

# MOSHE LEWIS, MD

## CONSENT AND AGREEMENT TO RECEIVE OR CONTINUE INTRACTABLE PAIN TREATMENT

The following Pain Management Consent and Agreement is a contract between the patient, \_\_\_\_\_, and Golden Gate Institute of Integrative Medicine (hereinafter referred to as "GGIIM") including, but not limited to, the clinic, its providers, and its medical personnel.

### Specific Points of Agreement

1. Patients must be capable of and agree to attend a monthly clinic visit.
2. Patients must be mentally competent to responsibly and safely self-administer pain medications.
3. Patients are not fully accepted in treatment until they have been treated for at least two (2) consecutive months.
4. Patients may not refill, request, change, or alter medication between monthly visits.
5. Patient accepts all risks and complications of medication including, but not limited to, falls, accidental overdose, immune suppression, weight gain, constipation, and accidents.
6. If your physician at GGIIM is not your primary care physician, you must have a primary care physician for general medical care and not rely on GGIIM for non-pain medication and emergency care.
7. It is strongly recommended that all patients inform their family that they are enrolled in pain treatment, that they inform their family that they have accepted all risks of medication, and that the family may not sue GGIIM, its physicians, or medical personnel after the patient's death, regardless of the timing or cause of death.
8. This treatment program utilizes prescription medications and controlled drugs, which may produce dependence, addiction, and side effects, and they are only recommended as a last resort treatment. Patients who enter or continue this program accept full responsibility for all complications of medications given in this program. Therefore, it is recommended that this consent and agreement be shown to all family members, physicians, attorneys, ministers, pharmacists, and other concerned parties.
9. Patients who participate in this treatment program accept all responsibility for auto or other accidents and cannot blame the medications, the program, or the medical personnel.
10. This program does not guarantee or warrant that it can diagnose or effectively treat any disease including arthritis, neuropathy, stroke, cancer, or kidney failure among others. Enrollment in this program is elective based on the patient and the family's agreement that they are responsible for the outcome of any complications related to the patient's pain or causative disease.

**Patients who wish to begin or to continue pain treatment at GGIIM agree to all of the following points:**

### I. Definition of Severe, Intractable Pain

*Most patients who are treated here declare they meet the legal definition of the California Intractable Pain Act. The California Intractable Pain Act, passed in 1990, legally defines intractable pain as: "... a pain state in which the cause of pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the pain is possible, or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and surgeon and one or more physicians or surgeons specializing in the treatment of that area, system, or organ of the body perceived as the source of the pain."*

### II. Consent, Rules and Agreement

1. Patients accepted into the program consent to the rules, warnings, guidelines, stipulations, and procedures listed in this

agreement.

2. Patients may be given warnings and/or discharged if they violate any of the rules in this agreement.

**III. Severity of Intractable Pain**

The providers at GGIIM primarily treat severe, unrelenting, incapacitating, intractable pain that has not been curable by the usual medical and surgical treatments. It is only non-curable pain that needs continuous opioid administration.

**IV. Criteria for Admission to The Program**

Dependent upon opioid medications for pain control and/or Pain present for three months or more.

Previous non-narcotic treatments have failed. Pain is unrelenting, severe, and debilitating. Patient must be able to afford clinic visits on a monthly basis and any associated costs (urine toxicology screening). 6. Patient must be mentally fit to self-administer medication in a safe manner.

**V. What Are Opioid Medications?**

Treatment with these medications is given with the full understanding that these drugs may have side effects, and the patient assumes all risks. Commonly prescribed opioid medications as follows (list is NOT inclusive of all medications in the category class):

- Meperidine
- \* Hydromorphone
- \* Methadone
- \* Sublingual Fentanyl
- Buprenorphine
- \* Transmucosal Fentanyl
- \* Hydrocodone Oxymorphone
- \* Transdermal Fentanyl Morphine
- Oxycodone

**GOALS AND COMPONENTS OF THE INTRACTABLE PAIN PROGRAM** The goal of this program is to control and reduce the patient's intractable pain level by 50 to 90%. In addition, the providers strive to increase the patient's movement, energy, and self esteem. Treatment here is given with the understanding that the providers can neither completely eliminate nor cure pain. Furthermore, the patient accepts all risks and complications of any treatment.

**VII. Treatments Which Should Be Tried Before Utilization of Opioid Administration** Patients with chronic pain should try a number of different pain treatments before their pain is classified as intractable and in need of opioids. Listed below are many non-opioid treatments. If one or more treatments proves even minimally effective, it should be continued as an ancillary procedure to opioid treatment. Treatment is given or continued at GGIIM only if the patient declares that he/she has failed at least one of the non-opioid treatments listed below.

- \* Acupuncture
- \* Antidepressants
- Anti-Inflammatory
- \* Biofeedback
- \* Chiropractic
- \* Deconditioning
- Spinal Cord Stimulator
- Hontophoresis
- \* Muscle relaxants/ tranquilizers
- \* Nerve Blocks
- Non-Opioid Drugs
- Physical Therapy
- Surgery
- \* TENS
- \* Ultrasound

**VIII. Expected Complications And Side Effects Of Opioid Treatment**

Unfortunately, patients who take opioid medications must expect the following complications: constipation, nausea, itching, weight gain, and abscess/infection with injections.

Described here are some remedies that patients should attempt to minimize complications.

1. Constipation - Please read and follow the brochure on laxative use with chronic opioids.

2. Weight Gain - A low glycemic index or ketogenic diet is recommended. A thyroid hormone, testosterone and sex hormone workup is recommended and hormones prescribed, if medically indicated. In severe cases, a prescription weight

reduction medication may be necessary.

## **IX. Specific Items of Consent**

All patients must acknowledge, agree to, and abide by the following requirements:

1. Patients are to inform family members that they are personally responsible for their own medications, overdoses, and accidents, and that family members cannot file a lawsuit for any overdose, accident or even death that may occur.
2. Patients must inform their family members, attorneys, friends, and health providers that they have personally determined that they have intractable pain and require opioid drugs. Furthermore, all patients agree to inform these parties that any driving or other accidents are their personal responsibility and not due to medication.
3. All patients must have a primary care doctor. If your provider at GGIIM is not your primary care physician, then the provider is considered to be only a pain consultant. Your primary care physician must care for your emergencies and hospitalizations regardless of their cause. GGIIM's staff and providers are not available afterhours or on weekends except in emergencies and then only as triage in regards to chronic pain management. If you do have an emergency that requires a physician to examine you, please go to the nearest emergency room immediately,
4. Prescriptions will not be changed between visits or ahead of schedule.
5. Increased pain due to surgery is to be treated by contacting GGIIM ahead of the scheduled procedure, and your provider will prescribe a postoperative pain regimen.
6. Patients accept the risk of and are personally responsible for organ toxicity due to excess acetaminophen.
7. All intractable pain patients are to make every attempt to find gainful employment or an activity that occupies their time.
8. Patients who utilize illicit substances for therapeutic or recreational purposes may NOT receive treatment. These substances include, but are not limited to, marijuana, cocaine, heroin, DMSO, or another individual's prescriptions, Special exceptions for medical marijuana may be made on a case-by-case basis and are made at the sole discretion of your provider at GGIIM. You will need a physical exam for medical marijuana performed elsewhere to evaluate for the actual need for this drug.

## **X. Specific Consent Requirements For Participation. In The Program**

1. Please read all clauses carefully.
2. Take this agreement home and show to family members and all concerned parties.
3. GGIIM and your provider provide you with this document to help make your treatment as successful as possible and to inform you of the program procedures, limitations, potential side effects, and costs.
4. Your Basic Agreement: This document gives your consent and your agreement to follow the program rules. You have reported to your provider at GGIIM that you have severe, intractable pain that you believe cannot be without the use of one or more opioid medications. You must carefully read this consent agreement. Take it home to discuss with your family, friends, pharmacist, attorney, doctor, minister, or any other party you desire before agreeing to treatment with opioid medications. The points listed below must be fully understood and agreed to by you before opioids will be prescribed to you.

## **XI. Specific Points of Agreement And Understanding**

I have read, fully understand, and agree to the following:

1. I fully understand that all opioids for intractable pain will make me physically dependent upon them.
2. I fully understand that the resulting dependence from opioid use may last my lifetime and that statistics indicate that few people dependent upon opioids for pain relief are able to cease use and not relapse unless a cure for the pain occurs.
3. I am aware that the failure to use opioids as prescribed may leave me in pain.
4. I am aware that there are many ways to relieve intractable pain including, but not limited to, acupuncture, electrical stimulation, physical therapy, biofeedback, hypnosis, nerve blocks, mental health therapy, and non-opioid medications. These methods have either been unsuccessfully tried by me or are unacceptable to me as my only form of pain treatment, and at this time, I declare myself to have intractable pain and desire to be dependent upon opioids

as part of my pain treatment.

5. As one of my treatments, I fully understand that pain control may require that I take one or more of long-acting opioid medications. Furthermore, I have been informed that these opioids prevent or suppress pain and enhance the pain-relieving ability of short-acting opioids and other treatments provided in this program. If I cannot tolerate or if I refuse to take a long-acting opioid, I understand that I may be discharged from the program.
6. I am fully aware that the intractable pain program includes many special treatments designed to enhance the positive effects and to limit the side effects of opioids. These treatments include, but are not limited to, topical medications, injections, exercise, oral medications, and nutritional supplements.
7. I agree to undergo saliva, blood, and/or urine tests as deemed necessary by the clinic.
8. I understand that I will be dependent, and that if I suddenly discontinue my opioid, I will likely suffer withdrawal symptoms, which may include nausea and vomiting, pain flares, diarrhea, fever, seizures, flu-like syndrome, chills, headache, loss of appetite, depression, and a return of my pain. If I decide to discontinue opioid use without the agreement of my provider at GGIIM, I will not blame the clinic for the severity of the withdrawal symptoms as I have been informed of these affects prior to initiation of the medication.
9. I agree to take my opioid medications as prescribed and will obtain opioids from only one pharmacy, except in emergency situations.
10. I will select a pharmacy near GGIIM or near my home to fill my opioid prescriptions. I give the clinic my consent to release all my current and future records and to discuss my case with the pharmacy. If I change pharmacies, I will inform the clinic, and I automatically give my permission to give them my current and future records.
11. I understand that the clinic will discontinue prescribing opioids to me at any time I desire, although I understand that any withdrawal attempt may not be satisfactory and that it may result in increased pain. I also understand that the clinic will at any time refer me, at my request, to any non-opioid pain treatment that I desire.
12. I understand that the use of any mind-altering drug such as tranquilizers, stimulants, diet pills, sedatives, or alcohol with my opioids may lead to excess drowsiness, intoxication, or overdose and that use of any mind-altering drug with my opioid may impair my ability to safely drive a car or operate heavy machinery. Furthermore, I understand that I will be at an increased risk for a fall or other accident, and if this occurs, I accept full responsibility and will not blame GGIIM or its providers.
13. I am aware that regular opioid use may have any of the following side effects: constipation, nausea, itching, weight gain, and abscesses and infections with injections.  
**Females:** I am aware that opioid medication may stop my menstrual periods. If I should become pregnant, I understand that my baby will be dependent upon opioids and will need to undergo withdrawal after birth by the pediatrician/neonatologist.
14. I understand that if I consume opioids in an amount above that which is prescribed, if sell them, if I give them to someone else, or if I use another mind-altering drug, my provider at GGIIM reserves the right to refuse to prescribe additional opioids and to discharge me from the clinic for pain treatment.
15. I fully understand that the clinic may choose to do any of the following:
  - a. To not refill my opioid prescription by telephone.
  - b. To not refill my opioid prescription before my scheduled appointment.
  - c. To not refill my opioid prescription because my medications were lost or stolen. I further understand that the clinic reserves the right to discontinue further treatment if I make any of these requests.
16. Due to the highly dangerous and addictive nature of opioids, I agree to obtain opioid prescriptions prescribed by a provider at GGIIM, except in an emergency. If obtain opioids from another clinic or provider, I will inform GGIIM.
17. I fully understand that I cannot loan, give, or sell my opioids to another person. If I do this, the clinic may discharge me and may report me to the proper law enforcement agency.
18. I fully understand that it is my responsibility to make my monthly appointments PRIOR to running out of my medication. Missed or cancelled appointments do not justify a valid reason for GGIIM to provide refills of my medications.
19. I understand that I have the right to leave the treatment program at any time and to seek treatment elsewhere. In this event, the clinic will provide me with a prescription for one month's supply of opioids. I also understand that I can

reapply to the program but that I may not be reaccepted back into the program.

20. I fully understand that I will be given regular appointments at the clinic, which must be kept.
21. I fully understand that the clinic will consult with me on my opioid medication requirements and that I will tell the clinic my precise daily medication requirement. I also understand that the clinic will prescribe the precise amount of medication so that I will never run out of medication prior to my next appointment, as long as I maintain monthly clinic visits.
22. I agree to never take in excess of my prescribed opioid dosage nor to attend the clinic in an over-medicated state. If I fail to do so, I understand that GGIIM reserves the right to discharge me.
23. For patients who have another primary-care provider: I particularly understand the clinic's inability and limitations to diagnose and treat all serious medical problems that may cause complications and even my death. This includes, but is not limited to, cancer, heart disease, stroke, AIDS, and hormone deficiencies. I fully understand that the clinic may give me erroneous information, diagnosis, or treatment since many medical conditions and treatments cannot be determined in the clinics it primarily treats pain. I fully understand that protection of my health is my personal responsibility, and I will not hold GGIIM, its physicians, and its medical personnel medically, financially, or otherwise responsible for a failure to diagnose and/or properly treat a serious condition or prevent complications or side effects of medications.

## **XII. Serious Complications**

### **IMPORTANT-READ AND UNDERSTAND**

All intractable pain patients who take opioids and other medications in this clinic must be aware of four (4) serious, life-threatening complications encountered during opioid treatment of intractable pain. Furthermore, the patients must take full responsibility and not blame GGIIM nor its providers for any of the following. Furthermore, I understand the clinic reserves the right to discharge me if any of these complications develop.

#### **> Serious Complication #1:**

Patients who take amphetamine, cocaine, or other stimulants with opioids may develop hemorrhaging, swelling, adrenal gland failure, and liver failure. In addition, accidents may OCC.

#### **> Serious Complication #2:**

Patients who consume one or more alcoholic drinks per day may develop internal bleeding and liver failure. In addition, accidents may occur.

#### **> Serious Complication #3:**

Patients who take too many benzodiazepines (e.g. Valium, Ativan, Xanax, Restoril, and Halcion) may develop chronic sedation, fatigue, and adrenal gland failure. In addition, accidents may occur.

#### **> Serious Complication #4:**

Patients who take too many benzodiazepines as listed in #3, too many sedative muscle relaxants (e.g. Soma), too many sedating antidepressants (e.g. Elavil), and/or too many opioids may fall and fracture the hip, elbow, ankle, or another bone. There is an increased risk of accidents and seizures. Recent research shows there may be increased risk in the development Alzheimer's. The same may occur due to the taking of dosages above what is prescribed in the clinic.

## **XIII. Clinic Rules to Follow**

1. You must maintain a list of all medications that you are being prescribed and you are required bring the list into the clinic at each visit. This list should include accurate dosages of all prescribed medications from GGIIM and other physician offices.
2. Refills of medications by telephone are not permitted.
3. If you miss an appointment, refills of medications will not be given until you are seen at your next clinic visit, except in special circumstances that are determined by the provider.
4. Medications that are lost, stolen, or otherwise destroyed will not be refilled until the next appropriate visit.
5. Refills of medications before scheduled appointments may not occur.
6. Medications are to be taken as prescribed. You are to provide your local pharmacy your records and medical history if the pharmacy requests them.

7. Medications are not to be given or sold to anyone else.
8. If you are a cash-paying patient, fees must be paid at the time of the visit. No refunds will be provided even if the patient is discharged.
9. Patients must not obtain additional opioid medication from another provider, except in emergencies, in which the patient will inform GGIIM.
10. Violation of these rules may cause immediate dismissal from the program. If a patient is dismissed, medications, if prescribed at all, will be for up to two weeks.
11. Should your actions cause the clinic to dismiss you from the program, you are to return to your referring provider. No other referrals will be given.
12. Should irrefutable evidence be brought to GGIIM that prescribed medications are being illegally used by you, all patient/physician confidentiality will become null and void, and we will report you to the appropriate authorities.
13. Controlled substances, particularly opioids, are commonly used in our pain management program. They are commonly sought after for purposes other than intended. Therefore, it is imperative that you carefully guard your medication supplies and limit those family and friends who are aware that you have them. It is best to trust no one. No exceptions will be made for lost medication, and this may be considered a possible dismissible offense.
14. Patients are strongly encouraged to participate in the entire pain management program recommended by GGIIM and its providers including, but not limited to, topical treatment, exercise, injections, weight loss and nutritional supplements and will not be permitted to solely take opioid medications. The purpose of these ancillary treatments is to prevent complications and worsening of the root cause of the pain.
15. Patients agree to submit to saliva, urine, and/or blood samples for determination of compliance with the program. If patients do not have insurance, they will be billed for the test and must pay out of pocket.
16. Use of any other mind-altering drugs, including tranquilizers, stimulants, diet pills, sedatives, and alcohol not prescribed by the program may lead to excess drowsiness, intoxication, or overdose. Use of any mind-altering drug with or without your prescribed medications may impair your ability to safely drive a car. Furthermore, patients are at an increased risk for a fall or other accident. GGIIM and its providers cannot be held responsible for medications prescribed by outside providers, and the clinic reserves the right to restrict medication or to discharge the patient if the clinic believes another provider's prescribed medication might interfere with medications prescribed by the clinic.
17. Patients in the program may experience, at any time, some short- or long-term medical or surgical problem. The clinic will try to help as much as possible, however, it is the patient's responsibility to find an outside provider for these problems. Furthermore, all intractable pain patients are required to find a primary care physician within two (2) months of starting therapy at GGIIM. Failure to do so may be grounds for dismissal.
18. If a person, other than the patient, is found to possess a patient's medication, or if the patient loses or allows his/her medication to be stolen more than once, we will assume that the patient is too irresponsible to be prescribed opioid medications, and the patient will be discharged from the clinic.
19. In addition to guarding and protecting medication, it is the patient's responsibility to self-administer his/her own medication. Friends and family are not to be in charge of medication unless specifically directed to do so by the patient's physician. Medications prescribed to the patient but found on another person will be viewed by the program as being used by that other person.
20. To be admitted to the program, patients must be mentally competent and capable of self-care. If they are not, they are not suitable candidates for the program. GGIIM and its providers will only deal with the patient and will not permit interference from family or friends no matter how well-intentioned they might be.
21. Family and friends will not be permitted in the examination rooms or to give opinions on medications, pain severity, or treatment unless permitted by both the clinic staff and the patient. The clinic may require friends or family to leave the clinic at any time.
22. Patients, who attend the clinic with drowsiness, slurred speech, or poor coordination, may have their medication dosage altered or have their medication discontinued, and they may be required to attend the clinic on a more frequent basis,
23. GGIIM recommends the patient find a pharmacy that will fill the special order opioids required in the program. The clinic and its staff will not sanction, call, respond to, or otherwise find a suitable pharmacy. It is each patient's responsibility to fill prescriptions at the pharmacy of his/her choosing.

24. Injectable opioids are not permitted in this program unless the attending physician believes that an occasional injection is required to prevent an emergency room visit for severe breakthrough pain. Since patients on this program will require opioids for many years and likely for a lifetime, injectable opioids will eventually result in severe complications, Opioid suppositories may be prescribed for use in an emergency situation and to prevent emergency room visits.
25. A goal of this program is to prevent emergency room visits for severe, breakthrough pain. Patients are required to report to the clinic every occurrence of an emergency room visit.
26. I fully understand that my provider may change my opioid medication from pill to liquid form or may change the type of medication without my approval if my provider believes that my medication dosage may inhibit proper intestinal function or that the medications may have an adverse effect on me.
27. If the program receives any verifiable reports from an outside party that you abuse, distribute, or sell your medication, your provider will discontinue your treatment. In addition, you will be discharged from the program if the clinic receives outside reports that you are sedated, falling, or otherwise intoxicated. Additionally, patients must not associate with persons or parties that abuse drugs and behave in such a manner that will generate reports to the clinic.
28. I understand that many opioid medications contain acetaminophen (Tylenol) or aspirin. Included, but not inclusive, are the following: Fiorinal, Fioricet, Percocet, Percodan', Vicodino, Norcoo, Vicoprofeno, and codeine compound.
29. I am fully aware that liver or kidney disease may result from long-term use of acetaminophen (Tylenol) or aspirin. In addition, acetaminophen may produce stomach or intestinal bleeding. Furthermore, I will not hold GGIIM or its providers responsible for any of these complications should I experience them. Additionally, I will have my primary care physician test my liver and kidneys at least once annually to ensure that I am not experiencing liver or kidney damage. I will not hold the clinic or its providers responsible for checking my liver or kidneys. I will not hold the clinic or its physicians responsible if I develop liver, kidney, or other complications from acetaminophen (Tylenol), aspirin, or other prescribed medications.
30. I am fully aware that the clinic may prescribe opioids that do not contain acetaminophen or aspirin. I also understand, however, that these opioids may not control pain as well as when the opioids are combined with acetaminophen or aspirin. I agree to take my opioids drugs with a meal, antacid, or fiber supplement so as to help prevent stomach and intestinal complications (e.g. bleeding).
31. I am aware that opioid use may result in weight gain, constipation, and for sedation. Furthermore, I understand the clinic will attempt to prevent these complications but cannot guarantee success.
32. Falls or Accidents on Our Premises: I fully understand that my use of opioid medications make me impaired and puts me at an increased risk for falls and/or accidents. In the event that I fall or have an accident on clinic premises, I will not hold the clinic or its personnel legally, financially, or otherwise responsible. I pledge to use caution and to carefully walk on stairs, exit my automobile, and walk on parking lots and sidewalks. I will ask that anyone who accompanies me to my clinic visit assist in my ambulation.

#### **XIV. Future Changes in These Rules**

From time to time, these rules may require updating, and GGIIM reserves the right to do so without prior notification. Furthermore, I agree to follow all future rule changes.

#### **XV. Conflicts Between the Rules and Government Regulations**

If it should be discovered that any rule in this agreement conflicts with government regulations, this agreement would automatically be updated to conform to said regulations,

#### **XVI. Disagreements, Conflicts or Altercations Between Patients**

The clinic staff will not enter into any discussions nor take sides in disagreements, conflicts, or fights between patients. If clinic is made aware of any conflicts, including fights, between patients, both parties will be held responsible. Additionally, the clinic will warn both parties and will reserve the right to discharge both parties from the program. Patients are expected to treat each other with respect and decency, and no other behavior will be tolerated.

#### **XVII. Falls, Accidents or Thefts While On Our Premises**

Patients frequently are in a hurry and/or fail to pay attention; consequently, they trip or fall on steps, hallways, sidewalks, and parking lots, or leave personal items unattended. GGIIM, its providers, and its staff will not pay medical expenses nor accept liability or blame for any fall, accident, or loss on the clinic premises. Participation in the program is done with the

full understanding that any fall or accident on the clinic premises is the patient's responsibility. Patients waive all rights to file any legal claim should they fall or have an accident or become the victim of a theft while on clinic premises. Patients are encouraged to keep their belongings with them at all times and should not ask the staff to watch or hold anything for them.

### **XVIII. Allergies And Patient Responsibility**

Since you will be treated in this program for a considerable time period, you need to be aware that the program may not recall your allergies or other drug sensitivities that you may have. Consequently, you need to personally inquire about every new medicine you are given as to whether you may be allergic or sensitive to it. If you feel you cannot remember to make this inquiry with every new drug, you need to bring a support person or attendant, who will remember. You will not hold the clinic responsible if you are given a medicine to which you are allergic since it is your responsibility to ensure that the clinic and attending physicians are made aware of any allergies at the time a new medicine is prescribed or administered.

### **XIX. Mediation and Arbitration Of Disputes**

You agree to settle any and all disputes or claims, including but not limited to malpractice, accidents, fees, thefts, and damage to possessions, that you may have with the clinic solely by mediation or arbitration. If any dispute is not resolved within 30 days after the clinic is notified, the patient will be discharged from treatment, and the patient will assume responsibility for his/her continued care.

### **XX. Rules And Agreements For Patients Who Drive Vehicles**

1. You agree to not hold the clinic responsible if you have a vehicle accident while participating in the program.
2. You are aware that the medications given in the program may impair driving ability even if you have a tolerance to opioids.
3. You are aware that if you take any medications other than as prescribed, or if you take any abusable drug including, but not limited to, heroin, alcohol, marijuana, cocaine, methamphetamines, or tranquilizers while on this program, you are at an increased risk for being involved in a motor vehicle accident.
4. You agree to inform your family, attorney, and any other concerned party that any accident you have is not caused by medications issued in this program, provided the medications are taken as prescribed.
5. You are aware that you may be discharged if you are involved in a motor vehicle accident while driving to or from the clinic,
6. The medications prescribed in the program will not impair driving or cause accidents unless the patient takes the medication other than as directed or if the patient uses alcohol and/or other abusable drugs concurrently. The program at GGIIM will not accept any responsibility for motor vehicle accidents, victims, or deaths that may involve a patient in the program. As part of the program, the patient consents and agrees to all responsibility for such accidents.

### **XXI. Confidentiality**

The patient's medical information will be revealed only to persons and entities named in a release form signed by the patient. This is required by federal confidentiality regulations.

### **XXII. Scars From Injections**

Participation in the program may require local injections or blood-drawing. Needle puncture is done with the full understanding that they may result in scarring. Patients should fully understand that some drugs that are injected, such as opioids and cortisone, may result in permanent scarring. Patients will not hold the clinic or its providers responsible for such scars.

### **XXIII. Search And Seizure**

1. Enrollment in opioids treatment is done with consent to allow clinic staff to search any patient on clinic premises and to permanently seize the following:
  - a. Urine and containers
  - b. Weapons
  - c. Clinic possessions and records



d. Paraphernalia

2. Search will be done under the following circumstances: a. Suspicion of urine falsification b. Suspicion of theft of clinic possessions c. Reports that patient carries a weapon d. Appearance of bulge or suspicious appearance on patient
3. Any item seized may not be returned, and weapons will be turned over to law enforcement.
4. Discharge from the program may result from a search if it reveals incriminating evidence. Furthermore, it may result in discharge without detoxification and a report to law enforcement.

**XXIV. Injuries, Accidents Or Altercations While Taking Opioids**

1. Patients are usually given a test dose of opioids in the first month of treatment to determine if the patient is sensitive to opioids and if the patient may experience sedation, slurred speech, or other impairment. After the first month, the opioid dose is raised to determine if any side effects may result.
2. No patient is permitted to drive if he/she reports side effects of sedation, slurred speech, sleepiness, or other impairment. After one week, reports of sedation or other impairing side effects are considered to be the result of some substance use such as marijuana, methamphetamines, cocaine, alcohol, heroin, or tranquilizers and not the result of the prescribed opioids.
3. Any patient who has an injury, accident, or altercation while on opioids will be assumed to be misusing a substance, including prescription medication, and this substance misuse is the likely cause of the injury, accident, or altercation. Consequently, the patient will likely be urine-tested to determine the presence of prescribed and/or illicit substances. In addition, any prescription medication that can be misused and that can cause impairment will be discontinued.
4. An accident, injury, or altercation while on opioids is grounds for possible immediate and involuntary discharge.

**XXV. Special Notice For Physicians, Dentists, And Other Health Practitioners Who Treat An Opioid Patient**

1. Treatment with opioids is done only with a clear understanding that the patient will tell every physician, dentist, or other healthcare practitioner that he/she are enrolled in the pain program.
2. Enrollment in opioids treatment is done with the agreement of every patient that this notice and agreement will be shown to every physician, dentist, and healthcare practitioner who attends to the patient.
3. Physicians and other healthcare practitioners are to know that the opioids prescribed in this program have little, if any, sedation if taken as directed. Furthermore, any tranquilizers, benzodiazepines, or muscle relaxants may be abused and may cause sedation. GGIIM and its providers may not be held responsible for any side effects that may result from medications prescribed by physicians outside the clinic.
4. The patient's physicians and healthcare practitioners need to be aware that the clinic reserves the right and has the authority to discontinue any treatment or medication while the patient is in pain treatment.

**XXVI. Responsibility Of Concerned Parties**

1. Each and every patient is enrolled and retained in our program with the express understanding that the patient has shown this orientation and consent agreement to all concerned parties including, but not limited to, family members, healthcare practitioners, pharmacists, and attorneys.
2. Any written notice of concern must be written while the patient is actively enrolled in treatment and not after the patient is discharged for any reason. This includes discharge due to death, incarceration, hospitalization, or failure to pay fees.

**XXVII. Suicide**

Patients and their families are advised that patients with intractable pain often take their own lives. Enrollment is allowed with the express understanding that GGIIM and its providers cannot prevent suicide nor be responsible for this act should it occur. Furthermore, patients agree to and are advised to seek professional help and to inform their families if they experience suicidal thoughts.

**XXVIII. Complaints About Patients From Outside Sources**

We will not tolerate complaints about patients from outside sources, and we require our patients to behave off clinic

premises in such a manner such that we never receive complaints about them.

### **XXIX. Reprimands In Front Of Other Patients Or Visitors**

1. Patients who break any of the conditions listed in this agreement will be immediately reprimanded, even if other patients or visitors are present.
2. Quiet, polite, courteous, and non-offensive behavior is a necessity in the clinic. The protection of one patient's privacy and sensitivities, however, will not be done at the sacrifice of a therapeutic clinic atmosphere and community acceptance of the program.
3. Patients who enroll in the program do so with the express agreement to follow rules and accept reprimands in front of others if the conditions set forth in this document are not followed.

### **XXX. Removal From Premises Of Clinic**

Any patient instructed to leave the clinic premises for a rule violation must do so immediately. Failure to do so will require summoning of local law enforcement.

### **XXXI. Treatment Of Patients Who Are Over-Sedated**

1. Patients who are over-sedated, fall asleep, appear sleepy, or have slurred speech in the clinic will be assumed to have taken too many drugs and will be treated for a drug overdose, which may include, but is not limited to, the following: a. Give injectable opioid- and/or benzodiazepine-antagonists, which may result in withdrawal. b. Paramedic transport to the hospital. c. Opioid prescriptions may be withheld.

### **XXXII. Notice To Insurance Carriers, Attorneys, Pharmacists, Family Members, Health Care Providers, And Other Persons Concerned About One Of Our Patients**

1. The vast majority of the problems our program has encountered over the years has not been medical in nature but has instead been due to a great lack of understanding that a small subset of chronic pain patients experience a degree of severity and debilitation that requires a lifetime of opioid treatment. Patients in this category are often subjects of great discrimination and bias. They often find the pain so severe that they choose suicide as a preferable alternative.
2. We cannot communicate with anyone about a patient unless the patient signs a "Release of information" and requests that records be forwarded to an outside individual or entity. Even on verbal requests of our patients, we cannot engage in verbal discussion or send reports justifying or explaining the program. Federal Confidentiality Regulations only allow us to forward records when requested in writing, Verbal permission by our patients is not sufficient to allow us to legally discuss a patient's medical conditions or the patient's involvement in our program.
3. All intractable pain patients in our program have failed multiple non-narcotic pain treatments, appear incurable, have severe, constant pain, and are already dependent upon narcotic drugs for pain control when, and if, they are accepted to the program. Many patients are already taking one of the following narcotics upon referral and admission to our program: codeine, Vicodin, Lortab', or oxycodone (Percocet, Percodan', or Roxicodone). Be advised that two to four (2-4) doses of any of these opioids for over 20 to 30 continuous days determine dependence,
4. Our program consists of multiple components in addition to opioids drugs and may include physical exercise, nutritional supplements, topical medication, nerve blocks, and non-narcotic medication.
5. Treatment in the program may involve prescriptions for one long-acting and one shortacting opioid. The long-acting opioid is taken regularly to suppress pain, and the shortacting opioid is taken for breakthrough pain. In severe cases, several hundreds or even thousands of milligrams of opioids may be required each month.
6. We recognize that the opioids prescribed by the clinic can be dangerous and addicting. Therefore, only responsible persons can and will be allowed in the program. If we learn that a patient is irresponsible with opioid medication (e.g. prescribed medication is lost, sold, distributed, taken in other than prescribed dosage, taken with alcohol or other abusable drugs), we may discharge the patient even though it may result in the return of severe pain.
7. Suicide is common in patients with severe, intractable pain. We cannot always prevent it, and we accept no medical, legal, ethical, or financial responsibility in such cases.
8. Most patients with severe, intractable pain eventually end up requiring the use of a cane, walker, or wheelchair to ambulate. Such patients may become bedridden and may die at a relatively young age. Our program seeks to provide humanitarian relief and a better quality of life, but we cannot prevent the progression of the underlying painful condition, and we do not accept responsibility for such deaths or complications.

### **XXXIII. Grievances and Arbitration Of Disputes**

Enrollment and treatment in the program is done with the express understanding that the following arbitration and

grievance procedures will be used for settling any dispute involving a claim of malpractice, injury, damage, negligence, theft, discrimination, or breach of confidentiality. The program retains final and absolute determination for decisions on fees, admissions, and rule-breaking. Consequently, they are not subject to grievance and arbitration procedures unless the program agrees to it.

**1. Grievance Procedures**

- a. Patient enlists an ombudsman (e.g. minister, family member, friend, attorney, or social worker).
  - b. Ombudsman communicates, in writing, with the clinic's Medical Director relating the complaint.
  - c. The Medical Director meets with the patient and his/her ombudsman to resolve the grievance.
2. If the grievance is not resolved by the above procedure, both parties will pursue arbitration.
3. Discharge for failure to pay fees or other rule-breaking is not grounds for a grievance or arbitration procedure.
4. If a patient files a lawsuit against the clinic or any of its providers or staff, the patient may be detoxified and referred elsewhere since the clinic cannot competently and effectively provide narcotic treatment under an adversarial arrangement.

**XXXIV. Mental Competency**

Patients must be mentally competent to safely self-administer pain medications. Patients who may have mental illness, Alzheimer's disease, stroke, or other organic brain disease may be discharged from the program at any time by the discretion of the provider and clinic. Such a patient may be given the option of having his/her medication given to a responsible family member for administration to the patient.

**XXXV. Argumentative Patients**

Patients in the program may not argue with the clinic's providers nor its staff regarding medication type, dosage, quantity, or any other issue involving their treatment. Even if disagreeable or judged incorrect by someone, GGIIM personnel must follow their best judgment. Patients who disagree must not argue but should instead find another source of care. GGIIM reserves the right to discharge patients who are argumentative.

**XXXVI. Family Attendance**

GGIIM personnel may require a family member to accompany the patient to a clinic visit at their sole discretion. Failure to attend with a family member when requested to do so will result in a refusal to treat and a rescheduling of the appointment.

**XXXVII. Laboratory Requirements**

Intractable pain patients require regular laboratory testing (e.g. analysis of saliva, urine, and/or blood). Patients who do not obtain or do not consent to the required testing may be discharged from the program.

**XXXVIII. Day-Time Sedatives**

Patients with intractable pain may not take multiple daytime sedatives. These may include:

- \* Anti-depressants
- \* Anti-nausea
- \* Tranquilizers
- \* Muscle relaxants
- \* Other drugs that produce sedation

At its discretion, the program and the provider may refuse to prescribe any or all daytime sedatives and may discharge the patient from the program.

**XIX. Need For Primary Care Physician**

All patients are strongly encouraged to have a primary care physician. The providers at GGIIM cannot act as a substitute. Non-pain medications normally prescribed by a primary care physician will not be prescribed in this program, unless one of the providers is your primary care physician.

**XL. Failure To Improve With Opioids**

Patients who do not improve may be discharged. Treatment with opioids is considered a last stage treatment. When a

patient is given opioids, he/she must make changes to improve his/her pain, quality of life, and daily activities of living. If a patient claims he/she is not improving, the clinic cannot ethically continue treatment due to possible side effects and complications.

**XLI. Dress And Behavior In Clinic**

Many patients in our pain treatment program are extremely ill and some are even near death. Patients must dress in a manner appropriate to attend a medical office. Patients not wearing the proper attire (e.g. no footwear, short shorts, no shirt) or those who come to the clinic with poor hygiene (strong body odor) will NOT receive service. Voices must be kept at a low pitch. Smoking is strictly forbidden in the building. Patients should turn off their phones or put them into silent mode when a provider or staff member is in the patient room.

**XLII. Pharmacy Selection And Notification Of Enrollment**

1. Patients are requested to select a pharmacy that deals frequently with intractable pain patients. In addition, every patient gives our clinic authority to communicate with his/her pharmacy on all matters regarding his/her medical care.
2. There may be times when the selected pharmacy cannot supply the prescribed medications. At that time, the patient may go to another pharmacy on an "emergency basis" to get the prescribed medications. The clinic staff does not have the time to call around and find a pharmacy that can fill your prescription.

**XLIII. Children**

It is recommended that children not be brought into the clinic for office visit appointments.

**CONSENT AND AGREEMENT**

Intractable pain in our clinic is defined and regarded as a serious disease that not only produces debilitation but also causes destructive changes in the cardiovascular, endocrine, and immune systems. Potent drugs will always be needed to control true, intractable pain. The drugs themselves can be abused, misused, and destructive if taken other than prescribed, recommended, or advised.

Treatment by the providers at GGIIM is done only with the strict understanding that the patient has clearly informed his/her significant other, family, attorney, physician, pastor, or any other concerned party of his/her need for treatment of intractable pain. Furthermore, a patient, including the undersigned, signs this "Consent and Agreement" with the firm understanding that no family member is permitted to complain, to interfere with the patient's treatment, or to file any lawsuit against GGIIM, its providers, and medical personnel before or after the patient's death regardless of its cause. The patient agrees to share this document with family members and any other concerned parties.

**I fully understand and agree to the above Intractable Pain Program requirements.** I, the undersigned, agree and consent to all stipulations in this "Consent and Agreement."

Patient Name \_\_\_\_\_ DOB \_\_\_\_\_

Patient Signature \_\_\_\_\_ Date \_\_\_\_\_

Provider Name Dr. Moshe Lewis \_\_\_\_\_

Provider Signature  \_\_\_\_\_ Date \_\_\_\_\_