## This form is **NOT** required for treatment.

If you wish to participate in this study you must read and sign this consent

### **Consent to Participate in a Research Study**

**Protocol Title:** Comparison of Direct and Indirect Supervision of Psychiatry Residents impact on patient experienced quality of care

Researcher Name and Contact Information: Nicholas Ladd

Address: 125 Hendersonville Rd, Asheville, NC 28806

**Phone:** 828-398-3601

**Fax:** 828-333-5465

Email: Nick.Ladd@MAHEC.COM

#### What is the study about and why are you doing it?

This research is looking at the impact that supervising physicians have on your experience of quality during your visit. This research will help to guide residency training programs in the role supervising physicians should have in clinics to ensure quality care.

#### What are you asking me to do if I agree to be in the study?

To participate you would be asked to complete a quick 10 question survey after two sessions. One session would have an attending present for some portion of the visit, and the other session would not. No other part of your care would change. As part of this study you give the research team permission to access portions of your person health information (PHI), primarily related to your diagnoses to be included in research analysis. This will be done in a way to protect your privacy.

#### How will this study help me?

The information obtained from this study may not help you. However, it may help others by providing residency training programs information on how to use supervision to improve the quality of care provided. If you decide to participate, and complete both surveys, you would be entered into a drawing where two participants will win a \$250 cash card.

#### Are there any risks involved with being in the study?

There is a small risk of a breach of confidentiality, but all efforts will be made to keep your survey results and PHI in the strictest confidentiality. You will use a study ID when answering

Mission Health IRB Approval Date: 12/14/2021 your survey, with your resident physician not having access to your individual survey response. There are no other expected risks of participation.

#### What steps have been taken to minimize participant risk?

The information that you provide will be kept confidential on secure electronic servers. You will be assigned a study ID number that will be used for all documentation of study results. Only the researcher will have access to your survey results and these will be blinded so they are not aware of any one individuals response.

#### Will it cost anything to participate?

No.

#### Who can participate?

Any established adult patient that is legally able to consent to treatment and able to understand English. If you are a new patient of the practice you can participate after the first appointment as long as the study has NOT concluded.

#### What else do I need to know?

Your decision to participate in this study is voluntary. If at any time during this study you wish not to participate, you may do so without any consequence.

#### Whom can I contact with questions or concerns?

If you have questions or for a copy of the completed study, please contact Dr. Nicholas Ladd at (828) 398-3601. If you have concerns about the study, please contact the Institutional Review Board at Mission Hospitals at (828) 213-1105.

# AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

The privacy law, Health Insurance Portability & Accountability Act (HIPAA), protects your individually identifiable health information (protected health information). The privacy law requires you to sign an authorization (or agreement) in order for researchers to be able to use or disclose your protected health information for research purposes in the study entitled "Comparison of Direct and Indirect Supervision of Psychiatry Residents impact on patient experienced quality of care". Please read the information below to see if you agree to allow the use of your protected health information for this study.

Who will have access to your protected health information related to your participation in this research study?

Mission Health IRB Approval Date: 12/14/2021

- Dr. Nick Ladd, Primary Investigator
- Dr. Audrey Martinez, Co-Investigator
- Sarah Friedman, Research Project Coordinator
- Emily Aarons, UNC Medical Student
- Martin Arhin, UNC Medical Student

What protected health information will be used or disclosed?

For this study, we will collect demographic information, psychiatric diagnosis, psychiatry
resident and attending physician involved in the case, and length of time working with the
psychiatry resident.

What will your protected health information be used for?

• This study will help patients receiving care by residents by providing residency training programs information on how to use supervision to improve the quality of care provided.

Who will the researchers share your protected health information with?

- The Mission Health Institutional Review Board
- MAHEC employees when required to perform work related duties
- Dr. Scott Davis, Research Assistant Profesor at UNC Eshelman School of Pharmacy, for statistical analysis

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

The researchers agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and federal law.

You do not have to sign this Authorization. If you decide not to sign the Authorization:

- It will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.
- You will not be allowed to participate in the research study.

After signing the Authorization, you can change your mind and:

• Not let the researcher disclose or use your protected health information (revoke the Authorization).

- If you revoke the Authorization, you must send a written letter to: <u>Dr. Nick Ladd at 125 Hendersonville Road, Asheville, NC 28803</u> to inform him of your decision.
- If you change your mind and withdraw the authorization, you may not be allowed to continue to participate in this study.

You may not be allowed to review the information collected for the research until after the study is completed. When the study is over, you will have the right to access the information again.

This Authorization expires on 12/6/2023.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions or concerns about your privacy rights in this research study, you should contact the Mission Health Institutional Review Board at Ph: (828) 213-1105.

**HIPAA Agreement:** I authorize Dr. Nick Ladd and his research staff to use and disclose my protected health information for the purposes described above. I also permit my doctors and other health care providers to disclose my protected health information for the purposes described above.

I am the subject or am authorized to act on behalf of the subject. I have read this information, and I will receive a copy of this form after it is signed.

Participation Agreement: I have read the above information. The study has been explained to me in

the description above and any questions have been answered. I am indicating that I voluntarily agree to be in this study by checking the box below and signing. I understand that I will be asked to provide verbal consent again on the day of the appointment.	
I do consent to be a part of this study  I do NOT consent to a part be of this study	
Name: (printed)	Date of Birth:
Signature:	Date/Time: