Research Consent and Authorization Form

Rhode Island Hospital, The Miriam Hospital, EP Bradley Hospital,
Newport Hospital, and Gateway HealthCare

Name of Study Participant(s): _____

Principal Investigator: Dr. Beth Bock

Title of Research Study: Establishing Multi-site Feasibility and Fidelity of Yoga to Improve Management of Type-2 Diabetes

Study Key Information

You are being asked to take part in a research study. A research study helps scientists and doctors learn new information to improve medical practice and patient care. This form contains information that will help you decide whether to take part in the research. Taking part in this study is completely voluntary. Even if you decide to take part in the study, you are free to leave at any time if you change your mind. In the sections that follow, the word "we" means the research staff on this study. We will explain the study to you and answer any questions you may have. We encourage you to discuss this study with others (your family, friends, or your other doctors) before you agree to participate in the research. If you agree that you would like to participate in this research study, you will be asked to review and sign this consent. A copy will be given to you.

A. What is the purpose of the research?

You are being asked to take part in a research project because you have been diagnosed with type 2 diabetes. The purpose of this study is to test whether participation in a 12-week yoga program has a different effect on diabetes management compared to a 12-week program of standard exercise (like walking).

This multi-site study is being conducted at three locations: the Miriam Hospital [TMH], the University of Massachusetts, Lowell [UML] and the University of Alabama at Birmingham [UAB]. We expect to enroll 90 participants (30 at each site) into this study. This study is sponsored by the National Center for Complementary and Integrative Health (NCCIH), which is part of the National Institutes of Health (NIH).

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In this research study we want to learn more about how yoga compares to a standard exercise program to improve diabetes management.

B. What is experimental/new in this study

Exercise is recommended by the American Diabetes Association to improve control of blood sugar. We do not know whether a yoga program will be better or as good as a standard exercise program.

C. What do I have to do in this research?

If you decide to join this research study, the following things will happen: You will receive a referral to a local laboratory site where you will give a small amount of blood (about 2 teaspoons) for testing. You will be measured for height, and weight by our site staff and may be asked to get clearance from your healthcare provider. If these tests show you are eligible to continue participation, you will complete surveys online and you will attend one counseling session with a registered dietitian who will provide advice about your diet and how diet may affect your diabetes. You will be assigned at random to a twice weekly program of yoga or standard exercise (like walking) for 12 weeks.

Sessions will be held in person at each site (TMH, UML, UAB) or via the internet (e.g. Zoom) if the situation requires. You will participate in a focus group discussion of your experiences around week 12 or 13. You will be asked to participate in exercise on your own during the next 6 months and complete three more surveys at 12-week, 3 month and 6 month follow ups.

It will take you about 9 months to complete this study. During this time, we will ask you to participate in yoga or exercise at least twice weekly and make about 4-6 study visits. All visits will be conducted at your local site.

D. What could go wrong?

The risks of participating in beginning level yoga or exercise program are small. You may experience some muscle tiredness or soreness after exercise or yoga if you have not been exercising regularly. You may pull a muscle or otherwise injure yourself if you exercise or do yoga poses too vigorously – you should not experience any pain while practicing yoga or brisk walk. If you do, be sure to tell the study staff immediately. Similar to any other physical activity, there is slight risk of experiencing symptoms of hypoglycemia (low blood sugar) during yoga or exercise practice. To avoid this, you will be advised to carry a small snack high in sugar or carbohydrate and avoid long periods of fasting.

The most important potential risks to know about are muscle aches from exercise.

E. What are the benefits?

You may or may not benefit from taking part in this study. You may benefit from participation in an exercise or yoga program. Walking and Yoga are both good forms of exercise and like all exercise, offer health benefits. Others may benefit in the future from the information that is learned in this study.

The most important potential benefits to know about are you may be able to improve your blood sugar levels and gain better control of your diabetes through exercise.

F. Other things I should know about this research?

If we find out about new information from this research that may affect your health, safety or willingness to stay in this research, we will let you know as soon as possible.

G. If I don't want to take part in this research what are my other choices?

You do not have to be in this research study to be treated for diabetes. Your healthcare provider has discussed with you what your clinical treatment options are and which clinical treatment(s) might be right for you considering your medical history. These clinical treatment options include diet counseling, medications and exercising on your own. Each of the clinical treatment options has known rates of being effective, known risks, as well as possible drawbacks.

- **Please carefully read this form, additional detail about each item just described is found below.**
- **Please listen to the study team explain the study and this form to you.**
- **Please ask questions about anything that is not clear.**

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1. Nature and Purpose of the Study

You are being asked to take part in a research project because you are an adult who has type-2 diabetes but is generally healthy. In this study we are trying to learn more about how yoga compares to a standard exercise program (like walking) and their effects on blood sugar and diabetes management.

We expect to enroll 90 of participants (30 at each site; the Miriam Hospital [TMH], University of Massachusetts, Lowell [UML and University of Alabama at Birmingham [UAB]) into this study. The study is sponsored by the National Institutes of Health, National Center for Integrative Health (NCCIH).

2. Explanation of Procedures:

If you agree to take part in this study, first, some screening tests will be done to see if you are eligible to participate. You will be given a referral to a local Laboratory to have blood drawn. You will not eat for at least 8 hours before going to the lab so that we can test the glucose (blood sugar) while you are fasting. This lab test will also measure hemoglobin A1c (HbA1c) which is a measure of blood sugar over time. You also may be asked for your healthcare provider clearance for you to participate. You will be measured for height, weight, and hip/waist circumference by our staff at each site. If the screening tests show that you meet all study requirements, you will be instructed to complete the study survey online that asks about your health, your feelings about managing your diabetes and your mood. This survey should take about 30 minutes to complete. You will also be asked to wear an accelerometer (a small device that measures your physical activity) for 4 consecutive days and will be asked to provide saliva (spit) samples, that we will test for cortisol – which is a hormone related to stress. You will be informed of your assigned study program (yoga or exercise) at the end of the baseline survey.

If the screening tests show that you do not meet all the study requirements or if your healthcare provider does not sign consent (if needed), then you cannot be in the research study. If you are not eligible to continue in the study, we will not keep any of your identifying information (like name, address, phone number or date of birth), but we will keep the survey answers you provided so that we can understand more about everyone who wanted to enroll in the study and what might be different between those eligible and those who were not. Your identifiable private information or identifiable biospecimens that have been collected as part of the research will not be used or shared with other researchers for future research studies.

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If you are eligible to continue with the study, you will be randomly assigned, "randomized", into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Which group you are put in is done by a computer. Neither you nor the researcher can choose what group you will be in. You will have an equal chance of being placed in any group.

- Group A: Yoga Program: This program is led by certified, trained yoga instructors and is designed to include relaxation, stretching and breathing exercises designed for people with no previous experience with yoga. This group meets twice each week for 12 weeks and classes last approximately 60 minutes. Yoga sessions will be audio-recorded for quality control purposes. The recordings will be destroyed at the completion of the study.
- Group B: Standard Exercise Program: People in this group will be instructed to engage in moderate exercise (like walking) twice each week for approximately 60 minutes.

You will participate in either the yoga or standard exercise program you are assigned to. You will attend sessions twice weekly for 12 weeks either in person at your local site (TMH, UML, UAB) or via the internet (e.g. Zoom) if the situation requires.

Depending upon the situation with the Covid-19 pandemic, both the yoga program and the exercise program may be conducted remotely. If the study needs to "go remote" the study staff will inform you of this. You will then be able to attend yoga class from your home (by Zoom / internet), OR if you are in the standard exercise group, you will be given a physical activity program you can do on your own with regular check-ins by our study staff.

No matter which group you are in, you will receive general instructions and printed materials on diabetes care. But you are expected to continue with the medical treatment plan as prescribed by your physician/health care provider. While enrolled in the study, we ask that you report any injury or illness to the study staff.

At or around week 13 you will attend a single 1.5-2 hours focus group to discuss your experiences with the program. This discussion group will be audio recorded. Recordings will be maintained while a written record is made and then the recordings will be destroyed by the end of the study. You will not be identified by name on the written record. You will complete the same questionnaires, wear the device to track your physical activity for 4 days, provide saliva (spit) samples, be measured for weight and hip/waist circumference, and complete the same lab tests at the end of intervention. Except the saliva test, all other tests and surveys will be repeated at 3 months and 6 months follow up. You will be asked to report your physical activity levels weekly for the duration of the study. Altogether, you will be in this study for 9 months.

To compensate you for your time and effort you will be paid $50 for completing surveys and lab visits at enrollment, and again at 12 weeks, 3 months and 6 months follow up. You will be compensated $50 for attending the discussion group. (Total compensation possible is $250).

We will ask you what methods are best to reach you for appointment reminders. If you choose to use text messaging, this may include you receiving text messages from research staff and/or you sending text messages to research staff. Lifespan takes your confidentiality seriously and will take steps to protect the information contained in the text messages to the degree permitted by the technology being used. Depending on the nature of the study, some of the following steps may be taken: encrypting the data during transmission, eliminating sensitive health care information from the texts, storing all data gathered on secure servers, providing you with a secure device when the circumstances warrant, and/or remote data deletion in the event of a lost or stolen device. We will avoid sending any sensitive information in these text messages.

However, Lifespan can make no guarantees about the secure transmission of texts you send to us, nor can Lifespan guarantee security after you receive the text message from Lifespan. For example, text messages that display on your phone screen may be seen by someone close by or by someone you have allowed to use your phone. Also, if you do not password protect your phone and it is lost or stolen, anyone who finds it might view the information in the texts about your health or other topics. To try to lessen these risks, you should make sure your phone is password protected, only open and view messages where no one will be able to view the screen and delete messages as soon as possible after reading them. Additionally, when you trade in your phone, remember the SIM card (memory card used in cell phones) should be cleared.

Finally, it is also possible that the mobile phone company that transmits the text messages may keep copies of ALL your texts (those from the study, and your other texts) even after the study is ended. Lifespan has no control over these companies and cannot make any guarantees about their conduct.

Costs for participating in this study

The services you will receive are being performed only because you are participating in this research study. These 'research only' services include yoga or standard exercise program, diet counseling with the study dietitian and laboratory testing of blood and saliva samples. These services will be paid for by the study and will not be billed to you or your health insurance company. The study will provide reasonable reimbursement for parking (like quarters for

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parking meters) or will validate parking receipts for parking during study visit at our centers. The study cannot reimburse you for tickets due to overtime or illegal parking.

You are advised to continue the medical treatment as prescribed by your healthcare provider and follow-up with your healthcare provider for routine clinical services that you would have received even if you were not in the research study.

Contact Information:

You can call us with any concerns or questions about the research. If you have any questions or concerns about this study, you should call Ms. Kristen Walaska (401-793-8022), who is the coordinating research associate, or email Dr. Beth Bock, PhD, who is the researcher in charge of this study (Beth_Bock@Brown.edu).

3. Discomforts and Risks

The risks of participating in beginning level yoga or exercise program are small. You may experience some muscle tiredness or soreness after standard exercise or yoga if you have not been exercising regularly. You may pull a muscle or otherwise injure yourself if you exercise or do yoga poses too vigorously – you should not experience any pain while practicing yoga or brisk walk. If you do, be sure to tell the study staff immediately. Similar to any other physical activity, there is slight risk of experiencing symptoms of hypoglycemia (low blood sugar) during yoga or exercise practice. To avoid this, you will be advised to carry a small snack high in sugar or carbohydrate and avoid long periods of fasting. Some minor discomfort may be experienced during blood draw for glucose testing.

4. Benefits

You may or may not benefit from participating in this study. You may benefit from participation in an exercise or yoga class. Walking and yoga are both good forms of exercise and like all exercise, offer health benefits. You may benefit from receiving diet counseling from the study dietitian to help improve your diet and management of diabetes.

5. Alternative Therapies

If you want to increase your physical activity, or improve your health, you do not have to enroll in this study. There are many alternative programs such as those offered by the local YMCA. There may be other diabetes education programs offered in your location. You can call your local diabetes clinic or hospital to know about their programs:

- Hallett Center for Diabetes and Endocrinology at Rhode Island Hospital, (401) 444-8344
- Diabetes and Endocrine Center at Lowell General Hospital, (978) 323-0360
- Diabetes Unit at Massachusetts General Hospital, (617) 726-8722
- Department of Medicine, Division of Diabetes, Endocrinology, and Metabolism at University of Alabama at Birmingham, (205) 996-3636

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- University of Alabama at Birmingham, Endocrinology, Clinical Trials (205) 934-4112

6. Refusal/Withdrawal

It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If you join, but later the researcher or your doctor feels being in the study is no longer good for you, they may choose to take you out of the study before it is over. If new information becomes available that might change your mind about whether you want to stay in the study, the researcher will share this information with you as soon as possible.

There will be no consequences to you if you choose to withdraw from this study at any time. If you no longer want to participate in the yoga or exercise program but are willing to continue with other study procedures such as lab tests, surveys and the focus group you may do so by telling the study staff. If you wish to withdraw from all study participation, you should do so by writing a letter or email to the principal investigator, Beth Bock, PhD (Beth_Bock@Brown.edu, The Miriam Hospital, Coro West, Suite 309, 164 Summit Avenue, Providence, RI 02906). In addition, the sponsor may choose to end the study at any time, for reasons unrelated to health care.

Reasons the researchers would take you out of the study even if you wanted to stay in:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

Follow-up after Withdrawal of Consent

If you leave the study, it would still be useful for us to know how you do over the next 9-months. We would appreciate if you would permit us to get follow-up information about your health from your doctor or your medical record.

_____ If I withdraw from the study, you have my permission to collect information about my health from my doctor or medical record

_____ I do not give my permission for you to continue to collect information about me if I stop participating in the study.

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Signature of study volunteer _____ Date _____

You have the right to change your mind at any time regarding follow-up after withdrawal. If you decide to quit the study, please tell the head researcher Beth Bock, PhD (Beth_Bock@Brown.edu, The Miriam Hospital, Coro West, Suite 309, 164 Summit Avenue, Providence, RI 02906)

7. Medical Treatment/Payment in Case of Injury

A research injury is any physical or mental injury or illness caused by being in the study. If you are injured by a medical treatment or procedure, you would have received even if you were not in the study, that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions carefully. If you do experience a research injury, Lifespan or the study doctor can arrange medical treatment for you. Such treatment will be paid for as described below.

If you have insurance and have a research injury that is not covered by the study, it is possible that some or all the cost of treating you could be billed to your insurer. If your health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan might be able to help you pay if you qualify for free care under Lifespan policy. However, Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you have any complaints about this study or would like more facts about the rules for research studies, or the rights of people who take part in research studies, you may contact the Director, Research Protection Office in Lifespan Office of Research, at (401) 444-6246.

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information. (HIPAA)

Your research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. Federal law requires us to get your permission to use or disclose (release your information to someone outside of Lifespan) your health information for research purposes. If you sign this form, you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You

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may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study, you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

Generally, the entire research record and any medical records held by the hospital may be used and released for research purposes. The following people or businesses/companies might use, release, or receive such information:

- The researcher and their support staff;
- The study sponsor National Institutes of Health: National Center for Complementary and Integrative Health (NCCIH)
- Doctors, nurses, laboratories and others who provide services to you or the sponsor in connection with this study;
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, the Office of Civil Rights, European Medicines Agency
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving, and administering clinical trials and other healthcare or research activities.
- Accrediting Organizations

There are times when the law might require or permit Lifespan to release your health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that, so it is possible they might re-release your information.
You have the right to refuse to sign this form and not participate in the research. Your refusal would have no effect on your treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, you will not be able to enroll in the research study and will not receive treatment as a study participant.

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If you decide to quit the study after signing this form (as described in Section 6: Refusal/Withdrawal), no new information will be collected about you unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you quit the study to complete analysis and reports of this research. You will not be allowed to see or copy the information described in this form if the research is open. You may see and copy the information when the study is completed.

10. Additional Information

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 this Website at any time.

NIH Certificate of Confidentiality

The National Institutes of Health has issued a Certificate of Confidentiality for this research. This adds special protection for the research information and specimens that may identify you. The researchers may not disclose information that may identify you, even under a court order or subpoena, unless you give permission. However, a Certificate of Confidentiality does not prevent researchers from disclosing information about you if required by law (such as to report child abuse, communicable diseases or harm to self or others); if you have consented to the disclosure (such as for your medical treatment); or if it is used for other research as allowed by law. In addition, the Certificate cannot be used to refuse a request if a governmental agency sponsoring the project wants to audit the research. Any research information that is placed in your medical record would not be covered under this Certificate. The Certificate will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. The Certificate does not stop you from voluntarily releasing information about yourself or your involvement in this research. If others obtain your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Contact for Future Studies:

Your participation in **any research** is completely voluntary and you should feel no pressure to participate if you are contacted about another research study.
Please check and initial one of the options below regarding future contact about other research done by us or other researchers we are working with (collaborators).

_____ ☐ Yes, I may be contacted about participating in other research projects studying [insert category] disease or related conditions. I give permission for my contact

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information (name and mailing address and/or phone number) to be given to other researchers working with the study investigator.

_____ ☐ No, I do not want to be contacted about other research projects. **Do not** give my contact information to the staff of any other research studies

Signature Page for Adult Participants

Adult Participant

- I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.
- By signing below, I give my permission to participate in this research study and for the use of associated protected health information as described above (HIPAA). *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice.*
- **The Researcher is required to provide a copy of this consent to you.**

This informed consent document is approved for use with a valid IRB stamp at the top of each page. The document expires for use on the date listed within the IRB stamp.

DO NOT sign this document after this expiration date.

_____
Print name of Study Participant

_____
Signature of Adult Study Participant Date (MM/DD/YEAR) Time when signed

Research Investigator /or Designee's Statement & Signature

- I have fully explained the research described above, including the possible risks and benefits, to all involved parties (participant /parents/legal guardian as applicable).
- I have answered and will answer all questions to the best of my ability.
- I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the research.
- I have provided a copy of the consent form signed by the participant/parent/guardian and a copy of the hospital's privacy notification (if requested).

_____
Signature of researcher or designate Date (MM/DD/YEAR) Time when signed

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☐ **A copy of this complete (note total number of pages in footer) signed consent form has been given to the participant.**