I. **Purpose:** We are studying a model of how doctors prescribe medication which has been practiced at the Austen Riggs Center for over 15 years. To better understand if this model may be useful to other doctors, outside of the Austen Riggs Center, we have developed it into a *Manual of Psychodynamic Psychopharmacology*. This study will help us to assess the ease of use of this Manual and whether it may be useful for broader clinical education and clinical practice.

This study is assessing the usability of the Manual. It is not an assessment of your psychiatrist's ability or conduct.

II. **Procedures:** All doctors at the Austen Riggs Center (ARC) prescribe medication using the model outlined in the Manual. Your doctor has had extra training with this model. We anticipate recruiting 4 ARC patients for this study, to assess the use of the Manual in clinical practice. The main change you will experience from usual treatment is that there will be a camera recording your doctor. While the camera will be pointed at your doctor, your voice will be recorded and some part of your body may be video recorded as well. Somewhere between 1-3 sessions may be recorded, for periods of 20-50 minutes at a time. You will always be told when the camera is turned on and can always request to turn the camera off. Several trained raters (ARC clinical staff members) may view this recording to rate how doctors follow the Manual. In some cases, sessions or parts of sessions may be transcribed. After rating and transcription, the video will be destroyed. What will be left is the ratings, which will have no information that could reveal your identity. Raters will also review your doctor’s medication note. A list of study personnel is available upon request. Contact Dr. Mintz (Ext. 5315) or Dr. Gallagher (Ext. 5279) for more information.

III. **Risks:** It is possible that you may feel some distress due to the presence of the camera and/or the knowledge that your session is being recorded. People prone to paranoid or suspicious feelings may experience more distress. If you feel you might be too distracted or suspicious about being recorded, you should let us know, and consider not participating in this study. There may also be risks that are unforeseeable at this time. Any distress you feel may be discussed with your doctor. You or your doctor may stop the camera and/or discontinue your participation in the study at any time.

IV. **Benefits:** There are no direct benefits from this study. You will get to see the process of research. You will also be able to see a review of the study when it is over. The main benefit is to society. This study will help us learn more about the ways in which we prescribe medications at the Austen Riggs Center with the long-term goal of training others in this way of prescribing.

V. **Confidentiality:** Video from recorded sessions is confidential. Only research staff involved in this study and those at ARC who are responsible for research at ARC will have access to any information that could identify you. All recordings will be kept on password-protected digital media and stored in a locked cabinet. Sessions, or portions of sessions may be transcribed, but any information that may personally identify you (and your doctor) will be removed from the written transcript. After the ratings and transcription, the video will be destroyed, generally within 4-6 weeks. What will be left is the ratings and transcripts, which will have no personally identifying information. The de-identified transcripts may be used for teaching, including being in
publications or later editions of the Manual. In some cases, raters will also review one of your doctor’s medication notes.

In rare cases, researchers can be forced by a court to disclose data. We will keep your records private to the extent allowed by law. We may disclose your data to an appropriate authority if we believe your doctor engaged in unlawful or unethical behavior. Information may also be shared with the Institutional Review Board of the Austen Riggs Center, which oversees the protection of human research participants.

VI. Voluntary Participation and Withdrawal: Your participation in this study is voluntary. You have the right to refuse to be in this study. If you decide to be in the study and change your mind, you have the right to withdraw at any time. Until your data is made anonymous, you may also ask that your data be destroyed. Whatever you decide, you will not incur penalty nor will it affect your relationship with the Austen Riggs Center or its staff.

VII. Funding Sources: The Austen Riggs Center is providing funding for this research. This study also has funding through the Katkovsky Grant of the American Psychological Foundation, which supports research about medications and psychotherapy.

VIII. Questions: If you have any questions about this study, or believe you have suffered any injury because of participation in the study, you should contact the Principal Investigator, David Mintz, MD, at 413-931-5315. If you have questions or concerns about your rights as a participant in this research study, you may contact the Institutional Review Board which oversees the protection of human research participants. Elizabeth Weinberg, MD, the Austen Riggs Center Institutional Review Board Chair can be reached at 413-931-5256.

IX. Copy of Consent Form: We will give you a copy of this consent form to keep.

Agreement to Participate:

I have read the above information, have had the opportunity to have any questions about this study answered and agree to participate in this study.

Check one: Yes □ No □

I agree to be contacted for follow-up to this study, including feedback about the process and invitations to participate in further research.

Check one: Yes □ No □

I agree to have portions of de-identified transcripts of recorded sessions used for educational purposes, including publications and presentations.

Check one: Yes □ No □

(printed name) (signature) (date)