Study Title: Improved behavioral outcome in allogeneic hematopoietic stem cell transplant patients by reducing caregiver distress: Behavioral and physiological evidence

Principal Investigator: Mark Laudenslager, Ph. D.
COMIRB No: 13-2639
Version Date: July 20, 2015
Version No: Caregiver – 9

You are being asked to participate in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

Caregivers in general as well as their patients are a stressed group. Caregivers of allogeneic (receiving a transplant of other than their own blood components) blood or marrow transplant (BMT) (e.g., hematopoietic stem cell transplant (HSCT)) recipients are a particularly distressed group, since caregiver support for the transplant patient is required 24 hours a day 7 days a week for at least the first 100 days following transplantation. This study's goals are to learn more about the impact of scheduled stress management training on both the caregiver and their patient. This will be compared to voluntary participation in available support programs for caregivers of HSCT recipients. We will measure stress hormones (chemicals) in your hair that change in response to chronic stress. We will also collect blood samples in order to perform laboratory tests of various aspects of your body's defenses against illness as well as information contained in your DNA relevant to aging. These are experimental tests and have no clinical value at this time. We may save left over cells or fluid after the tests are performed for any new test that might be relevant to stress, health, and/or the caregiving experience.

You are being asked to be in this research study because you are between the ages of 18 - 85 and a caregiver of an allogeneic BMT patient.

Up to 450 local caregivers such as yourself as well as the person they will be taking care of will be contacted or enrolled in this research study.

What happens if I join this study?

If you join the study, you will be assigned to one of two groups: either receiving voluntary support services group provided at your patient's clinic or scheduled individualized training program provided at the clinic as well. To decide which group you will be in, we will use the method of chance. This method is like flipping a coin. Although you will know which group you are in, the study scientists will not. This information needs to be kept secret and not shared with others in the clinic who might be assigned to the other condition so that the study is based on scientific results, not on peoples' opinions.

If you are placed into the voluntary support services group you will be asked to do the following things:

1) You will be asked to **provide hair samples** prior to your patient's transplant and again at 12 weeks and 6 months following the transplant. We will collect about 50 strands of hair at the scalp from the back of your head. The hair is not plucked but carefully cut. The site is covered by hair from the crown of your head and, thus, is not visible following the haircut.

These hair samples will be used to measure the levels of cortisol, a stress-related chemical in your body. Cortisol is naturally released in response to both physical and emotional stressors.

2) You will be asked to **provide about 3 tablespoons of blood**. We will get blood by putting a needle into one of your veins and letting the blood flow into a glass tube. You may feel some pain when the needle goes into your vein. A day or two later, you may have a small bruise where the needle went under the skin. We ask that you provide blood before your patient's transplant and again at 12 weeks, and 6 months following the transplant. A second sample may be requested only in the unlikely event that a laboratory procedure does not function properly. This occurs rarely. The samples will be used to assess cells in your blood as well as chemicals that sometimes change with stress and for collecting DNA.

3) You will be asked to **fill out some questionnaires** about your mood (depression or anxiety) symptoms of stress you may be experiencing, how being a caregiver has affected your life, and your general physical and mental well-being. These questionnaires will take about 20-30 minutes to complete. You will fill out these questionnaires prior to your patient's transplant and again at 6 weeks, 12 weeks, and 6 months following the transplant. Your responses to these questions will tell us about how you are doing psychologically.

If you are randomized into the scheduled individualized training sessions you will be asked to do everything above **as well as**:

1) You will be asked to attend ten scheduled **individualized training sessions**. The scheduling will be around your specific availability. Each session will last about 60-75 minutes. Individual sessions will begin the week that your patient receives their transplant (before if possible) and will continue weekly for four sessions followed by about every other week for four more sessions with two additional sessions between 4-6 months post-transplant. There may be several occasions when you cannot make a session with the therapist and we will set up a video chat for your convenience instead (see Smartphone below). Each individual training session will be devoted to a separate topic. Some of these topics will include: what to expect from the caregiving experience, how to cope with stress, relaxation and breathing exercises, identifying the needs of your patient, stress management skills, managing relationships with others and the patient, communication skills, and other topics related to caregiving. You may be asked to sign an additional consent for use of video recordings made during the sessions with the therapist for a training DVD or scientific conferences.

2) You will be asked to do practice a form of relaxation using a FDA approved device called emWave2 (Heartmath, Inc)**.** The emWave2 is a small hand-held electronic device about the size of a smartphone. To use it you place your index finger on a special sensor (or you can use a simple sensor that attaches to your ear) your pulse will be monitored. You will see a line of blue lights that give you visual feedback for controlling relaxation (generally accomplished by slowing your respiration). The emWave2 can help you develop a slower breathing rate. It is thought this will help

Initials: _____

reduce stress and anxiety. During your first individual session you will receive an emWave2 (Heartmath, Inc). You will receive an explanation of how to use the device. After training to use the emWave2, we ask that you practice with the device daily as well as when you feel distressed during the 12 weeks of the individual sessions. We also encourage you to continue using the emWave2 after the training sessions are completed.

3) You will be asked to use a **Smartphone**. If you do not have a Smartphone, we will provide one for you at no cost. The Smartphone will be used for sessions when you are unable to come to the transplant center. You will receive training in the use of the Smartphone calendar app for scheduling patient's appointments as well as your own scheduled sessions. Reminders for scheduled session appointments will be sent by text message to the Smartphone. If you choose, we will upload any selected apps to your Smartphone that could send you brief statements each day that are positive and reinforcing.

Study participation will last for 6 months. You may withdraw at any time during the study. If at any time the patient should withdraw from the study for any reason, we would like for you to continue your participation in the study. However you are free to withdraw at anytime.

What are the possible discomforts or risks?

While in the study you may find out that you have a psychiatric condition that you did not know about before starting the study. We will provide appropriate resources and referrals as needed if you choose to utilize these services you would be responsible for any associated costs.

Discomforts you may experience while in this study include emotional distress or embarrassment when asked to think about your feelings related to your experience as a caregiver of your patient. You will be provided with references for community providers if you experience emotional distress or embarrassment if you request or it is believed to be helpful to you by our staff. If you choose to utilize these services you would be responsible for any associated costs.

Some participants may feel burdened by filling out the questionnaires. You are encouraged to participate only if you feel that filling out these questionnaires will not be a burden.

You may experience slight uneasiness while having hair collected.

Risk of Blood Draw

In this study we will need to get about 3 tablespoons of blood from you. We will get blood by putting a needle into one of your veins and letting the blood flow into a glass tube. You may feel some pain when the needle goes into your vein. A day or two later, you may have a small bruise where the needle when under the skin.

The study may include risks that are unknown at this time.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about a treatment for the stress of caregiving, specifically for BMT patients. This study is not designed to treat any illness or to improve your health. Also there are risks as mentioned in the Discomforts and Risk Section.

Initials: _____

Who is paying for this study?

This research is being funded by a Federal agency, the Patient-Centered Outcomes Research Institute.

Will I be paid for being in the study?

No matter which group you are assigned, you will be paid $10.00 for each blood draw taken throughout the study. You will be paid $10.00 for each hair sample and $15.00 for completing questionnaires. A subject completing all blood draws, hair samples and questionnaire packet could receive up to a total of $120.00. If you leave the study early, or if we take you out of the study early, you will be paid only for the sample collections you have completed. It is important to know that payments for participation in a study are taxable income.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, the person you will be taking care of will still receive their normal medical care. The only care that you will lose is the support you are getting as part of this study. You might be able to get that same kind of support care outside of the study. Ask your study doctor.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

What happens if I am injured or hurt during the study?
If you have an injury while you are in this study, you should call Mark Laudenslager, Ph.D. immediately. His phone number is 303-724-9278.

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researchers carrying out this study are Mark Laudenslager, Ph.D., Andrea Maikovich-Fong, Ph.D., ABPP (Presbyterian/St. Luke's Medical Center), and Benjamin Brewer, PsyD (University of Colorado Hospital). You may ask any questions you have now. If you have questions later, you may call Mark Laudenslager, Ph.D. at 303-724-9278. You will be given a copy of this form to keep.

Initials: _____

You may have questions about your rights as someone in this study. You can call Mark Laudenslager, Ph.D. with questions. You can also call the Colorado Multiple Institutional Review Board (COMIRB). You can call them at 303-724-1055.

Who will see my research information?

The University of Colorado Denver and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver
- University of Colorado Hospital
- Presbyterian/St. Luke's Medical Center

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver and its affiliate hospitals may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Mark Laudenslager, Ph.D.
12700 E 19th Ave, Mail Stop C268-09
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- Patient-Centered Outcomes Research Institute, who is a government agency paying for this research study.

Initials: _____

- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also publish the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

A Certificate of Confidentiality has been obtained from the Federal Government for this study to help insure your privacy. This Certificate means that the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative or other proceedings. But, if you request disclosure, we can release the information.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA)

Genetic Information Nondiscrimination Act (GINA)

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

What Will Happen to my Recorded Information?

As part of this study we will be recording individual sessions of subjects in the scheduled sessions. We will use digital video media. We will keep this information secure and private. We will store it for 5 years. At the end of that time, we will destroy it. The purpose of this video is for training purposes and for the scientists to verify that all of the therapists have followed the same methods during the training sessions.

Initials: _____

The investigator (or staff acting on behalf of the investigator) will also make some of the following health information about you available to: Blackburn Laboratory.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Research Visit and Research Test records
- Psychological and mental health tests
- Other: aging markers in white blood cells

What happens to Data, Blood and Specimens that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The data or other specimens are given by you to the investigators for this research and so no longer belong to you.
- Both the investigators and any sponsor of this research may study your data and other specimens collected from you.
- If data or other specimens are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that being in this study is voluntary. I choose to be in this study: I will get a copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

Investigator:_____ Date:_____

Initials: _____

Appendix A

Table of Procedures Caregiver (Voluntary Support Services)

	Base	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12	Month 6
Blood collection	X												X	X
Hair Collection	X												X	X
Questionnaires:														
Demographics	X													
Hormone Status (*Females Only*)	X													
General Health Questions	X						X						X	X
PSS	X						X						X	X
CES-D	X						X						X	X
STAI	X						X						X	X
CRA	X						X						X	X
PSQI	X						X						X	X
CSNAT	X													X
Exit Questionnaire														X

PSS- Perceived Stress Scale
CES-D – Center for Epidemiological Studies Depression Scale
STAI – State Trait Anxiety Inventory
CRA – Caregiver Reaction Assessment
PSQI - Pittsburgh Sleep Quality Inventory
CSNAT - Carer Support Needs Assessment Tool

Initials: _____

Appendix B

Table of Procedures Caregiver (Scheduled Individualized Training Sessions)

	Base	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12	Month 4	Month 5	Month 6
fPER Session		X	X	X	X		X		X		X		X	X	X	
emWave2		4-5X	4-5X	4-5X	4-5X	4-5X	4-5X	4-5X	4-5X	4-5X	4-5X	4-5X	4-5X			
Blood collection	X												X			X
Hair Collection	X												X			X
Questionnaires:																
Demographics	X															
Hormone Status (*Females Only*)	X															
General Health Questions	X						X						X			X
PSS	X						X						X			X
CES-D	X						X						X			X
STAI	X						X						X			X
CRA	X						X						X			X
PSQI	X						X						X			X
CSNAT	X															X
Caregiver Intervention Feedback													X			
Exit Questionnaire																X

PSS- Perceived Stress Scale
CES-D – Center for Epidemiological Studies Depression Scale
STAI – State Trait Anxiety Inventory
CRA – Caregiver Reaction Assessment
PSQI - Pittsburgh Sleep Quality Inventory
CSNAT - Carer Support Needs Assessment Tool

Initials: _____

Optional Consent and Authorization for Data and Specimen Banking for Future Research

Mark Laudenslager, Ph.D. would like to keep some of the blood that is taken during the study but is left over from other tests. If you agree, the blood samples will be kept and may be used in future research to learn more about stress disorders. The research that is done with your blood samples is not designed to specifically help you. It might help people who have stress disorders and other diseases in the future. Reports about research done with your samples will not be given to you or your doctor. These reports will not be put in your health records. The research using your blood samples will not affect your care.

The choice to let Mark Laudenslager, Ph.D. keep the blood samples for future research is up to you. No matter what you decide to do, it will not affect the care that you or your patient will receive as part of the study. If you decide now that your blood samples can be kept for research, you can change your mind at any time and contact your study doctor to let him or her know that you do not want Mark Laudenslager, Ph.D. to use your blood samples any longer, and they will no longer be used for research. Otherwise, they may be kept until they are used up, or until Mark Laudenslager, Ph.D. decides to destroy them.

When your blood samples are given to other researchers in the future, Mark Laudenslager, Ph.D. will not give them your name, address, phone number or any other information that will let the researchers know who you are.

Sometimes blood samples are used for genetic research (about diseases that are passed on in families). Even if your blood samples are used for this kind of research, the results will not be told to you and will not be put in your health records. Your blood samples will only be used for research and will not be sold. The research done with your samples may help to develop new products in the future, but there is no plan for you to be paid.

The possible benefits of research from your blood samples include learning more about what causes stress disorders and other diseases, how to prevent them and how to treat them. The greatest risk to you is the release of information from your health records. Mark Laudenslager, Ph.D. will protect your records so that your name, address and phone number will be kept private. The chance that this information will be given to someone else is very small. There will be no cost to you for any blood collected and stored by Mark Laudenslager, Ph.D.

The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not be able to join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver and its affiliate hospitals may not be covered by this promise.

Initials: _____

Consent Form Approval

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Mark Laudenslager, Ph.D.
12700 E 19th Ave, Mail Stop C268-09
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

Collected data may be discussed or presented at research meetings. Results of research may be printed in journals but your name will always be kept private.

Please read each sentence below and think about your choice. After reading each sentence, circle "yes" or "no." If you have questions, please talk to your doctor or nurse. Remember, no matter what you decide to do about the storage and future use of your samples, you may still take part in the study.

I give my permission for my blood to be stored in a central tissue bank by Mark Laudenslager, Ph.D. for future use by the study investigators:

1. I give my permissions for my blood samples to be kept by Mark Laudenslager, Ph.D. for use in future research to learn more about how to prevent, detect, or treat stress disorders.

   ☐ Yes ☐ No _____Initials

2. I give my permissions for my blood samples to be used for research about other health problems such as stress disorders like heart disease or cancer.

   ☐ Yes ☐ No _____Initials

3. I give my permission for my study doctor (or someone he or she chooses) to contact me in the future to ask me to take part in more research.

   ☐ Yes ☐ No _____Initials

I agree to take part in the study having to do with research on blood as indicated above.

I have read this description about the storage of my samples or it was read to me. I understand the possible risks and benefits of this storage. I understand and authorize the access, use and disclosure of my information as stated in this form. I agree to take part in the storage and future research use of my blood as indicated above.

Signature_____ Date_____

Initials: _____

Study Title: Improved behavioral outcome in allogeneic hematopoietic stem cell transplant patients by reducing caregiver distress: Behavioral and physiological evidence

Principal Investigator: Mark Laudenslager, Ph. D.
COMIRB No: 13-2639
Version Date: July 22, 2015
Version No: Patient - 7

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

Caregivers in general as well as the loved one for whom they care are a stressed group. Caregivers of allogeneic (receiving a transplant of other than their own blood components) blood or marrow transplant (BMT) (also referred to as hematopoietic stem cell transplant (HSCT)) recipients are a particularly distressed group, since caregiver support is required 24 hours a day 7 days a week for at least the first 100 days following transplantation. This is an equally difficult time for the patient as well. This study's goals are to learn more about the impact of scheduled stress management training on both the caregiver and their patient. This will be compared to voluntary participation in available support programs for caregivers of BMT recipients such as yourself. We will measure your stress by a hormone (chemicals) present in your hair that changes in response to chronic stress. These are experimental tests and have no clinical value at this time.

You are being asked to be in this research study because you are between the ages of 18 – 85 and are receiving an allogeneic bone marrow transplant recipient and your caregiver is also agreeing to participate in this study.

Other people in this study

Up to 450 local allogeneic HSCT patients and their caregivers who will be taking care of them will be contacted or enrolled in this research study.

What happens if I join this study?

If you join the study, you will be asked to do the following.

1) You will be asked to **provide hair samples** prior to your transplant and again at 6 months following the transplant. We will collect a small amount of hair (less than 50 single strands of hair) from the

Initials: _____

back of your head at the scalp level. This site is covered by hair from the crown of your head and, thus, is not visible after collection. We can show you a video of this process if you wish.

These hair samples will be used to measure the levels of cortisol, a stress-related chemical in your body. Cortisol is naturally released in response to both physical and emotional stressors.

2) You will be asked to **fill out some questionnaires** about symptoms of stress you may be experiencing, your quality of life, and your general physical and mental well-being. These questionnaires will take less than30 minutes to complete. We are asking that you complete this questionnaire prior to your transplant and again at 6 weeks, 12 weeks, and 6 months post-transplant. Your caregiver will be completing these questionnaires at the same time as yourself. Additionally your caregiver will be randomly assigned (like flipping a coin) to one of two treatment groups.

3) You will also give permission for a qualified individual (physician or highly trained medical professional) to **review your medical records** pertaining to the blood or marrow transplant during your course of treatment.

Study participation will last for 6 months. You may withdraw at any time during the study.

What are the possible discomforts or risks?

The study may include risks that are unknown at this time.

Discomforts you may experience while in this study include emotional distress or embarrassment when asked to think about your general health.

Some participants may feel burdened by filling out questionnaires. You are encouraged to participate only if you feel that filling out the questionnaires will not be a burden.

You may experience slight uneasiness while having your haircut.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about an intervention designed to help reduce the stress that caregivers of BMT patients' experience. This study is not designed to treat any illness or to improve your health. Also there are risks as mentioned in the Discomforts and Risk Section.

Who is paying for this study?

This research is being funded by the Patient-Centered Outcomes Research Institute.

Will I be paid for being in the study?

You will be paid $10.00 for providing a hair sample and $15.00 for completing questionnaires. A subject providing one hair sample and completing the questionnaire packets could receive up to a total of $80.00. If you leave the study early, or if we take you out of the study early, you will be paid only for the sample collections completed. It is important to know that payments for participation in a study are taxable income. You will not be paid to be in the study.

Initials: _____

Will I have to pay for anything?
It will not cost you anything to be in the study.

Is my participation voluntary?
Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, you will continue to receive your normal medical care.

Can I be removed from this study?
The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

What happens if I am injured or hurt during the study?
If you have an injury while you are in this study, you should call Mark Laudenslager, Ph.D. immediately. His phone number is 303-724-9278.

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

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The researchers carrying out this study are Mark Laudenslager, Ph.D., Andrea Maikovich-Fong, Ph.D., ABPP, (Presbyterian/St. Luke's Medical Center), and Benjamin Brewer, PsyD (University of Colorado Hospital). You may ask any questions you have now. If you have questions later, you may call Mark Laudenslager, Ph.D. at 303-724-9278. You will be given a copy of this form to keep.

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We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

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We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

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- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also publish the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

A Certificate of Confidentiality has been obtained from the Federal Government for this study to help insure your privacy. This Certificate means that the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative or other proceedings. But, if you request disclosure, we can release the information.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA)

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)

Initials: _____

- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records
- Psychological and mental health tests

What happens to Data and Specimens that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The data or any other specimens are given by you to the investigators for this research and so no longer belong to you.
- Both the investigators and any sponsor of this research may study your data and other specimens collected from you.
- If data or other specimens are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that being in this study is voluntary. I choose to be in this study: I will get a copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

Investigator:_____ Date:_____

Initials: _____

Appendix A

Table of Procedures Patient

	Base	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12	Month 6
Chart Review														X
Hair Collection	X													X
Questionnaires:														
Demographics	X													
Hormone Status (*Females Only*)	X													
General Health Questions	X						X						X	X
PSS	X						X						X	X
CES-D	X						X						X	X
STAI	X						X						X	X
PSQI	X						X						X	X
FACT-BMT	X						X						X	X
Exit Questionnaire														X

PSS- Perceived Stress Scale
CES-D – Center for Epidemiological Studies Depression Scale
STAI – State Trait Anxiety Inventory
PSQI - Pittsburgh Sleep Quality Inventory
FACT-BMT - Functional Assessment of Cancer Therapy - Bone Marrow Transplantation

Initials: _____