

FORMULA #12 CLINICAL TRIAL REGISTRATION FORM

[all information is kept strictly medically confidential]

Parkinson's Group (if applicable): _____ Date: _____

Name: _____ Age: _____ Sex: Male Female

Height: _____ Weight: _____ Age at diagnosed: _____ Ethnic/racial background: _____

Address: _____
 _____ } [PLEASE PRINT]

Telephone: () - - Physician (optional): _____

Email: _____

Confirm Eligibility Criteria For The Formula #12 Trial — Please check boxes if they apply

1. **I do not have the following medical conditions:**
 - (a) any currently ongoing severe psychological or mental health problems,
 - (b) any life-threatening diseases, (c) diabetes for which I am taking insulin..
2. **I do not have allergies to soy, soybeans, lemons or lemon juice, or alpha lipoic acid.**
3. **I am not under any current therapy for cancer using chemotherapy.**
4. **I am not under 21 years of age, pregnant, or breast-feeding a child.**
5. **I have not had Parkinson's diagnosed for more than approximately 5 years.**

Prescription drugs [for Parkinson's and any other diseases]: _____

Dietary Supplements [list all]: _____

Current Parkinson's symptoms:

	<u>Level of Severity</u>				
[check each box that applies and rank its severity]	(0	1	2	3	4)
	not	infrequent	some	bad	very
	a problem	problems	problems	bad	bad
<input type="checkbox"/> Tremors in hands and/or legs _____					
<input type="checkbox"/> Speech difficulties _____					
<input type="checkbox"/> Rigid facial expression _____					
<input type="checkbox"/> Heavy and/or rigid extremities _____					
<input type="checkbox"/> Constipation _____					
<input type="checkbox"/> Difficulty with posture _____					
<input type="checkbox"/> Mobility problems _____					
<input type="checkbox"/> Confusion _____					
<input type="checkbox"/> Hallucinations _____					
<input type="checkbox"/> Balance difficulties _____					
<input type="checkbox"/> Fatigue _____					
<input type="checkbox"/> Chewing or eating difficulties _____					
<input type="checkbox"/> Stiffness or weakness _____					
<input type="checkbox"/> Slower movements _____					
<input type="checkbox"/> Weak voice _____					
<input type="checkbox"/> Difficulty with daily activities _____					
<input type="checkbox"/> Other: _____					
<input type="checkbox"/> Other: _____					

Consent to Enroll in a Clinical Trial of the Formula #12 Dietary Supplement

Purpose of Informed Consent: In current medical practice, subjects participating in the research investigation of a dietary supplement, device, or procedure must give informed consent to such participation, since informed consent includes an understanding of the investigation. The purpose of this research study is to determine the quality of life health benefits, if any, of the Formula #12 dietary supplement including whether use of Formula #12 is associated with any enhancement of the quality of life of Parkinson's patients. If you have questions during the course of the clinical trial, or have questions regarding your rights as a research subject participating in this trial, you may call the clinical trial sponsors at 402-551-1020 [you may call any time day or night]. You understand that your general health and Parkinson's symptomatology will be followed by questionnaires while taking the Formula #12 dietary supplement. You recognize that you may or may not experience any change in your Parkinson's Disease presentation. You recognize that it has not been confirmed whether Formula #12 dietary supplement will have any effect on your Parkinson's Disease presentation. You understand that the primary purpose of this study is to determine whether or not any such effects can be identified. You have been informed that you may withdraw from this clinical trial at any time for any reason at no penalty. If the trial administrator determines that you may no longer be eligible for participation according to the inclusion or exclusion criteria, or for other reasons as may arise during the trial, participation may also be terminated as determined by the trial administrator.

Confidentiality of Records: The results of this research may be published to inform other physicians and scientists. However all your records will remain confidential, and at no time will your name or other identifying information be released to the public or used in published reports. You understand that if your records in this trial are inspected by government agencies as required by law for monitoring clinical research trials, the study sponsor will use all reasonable efforts to protect your privacy and confidentiality of all your medical information.

Compensation and Fees: You understand you will receive the Formula #12 dietary supplement without charge during the time you elect to remain on this trial or until participation terminates [you may withdraw at any time]. There are no trial fees or charges for the Formula #12 supplement for as long as you participate in this study. Also there are no shipping or handling fees. If it is determined that another extended study may follow this one, and if you desire, every effort will be made to continue to provide you Formula #12 until such further studies begin, without charge to you, if such supplement inventory is available to provide to participants. Priority for enrollment will be preserved for participants in this study for future studies without obligation on the part of the participant.

Information on Research: You agree to take the recommended daily amount of Formula #12 daily which shall be comprised of four separate doses. You understand that you will not be required to alter any other aspect of your normal activities. Weekly you will be contacted by your trial administrator to fill out a questionnaire with regard to any changes in your personal health history. It is not known if the Formula #12 dietary supplement being studied can favorably impact any Parkinson's Disease symptoms. The supplement was selected based on a review of peer-reviewed medical literature and on previous limited Case Study results. There is no unequivocal proof or wide consensus among neurology specialists that any dietary supplement will have any positive or negative effect on Parkinson's Disease.

Symptoms and Side Effects: Your reaction to Formula #12 is not known. You will however be monitored so that adverse or unpleasant side-effects will be discovered if any should occur. The supplement dosage may be reduced, or stopped for a period of time, or discontinued completely in the event of any adverse side-effects. You agree to report any symptoms or changes in your health to the study coordinator(s). There have been no previous reports of any side effects in the two years of case study work with this supplement.

Risks and Benefits: The dose level of the Formula #12 is within the framework of previously accepted clinical use. There is no reason to think this supplement will in any way harm you, but this is not known. If there are any potential adverse effects with the supplement, you will be informed that you must withdraw from the study and stop taking the supplement. You may or may not experience any favorable outcomes whether you take or do not take the supplement used in this study. You may develop some positive health and well-being effects as a result of taking the supplement. Such benefits cannot be predicted or guaranteed, and none have been promised to you. The published scientific literature relevant to the supplement in combination with past case studies suggest some potential beneficial effects may impact Parkinson's Disease symptoms in general, but again, none have been promised to you. Dietary supplement benefits cannot be predicted with certainty. If beneficial effects to you are evident during participation in the study, it may be suggested that you continue using the dietary supplement after completion of the trial. If the trial administrator is able to make suitable arrangements and there is product inventory, every effort will be made to provide Formula #12 without any charges at least until further trials can be arranged [which will also be pursued as a no-charge trial]. This supplement may be found to be useful for improving the quality of life of Parkinson's patients. This could help many such affected people in the world. If you choose not to take part in this study, you can pursue any other measures to enhance your health and general well-being. You are not obligated to take any actions if you decide not to enter this trial, and you may be eligible for any other available research programs, trials, or studies as offered by others. Your participation in this study is entirely voluntary. **By signing below, you indicate (1) you have fully reviewed and understand the contents of this consent form, (2) willingly consent to participate, and (3) authorize your trial sponsors to begin this trial.**

X _____
Participant's Name (please print)

X _____
Participant's Signature

X _____
Date

To enroll, complete both sides, sign where indicated, and return to: TRI — 418 N. 38th Street — Omaha, NE 68131
[or fax to: TRI — 402-556-5743]

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