CHRONIC LOW BACK PAIN CLINICAL RESEARCH STUDY

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(PATIENT NAME)

_____ Patient meets cited inclusion / exclusion criteria for Dx diagnosis of Chronic Non-specific Low Back Pain (CNSLBP) and is returned for reviewed consent and assignment to one of two intervention protocol clinical trials being conducted through Alliant Spine Project's clinical research program at Alliant Continuum Care, PLLC, attention Tim Sobie, PT.

____ The patient is at adverse risk for participation in ANY further physical medicine intervention from any PM&R MD, DO, ND, PA-C, ARNP, or any physical therapy procedure from a PT, PTA, OT/R, COTA, DC, LMP, L.Ac. due to medical complications involving:

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…and these findings are cited in my attached report, including my PLAN cited to refer to this patient to a qualified medical vs surgical specialist not specialized in physical medicine.

_____

Physician Signature Print Name Date

PLEASE **FAX** THIS COVER SHEET + PATIENT REFERRAL + ANY REPORTS to

TIM SOBIE, PT

253-572-4643

(Phone) 253-572-4611

Research Coordinator Assistant: Kenny Li, B.Sc. Kinesiology

Clinical Director & Principal Researcher: Tim Sobie MS, PT (Ph.D. Candidate)

***Medical Evaluation of Subjects Prior to Entry:**

All Subjects must have a medical assessment to rule out serious medical pathology (malignancy, infection, fracture, vascular problems, acute inflammatory or auto-immune disease, etc.) and otherwise meet diagnostic criteria for having *Chronic, Non-Specific Low Back Pain without Radiculopathy*, preferably by an orthopedic or physical medicine specialist. Also have medical clearance to engage in physical exercise without untoward cardiac, respiratory, metabolic, or neurological events that would contraindicate participation in a moderate to potentially strenuous level of activity.

****Inclusion / Exclusion Criteria**: (Age Range 18-80, and open to all genders, classes, ethnicities, orientations, and race)

In short, any patient wishing (or being recommended and referred) to participate as a volunteer subject in this clinical intervention / comparative research trial must present with clinical presentation, diagnosis, and /or history of **chronic, non-specific low back pain (CNSLBP)**, recurrent and/or persistent, and **lasting greater than 3 months**.

- Patients presenting with ***peripheral radicular symptoms distal to knee*** are excluded from the study.
- Patient who present with ***history of surgical lumbar spine fusion*** and/or resultant 'failed spine syndrome' are currently excluded from this study.
- Patients who have ***pending litigation / attorney representation*** are excluded from the study.
- If subjects are believed ***pregnant, or are < 6 –months post-partum*** are excluded from the study.
- If patients ***have undergone any lumbar surgery or any other invasive surgical procedure within the previous 12 months***, they cannot meet criteria to participate in the study. Exception is made for having undergone epidural procedure and /or pain device implants- but **not** if sooner than the previous 3 months.
- **Co-presentation of orthopedic hip, knee, or podiatric foot problems or fibromyalgia syndrome** confirmed by rheumatology (as well as **RA-rheumatoid arthritis** or **other auto-immune condition**) will be considered on a case to case basis prior to entry into study in discussion collaboration with the attending or primary care physician.
- All subjects **must be fluent in written and spoken interpretation of English language**.

Subjects between ages 18 and 80 will be allowed to maintain their current medication regimen throughout the course of the study, but will not be permitted to abruptly increase or abruptly discontinue their dosage. Instead, they can opt to gradually titrate down their average dosing amounts gradually over time, week by week during the 8-week course of the study. Where applicable, limit alcohol to 2 drinks / day. We will permit, track and attain records of difference for medication intake, during the course of treatment, after the 8-weeks, and before the 6-month extended follow-up.

Subjects will be asked not to seek any other form of physical, behavioral, and /or medical/surgical, over-the-counter, or newly prescriptive interventions during the 8-week course of the study *and* to remain as participants in the study.
This would include other physical therapy, massage & bodywork, chiropractic, osteopathy, acupuncture, interventional pain specialists, naturopathic interventions, counselors, biofeedback practitioners, yoga, pilates, personal trainers, energy healers, etc. , and *medical cannabis* –(unless already in use as a medical regimen).

PLEASE SIGN AND RETURN PAGE 1 of this document and provide CONTACT INFORMATION OF PATIENT so that we may contact them for an initial or follow-up appointment to screen as a Prospective LBP Research Participant who further meets the designated diagnostic criteria of CNSLBP for the study (ICD- 724.2). **Thank You for your referral and consideration.** Contact us at 253-572-4611 for questions. Tim Sobie MS, PT, Ph.D. Candidate. www.alliantspine.com