THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION

Form Version Date: July 23, 2020

STUDY INFORMATION:

Study Title: A Phase III Trial of Sc**H**eduled Tel**E**hea**L**th Intervention in **P**atients with **M**yelo**P**roliferative **N**eoplasms HELP – MPN

Principal Investigator: John Mascarenhas MD

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SUMMARY OF THIS RESEARCH STUDY:

In medicine, there are many unanswered questions. A “research study” is when scientists try to answer a question about something that we don’t know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time, and it will not affect your ability to get medical care within the Mount Sinai Health System.

The purpose of this research study is to test the efficacy of regularly scheduled, weekly telehealth visits with advanced practice provider (APP) versus usual standard of care scheduled visit on distress levels in subjects with myeloproliferative neoplasms (MPN), including essential thrombocythemia (ET), polycythemia vera (PV) and myelofibrosis (MF) during the global coronavirus disease -19 (COVID-19) pandemic.

COVID-19 is a highly contagious disease and has a high death rate in people older than 70 years. People older than 70 years are at high risk for severe respiratory disease. Furthermore, cancer patients, including patients with MPNs when infected with COVID-19, are three times more likely to suffer bad outcomes like intensive care unit admission, ventilator support, or death.

People with MPN are at increased risk for clotting, bleeding, and progression to acute myeloid leukemia (AML). These diseases are also associated with heavy symptom burden like tiredness, decreased appetite, and itching that dramatically affect the quality of life and functionality. During a time of global health crisis, MPN patients are particularly at risk of having poor outcomes due to disease and treatment-related complications. In many cases, measures to decrease COVID-19 exposure have physically isolated patients from their care teams, increasing the risk of undiagnosed MPN-related clinical worsening, treatment-related side-effects, disease progression, or psychological distress.

This study proposes that the regularly scheduled weekly telehealth visit by the treatment team will decrease the psychological distress in comparison to the usual standard of care scheduled visits in subjects with MPN.

Standard of care visits maybe a phone call, telehealth visit, or an in-person visit with your team and will be determined by your care team and not by the study.

Response to the weekly scheduled telehealth or standard of care visits will be measured based upon by a reduction of psychological distress, increase in quality of life, and reduction of other symptoms associated with MPN.

The safety of this study will be measured by collecting data on side effects that you may or may not experience. Possible side effects include any new symptoms related to the medications you are currently taking, infections or change in treatment.

You are being asked to participate in this study because you have a Myeloproliferative Neoplasm (MPN): Essential thrombocythemia (ET), Polycythemia Vera (PV) or Myelofibrosis (MF).

If you choose to participate, you may be randomly assigned to either regularly scheduled weekly telehealth visits or standard of care visits as decided by your treating physician.

If you were randomly assigned to the weekly telehealth visit, your participation would be as follows: Each visit is approximately ten minutes long weekly for eight weeks. Participation may last for 12 months to assess any changes in your clinical course at 3, 6 and 12 months. At any time, you can end your participation for any reason and there will be no financial or clinical consequence to you.

If you were randomly assigned to the standard of care group, your participation is as follows: study directed visits will occur at screening, week 1, week 8, and end of study. However, participation may last for 12 months to assess changes in your clinical course at 3, 6 and 12 months.

Visits all through the core study will be for 2 months (8 weeks) and the frequency of the visits will depend on which arm you are randomly assigned to. Visits will include medical history, including medications and related side effects. During your participation in this study, you will be asked to take surveys that will tell us about how you are doing and provide information about any side effects, you may experience.

There is the risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

A member of the research team is available to answer any questions you may have about this study. Please feel free to ask questions that you may have before you decide to participate. You will be given an unsigned electronic copy of the consent to review or discuss with family or friends before deciding. If you choose to participate, any new information that develops during this research study, such as new risks or benefits, will be given to you promptly. If you participate, you will be given an electronic copy of this signed and dated form.

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If you are interested in learning more about participating in this study, please continue to read below.

PARTICIPATION IN THIS RESEARCH STUDY:

This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you have an MPN: ET,PV or MF. MPNs are an uncommon type of blood disease that affects your body's normal production of blood cells. The production of blood cells normally occurs in your body's bone marrow; however, people with MPNs bone marrow is often abnormal which leads to abnormal blood counts and weakness, fatigue and in many cases, an enlarged spleen.

DISCLOSURE OF FINANCIAL INTERESTS:

This study was developed by Dr. Mascarenhas, who the lead investigator of this trial and it will be conducted at Mount Sinai and other hospitals. Funds for this study will be provided by a philanthropic fund from the MPN Program at Icahn School of Medicine at Mount Sinai.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study will be 2 months (8 weeks) for the core study and the frequency of the visits will depend on which arm you are randomly assigned to. Participation may last for up to 12 months.

The number of people expected to take part in this research study at this site, the Icahn School of Medicine at Mount Sinai, is about 50. This study will also be conducted at other sites. The total number of people expected to take part in this multi-site research study is 127.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

No procedures may take place until you have agreed to participate in this study and signed this form. All procedures will take place through a telehealth visit unless otherwise specified.

Screening:

- Medical History: A complete history
- You will be asked to provide information about your age, race, gender, and ethnicity.

- You will be asked to provide information about your prior medical history including all active conditions and conditions you have been told you have within the last 10 years. You will also be asked to provide information about what treatment, if any you have had for these conditions.
- Current medications will also be reviewed. It is important that you tell your study doctor about any medications you are currently taking or have taken within the last 30 days. Please tell your study doctor about all medications including over-the-counter medications, vitamins, herbal medications, and alternative medicines.
- You will be asked about any transfusion history you have had within the last 3 months.

If the screening, tests, and procedures show that you can continue in the study, and you choose to take part, then you will need the following tests and procedures during the study period outlined below.

You are to start the first day of the study within 7 days of completing the screening procedures. All visits are telehealth and do not require an in person visit as a part of study visit. During these visits, do not forget to tell your study doctor if you start taking any new medicines, feel unwell or want to stop participation in this study for any reason. If you require an in person visit, then your care team can schedule that as needed and that will not interfere with, change, or stop your participation in the study.

Standard of Care Arm:

Week 1, Week 8 and End of Study Visit (EOS)

- A thorough history including a review of current medical conditions and medications you are taking.
- You will be asked verbally to complete a questionnaire about your psychological symptoms, MPN associated symptoms, quality of life and if participating in the study was worth it. You will be asked about the all the events that happened since you were enrolled in the trial. This includes hospital admission, clotting, major bleeding, major infection including COVID-19, change in MPN directed treatment.

Week 12, 24, 48, EOS (if continuing past core study period)

- You will be asked verbally to complete a questionnaire about your psychological symptoms, MPN associated symptoms, and quality of life.
- You will be asked about the all the events that happened since *you were* enrolled in the trial. This includes hospital admissions, clotting, major bleeding, major infections including COVID-19, and change in MPN directed treatment

Early Termination Visit:

If you are withdrawn from the study, or choose *to* withdraw from the study, you will be urged to meet with your study doctor for a final evaluation of your symptoms and general health. The procedures will be the same at the End of Study Visit procedures.

Intervention Arm:

Week 1-,7

- You will be asked about symptom history, medications and health education about COVID-19 pandemic will be reinforced.
- You will be asked about the all the events that happened since you were enrolled in the trial. This includes hospital admission, clotting, major bleeding, major infection including COVID-19, change in MPN directed treatment.

Response evaluation will be done after 8 and 12 weeks of the study. The response to the study intervention of weekly scheduled telehealth visits versus standard of care will include asking you questions about anxiety/distress, symptoms and quality of life.

End of Study Intervention Visit – Week 8

- a review of current medical conditions and medications you are taking.
- You will be asked verbally to complete a questionnaire about your psychological symptoms, MPN associated symptoms, quality of life and if participating in the study was worth it.
- You will be asked about all the events that happened since you were enrolled in the trial. This includes hospital admissions, clotting, major bleeding, major infections including COVID-19, and change in MPN directed treatment.

Week 12, Week 24 and Week 48, EOS (if continuing past core study period)

- You will be asked verbally to complete a questionnaire about your psychological symptoms, MPN associated symptoms, and quality of life.
- You will be asked about the all the events that happened since you were enrolled in the trial. This includes hospital admissions, clotting, major bleeding, major infections including COVID-19, and change in MPN directed treatment

Early Termination Visit:

If you are withdrawn from the study, or choose to withdraw from the study, you will be urged to meet with your study doctor for a final evaluation of your symptoms and general health. The procedures will be the same at the End of Study Visit procedures.

Because this project involves the use of telehealth, it is necessary that we make a note of your participation in the electronic medical record. That way anyone treating you will be aware of your participation and may be able to avoid any unfortunate outcomes that could arise if your research participation were unknown.

Clinically Relevant Research Results:

Results of clinical tests performed during the study will be shared with the subject.

USE OF YOUR DATA AND/OR SPECIMENS:

No specimens are collected during this study.

The researchers would like to ask your permission to keep the data collected from you during this study to use in future research studies. In the future, your identifiable information may be removed from the private information that are collected as part of this research. After this removal, the information could be used for future research studies or shared with other research teams for future research studies. You will not be informed of the details of specific research that is done with your medical information. That means that a research project might be done that you would not consent to if provided with the details of that research project.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for the following things: complying with requirements of the study and regular attendance to study visits.

COSTS THAT MAY RESULT FROM PARTICIPATION:

Taking part in this research study may lead to added costs to you.

You or your insurance company will be responsible for the costs of all items and services during the research study that you would have received for your condition if you were not enrolled in this research study. You or your insurance company will also be responsible for the costs of all services that occur during the research study that your physician believes are medically necessary to treat you.

PAYMENTS THAT MAY RESULT FROM PARTICIPATION

You will not be paid for taking part in this study.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. You may or may not benefit from participation in this research based upon if the telehealth intervention is effective for you. Your condition may not get better or may get worse during your participation in this study. The knowledge learned from this research study may be helpful to other people with a myeloproliferative neoplasm. However, no benefit, to you or others, can be promised because of your participation in this research.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

Risks from the research

The investigators have designed this study to learn about the efficacy of regularly scheduled weekly telehealth visit during a COVID-19 pandemic. This study may not improve your condition or disease, or it may make your condition or disease worse.

Risks from the specific research procedures (drug(s), interventions, or procedures)

There is the risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

OTHER POSSIBLE OPTIONS TO CONSIDER:

Your other choices may include:
• Getting care without being in a study
• Taking part in another study

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

For medical emergencies, call 911. If you are injured or made sick from taking part in this research study, medical care will be provided. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.

For more information on clinical trials and medical insurance coverage, you can visit the National Cancer Institute's website at: http://cancer.gov/clinicaltrials/understanding/insurance-coverage. Another way to get this information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

No other compensation will be offered by the sponsors of this study or the Mount Sinai Health System Hospitals.

You are not waiving any legal right to seek additional compensation through the courts by signing this form.

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

Your participation in this study is voluntary. You may refuse to take part in this study or once in the study you may stop at any time without any penalty. This will not affect your ability to receive medical care at any of Mount Sinai's hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff and tell them if you want to leave the study. Additionally, for your safety, if you leave the study early, you may be asked to return to the study doctor's office for a final study visit.

If you stop being in the research study, already collected information may not be removed from the research study database and will continue to be used to complete the research analysis. You may be asked whether the study doctor can collect information from your routine medical care. If you agree, this data will be handled the same as research data.

If you decide you don't want your samples and/or data to be used for research anymore, you can contact the researcher and ask to have your samples and/or data removed from future use. If any samples or data have already been shared without your identity, it won't be possible to retrieve them because no one will know who you are. Samples and data that have already been used will not be affected by your decision. Any samples and/or data that are still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your samples and/or data will take place. If your samples have already been deposited in an external repository, the study team will request that your samples be removed.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If data has been stored as part of the research study, they too can be destroyed without your consent.

If you leave the study before the planned final visit, you may be asked by the study doctor to have some tests or procedures done so that you can leave the study safely.

CONTACT INFORMATION:

If you have any questions, concerns, or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Principal Investigator (PI), John Mascarenhas, MD at phone number (212) 241-3417.

If you experience an emergency during your participation in this research, contact the PI and call 911 or go to the emergency room.

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the

research team at the Program for the Protection of Human Subjects at 212-241-8200. Questions, concerns or complaints about research can directed to PPHS.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

To the extent allowed by law, every effort will be made to keep your personal information confidential. Medical records, which identify you and the consent form signed by you, will be looked at by the study doctor and the research staff at Mount Sinai and may be looked at by the Institutional Review Board, PPHS. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/ or publications.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health, including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about laboratory test results
- Results from diagnostic and medical procedures including but not limited to X-rays, physical
- examinations and medical history
- Billing records

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study. Your information may be given to the participating investigators of this research study. Information about you and your health which might identify you may be given to:

- Department of Health and Human Services agencies
- The FDA
- The Institutional Review Board
- Accrediting agencies
- Data safety monitoring boards
- Health insurers and payers
- Mayo Statistics and Data Center for monitoring and analysis

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health information confidential. If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

In almost all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, or a contract research organization, will come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. They are authorized to remove information with identifiers if necessary to complete their task. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled. You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

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 study doctor at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but

you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

HIV-related information that either is collected as part of the research or that may already exist in your medical record might be accessed for the research by the research staff and the study sponsor, but will not be shared with others without your authorization, unless federal or state law requires the disclosure. You have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights or New York City Commission on Human Rights. These agencies are responsible for protecting your rights.

Collection of Identifiable Private Information:

Identifiers might be removed from your identifiable private information or identifiable biospecimens. After such removal, the information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent (or consent from your legally authorized representative).

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ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

_____	_____	_____	_____
Signature of subject	Printed Name of Subject	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____	_____	_____	_____
Signature of consent delegate	Printed Name of consent delegate	Date	Time

WITNESS SECTION:

When a witness is required to observe the consent process, it should be documented below (for example, when subject is illiterate, visually impaired, or this document accompanies a short form consent).

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

_____	_____	_____	_____
Signature of Witness	Printed Name of Witness	Date	Time