidential, that is members of the research team collecting data will know who has agreed to participate but your answers to study questions will remain anonymous and will only be shared as aggregate data or summaries as part of published research and will not be connected with any names or other identifying information. No identifying information will be shared with St. Jude ID Clinic from this study.

While unlikely, the following may look at the study records:

- Meharry Medical College Institutional Review Board
- St. Jude Children's Research Hospital Institutional Review Board
- St. Jude Children's Research Hospital ID Clinic Staff
- Office for Human Research Protections (OHRP)
- Ending the Epidemic Program Committee Human Research Protection Program (HRPP)

Data (or information from this study) will be stored electronically by the research team on the password protected computer of the study coordinator or interviewer. Once the study has been completed, study information (data) will be sent by email to the primary investigator of this study. Access to the computer will be password protected, and the computer will be HIPAA compliant (follow privacy guidelines of the Health Insurance Portability and Accountability Act).

SUBJECT RIGHTS

Any questions you have involving the research and your rights may be addressed to Dr. Lauren Brown at 615-557-3499 or the chair of the Meharry Institutional Review Board, at 615-327-6735. Your participation in this study is voluntary and you are free to withdraw at any time without penalty or loss of benefits that you are otherwise entitled to. You will be given a copy of this form to keep.

The HIPAA Privacy Rule defines the situations in which PHI (protected health information) may be used or given to someone outside of the hospital to be used or released for research and other purposes. PHI includes information such as your name, MRN, date of birth, or other identifying information, including research information placed in your medical record.

To do this research, St. Jude Children's Research Hospital (St. Jude) will need to collect, use, and share your private health information. St. Jude is required by law to protect your health information. By signing this consent form, you give St. Jude permission to use and/or release (share) your private health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

If you sign this consent form, you give permission to all researchers and their staff involved in the study at St. Jude to use or release (share) your health information that identifies you for the research study described in this document.

If you sign this consent form, you give St. Jude permission to share your information for future research studies about disease or advancing science and for future unspecified research. You also give permission for us to place this information on databases as described below under Privacy and Confidentiality.

Any information placed in the medical record becomes a permanent part of your record, is kept indefinitely, and is not protected by a Certificate of Confidentiality (Certificate of Confidentiality, if included with this study, is described below under Privacy and Confidentiality). It is protected like any other part of your medical record as described in the Notice of Privacy Practices. You have the right to see, copy, and ask for changes to your PHI that will be used or shared. However, research information may not be available until after the end of the study.

When you first registered at St. Jude, you received a copy of the St. Jude Notice of Privacy Practices. It tells how your PHI, including research information placed in your medical record, may be used or given to someone outside of St. Jude. You have the right to read the Notice of Privacy Practices before you sign this consent form. It may have changes since you first registered at St. Jude. You can find it at the bottom of every page on the St. Jude internet website: www.stjude.org

The people who may view, request, receive, or use your private health information include St. Jude researchers and their staff, and other doctors, nurses, and staff members. Additionally, St. Jude may share your information with other people or groups of people. These include:

- Office of Human Research Protections (OHRP)
- National Institutes of Health (NIH)
- Accrediting agencies like the Joint Commission

- St. Jude Children's Research Hospital Institutional Review Board (IRB) and other committees or people involved in overseeing research studies
- Others who have access to your medical record by authorization or law
- Other approved health care providers
- Meharry Medical College Institutional Review Board and Medical College staff involved in the study

You do not have to sign this consent form which gives your permission, but if you do not, you may not receive research-related treatment.

Please note that you may change your mind and take back (revoke) this permission at any time. Even if you take back this permission, St. Jude Children's Research Hospital may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To take back this consent form/permission, you must write to:

HIPAA Privacy Officer
St. Jude Children's Research Hospital
262 Danny Thomas Place, Mail Stop 280
Memphis, TN 38105

This permission does not have an expiration date.

Confidentiality

We will protect the confidentiality of your information to the extent reasonably possible.

Researchers and study staff are required by law to report suspected child abuse, threat of harm to self or others, and certain diseases that spread from person to person.

Research data obtained from this study from standard of care tests and procedures and research tests and procedures such as tumor and normal specimens and genetic data, are often shared with the research community using various databases, including those maintained by St. Jude, the federal government, and international collaborative databases. This is to advance scientific discovery, and to satisfy requirements of organizations that fund research, and journals that publish the results of research.

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Researchers approved to access information in the database must agree to protect the information and not to try to identify you. Examples are the St Jude Cloud, which is run by St. Jude, the database of Genotypes and Phenotypes which is run by the Federal Government, and the European Genome-Phenome archive. These are databases available to researchers to use genomic information from tumor and non-tumor samples to study genetic changes in pediatric diseases.

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If you decide you would like to take part in this research study, please ask any questions you have, and read and sign this consent form. You will be given a copy of it to keep. A copy of this consent form will also be put in your patient notes, one will be put with the study records, and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this informed consent document and to consider taking part in this study.

RESEARCH PARTICIPANT STATEMENT (Age 18 years and older):

I have read this consent form or it was read to me. I have been encouraged to ask questions and all of my questions were answered. I agree to take part in this research study.

_____	_____	_____AM/PM	
Research Participant Signature	Date	Time	(circle one)

RESEARCHER/DESIGNEE STATEMENT:

I have explained the research to the participant and his/her parent(s) or legal guardian(s). The research participant and parent(s)/guardian(s) were encouraged to ask questions and all questions were answered to their satisfaction. A copy of this consent form has been given to the participant or his/her representative.

		_____AM/PM	
Researcher/Designee Signature	Date	Time	(circle one)

_____

Researcher/Designee Print Name

		_____AM/PM	
Interpreter (if needed) Signature	Date	Time	(circle one)