The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title: **Development of a Group Emotion-Focused Behavioral Intervention for Diabetes Distress and Glycemic Management in Patients with T2D (Study Two – Full RCT)**

Principal Investigator: **Emil F. Coccaro, MD**

Sponsor: **NIDDK**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether, or not, to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether, or not, to be a part of this study. More detailed information is listed later in this form.

Type 2 Diabetes (T2D) is a major public health problem, but many T2D patients have difficulty keeping their blood sugars from being too high. One reason for this may be difficulties in keeping emotion under control. In this study, we are adapting an emotion-focused individual-based intervention into a group-based intervention. To do this we need to see if this new intervention can reduce diabetes distress (and improve A_{1c} levels) compared with an intervention that does not focus on emotions. You are being asked to take part in this study because you are a patient with T2D that is under less than optimal control. We are recruiting up to 180 patients like

you to take part in this specific study. The study will involve sixteen (16) sessions over about a six (6) month period: One (1) evaluation session, one (1) preparation session, ten (10) weekly 75-minute sessions, done in a group with up to 9 other people, over three months, one (1) evaluation after the first five (5) intervention sessions, one (1) end of intervention evaluation session, one (1) post-intervention evaluation session three months later, one (1) individual feedback session after the end of the intervention, and one (1) post-intervention session three months later. One group will focus on managing emotions, while the other will focus on heart health, in those with Type 2 Diabetes. You will be randomized to one of these groups or the other determined as in the "flip of a coin". You will be compensated up to $250 for your participation in this study if you complete all study activities. Participation may not benefit you medically. Potential adverse events include boredom, fatigue, possible emotional upset while answering questions, bruising from finger sticks, and risk of a breach of confidentiality. You can stop your participation in the study at any time without penalty to you.

1. Why is this study being done?

T2D is a major public health problem associated with high blood sugar levels. Treatment is available to lower blood sugar levels, but many T2D patients still have difficulty keeping their blood sugars from being too high. One reason for this may be difficulties in keeping emotions in control and awareness of emotional issues. In this study, we are testing if an intervention that can improve how one deals with their emotions will better help T2D patients control their blood sugar levels. You are being asked to take part in this study because you have T2D that is under less than optimal control.

2. How many people will take part in this study?

Up to 180 individuals will take part in this specific study.

3. What will happen if I take part in this study?

Visit #1: Evaluation for Study.

If you agree to take part in this study, you will give informed consent and provide a blood sample (few drops of blood via fingerstick) for a HbA_{1c} level for an instrument in our office. If your HbA1c level is at least 7.5 mg percent, you will be asked to complete a questionnaire assessing your mood and the level of distress you may have about taking care of your diabetes. This part of the visit will take about 15 minutes or less. If your level of diabetes distress is high enough, you will be asked to complete an interview, and other questionnaires, regarding your medical history, emotions, and how you take care of your T2D condition; this part of the visit could take an additional 45 minutes. These assessments will be completed on digital tablets after instruction by research staff. If you meet study eligibility criteria, you will be scheduled for a second visit. If you do not meet criteria for this study, you will be informed of this and referred to our T2D Treatment Program here at OSUMC.

Visit #2: Preparation for Study Entry:

An individual session done with a study therapist to assess and prepare you for the group experience in this study. This visit will be about 30-60 minutes. If you continue to meet study criteria for this study, you will then be randomized to a group designed to work on your skills on handling emotions or a group designed to improve your skills in dealing with medical issues

related to diabetes. The decision of which group you will be in will be randomized. Randomization means that the group you will be in will be decided by chance, like the flip of a coin. If you do not meet criteria for the study, or you do not wish to continue, you will be referred to our T2D Treatment Program here at OSUMC.

Visits #3 - #7:

At these visits you will participate in five (5) weekly 75-minute group visits with one of the study therapists. In addition to these group visits, there will be home assignment exercises as well.

Visit #8:

At this visit you will have your serum HbA_{1c} checked again (few drops of blood via fingerstick from the HbA1c instrument in our office) and you will complete the same set of questionnaires you completed at Visit #1. This visit will take place at about one week after Visit #7 and before Visit #9.

Visits #9 - #13:

At these visits you will participate in a next set of five (5) weekly 75-minute group visits with one of the study therapists. In addition to these group visits, there will be home assignment exercises as well.

Visit #14:

At this visit you will have your serum HbA_{1c} checked again (few drops of blood via fingerstick from the HbA1c instrument in our office) and you will complete the same set of questionnaires you completed at Visit #1 and #8. This visit will take place at about one week after Visit #13 (and no later than 14 days after Visit #13).

Visit #15:

At this visit and you will take part in a group session with up to nine (9) other individuals like yourself in this study to give us you detailed feedback on this intervention. This visit may be in person or by remote using TEAMS or ZOOM and will take place about a week after Visit #14.

Visit #16: Three-Month Follow-Up.

At this visit you will have your serum HbA_{1c} checked again, and you will complete the same set of questionnaires you completed at Visits #1, #8, and #14. This visit will take place at about three months after Visit #14.

Audiotaping of Group Sessions.

For purposes of research and supervision of research, the group sessions will be audio-recorded and transcribed . The audio-recordings and transcripts will be kept in locked cabinets until 6 years after the study is complete. The transcripts will not identify you specifically.

***Please note that you cannot be in this study if you do not agree for group sessions to be audio recorded*.**

4. How long will I be in the study?

You will be in the first part of this research study for about 15-16 weeks, starting from your initial visit. The total time involved will be about 17.5 hours. The second part will last an additional 12 weeks as part of the follow-up period which will include one visit for about one hour making the entire total time in this study about 18.5 hours. After that your participation in this study will be considered complete.

You may be removed from the study without your consent if:

- You are unable to meet the requirements of the study and/or unable to comply with study procedures
- New information becomes available that indicates that participation in this study is not in your best interest
- If the study is stopped.

5. What are the risks of the study?

Completing Interviews, Questionnaires and Intervention

- Mild boredom and/or fatigue from answering questions
- Become emotionally upset while answering questions

Blood Sampling from Fingersticks

- Pain/discomfort
- Risk of infection
- Bruising
- Blood clotting
- Bleeding at blood drawing sites
- Rarely, a short-lived dizziness after blood is drawn

Breach of Confidentiality

Although all your information will be confidential and not released outside of the study, there is always a potential risk of breach of confidentiality. Thus, while we ask other group participants to keep the discussion in the group confidential, we cannot guarantee this. Please keep this in mind when choosing what to share in the group setting."

Finally, there may be other risks that could arise which are not reasonably foreseeable. If new information becomes available which could influence your willingness to continue, this new information will be discussed with you.

6. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

7. What benefits can I expect from being in the study?

If you agree to take part in this study, there may be no medical benefit to you.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There will be no costs to you or your insurance companies resulting from your participation in this research study.

10. Will I be paid for taking part in this study?

We compensate you for time spent in completing the research assessments (interviews, questionnaires, fingerstick for HbA_{1c}) in the context of this research study as follows:

- Visit 1: $ 25
- Visit 2: $ 25
- Visit 8: $ 25
- Visit 14: $ 50
- Visit 15: $ 50
- Visit 16: $ 75

These payments will be provided to you using a reloadable debit card (ClinCard) within a few days of completing the visit. The total compensation you may receive is $250. Your name, address and social security number will be shared with the University controller's office to issue this payment. If you decide to stop participating in the study before study completion, you will still be paid for the time you spent in completing the research assessments. By law, payments to participants are considered taxable income.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable

state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information be used or shared for future research?

Yes, de-identified information may be used or shared with other researchers if you agree for that information to be stored for this purpose.

The data collected in this study:

You may opt to allow us to use any relevant data collected from your participation in this study if you choose to participate in our future studies. (Choosing "No" will not disqualify you from this research.)

*Please **mark and initial** whether or not you grant permission for your collected data to be used by use in future research we conduct:*

☐ **Yes, I authorize the use of the data I provide in this current study for future studies in which I may participate.** _____ **Initials** _____ **Date**

☐ **No, I do not authorize the use of the data I provide in this current study for future studies in which I may participate.** _____ **Initials** _____ **Date**

14. Will my study-related information be kept confidential?

We will work to make sure that no one sees your survey responses without approval. But, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you. In addition, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration (FDA);
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study (NIDDK), their agents or study monitors.

Study records that identify you will be kept confidential. All the information obtained from study subjects remains confidential in locked files. This information is only available to investigators and study staff involved with this project. All personnel are trained not to discuss any aspects of specific subjects with those not on the research team and not among themselves in public places. All paper research files are kept in locked cabinets/offices where only the principal investigator (Dr. Coccaro) and study staff have access. All assessment and outcome data (e.g., self-report questionnaires and interviews) entered into our computer databases will NOT be stored with any personally identifying information about you. Instead, these databases will use a code

number so we can identify that the information from different questionnaires, etc. come from the same person.

As part of the study, Dr. Coccaro and the research team will report the results of your study-related procedures and tests explained above to the Sponsor after the study is completed. However, no information that could identify you will be released to the sponsors of this study (NIDDK).

The study results will be kept in the research records and be used by the research team indefinitely. Data from this study may be used in medical publications or presentations. Your name and other identifying information will be removed (becoming "de-identified") before this data is used. If we wish to use identifying information in publications, we will ask for your approval at that time. This consent form will be kept by the research team for a maximum of 6 years.

In addition, as per policy of NIDDK, de-identified data will be deposited in a data repository, which restricts access to the data to qualified investigators with an appropriate research question who sign a Data Use Agreement (DUA). This DUA limits subsequent use to the terms of the approved request and requires that users maintain data security, and refrain from any attempts to reidentify research participants or engage in any unauthorized uses of the data. To request access to the data, the user must submit a valid scientific question, include a statistical analysis plan, and complete all required fields on the data request form. Personnel from the data repository will review the data request for completeness. Anyone who has submitted an approved data request and signed a DUA will be given access to the data for a set period.

Finally, a description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

Limits of Confidentiality on Clinical Information

The only conditions that require a break in confidentiality are if you report: a) a likely risk of suicide; b) a violent threat against a specific person; c) current abuse or harm against another individual, including children or the elderly. If partner or elder abuse is evidenced, we will provide the victim with referrals of agencies that provide social services and legal counseling. If child abuse is evidenced, we have the obligation to report child abuse to Child Protective Services. In addition, we can refer the abused child for appropriate treatment in our division of Child Psychiatry or to another mental health provider.

If you are discovered to be acutely homicidal or suicidal during this study, you may be hospitalized in a mental health facility (either voluntarily or involuntarily as necessary). If, for whatever reason, you are not hospitalized when it is determined that you are either homicidal or suicidal (e.g., we receive a phone call from you or another person) the police will be alerted to bring you to a Psychiatric Emergency Room. In cases of ongoing child abuse, Child Protective Services will be contacted and we can assess the need for further clinical evaluation and treatment of the child and then refer the child in question to our own Department of Psychiatry or to another outside mental health provider. If the partner/child abuse is not current, we can assess the need for further clinical evaluation and treatment and then refer the subject in question to our own Department of Psychiatry or to another outside mental health provider.

Certificate of Confidentiality

The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations.

Study information that has health implications may be placed in your medical record where authorized employees may see the information. Further, authorized requests for your records (medical record release for continuity of care) may result in research-related information being released.

Please talk to your study team or contact the Office of Responsible Research Practices at 614-688-8641 if you have questions.

You may also visit the NIH website at https://grants.nih.gov/policy/humansubjects/coc.htm to learn more.

Will I be contacted in the future?

You have the option to choose to be contacted in the future to take part in more research in our lab. (A "No" answer will not disqualify you from this research.)

Yes, I can be contacted in the future:

☐ **Yes _____ Initials _____ Date _____**

No, do not contact me in the future:

☐ **No _____ Initials _____ Date _____**

If you choose "Yes", please keep in touch with our lab and maintain a current address and telephone number on file. Please notify our research staff if your legal name changes.

The data collected in this study will be used for the purpose described in the form and will be labeled with a unique code number.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

The following information may be used and given to others: Current and Past Medical records; Research records; Records about phone calls made as part of this research; Records about your study visits; Information that includes personal identifiers, such as your name, or a number associated with you as an individual; and Diaries and questionnaires.

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

The sponsor of this research which is the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). In addition, authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information; and others including members of the data safety monitoring board for this study.

IV. Your information may be given to:

· The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;

· The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

· To do the research;

· To study the results; and

· To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. <u>May I review or copy my information</u>?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact **Dr Coccaro:**

Emil Coccaro, MD
Department of Psychiatry and Behavioral Health / OSUMC
460 Medical Center Drive
Columbus, OH 43210
Phone: 614-685-5623

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact the HIPAA Privacy Officer, The Ohio State University Wexner Medical Center, Suite E2140, 600 Ackerman Road, Columbus, OH 432210 or at 614-293-4477.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Dr Coccaro at** 614-685-5623.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

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Printed name of participant	**Signature of participant**
	AM/PM
	Date and time

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time