University of Illinois at Chicago
Research Information and Consent and Authorization
for Participation in Biomedical Research

A Phase I/II Randomized, Placebo-Controlled, Double-Blind, Single-Center, Tolerability And Preliminary Efficacy Study Of use of Brimonidine Eye Drops for Treatment of ocular Graft-vs-Host Disease (oGVHD)

You are being asked to participate in a research study. Researchers are required to provide a consent and authorization form such as this one to tell you about the research, to explain that taking part is voluntary, to describe the risks and benefits of participation, and to help you to make an informed decision. You should feel free to ask the researchers any questions you may have. You can take the consent form home to think about, and discuss with family and friends, about participating in the research before making your decision.

Principal Investigator: Sandeep Jain, MD
Title: Associate Professor of Ophthalmology
Department: Department of Ophthalmology and Visual Sciences
Address and Contact Information: 1855 W Taylor Street, Chicago, IL 60612
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Emergency Contact Name and Information: Dr. Sandeep Jain, Ph. No. 312-918-0900
Sponsor: Department of Ophthalmology and Visual Sciences; Ocugen (partial funding)

Conflict of Interest

Your health care provider may be an investigator on this research protocol, and as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from a clinician who is not associated with this project. You are not obligated to participate in any research project offered by your clinician. Your participation in this research study is voluntary and you do not have to participate. The decision to not participate will not affect your clinical care now or in the future.

Why am I being asked?

You have been asked to participate in the research because you have been diagnosed with Meibomian gland dysfunction (MGD) that bothers you or that limits your activities.

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future dealings with the University of Illinois at Chicago. **If you decide to participate, you are free to withdraw at any time without affecting that relationship.**

The maximum number of subjects requested in this study is 51.

What is the purpose of this research?

This research is being done to test how well subjects handle Brimonidine and if Brimonidine might be effective for MGD treatment. Right now, there are no drugs approved by the US Food and Drug Administration (FDA) to treat MGD; that includes Brimonidine. So for this study Brimonidine will be considered an investigational drug because the FDA has not approved Brimonidine to treat MGD. Brimonidine does have FDA approval for the treatment of glaucoma either alone, or along with other anti- glaucoma medications.

Dry eye disease can be of two types: 1) Aqueous tear deficiency (deficiency of tears naturally produced by the eyes) and 2) increased tear evaporation (increased loss of natural tears due to increased evaporation from the surface of eye). Meibomian glands are glands in your eye lids that give off oil on the surface of the eye. This prevents too much evaporation of tears from the eye surface. When these glands are diseased, as can happen in MGD, it can lead to evaporative dry eye.

Clinically MGD is recognized by the presence of dilated blood vessels along the edge of the eyelid that probably lead to eye lid pain, redness and eye swelling. A substance released from nerves, CGRP, is one cause of dilated blood vessels.[9] Brimonidine can lessen the release of CGRP on the surface of the eye, or reduce its action that leads to dilated vessels. Brimonidine can also directly act on blood vessels on the eye surface to reduce dilation. This should help reduce eye lid pain, redness and swelling in patients with MGD, and that is the goal of this study.

MGD can happen with numerous conditions such as Rosacea, Sjögren's syndrome, and oGVHD. In order to limit the influence of differing causes on the outcome of this trial, we have limited the screening to MGD that accompanies oGVHD
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What treatment(s) are in this study?

This Randomized, Placebo-Controlled, Double-Blind study will have three treatment groups. You and all other subjects will either receive the study drug (Brimonidine: 0.15% or 0.075%) or placebo (Refresh Plus Artificial tears), to be used as eye drops two times a day for twelve weeks.

What procedures are involved?

This research will be performed at Department of Ophthalmology and Visual Sciences, Eye and Ear Infirmary (EEI), 1855 W. Taylor Street, Chicago IL 60612. The visits will be held either in the Cornea Clinic (Third Floor EEI, Friday, 9 a.m. - 4 p.m.) or in the Comprehensive Ophthalmology Clinic (First floor EEI, Tuesday, 9 a.m.- 1 p.m.; and Thurday, 9 a.m. - 4 p.m).

The study includes a Screening Visit and a Day 1 Visit that will take about 90-120 minutes each. The day 1 visit can be the same as your screening visit, or may be scheduled at any time in the next 7 days. Then you will come to the site for visits every 3 weeks (6-7 visits total) over the next 15 weeks. Each of those visits will take about 60-90 minutes on an average. The details of each of these visits are explained below.

All study procedures detailed below are research related. The study procedures are:

Visit 1

Screening Visit

At the screening visit, you will be asked to sign this form if you are willing to participate in the study. You may ask any questions you have and should have your questions answered to your satisfaction before you sign the form.

After you sign this form, we will ask for information about your birth date, gender, race and ethnic origin, and current menstrual status if you are a female.

We will ask you questions about your medical history, allergy history (including medications and food), substance abuse history (including drugs and alcohol) and any medications that you are taking or have taken in the past 30 days (including prescriptions, over the counter and herbal products).

We will ask you for a history of any eye problems other than MGD that you may have had. For the MGD, we will need to know when it started and any medications or treatments you had for your MGD. We will confirm the MGD by looking in your medical record. You can continue to use all your eye drops while you are in the study.

You will have an eye exam that includes a:

1. Ocular Surface Disease Index (OSDI): You will be asked questions from a questionnaire which will relate the effect of your dry eye disease on your quality of life. Your answers will help us work out your OSDI. You may read through this questionnaire before consenting for the study. You are free to refuse to answer any of the questions. It takes an average of 2- 5 minutes for most people to complete the questionnaire.
2. Slit lamp examination (a special lens and a bright light will be used to provide a view of the structures within your eyes),
3. Ocular surface redness score (a score the doctor makes based on how red your eye is),
4. Schirmer 1 test (a test that uses a very thin filter paper that is put under your eye-lid for 5 minutes to catch your tears), and
5. Rose Bengal staining (a dye that stains your eye so eye damage can be easily seen). This staining is temporary and does not interfere with vision.

If you are a female, you may be asked to have a urine pregnancy test (if necessary). If you are of childbearing age, you will be asked to use a method of birth control that is acceptable to you and the study doctor. This may include oral birth control pills, birth control implants/shots or patches, barrier methods or abstinence. You will not be included in the study if you refuse to use any birth control measure, including abstinence.

You will be permitted to continue all your eye treatments which may include, but not limited to the use of artificial tears, cyclosporine, corticosteroids, eyelid massage, contact lens, or warm compresses. The number of drops and frequency will be recorded.

If you agree to enter the study, we will schedule your first treatment visit.

Visit 2
Day 1 (Randomization and First treatment visit)

Visit 2 will be performed on the same day as the screening visit, or will be scheduled within 1 week after your screening visit. You will be randomized to one of three treatment groups (eye drops with Refresh plus Artificial Tear (placebo), eye drops with Brimonidine 0.15%, or eye drops with Brimonidine 0.075%). Randomization means that you are put into a group by chance (like flipping a coin). A computer program will place you in one of the study groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in one of the three groups. Also, neither you nor your doctor will be aware of the assigned treatments as it is a double-blind study. At the Day 1 visit, before you receive your research medication, the following information will be gathered:

1. Your vital signs will be taken. Vital signs include: blood pressure taken while you are relaxed in a sitting position for at least 3 minutes, pulse (measures your heart rate) and temperature.
2. Best Spectacle Corrected Visual Acuity will be recorded
3. Ocular Surface Disease Index (OSDI): You will be asked questions from a questionnaire which will relate the effect of your dry eye disease on your quality of life. Your answers will help us work out your OSDI. You may read through this questionnaire before consenting for the study. You are free to refuse to answer any of the questions. It takes an average of 5 minutes for most patients to answer the questionnaire.
4. Schirmer 1 test (a test that uses a very thin filter paper that is put under your eyelid for 5 minutes to catch your tears)
5. Keratograph Oculus Redness Score: Keratograph performs a non-invasive tear film analysis of your eye. It will use a bowl with a camera aperture that has a fixation mark in the center. The device provides consistent illumination, allowing scanning of the exposed area to take place. The Keratograph then analyzes the scanned area. This system generates a score automatically.
   > Non-invasive Keratography Tear Film Break-up Time (NIKBUT): The non-invasive Keratograph tear film break-up time (NIKBUT) measures tear film stability of your eyes automatically within seconds.
   > Tear Meniscus Height (TMH): TMH measures the height of the thin strip of tear fluid layer along the eyelid. TMH is measured twice for each of your eye using infrared images

derived from Oculus TMH tool. Oculus TMH measurement is generated automatically by Oculus K5M software.

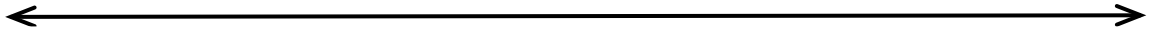
6. TearLab Osmolarity Test: The TearLab Osmolarity Test measures the osmolarity (salt concentration) of your tears to aid in the diagnosis of dry eye disease. It determines the osmolarity of your tears using nanoliter volume of your tear fluid.
7. LipiView II Examination: It images your Meibomian glands, images are then processed, displayed, and combined to provide accurate visualization of Meibomian gland structure.
   > Lipid Layer Thickness (LLT):
   > Gland Drop Out Grade
   > Meibomian Gland Evaluator (MGE)
8. Your external eye and eye lids photographs will be taken to record the eye findings (eye redness, lid disease)
9. You will have a slit lamp examination of your eyes
10. Ocular surface redness score
11. Rose Bengal staining (a dye that stains your eye so eye damage can be easily seen)
12. Any changes in your medications will be recorded.
13. Adverse (bad) effects (AEs)/ drug reactions since the last visit.

Once the above information is complete, you will receive your first dose of research eye drops. The first dose of the research eye drops will be administered by the researcher.

After you receive your first dose of the research medication, at the Day 1 visit you will:

1. Be trained on how to administer the study eye drops yourself and will be given a 4 week supply of the study eye drops to take home. At the time you receive the eye drops, you will be given instructions about instilling the drops.
2. You will receive a study diary on which to record the use of each dose and any adverse effects.
3. You will again be asked about any adverse events you may be feeling.
4. You will be asked to complete a Visual Analogue Scale (VAS): You will be asked to place a single slash mark across the horizontal line between the end labeled "completely intolerable" (0 mm) and "easily tolerable" (100mm). The VAS rating is as follows:

Please rate the degree of comfort or lack of comfort associated with administering the eye drop by making one slash mark on the line below:



Completely Intolerable **Easily Tolerable**

Visit 3
Week 3 (± 2 days)
Visit 3 will be scheduled 1 week after the day of your first treatment with the study eye drops. At Visit 3, the following information will be gathered:

1. Your vital signs will be taken (blood pressure, pulse and temperature)
2. Best Spectacle Corrected Visual Acuity (BSCVA) will be recorded

3. OSDI
4. Keratograph Oculus Redness Score
   > Non-invasive Keratography Tear Film Break-up Time (NIKBUT)
   > Tear Meniscus Height (TMH)
6 Visual Analogue Scale
7 External eye and eye lids photographs
8 You will have a slit lamp examination of your eyes
9 Subject Global Assessment (SGA) –You will be asked to compare your dry eye symptoms on this day to your symptoms on the first visit by checking a box on the SGA
10 Clinical Global Impression – the Principal Investigator will look at your Dry Eye symptoms and your eye exam findings today to see if there is any change from the previous visit
11 Your diary where you recorded changes in your medications, problems with your drug schedule and adverse events will be reviewed
12 You will be given study medication refill if you run out of the study drug.

Visit 4
Week 6 (± 2 days)

At visit 4, the following information will be gathered:

1. Your vital signs will be taken (blood pressure, pulse and temperature)
2. Best Spectacle Corrected Visual Acuity will be recorded
3. OSDI
4. Keratograph Oculus Redness Score
   > Non-invasive Keratography Tear Film Break-up Time (NIKBUT)
   > Tear Meniscus Height (TMH)
5. TearLab Osmolarity Test
6. LipiView II Examination
   > Lipid Layer Thickness (LLT)
   > Gland Drop Out Grade
   > Meibomian Gland Evaluator (MGE)
7. Subject Global Assessment (SGA) –You will be asked to compare your dry eye symptoms on this day to your symptoms on the first visit by checking a box on the SGA
8. Visual Analogue Scale
9. External eye and eye lids photographs
10. You will have a slit lamp examination of your eyes
11. Clinical Global Impression – the Principal Investigator will look at your Dry Eye symptoms and your eye exam findings today to see if there is any change from the previous visit
12. Your diary where you recorded changes in your medications, problems with your drug schedule and adverse events will be reviewed
13. You will be given study medication refill if you run out of the study drug.

Visit 5
Week 9 (± 2 days)

At this visit, the following information will be gathered:

1. Your vital signs will be taken (blood pressure, pulse and temperature)
2. Best Spectacle Corrected Visual Acuity will be recorded
3. OSDI
4. Keratograph Oculus Redness Score
   > Non-invasive Keratography Tear Film Break-up Time (NIKBUT)
   > Tear Meniscus Height (TMH)
5. Subject Global Assessment (SGA) –You will be asked to compare your dry eye symptoms on this day to your symptoms on the first visit by checking a box on the SGA
6. Visual Analogue Scale
7. External eye and eye lids photographs
8. You will have a slit lamp examination of your eyes
9. Clinical Global Impression – the Principal Investigator will look at your Dry Eye symptoms and your eye exam findings today to see if there is any change from the previous visit
10. Your diary where you recorded changes in your medications, problems with your drug schedule and adverse events will be reviewed
11. You will be given study medication refill if you run out of the study drug.

Visit 6
Week 12 (± 2 days)

At this visit, the following information will be gathered:

1. Your vital signs will be taken (blood pressure, pulse and temperature).
2. Best Spectacle Corrected Visual Acuity will be recorded
3. OSDI
4. Rose Bengal staining and Schirmer 1 test
5. Keratograph Oculus Redness Score
   > Non-invasive Keratography Tear Film Break-up Time (NIKBUT)
   > Tear Meniscus Height (TMH)
6. TearLab Osmolarity Test
7. LipiView II Examination
   > Lipid Layer Thickness (LLT)
   > Gland Drop Out Grade
   > Meibomian Gland Evaluator (MGE)
8. Subject Global Assessment
9. Visual Analogue Scale
10. External eye and eye lids photographs
11. You will have a slit lamp examination of the eyes.
12. Clinical Global Impression
13. Your diary where you recorded changes in your medications, problems with your drug schedule and adverse events will be reviewed
14. You will be asked to return the used and left-over eye droppers. You will not be required use the study drug any longer.

Visit 7
Week 15 (± 2 days)
Follow-up Visit

At this visit, the following information will be gathered:

1. Your vital signs will be taken (blood pressure, pulse and temperature).
2. Best Spectacle Corrected Visual Acuity will be recorded
3. OSDI
4. Subject Global Assessment
5. External eye and eye lids photographs
6. You will have a slit lamp examination of the eyes.
7. Clinical Global Impression
8. Your diary where you recorded changes in your medications, problems with your drug schedule and adverse events will be reviewed
9. You will be asked to return the used and left-over eye droppers. You will not be required use the study drug any longer.

Besides this research drug, you will continue to receive the standard care for your condition all through the study and this would occur whether or not you participated in the research.

What are the potential risks and discomforts?

The intervention in this study is topical application (to your eye) of eye drops containing either Refresh plus Artificial Tear or study drug (Brimonidine: 0.15% or 0.075%).

Enough evidence already exists about use of Brimonidine 0.15% eye drops in glaucoma to suggest that it is a safe drug for application to the eyes, with no significant serious adverse events. The most commonly reported adverse events have included dry mouth, conjunctivitis (eye redness, pain) and eye burning and/or stinging in 1-12% of patients.. The most common side effects in the body other than the eyes include altered sense of taste, tiredness, dry mouth and headache in very few patients. These side effects were in glaucoma patients were usually mild, short-lived, and usually not severe enough to require a physician to stop Brimonidine.

The most likely discomforts you may experience by having Brimonidine administered in eye drops are eye burning, irritation or red eyes. To see how you react to the study medication, your first dose will be given to you by the investigator in the clinic itself. Afterwards you be asked to rate your tolerability of the drug on the Visual Analogue Scale. You will be asked to complete the Visual Analogue Scale at all of the subsequent visits as well.

An allergic reaction to the drug cannot be predicted beforehand. In event of an allergic reaction, the drug will be stopped immediately, and your symptoms will be managed appropriately depending on how severe your reaction is.

You should contact the research team immediately in case you develop any of the above symptoms. If you experience worsening of your MGD at any time during the study, you should contact the research team immediately.

You may experience mild anxiety or embarrassment in answering questions of a personal nature regarding your health and well-being. You do not need to answer any questions that make you uncomfortable.

If you take part in another research study at the same time as you take part in this study, it may affect the way you react to the study eye drops. You should inform the researchers if you are currently enrolled in another research study.

Please keep the study drug out of the reach of children or others who may not be able to read or understand the directions on the label. Do not let anyone else take the study drug besides you.

There is always a risk of a loss of confidentiality. Every possible care will be taken to maintain the confidentiality of your information. Information will be saved as coded data that has been stripped of all identifiers and random study ID number will be assigned to you and it will be linked with the master code list. The master code list will link your MRN to the study ID number given to you so that information could be linked back to you. The data collected, master code list will be accessible only to the PI and the research team involved in this project. The data collected and master code list will be stored on PI's desktop in separate locations. The desktops will be password protected. Hardcopy data, consent forms and other study documents, and specimens will be stored in locked cabinets in PI's locked laboratory and locked office.
When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

What are the reproductive risks?

If you are a woman: There are no adequate and well-controlled studies of Brimonidine use in pregnant women. Participating in this research may involve risks to pregnant women and/ or an unborn baby which are currently unforeseeable. To protect against possible side effects of the study drug, you will not be enrolled in the study if you are pregnant or nursing a child. If you are a woman of childbearing ability, you will have a urine pregnancy test prior to your enrollment in the study. You will be asked to use a method of birth control that is okay to you and the study doctor. This may include oral birth control pills, birth control implants/shots or patches, barrier methods or abstinence. If you refuse to use any birth control measure, including abstinence you will not be allowed in the study. If you think that you have become pregnant during the study, you must tell the doctor immediately. If you become pregnant, your participation will be immediately stopped.

Will I be told about new information that may affect my decision to participate?
During the course of the study, you will be informed of any new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

Are there benefits to taking part in the research?
You may not directly benefit from participation in the research. It is hoped that knowledge gained from this research may benefit others with MGD in the future.

What other options are there?

You have the option to not participate in this study.

What about privacy and confidentiality?

The people who will know that you are a research subject are members of the research team, and if appropriate, your physicians and nurses. No information about you, or provided by you, during the research, will be disclosed to others without your written permission, except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care or when the UIC Office for the Protection of Research Subjects monitors the research or consent process) or if required by law.

Study information which identifies you and the consent form signed by you will be looked at and/or copied for examining the research by the UIC Office for the Protection of Research Subjects, State of Illinois Auditors, and by the FDA.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

A possible risk of the research is that your participation in the research or information about you and your health might become known to individuals outside the research.

Will health information about you be created, used or shared with others during this study?

State and federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect your health information. This section of this form describes how researchers, with your authorization (permission), may use and release (disclose or share) your protected health information in this research study. By signing this form you are authorizing Dr. Sandeep Jain and his research staff to create, get, use, store, and share protected health information that identifies you for the purposes of this research.

The health information includes all information created and/or collected during the research as described within this consent form and/or any health information in your medical record that is needed for the research and that specifically includes: name, date of birth, medical record number, your eye diagnosis and findings, and the treatments that you are on.

The following information will be recorded in your medical record: that fact that you are participating in a research study, and results from the BSCVA (Best Spectacle Corrected Visual Acuity) and slit lamp exam as well as vital signs collected during the study.

During the conduct of the research, the researchers may use or share your health information:

- With each other and with other researchers involved with the study;

- With review boards including the University of Illinois at Chicago Institutional Review Board, the University of Illinois Medical Center and its representatives, and other persons who watch over the safety, effectiveness, and conduct of research;
- With the FDA.
- With Ocugen

How will your health information be protected?

The researchers agree to protect your health information and will only share this information as described within this research consent/authorization form.

When your health information is given to people outside of the research study, those agencies that receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it. They may also share your information with others without your permission, if permitted by laws that they have to follow.

What if I am injured as a result of my participation?

You may have medical problems or side effects from taking part in this research study. If you believe that you have become ill or been injured from taking part in this study, treatment may be obtained through:

- The UIC Medical Center OR
- Your regular doctor OR
- The treatment center or clinic of your choice.

If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

You may contact the researcher Sandeep Jain, MD at 312-996-8936 to talk to them about your illness or injury.

You or your insurance company will be billed for this medical care. Your insurance company may not pay for some or all of this medical care because you are participating in a research study. There are no plans for the University to provide free medical care or to pay for research-related illnesses or injuries, or for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries.
By signing this form you will not give up any legal rights.

What are the costs for participating in this research?

You will be reimbursed for some of your expenses. $50/ visit will be given to each subject on Visit 2 (Day 1, First treatment visit) and on the five subsequent visits afterwards till Visit 7 (total 6 visits) to offset to some extent your parking/ transportation expenses. Costs of all research-related procedures will be covered by Ocugen.

Will I be reimbursed for any of my expenses or paid for my participation in this research?

You will receive [$50 cash] for each completed study visit. If you do not finish the study, you will be compensated for the visits you have completed. If you complete the study, you will receive a total of $300. You will receive your payment immediately after each visit as cash.

Can I withdraw or be removed from the study?

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without affecting your future care at UIC. For your safety, however, you should consider the investigator's advice about how to leave the study. If you leave the study before the final planned study visit, the investigator may ask you to complete the final steps.

The researchers and sponsor also have the right to stop your participation in this study without your consent if they believe it is in your best interests or you were to object to any future changes that may be made in the study plan.

Your Authorization for release of health information for this research study expires six years after the end of the study, but can be canceled sooner if you decide to withdraw your permission.

You may change your mind and cancel this Authorization at any time. To cancel this Authorization, you must write to:
Sandeep Jain, MD
Department of Ophthalmology and Visual Sciences
1855 W Taylor Street, Chicago, IL 60612

If you cancel this Authorization, you may no longer be allowed to take part in the research study. Even if you cancel this Authorization, the researchers may still use and disclose health information they have already obtained as necessary to maintain the integrity and reliability of the research and to report any adverse (bad) effects that may have happened to you.

Who should I contact if I have questions?

Contact the researchers at 312-918-0900 (clinical trial line), OR

The principal investigator: Sandeep Jain, MD at 312-996-8936 or jains@uic.edu:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury (or a bad reaction to the study treatment), and/or
- if you have questions, concerns or complaints about the research.

What are my rights as a research subject?

If you have questions about your rights as a research subject or concerns, complaints, or to offer input you may call the Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

If you have questions or concerns regarding your privacy rights under HIPAA, you should contact the University of Illinois at Chicago Privacy Officer at Ph: (312) 996-2271.

What if I am a UIC student?

You may choose not to participate or to stop your participation in this research at any time. This will not affect your class standing or grades at UIC. The investigator may also end your participation in the research. If this happens, your class standing or grades will not be affected. You will not be offered or receive any special consideration if you participate in this research.

What if I am a UIC employee?

Your participation in this research is in no way a part of your university duties, and your refusal to participate will not in any ways affect your employment with the university, or the benefits, privileges, or opportunities associated with your employment at UIC. You will not be offered or receive any special consideration if you participate in this research.

Remember:

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Right to Refuse to Sign this Authorization

You do not have to sign this Consent/Authorization. However, because your health information is required for research participation, you cannot be in this research study if you do not sign this form. If you decide not to sign this Consent/Authorization form, it will only mean you cannot take part in this research. Not signing this form will not affect your non-research related treatment, payment or enrollment in any health plans or your eligibility for other medical benefits.

Signature of Subject

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this signed and dated form. If you have not already received a copy of the Notice of Privacy Practices, you should ask for one.

Your signature below indicates that you are providing both consent to participate in the research study and authorization for the researcher to use and share your health information for the research.

Signature

Date

Printed Name

Signature of Person Obtaining Consent

Date (must be same as subject's)

Printed Name of Person Obtaining Consent