

# Unproven Stem Cell Intervention Patients' Bill of Rights

Patient-centered care is the provision of safe, effective and timely medical care achieved through cooperation among the physician, an informed patient (and family) and a coordinated healthcare team. The Unproven Stem Cell Intervention Patients' Bill of Rights protects you when you volunteer as a patient or as a healthy subject to receive an unproven stem cell intervention. Your rights and safety are protected by interventions that provide an awareness of your medical choices, of any risks or benefits, and of possible consequences of choosing an unproven Intervention and how it may change your arthritis care management plan, affecting future treatment options. The list below summarizes your rights as a patient and is imperative to review and discuss with the physician treating you for your arthritic condition (may be reviewed in combination with provisions listed in the Arthritis Foundation Innovative Care Provisions).

You have the right:

- To be treated regardless of socioeconomic status;
- To safe, considerate and respectful care, provided in a manner consistent with your beliefs;
- To receive care from a licensed, board-certified physician specializing in your arthritis disease state (AAOS Board-certified in orthopaedics and/or sports medicine, musculoskeletal, rheumatology fellowship-trained) as well as proper training in orthobiologics through an accredited CME provider (AAOS/ORS; science, benefits & risks, formula differentiations, delivery, adjuvant interventions, rehab, recovery, etc.);
- To receive complete information about diagnosis, treatment, and prognosis from your physician, in terms that are easily understood;
- To receive information necessary for you to give fully informed consent prior to an unproven intervention, including a description of the intervention, all risks and potential benefits, the probable duration of any incapacitation, any alternatives and how the intervention may exclude you from receiving a future treatment or future participation in a clinical trial;
- To contact someone who can correctly address any question related to an observed change that may be resultant to the treatment. (If you notice something that is unexpected, ensure there is someone available to reach immediately to discuss it. Since such therapy can potentially have other, unexpected side effects, being able to report and get a response in a very timely manner might be crucial);
- To request the facts and ask for information before getting treatment—even if the stem cells are your own;
- To your stem cells being prepared in a Good Manufacturing Practice (GMP) Facility;
- To ownership of your stem cells and approval or disapproval of your cells being commercialized/cultured/used;
- To full disclosure of anticipated costs and insurance concerns with coverage or denial or coverage of related and/or future Interventions;
- To full disclosure of anticipated costs when the Intervention is not part of a clinical trial, but instead an unregulated, experimental intervention without ethics committee or FDA oversight (physician-directed and off-label use);
- To know where to go for continuity of care if this differs from the intervention facility;
- To follow up, both short (for example, up to two years for knee OA interventions) and long-term (beyond two years for knee OA);
- To expect that a medical summary for the intervention will be sent to your referring physician;
- To expect that all communications and records pertaining to your care will be treated as confidential to the extent permitted by law;
- To ask if the FDA has reviewed and approved the intervention;
- To ask why not if the FDA has not approved the intervention;
- To ask your physician to confirm the FDA has reviewed the intervention by showing you the documentation on safety and efficacy data;
- To ask your physician if your Intervention is part of a study and to give you the FDA-issued Investigational New Drug (IND) application number and the chance to review the FDA communication acknowledging the IND. A clinical trial requires an IND application and you must sign a consent form that explains the experimental intervention;
- To ask the study sponsor for the clinical investigator's brochure, which includes a short description of the product and information about its safety and effectiveness;
- To not be charged when participating in a clinical trial;
- To the results of your trial being made available to you in a summary with context most valuable to patients (regardless of results being negative or positive);

Communication is the Best Medicine

What can you do?

- When appropriate, discuss the following with your treating physician, the one you see who is specialized in care of your arthritis condition (the same questions apply if you seek interventions with a stem cell intervention provider who is not already part of your care management team):
  - Diagnosis
  - Treatment alternatives
  - Course of care
  - Expectations for treatment outcomes and recovery time
  - Benefits and risks of treatment or possible complications
  - Pre-treatment tests or evaluations needed
  - Stem cell type of intervention details
    - what stem cells exactly (auto/allo, derived from where, passage #, same day vs cultured, harvesting details, donor details, storage details, growth medium- bovine/allergies, etc.)
    - additional medications
    - steroids - ensure any adjuvant medications/injections are not cytotoxic for the cells you're receiving)
    - related interventions- cell harvest, cell implantation- injectable, surgery, etc.
    - prior and expected outcomes
    - contraindications (auto-immunity concerns, immune suppressed, cancer, medications, etc.)
- Ask about your physician's experience in diagnosing and treating your type of condition (e.g., whether board certified in the specialty, how many interventions does he/she perform each year, whether or not he/she will perform the intervention, prior complications, how resolved).
- Come prepared with lists that include:
  - All the medications you take including prescription, over-the-counter, herbal and vitamins
  - Your treatment and surgical history with dates
  - Your complete family medical history
  - Questions you want answered
- Bring a family member or friend with you.
- Ask questions, voice concerns and speak up when you do not understand. Ask your physician how he/she likes to communicate after the visit: calls, emails, times available, etc.
- Always be honest and complete when talking with your physician. Share your view and don't hold back information.
- Ask your physician for easy-to-read brochures or other patient-friendly literature so you can learn about your diagnosis, medical tests and treatment.

If you still have concerns after adequate discussion with your physician consider asking:

- If I want a second opinion, whom can I consult?
- Will I have pain following the Intervention? What pain relief or pain control measures will I be given?
- What are my limitations during recovery? Will I need assistance at home afterwards? For how long?
- When can I return to work? When can I drive my car? When can I have sexual activity?
- Is there anything that I can do to increase my chances for a successful outcome?

If you are participating in a research clinical trial, the consent form identifies the Institutional Review Board (IRB) that assures the protection of your rights. You may contact the IRB with any concerns. If you are interested in learning more about clinical trials and or searching for legitimate stem cell clinical trials which are regulated and compliant with an approved clinical research study protocol and informed consent, please refer to the Arthritis Foundation's patient education resources, and you may search for trials on the Arthritis Foundation's Arthritis Trial Finder.

**Verification of Review**

Patient signature		Date	
Physician signature		Date	