Regenerative / Injection Therapy Patient Screening

REGENERATIVE MEDICINE & INJECTION PROCEDURES PACK

Patient / DOB _____

Proposed procedure _____

Treatment area _____

Current medications _____

Allergies _____

Relevant diagnoses _____

Prior injections/procedures _____

- ■ Active infection
- ■ Immune suppression
- ■ Cancer history/current treatment
- ■ Allergy to planned agents
- ■ Uncontrolled medical condition
- ■ Anticoagulant/bleeding concern
- ■ Pregnant/breastfeeding
- ■ Poor wound healing
- ■ Recent surgery/injection
- ■ Other clinician-review concern

Exam/imaging reviewed _____

Eligibility / modifications _____

Patient / Clinician Signature: _____ **Date:** _____

Second Reviewer / Clinician: _____ **Date:** _____

PRP Procedure Informed Consent

REGENERATIVE MEDICINE & INJECTION PROCEDURES PACK

I consent to collection of my blood, preparation of platelet-rich plasma (PRP), and administration as documented by my clinician. I understand outcomes vary and benefit cannot be guaranteed.

- ■ Blood-draw discomfort/bruising
- ■ Bleeding
- ■ Nerve/tissue injury
- ■ Temporary symptom worsening
- ■ Pain/swelling
- ■ Infection
- ■ Inflammatory reaction
- ■ No improvement / need for additional treatment

Indication _____

Treatment area _____

Preparation system _____

Alternatives discussed _____

Patient / Clinician Signature: _____ **Date:** _____

Second Reviewer / Clinician: _____ **Date:** _____

PRF Procedure Informed Consent

REGENERATIVE MEDICINE & INJECTION PROCEDURES PACK

I consent to collection and preparation of my own blood for platelet-rich fibrin (PRF) treatment. I understand preparation and intended use should be documented for the actual procedure and that results vary.

- ■ Blood-draw discomfort
- ■ Bruising/bleeding
- ■ Inflammatory reaction
- ■ Unsatisfactory response
- ■ Pain/swelling
- ■ Infection
- ■ Nerve/tissue injury
- ■ Need for repeat/additional treatment

Indication _____

Treatment area _____

Preparation/use _____

Alternatives _____

Patient / Clinician Signature: _____ **Date:** _____

Second Reviewer / Clinician: _____ **Date:** _____

Joint / Musculoskeletal Injection Consent

REGENERATIVE MEDICINE & INJECTION PROCEDURES PACK

I consent to the injection procedure identified below. Risks depend on anatomy, medication/product, technique, and patient factors.

- ■ Pain
- ■ Infection
- ■ Allergic reaction
- ■ Vascular injury
- ■ No benefit
- ■ Bleeding/bruising
- ■ Temporary flare
- ■ Nerve injury
- ■ Tendon/cartilage/tissue injury where relevant
- ■ Need for additional treatment

Joint/region _____

Agent/product _____

Guidance method if used _____

Alternatives discussed _____

Patient / Clinician Signature: _____ **Date:** _____

Second Reviewer / Clinician: _____ **Date:** _____

Trigger Point / Soft-Tissue Injection Consent

REGENERATIVE MEDICINE & INJECTION PROCEDURES PACK

I consent to injection of the identified muscle/soft-tissue area using the agent documented in my record.

- ■ Pain/bruising
- ■ Bleeding
- ■ Infection
- ■ Temporary worsening
- ■ Allergic reaction
- ■ Nerve injury
- ■ Pneumothorax or organ injury depending on anatomical site
- ■ No benefit

Treatment area _____

Agent _____

Special anatomical risks discussed _____

Patient / Clinician Signature: _____ **Date:** _____

Second Reviewer / Clinician: _____ **Date:** _____

Product / Biologic Regulatory Disclosure Worksheet

REGENERATIVE MEDICINE & INJECTION PROCEDURES PACK

Use this worksheet to document the exact product and its regulatory status. Do not characterize a human cell/tissue, exosome, stem-cell, Wharton's jelly, amniotic, or other biologic product as FDA-approved unless that specific product and use are in fact approved. FDA has warned that many regenerative products marketed for disease or orthopedic treatment are unapproved.

Product _____

Manufacturer/source _____

Lot/identifier _____

Product category _____

FDA approval/licensure status verified _____

HCT/P or other regulatory basis asserted by supplier _____

Intended clinical use _____

On-label/off-label/unapproved status discussed _____

Patient disclosure provided _____

Source documents retained _____

Patient / Clinician Signature: _____ **Date:** _____

Second Reviewer / Clinician: _____ **Date:** _____

Injection Procedure Record

REGENERATIVE MEDICINE & INJECTION PROCEDURES PACK

Patient _____

Date _____

Procedure _____

Anatomic site _____

Laterality _____

Skin prep _____

Local anesthetic _____

Product/medication _____

Dose/volume _____

Lot/expiration _____

Guidance method _____

Needle/equipment _____

Tolerance _____

Immediate complications _____

Post-procedure instructions _____

Follow-up plan _____

Patient / Clinician Signature: _____ **Date:** _____

Second Reviewer / Clinician: _____ **Date:** _____

Post-Procedure Instructions & Warning Signs

REGENERATIVE MEDICINE & INJECTION PROCEDURES PACK

I received procedure-specific instructions. Depending on the procedure, worsening pain, fever, spreading redness, drainage, new weakness/numbness, shortness of breath, severe allergic symptoms, significant bleeding, or other concerning changes may require prompt clinical or emergency evaluation.

Procedure _____

Activity restrictions _____

Medication instructions _____

Wound/site care _____

Practice contact _____

Follow-up date _____

Patient / Clinician Signature: _____ **Date:** _____

Second Reviewer / Clinician: _____ **Date:** _____

Regenerative / Injection Adverse Event Record

REGENERATIVE MEDICINE & INJECTION PROCEDURES PACK

Patient/record identifier _____

Procedure/product _____

Date/time _____

Lot/source _____

Symptoms/findings _____

Severity _____

Immediate treatment _____

Clinician notified _____

Transfer/EMS _____

Manufacturer/vendor notified if appropriate _____

FDA MedWatch or other reporting considered _____

Outcome _____

Follow-up _____

Governance/root-cause review _____

Patient / Clinician Signature: _____ **Date:** _____

Second Reviewer / Clinician: _____ **Date:** _____

Procedure Follow-Up Assessment

REGENERATIVE MEDICINE & INJECTION PROCEDURES PACK

Procedure/date _____

Treatment area _____

Pain/function before _____

Pain/function now _____

Patient-reported benefit _____

Activity/function change _____

Medication change _____

Adverse effects _____

Exam/findings _____

Next plan / additional treatment _____

Patient / Clinician Signature: _____ **Date:** _____

Second Reviewer / Clinician: _____ **Date:** _____

Patient Expectations & Non-Guarantee Acknowledgment

REGENERATIVE MEDICINE & INJECTION PROCEDURES PACK

I understand response to injection or regenerative procedures varies and no specific degree or duration of improvement is guaranteed. I understand alternatives, including no procedure and other established treatments, should be discussed based on my condition.

Patient goal _____

Expected course discussed _____

Alternatives discussed _____

Questions answered _____

Patient / Clinician Signature: _____ **Date:** _____

Second Reviewer / Clinician: _____ **Date:** _____