

Patient Registry Information Sheet

Dear Functional Medicine Patient,

Thank you for visiting the Center for Functional Medicine at Cleveland Clinic! Our medical appointments are designed to provide you with knowledge and practical experience to facilitate health lifestyle practices that lead to optimal health.

The Center for Functional Medicine collects clinical care and outcomes data on all patients. This data may be utilized for research purposes, or to improve both clinical care and departmental operations. We recently launched a registry for patients participating in one-on-one appointments or shared medical appointments in the Center for Functional Medicine. A patient registry is a collection - for one or more purposes - of standardized information about a group of patients who share a condition or experience. The registry will enable us to answer research questions, develop research hypotheses, monitor patient outcomes, study best practices in care or treatment, and improve/monitor the quality of health care that we provide. Patients are automatically enrolled but you can decide if you want to opt-out, or be excluded, from the registry.

If you decide to participate in our registry, standard of care information will be collected from your Electronic Medical Record (EMR) starting with your first visit and at follow-up time points which vary based on the program you've enrolled in. Long-term follow-up data will be collected at 3, 6, 9, and 12 months. The following information will be collected from your EMR:

- Identifiable Information (Name, Date of Birth, Medical Record Number)
- Demographic Information (Gender, Race, Ethnicity, Age, Insurance Provider)
- Visit Information (Date(s) of Service, Provider Name(s), Diagnoses, Vitals, Body Composition, Laboratory Results)
- Quality of Life Questionnaires (Medical Symptom Questionnaire, PROMIS) and Program Surveys
- Medication/Supplementation History
- Costs (related to visits, procedures, and supplements)

The registry is considered low risk. Every possible measure will be used to maintain your privacy and confidentiality. The above information will be stored in a password protected database and maintained on a secure encrypted Cleveland Clinic server. Only authorized medical and research personnel will have access to identifiable data. Data analysts' will not be given access to your name or other identifiers. Outcomes data will be reported in aggregate, not by or with personal identifiers.

You will not personally benefit from participating in the registry, however, the information we gather from you may generate knowledge that can help others who wish to practice lifestyle modifications to promote health.

Your participation in this registry is completely voluntary and you may opt-out, or stop your participation, at any time. If you choose to opt-out of the registry, your current or any future relationships with the Center for Functional Medicine will not be affected.

If you have any questions regarding the registry or you do not wish to have your data used for research purposes, you must email me at shallcaccf.org with your request to opt-out and provide your full name, phone number and date of birth. If you have any questions regarding your rights as a registry participant, please call the Cleveland Clinic Institutional Review Board at (216) 444-2924. Thank you for your participation in the registry.

Sincerely,

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