Research Subject Study Information Sheet (Interview)

Title of Study: Optimizing Preimplantation Kidney Transplant Biopsy Interpretation with Artificial Intelligence Assistance

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Overview of Key Study Information

You are being invited to take part in a research study being conducted by researchers from NYU Langone Health. Your participation is voluntary which means you can choose whether or not you want to take part in this study. Here is a brief overview:

The purpose of this research study is to reach an agreement for how Artificial Intelligence (AI) -assisted biopsy interpretation will be implemented in clinical practice.

This study has more than one part: 1) Interview and 2) Delphi Panel. Participation in the overall study will last about 3 hours. For the interview portion of the study, you will be asked to complete an interview with a member of the study team. Depending on preference, the interview will take place over the phone or a secure video-conferencing platform called WebEx. During the interview, you will be asked if you are willing to be contacted about the Delphi Panel that will take place at a later time.

A comprehensive list of all possible risks and discomforts related to the interview portion of this study is included in the *Subject Information Sheet* below. The most common risk is discomfort from answering questions. You will not benefit directly from being in this study.

The alternative to participating in this study is to not participate. Your decision whether or not to participate will not affect your relationship with NYU Langone Health.

This overview does not have all of the information you will need to know before deciding whether or not to participate. For in-depth details about this study, please refer to the full *Subject Information Sheet* below. For questions and concerns regarding any of this information, please contact Macey Levan at macey.levan@nyulangone.org.

1. About volunteering for this research study

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and form with your family and friends. If you have any questions about the study or form, please ask us.

As an NYU Langone Health employee, your decision to participate, decline, or withdraw will have no impact on your employment, salary, or performance evaluation.

2. What is the purpose of this study?

The purpose of this research study is to reach an agreement for how AI-assisted biopsy interpretation will be implemented in clinical practice.

We are asking you to take part in this study because you are an established expert working in the field of kidney transplantation.

3. How long will I be in the study? How many other people will be in the study?

This study has more than one part. The overall study will last about 7-9 months. Your participation in the interview portion of this study will last 45-60 minutes. We aim to enroll up to 100 people in the interview portion at NYU Langone Health. Up to 50 people will be invited to take part in the Delphi Panel portion of the study.

4. What will I be asked to do in the study?

For the interview portion of this study, you will be asked to complete one interview over phone or WebEx with a member of the study team. The interview will include several questions about your attitudes/ perceptions about AI-assisted biopsy interpretation. The interview will last approximately 45-60 minutes. You are not required answer every question.

We would like to audio-record the interview so we can better capture what you said. We will only audio-record the interview with your permission. The audio recordings will not be used for advertising or non-research purposes. The audio recordings will be labeled only with a code number, which will be kept in the Principal Investigator's files. Audio recording is optional for participation. If you do not wish to be audio-recorded, you can still participate in this study. You have the right to review the recordings and to request that all or any portion of the recording be erased. The audio recordings may be sent to an outside company so that the spoken words can be transcribed, or the audio recording will be auto-transcribed by Webex audio recording software. This will help the study team to analyze the results we receive from the interviews we will conduct with all of the participants.

Some of the participants will be invited to take part in the Delphi Panel portion of this study which will take place at a later time. This portion of the study involves completing up to four rounds of structured surveys online over a time period of 4-6 months. More information will be provided at a later time. We will ask you during the interview if you are willing to be contacted about the Delphi Panel portion of this study. Willingness to be contacted does not mean you will have to take part in the Delphi Panel portion of this study.

If you choose to participate in the interview portion of this study, we will ask you to provide consent verbally before the start of the interview.

Any data that could identify you, collected and/or used for the purposes of this research, will not be used or distributed for future research studies.

5. What are the possible risks or discomforts?

There is a risk that being recorded might cause distress or anxiety. You will be free to stop the interview anytime if this is the case or for any other reason. You may also skip any question that makes you feel uncomfortable. There is a risk that your name could be divulged as a participant in these interviews to someone not part of the study team. This risk will be minimized by storing the de-identified transcripts separately from any identifying information. Additionally, we will collect as little potentially identifiable information about you as possible, and all data will be stored securely on NYULH password-protected computer, only accessible to the study team. The research may involve risks that are currently unforeseeable.

6. What if new information becomes available?

During this study, we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available. If new information becomes available to the study team that indicates the study team no longer needs your interview, we will cancel your interview and let you know.

7. What are the possible benefits of the study?

You are not expected to benefit directly from participating in this study. However, we hope the results from this research will help improve clinical utility of preimplantation biopsies and reduce inappropriate organ discard in the future.

8. What other choices do I have if I do not participate?

You have the option not to participate in this study. If you choose not to participate, you do not have to complete the interview. Your decision to participate, decline, or withdraw participation will have no impact on your professional relationship with NYU Langone Health or your employment, salary, or performance evaluation at your own institution.

9. Will I be paid for being in this study?

You will be paid a $50 electronic gift card after completing the interview. If you choose to leave or are withdrawn from the study for any reason before finishing the entire interview, you will not be paid.

10. Will I have to pay for anything?

You will not have to pay anything to participate in this interview.

11. What happens if I am injured from being in the study?

We do not anticipate that you will be injured from being in this study. However, if you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

There are no plans for NYU Langone Health to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits and all information has been collected. If you decide to participate, you can leave the study any time. Leaving the study will have no impact on your professional relationship with NYU Langone Health.

13. How will you protect my confidentiality?

To protect your confidentiality, we will ask you not to verbalize your name or any other identifying information during the interview. The information collected in this study will be stored on a secure NYU Langone Health network. Only the researchers involved in this research will have access to your data. Your research data will also be "coded" with unique numbers so that the research data is not stored with information that will identify you such as name. This is to minimize the loss of private information. The audio recordings will also be stored on a secure NYU Langone Health network and will be deleted once we have transcribed the interviews. No names will be included in the transcripts.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those listed in this section.

Who may use and share information in connection with this study?

The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study.
- De-identified data such as transcripts will be made available to other scientists via a repository.

- Governmental agencies responsible for research oversight (e.g., the U.S. Food and Drug Administration or FDA).

14. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU Langone Health IRB Office number is 212-263-4110. The NYU Langone Health IRB is made up of doctors, nurses, non-scientists, and people from the Community.

15. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this form.

If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the NYU Langone Health IRB at 212-263-4110.

16. How do I let you know I want to take part in this study?

For the interview portion of this study, you will be asked to provide verbal consent before the start of the interview. By providing your consent, you are agreeing to take part in the interview portion as described to you. This means your questions have been answered and you have decided to volunteer. If you consent to be audio-recorded, you are agreeing to the use of the audio recordings for study purposes only.