Participant Name: Click or tap here to enter text. Date:Click or tap to enter a date.

Title of Study: Confirmatory Trial for Alleviating Fatigue in Multiple Sclerosis (CAFÉ-MS)

Principal Investigator: Francesca Bagnato, MD, PhD; Multi-site PI: Stephanie Buxhoeveden, MD

VA Facility: Tennessee Valley Healthcare System

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the Department of Defense. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary. You will be consented via Docusign.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn more about managing fatigue in people with Multiple Sclerosis. The purpose of this research is to test two different experimental online programs as potential treatments for fatigue in individuals diagnosed with multiple sclerosis (MS). These programs both contain potentially useful information on MS and fatigue.

This research study is expected to take approximately 3 years. Your individual participation in the project will take 12 months.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might choose to participate in this study if you are a person with Multiple Sclerosis who experiences fatigue. A possible benefit to you is that you may experience a reduction in your fatigue symptoms from participating in this study, but this cannot be guaranteed.

For a complete description of benefits, refer to the Detailed Information section of this form.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

Using the online programs and/or completing the outcome questionnaires may worsen your fatigue. There may be some unanticipated discomforts or risks in addition to those specified above, but precautions will be taken to ensure your personal safety and to minimize any discomforts.

For a complete description of risks, refer to the Detailed Information section of this form and/or Appendix.

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

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For a complete description of alternate treatment/procedures, refer to the Detailed Information section of this consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Francesca Bagnato, MD, PhD at the Tennessee Valley Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: (615) 975-9572.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

You are being asked to take part in a research study at the VA Tennessee Valley Healthcare System (TVHS) Medical Center because you have MS and are experiencing fatigue. This study is sponsored by the Accelerated Cure Project, Inc.

Fatigue is commonly experienced by people with MS but there are few treatments available to help with this symptom. The experimental online programs in this study for fatigue in MS are being evaluated as possible treatment options. These online programs both contain potentially useful information on MS and fatigue. They differ in some respects, but both are intended to provide information that could help you understand and manage any fatigue symptoms you are experiencing. Neither of these programs has been approved as a treatment by the FDA in the U.S.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 3 years. Your individual participation in the project will take 12 months. We expect to recruit 2,000 subjects across all sites and 100 subjects at this local site.

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WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

All study activities will take place online. If you consent to participate in this study and are determined to be ineligible for the trial will receive an email message letting you know that you are not eligible and thanking them for their interest in the trial. That message will also include current information about the iConquerMS PPRN and an invitation to join the PPRN as a way of contributing to MS research.

If you consent to participate in this study and are eligible, the general procedures include being assigned to one of three experimental groups, using one or both of the experimental online programs, and submitting responses to online questionnaires through the secure study website. The goal of the study is to evaluate how helpful these programs might be in treating fatigue in people with MS.

You will receive an email message letting you know that they are eligible for the trial and requesting that they log in to their registered account where they will find the baseline questionnaires that they should complete. Upon completion of the baseline questionnaires, the Eligible Candidate will become a Trial Participant and will be randomized to one of the three trial arms/treatments.
You will be invited to create an account on the CAFE-MS trial website and on the website of a company called GAIA, where the two online programs will take place. You will be assigned a code so that your data will not be associated to your name and your identity will be protected.

You will be randomly assigned (like drawing straws) to one of three experimental groups. You will complete study questionnaires on the CAFE-MS website at various timepoints throughout the study. You will be responsible for completing the online programs that you are assigned to. You will also be responsible for completing a set of online questionnaires at the beginning of the study (baseline), and/or at 1 months, 2 months, 3 months, 4 months, 5 months, 6 months, 9 months and 12 months. It is important that you use the program regularly over the course of the study.

You are also responsible for reporting any events or symptoms occurring during the study that cause you to think that this research may have hurt you or made you sick. These events should be reported to the research team at the phone number(s) listed on the first page of this document.

1. **Screening procedures**

You will be asked to complete an online questionnaire to determine whether you are eligible for this study. This questionnaire will collect information about your MS, demographics (such as age and state of residence) and fatigue.

We may also need to obtain documentation of your MS diagnosis. If this is the case, we will ask for your permission to have access to your medical records or offer a visit with Dr. Bagnato at the research clinic at TVHS either in-person or via secure VVC. Any records collected will be retained behind a secure VA firewall.

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission, called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The research team may also collect other information including your name, date of birth, and clinical information from your medical records.

2. Questionnaires

You will be asked to complete a set of online questionnaires at the beginning of the study (baseline), and/or at 1 months, 2 months, 3 months, 4 months, 5 months, 6 months, 9 months and 12 months. These questionnaires will include the following.

- Questionnaires about your demographics (e.g., sex, race/ethnicity) and MS history (baseline only)
- Questionnaires about your fatigue level (all timepoints)
- Questionnaires about your MS symptoms and quality of life (all timepoints)
- A questionnaire about any other fatigue treatment you are receiving (baseline, 3 months, 6 months and 12 months)
- A questionnaire asking whether, in the 4 weeks prior to answering the questionnaire, you started a new medicine for your MS, experienced or were treated with a steroid (3 months, 6 months and 12 months)
- A questionnaire about your ability to carry out daily activities (baseline, 3 months, 6 months and 12 months)
- A questionnaire about your satisfaction with the program (6 months and 12 months)

You will have the option to skip any questions that you do not wish to answer.

You can expect to spend from 10 to 60 minutes at any given timepoint completing these questionnaires.

3. Experimental Phase (12 months in duration)

After completing the baseline questionnaires, you will be randomly assigned by the study portal to one of three experimental groups. It is important for you to understand what may happen as a result of assignment to an experimental group before deciding to participate. This random assignment helps ensure that the study results are unbiased and scientifically valid. Neither you nor the research team will have control over which group you are assigned to. You will not know whether you are in Fatigue Program A group or in Fatigue Program B group but participants will be aware if they are assigned to Treatment-As-Usual group.

All study participants will continue to receive their usual treatment for their MS prescribed by their doctors throughout this study. This includes medications and other types of treatment. You can keep using any treatments for fatigue that you are already using.

The following list describes the three experimental groups you may be assigned to.

1. During the initial 6 month period of the study, you will be provided access to an online fatigue program (A), in addition to continuing to receive your usual treatment for MS as prescribed by your physician (Fatigue Program A group). You will be asked to complete questionnaires every month for 6 months.
2. During the initial 6 month period of the study, you will be provided access to an online fatigue program (B), in addition to continuing to receive your usual treatment for MS as prescribed by your physician (Fatigue Program B group). You will be asked to complete questionnaires every month for 6 months.

   Note: Online fatigue program A is distinct from online fatigue program B.
3. You will continue to receive your usual treatment for your MS as prescribed by your physician during the initial 6 month period of the study (Treatment-As-Usual group). You will be asked to complete questionnaires every month for 6 months.

For participants in Fatigue Program A group or Fatigue Program B group:

- Modules from the programs (A or B) can take between 15 minutes to one hour to review.
- You will be asked to access the program once or twice per week, with the entire program to be completed over a 6-month period.

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- At the end of the 6 months, you may be offered the other online fatigue program for 6 months. Whether you are offered another online fatigue program or not, you will continue your usual treatment for your MS and will complete questionnaires every 3 months for the remainder of the study.

For participants in the Treatment-As-Usual group:

- At the end of the 6 months, you will be offered a choice between the two experimental online fatigue programs (A or B) for 6 months in addition to your usual treatment for your MS and will complete questionnaires every 3 months for the remainder of the study.
- Modules from the programs (A or B) can take between 15 minutes to one hour to review.

4. Extension Phase after 180 days for certain program groups

After completion of 180 days of treatment in any of the three assigned groups, you may receive an email notification with an offer to use a different online program, but you will not be aware of its exact identity for another 180 days. The purpose of the Extension phase is to examine longer term stability effects of experimental on-line programs. Your study doctor will discuss your options before transition to Extension phase after 180 days.

Participation is voluntary, and you may refuse to participate or leave the study at any time.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

You are responsible for completing your questionnaires as instructed and asking questions as you think of them. You are also responsible for reporting any events or symptoms occurring during the study that cause you to think that this research may have hurt you or made you sick. These events should be reported to the research team at the phone number(s) listed on the first page of this document

If the study team needs to request copies of medical records, the study team will ask your permission to have access to these medical records. This may require you to sign a VA Form Letter 10-212 or visit Dr. Bagnato at the research clinic at TVHS.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

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Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

The risks of this study include the possible loss of privacy or breach of confidentiality. We will take steps to reduce this risk, such as assigning a de-identified study code to your data that is collected during the course of this study.

Any psychological risks involved are minimal; however, you may experience some momentary frustration when attempting to perform tasks during which you experience difficulty. The researchers will try to minimize any frustration that may occur.

Using the online programs and/or completing the outcome questionnaires may worsen your fatigue.

There may be some unanticipated discomforts or risks in addition to those specified above, but precautions will be taken to ensure your personal safety and to minimize any discomforts.

In addition to these risks, taking part in this research may harm you in unknown ways.

The risks to an embryo, fetus or infant from exposure to the study procedures are unknown.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We cannot promise any benefits to you or others from your taking part in this research. However, a possible benefit to you is that you may experience a reduction in your fatigue symptoms from participating in this study, but this cannot be guaranteed

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Your medical records will be maintained according to this medical center's requirements and the Privacy Act of 1974. All information obtained about you during the research study will be kept as confidential as legally possible and will be accessible only to the investigators and members of the research team, the sponsor (when applicable), and any appropriate government agency. Research records, like any other hospital records, may be inspected by federal regulatory authorities, including the VA Office of Research Oversight, the VA TVHS Research Compliance Officer, the FDA, state regulatory authorities, and legally authorized parties.

De-identified information will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor, Accelerated Cure Project (ACP), Inc.
- Organizations collaborating with the research sponsor;
    - Five (5) Veterans Health Administration Medical Centers (Washington, DC; Baltimore, MD; Seattle, WA; Portland, OR; and Nashville, TN), two (2) German universities (Charité – Universitätsmedizin Berlin and University Medical Centre Göttingen) and a German company (GAIA AG)
- Government agencies, such as the FDA and Department of Defense (DoD)
- WCG Institutional Review Board (IRB) that reviewed this research. An IRB is a group of people who perform independent review of research studies, following US Federal Government rules, to protect rights and welfare of the people taking part in research studies.

The information that is contributed to this study will be stored securely in the study's online database using industry-standard security controls and will be associated with a code that de-identifies the information. Your contact details will be stored separately in the same secure fashion in the database associated with the code and used only for communicating with you.

By consenting to participate in this study, you give permission for uses and disclosures of the information about you and your health that you or study personnel contribute to the CAFE-MS study website. Your information will be kept as confidential as possible under local, state, and federal law, but absolute confidentiality cannot be guaranteed.

Your study-related information will be used by members of the research team at ACP and the other collaborating organizations. If a regulatory audit takes place, government officials who oversee research are allowed to view research records. Representatives from the US Department of Defense, the funder of this study, will also be authorized to review research records.

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Some of the persons or groups that receive your study information may not be required to comply with the Health Insurance Portability and Accountability Act (HIPAA) privacy laws. Your information may lose its federal protection if those persons or groups disclose it. Permission granted on this date to use and disclose your health information remains in effect indefinitely. By electronically signing this form you give permission for the use and disclosure of your information for the purposes of the study at any time in the future. Any research information that is placed in your medical record may be kept indefinitely.

We may publish the results of this research. However, we will keep your name and other identifying information confidential. We protect your information from disclosure to others to the extent required by law. We cannot promise complete privacy.

While we will do our best to keep the information you share with us confidential, it cannot be absolutely guaranteed. Individuals from WCG IRB and Federal regulatory agencies may look at records related to this study to make sure we are adhering to research regulations and the protocol and minimizing risks to human subjects. The results of this research may be published or presented to others. You will not be named in any reports of the results.

In addition, we will share study data with our collaborating organizations and may use de-identified data (data without your name or information that can be used to directly identify you) for future studies. Data will be transmitted via a HIPAA-approved confidential server. Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information.

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

Additionally, you will be able to view the research results of this study, when available, on the Accelerated Cure Project website (www.acceleratedcure.org), the iConquerMS website (www.iconquerms.org), and the study trial CAFE-MS website. These research results may also be shared with other advocates and interested partners in MS.

This study involves access of Protected Health Information (PHI) date/limited data set for research as listed: Medical Record Number or First letter of your last name, last 4 of your SSN and date of birth. This protected information will be used only by the PI to assess your eligibility to the study. Thereafter, demographic and clinical data will be collected and stored in an anonymous manner.

Any image and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result

of the tests done. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

All efforts, within reason, will be made to keep your PHI private. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. Using or sharing (disclosing) such data must follow federal privacy rules. By signing the consent form for this study, you are agreeing (Authorization) to the use and sharing of your PHI, for example if needed for your clinical care or study oversight. This may include sharing your PHI with the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. Moreover, if you decide to be in this research study, you are agreeing to let Dr. Bagnato and her study team use and share the results of your study and/or non-study linked medical records, MRI and lab results, as well as parts of your medical record, to groups including the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, Food and Drug Administration, National Institutes of Health and insurance companies for billing purposes. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

We will include information about your study participation in your medical record.

Health Insurance Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal laws and the federal medical or HIPAA Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by these laws and the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. Other information such as HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment may be viewed or collected, if necessary or if there are interviews or surveys where you, as the research subject, provide that information to the research team.

The research team may also need to disclose or share your information to others as part of the research and study progress. Others may include the following:

- Federal agencies required to monitor or oversee research: The Food and Drug Administration (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office (GAO), Department of

Defense (DoD), local Institutional Review Board (IRB), and the US V.A. Multiple Sclerosis Centers of Excellence: Baltimore, Washington DC, Portland, Seattle.

- A non-VA Institutional Review Board (IRB) at World Courier Group (WCG) who will monitor the study
- Study Sponsor/Funding Source: Accelerated Cure Project; VA or non-VA person or entity who takes responsibility for; initiates, or funds this study
- Compliance and Safety Monitors: Holland Research LLC, who advises the Sponsor or PI regarding the continuing safety of this study
- Other:
    - GAIA Group- collaborating organization
    - Charite-Universitatsmedizin Berlin- collaborating organization
    - University Medical Center Gottigen- collaborating organization
    - Any physician who will need to take care of you should incidental findings be seen
    - VA Institutional Review Board, and the local VA medical facility Human Research Protections Program.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or the HIPAA Privacy Rule regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted you will not have access to your research related health records.

This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you can ask a member of the research team to give you a form to revoke your authorization in writing. Your written request will be valid when the research team receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Francesca Bagnato and her research team can continue to use information about you which the research team has relied upon for the research and that

was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

There will be no cost to you for participating in this study, other than the cost of your usual treatment. All study-related online programs are offered at no charge to you.

You or your insurance will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WILL YOU BE COMPENSATED FOR YOUR TIME AND INCONVENIENCE?

If you are eligible for the study, you will be compensated $15 (paid via a digital or physical gift card) for completing the baseline screening and subsequent health surveys at **each** of the 8 time-points for a maximum of $120. You will receive a total of $120 if you complete all the questionnaires.

In order to process payments for stipends or reimbursements, information about you is needed by Accelerated Cure Project, Inc.. By signing this form and providing HIPAA authorization you consent to the release of personally identifying information about you including your: Name, Address, Date of Birth and Social Security Number in order to mail or email compensation.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

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Compensation may or may not be available to you under applicable state and federal law in the event that you suffer physical injury or illness arising from this study. By agreeing to participate in this study you are not waiving or giving up your legal rights to seek compensation.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call

DURING THE DAY:

Dr. Francesca Bagnato at (615) 975 - 9572

AFTER HOURS:

Dr. Francesca Bagnato at (615) 835 - 92452 or Dr. Michael Cooper at (615) 873 8206

DO I HAVE TO TAKE PART IN THE STUDY?

You are not required to take part in this research study. Your participation is entirely voluntary, and you will not be penalized or lose any benefits to which you are otherwise entitled if you choose not to participate. You can refuse to participate now, or you can withdraw from this study at any time after giving your consent without affecting your healthcare/services or other rights. This will not interfere with your regular medical treatment.

If you are a VA employee or student, your refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress as applicable.

If you choose to withdrawal, that the investigator may continue to review any data already collected for the study but cannot collect further information, except from public records, such as survival data.

If you decide to leave this research, contact the research team at the phone number(s) listed on this document.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The investigator(s) may also stop your participation in this study without your or your legal authorized representative's consent for reasons such as: it will be in your best interest; you do not follow the study plan; you experience a study-related illness or injury; you need a treatment

not allowed in this research; You have an event or symptom that requires stopping the research; the research is canceled by the FDA, IRB, DOD, or the sponsor

You may be withdrawn from the study if laboratory tests suggest that it is not safe for you to continue. If you are removed from the study, you will be told the reason why.

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Bagnato at (615) 975-9572. If overnight or weekend, please page Dr. Bagnato directly at (615) 835-9452. Alternate Contact Person Michael Cooper at this phone number: (615) 873-8206.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Tennessee Valley Healthcare System (VATVHS) Institutional Review Board Office at (615) 873-7974 or the Research and Development Service Office at (615) 873-8066.This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VATVHS Patient Advocate at (615) 873-7225 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may contact WCG IRB at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team
- You want to talk to someone else about the research
- You have questions about your rights as a research subject

You may also call the researcher at the number on the first page of this form (24 hours) if any problems occur as a result of participating in this research.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

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In the event new information becomes available that may affect the risks and/or benefits associated with this study or your willingness to participate in it, you and your physician will be notified so you can make a decision whether or not to continue your participation in this study.

FUTURE USE OF DATA AND RE-CONTACT

At the end of the study your VA information will be retained in your research record in accordance with Veterans Health Administration (VHA) and Federal Records Control Schedule policies. Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies. The study results will be kept in your research record for at least 10 years after the study is finished. Research data (both within and outside of your medical file) will be kept for an unknown length of time. Additionally, your Authorization for the collection, use, and sharing of your PHI does not expire.

Original data (eCRFs and ePROs) will be stored electronically by the coordinating center for at least 2 years after marketing approval according to Title 21 of the Code of Federal Regulations. Archiving of source data is left to the discretion of the Principal Investigator but has to last at least for 3 years after marketing approval.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.

Data collected in this research might be used for future research or distributed to another investigator for future research without your additional consent. Neither you nor your doctors will be informed of your individual results from these future research and future research will not affect your current treatment in any ways.

If your data is used for commercial profit, you will not share in this commercial profit.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms./Research Coordinator_____
has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

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Participant Name: Click or tap here to enter text. Date:Click or tap to enter a date.

Title of Study: Confirmatory Trial for Alleviating Fatigue in Multiple Sclerosis (CAFÉ-MS)

Principal Investigator: Francesca Bagnato, MD, PhD; Multi-site PI: Stephanie Buxhoeveden, MD

VA Facility: Tennessee Valley Healthcare System

I agree to participate in this research study as has been explained in this form.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

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