

INFORMED CONSENT TO PARTICIPATE IN INVESTIGATIONAL STUDY OF ENZYME POTENTIATED DESENSITIZATION
INVESTIGATIONAL REVIEW BOARD: GREAT LAKES COLLEGE OF CLINICAL MEDICINE (GLCCM)

TITLE OF PROJECT:

Investigation of the efficacy of EPD immunotherapy on various conditions involving immune dysfunction and various other medical conditions.

PURPOSE AND LENGTH OF STUDY:

Dr. W.A. Shrader, Jr. (the principal investigator), and Dr. «LASTNAME», an officially registered investigator for this study, will be doing a 5 year study to determine the possible beneficial effects of EPD immunotherapy for various medical conditions as outlined in the Initial Evaluation EPD Questionnaire. EPD immunotherapy is still considered investigational in this country, and is neither approved or disapproved by the FDA (nor is any immunotherapy technique used in this country approved by the FDA).

PROCEDURE:

After suitable testing has been done, as outlined by Dr. «LASTNAME», and after following the guidelines in the EPD Patient Instruction Booklet (American EPD Society), you will be given a treatment of EPD allergens, as outlined in the EPD Patient Instruction Booklet. Treatments will be given intradermally (into the skin) on the forearm or by the cup method if deemed appropriate, at an interval of generally every 2 months for the first 6-10 treatments. Treatments also may be given every 3 months or longer, if determined appropriate after the second treatment, during the first 6 to 10 treatments, or 1 to 3 times yearly for pure seasonal hay fever, if a patient is *totally asymptomatic* between seasons. After that time, treatments can usually be lessened in frequency. You will be required to wait in the office for up to ½ hour after your treatment, or longer if you have a significant local reaction, at your doctor's discretion.

You may discontinue treatments at any time if you feel they are not working for you. In addition, you may discontinue treatments when you feel you no longer require them.

AVAILABLE ALTERNATIVES:

Instead of receiving EPD immunotherapy, you may elect to follow certain strict dietary guidelines to improve your condition(s). You may also elect to receive "standard" allergy shots, which are given anywhere from 2 to 3 times weekly to once a month. Also you may elect to be treated sublingually with allergen extracts administered according to a dose schedule (some or all of these options may not be offered at this office). Several "alternative" treatments are also available to treat your problems (acupuncture, homeopathy, herbs, and others).

BENEFITS AND RISKS (SIDE EFFECTS):

Adverse reactions are not common with EPD therapy. However, some patients may experience symptoms from 2 to 5 days after an EPD treatment. These usually consist of a worsening of your usual symptoms, or occurrence of symptoms you have had before. A small minority of patients have reported adverse reactions for up to 3 weeks after an EPD treatment. Most all adverse reactions, when and if they occur, are less with the second treatment and subside by the third treatment. Local swelling is not common.

Patients being treated for virally-induced Chronic Fatigue Syndrome (CFIDS) with the arginine protocol are likely to experience a recurrence of their *original* symptoms with one of the first 3 treatments. These symptoms may be severely disabling, and may last until the next treatment. Treatments are given every 10 weeks while using arginine. However, with the treatment following the return of severe symptoms, the symptoms will likely disappear or considerably lessen, after which time you will generally have been successfully treated for the viral component of your illness. **Patients who stop EPD after having had an adverse reaction to one of the first 3-5 treatments are at risk for considerable worsening of symptoms for up to a year or longer. When you sign this form, you must assume you will make a commitment to a minimum of 6 treatments when you start EPD, to avoid this possibility.**

Allergy testing on the skin may cause you to not feel well for several days after testing. In addition, you may experience swelling of several of the test sites, or even mild hives, for which you can take an antihistamine. Severe or even fatal reactions have also been known to occur from skin testing, but these are rare and have not occurred with proper testing methods. Bruising and/or pain may occur after a blood test (venipuncture).

The benefits of EPD have been shown by a number of studies and a list of these references are available from this office. EPD has shown distinct benefit for use in the treatment of a considerable number of medical conditions not treatable by any other method of immunotherapy, such as hyperactivity, ulcerative colitis, rheumatoid arthritis, CFIDS and moderately severe adverse reactions to chemicals, to name just a few.

PREGNANCY:

EPD immunotherapy is considered to "investigational" in the U.S. During over 20 years' use in the U.K. and elsewhere, EPD has never been associated with any known birth defect, and has been used during pregnancy. However, *Dr. McEwen legally must advise EPD not be given during pregnancy.* We therefore must advise you that the effects of EPD if used during pregnancy must be considered uncertain. Should you chose to continue EPD when you are pregnant, your signature on this consent form hereby releases Dr. «LASTNAME», Dr. Shrader, Dr. McEwen and GLCCM unconditionally from any and all liability, as a result of any real or theoretical adverse effects of EPD on mother or child during pregnancy or after birth. Should you become pregnant during EPD therapy and wish to discontinue it, you are free to terminate your EPD immunotherapy at any time.

IF YOU HAVE QUESTIONS OR AN EMERGENCY:

Dr. _____ or his/her staff will be available to assist you whenever possible, and during office hours. The doctor can be reached at his/her office, at home if he/she has a listed phone number, or you can call the _____ hospital emergency room at _____ in an emergency.

FREE TO DECLINE:

You are free to decline participation in this study, or to withdraw consent and discontinue participation at any time without prejudice to yourself.

NO COMPENSATION TO PARTICIPANTS

No compensation will be provided by the investigator or other party, except by your insurance company as their usual reimbursement for your testing and treatment.

I understand that the Great Lakes College of Clinical Medicine has no policy to medically treat or compensate for physical injuries incurred as a result in participating in biomedical or behavioral research, on in this study.

I also understand that Dr. «LASTNAME» or his/her staff have no policy to compensate for physical or other injuries incurred as the result of participating in biomedical, behavioral research or in this study, except as specified by «STATE» State Malpractice Insurance law.

CONFIDENTIALITY:

All personal patient records will remain strictly confidential to Dr. «LASTNAME» and his/her staff. Study data will be available for review by Dr. W. A. Shrader, Jr., the EPD Study Group and Dr. L. M. McEwen of London, England. The Institutional Review Board of the Great Lakes College of Clinical Medicine and the FDA will also, for your safety, have the authority to inspect and review these records at any time. This data will eventually be combined with data from other participants for publication, and will be presented and/or published alone or combined with other data. You will be notified of any changes in this protocol and may withdraw your consent if you should wish.

COPY OF THIS CONSENT FORM:

You may have a copy of this consent form at any time.

COSTS:

The costs of testing and treatment with EPD have already been -- or will be -- reviewed with you, and a written estimate of all costs involved has been (or will be) given to you or is available. Insurance should cover a portion of your office visits and testing, but may not cover nutritional supplements or EPD immunotherapy treatments.

WARRANTIES:

No warranties expressed or implied are made for the safety of the nutrients, medications, EPD itself or other products provided or required by this study.

WAIVER OF LIABILITY:

I, _____, and Dr. «LASTNAME» (Investigator) grant a waiver of liability to the Great Lakes College of Clinical Medicine and its Institutional Review Board.

PERMISSION TO PUBLISH:

I give my permission to publish the results of this investigational medical research project.

DATE OF SIGNATURE: _____

PATIENT'S NAME: _____

PATIENT'S SIGNATURE: _____

WITNESS'S SIGNATURE: _____

NOTE: If you experience what you feel are severe problems with EPD, and your physician is unable to address them, or you have not made your physician aware that you have had problems, please notify, in writing: Dr. W.A. Shrader, Jr., Principal investigator, 141 Pasco de Peralta, Santa Fe, NM 87501.

American EPD Society Guidelines for Use of EPD (*sign and return to us*)

Recognizing that the use of EPD is a privilege and understanding the necessity of full cooperation on the part of all EPD users in America, I, the undersigned agree to follow the guidelines established by the AEPDS and listed below in regards to EPD immunotherapy.

1. *I will not advertise EPD by name in any media whatsoever, unless given express permission by Dr. Shrader in writing. However, I may mention EPD by name to groups to which I've been invited to speak regarding EPD or about my treatment techniques in general. I may mention EPD in writing or interviews, which will be produced in writing or other media, as long as the information is specifically solicited. If I mention EPD, I will make it clear that EPD is not FDA-approved, but is supervised under an FDA-approved investigation protocol and IRB.*
2. *I will use the IRB-approved EPD Patient Instruction booklet (the "pink book"), available from Dr. W.A. Shrader, Jr., for all patients, as is part of the IRB Protocol. The complete, original Booklet will be provided to all of my patients (no modifications or copies) in order to ensure their understanding of their responsibilities. In addition, I will follow the guidelines in this booklet as will my staff. If I have concerns about what is in the booklet, I will address those to Dr. Shrader.*
3. *I will require that all patients (except those with simple, seasonal hay fever) follow the strict 3 to 4-day EPD diet as outlined in the Patient Instruction Booklet.*
4. *I will use the Vitamin A, Vitamin D, magnesium, zinc and folic acid schedule on all patients on EPD (age appropriate), except when treating simple, uncomplicated, pollen-sensitive rhinitis, or unless there are specific contraindications (caution for Vitamin A with women who might become pregnant).*
5. *I will follow the recommended bowel preparation protocols for all patients who I recognize have any significant problems with dysbiosis or who have autoimmune disease, unless contraindicated, taking patients' ages into consideration.*
6. *If I desire to change any of the mandated guidelines for dosage, usage or medications associated with EPD, I will first contact Dr. Shrader or Dr. McEwen for advice regarding the advisability of this action. If either advises me the modification will not likely interfere with EPD, I will contact the EPD Study Office for a Registered Protocol Number for the proposal.*
7. *I will give a full orientation, done by my staff or myself to all patients on EPD immunotherapy, after they have read and understood, to the best of their ability, the EPD Patient Instruction Booklet, before they receive an EPD treatment.*
8. *In complicated patients, I will realize that patients need to be treated as "whole" patients, and I will address such factors, other than simply the treatment of "allergy". I will be especially aware of the important role of appropriate gastrointestinal evaluation and therapy, as the function of the gut may have significant impact on the outcome of EPD therapy, especially with the complicated patient and the patient with significant autoimmune disease. I will be certain that nutritional problems are rectified to the best of my ability before starting EPD.*
9. *I will participate in the IRB protocol, using the questionnaires from the EPD Study Group, and the approved Informed Consent forms, and I will submit all forms to the Study Office in a timely fashion.*
10. *I will not treat pregnant women with EPD, except at my own risk, as Dr. McEwen has mandated against use of EPD in pregnancy. Further, if I choose to do this, I will obtain signed, specific informed consent.*
11. *When I see another EPD physician's patient who is visiting my area who feels he or she is doing well on EPD, but simply needs their injection, I will neither alter the dose nor perform other than a "simple" visit unless I first consult with that physician. My charge for the injection shall be "reasonable and customary".*
12. *If I see another physician's patient who feels he or she is not doing well on EPD, and has seen me partially or entirely because of that fact, I will advise the patient of any further work-up or testing I feel is necessary. I will contact the other physician and discuss the case with him or her in order to obtain a more complete understanding, and to make the other physician aware of problems his or her patient is having.*
13. *Should one of my patients request a consultation with Dr. Shrader, I will honor that request and agree to allow Dr. Shrader to act as a consultant with me and/or with the patient supervised directly by me. I understand that Dr. Shrader may charge the patient for the time spent discussing the patient with me and with the patient. Treatment recommendations by Dr. Shrader will be discussed with me and will be described in writing by Dr. Shrader. I understand that this does not apply to "routine" questions regarding patients or general use of EPD from me or my staff, which may be answered briefly by phone, fax or other electronic communication by Dr. Shrader or his staff.*
14. *I will not allow EPD to be administered if I am not physically present in the office.*
15. *I will neither collect any data from this study intended for publication in any scientific journal, nor will I submit any data regarding EPD immunotherapy whatsoever for publication until the initial study data has been published by Dr. Shrader (and/or the Study Group as a whole). Should I wish to write about EPD after that time in any "non-medical" journal, I will not do so without written permission from the Principal Investigator (Dr. Shrader) and from Dr. L. M. McEwen. I understand there are no restrictions on publication in any medical journal after the initial data is published by the EPD Study Group.*
16. *If I am uncertain of any of the above Guidelines, I will contact the EPD Central Office.*

Signed _____ Printed Name: _____ Date _____

INFORMED CONSENT TO PARTICIPATE IN INVESTIGATIONAL STUDY OF ENZYME POTENTIATED DESENSITIZATION
INVESTIGATIONAL REVIEW BOARD: GREAT LAKES COLLEGE OF CLINICAL MEDICINE (GLCCM)

The FDA requires the inclusion of the following *PATIENT BILL OF RIGHTS* (in italics immediately below):

This is my consent for EPD Immunotherapy.

Are you participating in any other research project? ___ Yes ___ No

Experimental Subject Bill of Rights

Persons who participate in a medical experiment are entitled to certain rights:

These rights include but are not limited to the subject's right to: Be informed of the nature and purpose of the experiment;

Be given an explanation of the procedures to be followed in the medical experiment, and any drug(s) or device(s) to be utilized;

Be given a description of the any attendant discomforts and risks reasonably to be expected;

Be given a disclosure of any benefits to the subject reasonably to be expected, if applicable;

Be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;

Be informed of the avenues of medical treatment, if any available, to the subject after the experiment if any complications should arise;

Be given the opportunity to ask questions concerning the experiment or the procedures involved;

Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;

Be given a copy of the signed and dated consent form;

Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

TITLE OF PROJECT:

Investigation of the efficacy of EPD immunotherapy on various conditions involving immune dysfunction and assorted other medical conditions.

PURPOSE AND LENGTH OF STUDY:

Dr. W.A. Shrader, Jr., (the principal investigator of this study), and Dr. «LASTNAME», an officially registered investigator for this study, will be doing a long-term study (over 5 years) to determine the possible beneficial effects of EPD immunotherapy for various medical conditions as outlined in the Initial Evaluation EPD Patient Questionnaire. EPD immunotherapy is considered "investigational" in this country, and is not yet approved by the FDA.

PROCEDURE:

After suitable testing has been done, as outlined by Dr. «LASTNAME», and after following the guidelines in the EPD Patient Instruction Booklet (American EPD Society), you will be given a treatment of EPD allergens, as outlined in the EPD Patient Instruction Booklet. Treatments will be given intradermally (usually between 1-5 injections into the skin) on the forearm(s), or rarely the legs, or by the cup method if deemed appropriate, at an interval of generally every 2-3 months for the first 6-9 treatments. EPD Treatments may be given less often than every 2-3 months any time after the second treatment, if determined appropriate by your physician, or 1 to 3 times yearly for pure seasonal hay fever, if you are *totally asymptomatic* between seasons. EPD treatments can generally be lessened in frequency over time. You will be required to wait in the office for up to ½ hour after your treatment, or longer if you have any significant local reaction(s), at your doctor's discretion.

You may discontinue treatments when you feel you no longer require EPD (average is often between 16-18 treatments).

AVAILABLE ALTERNATIVES:

Instead of receiving EPD immunotherapy, you may elect to follow certain strict dietary guidelines to improve your condition(s). You may also elect to receive "standard" allergy shots, which are given anywhere from 2 to 3 times weekly to once a month. Also you may elect to be treated sublingually or by injection with various allergen extracts administered according to a dose schedule (some or all of these options may not be offered at this office). Several "alternative" treatments are also available to treat your problems (acupuncture, homeopathy, herbs and others).

BENEFITS AND RISKS (SIDE EFFECTS):

Adverse reactions are not common with EPD therapy. However, some patients may experience symptoms from 2 to 5 days after an EPD treatment. These usually consist of a worsening of your usual symptoms, or the occurrence of symptoms you have had in the past. A small minority of patients have reported adverse reactions for up to 3 weeks after an EPD treatment. Most all adverse reactions, when and if they occur, are less with the second treatment and usually subside by the third treatment. Local swelling is not common, but can occur, especially with the inhalant portion of EPD.

Patients being treated for virally-induced Chronic Fatigue Syndrome (CFIDS) with an arginine protocol are likely to experience a recurrence of their *original* symptoms with one of the first 3 treatments. These symptoms may be severely disabling, and may last until the next treatment. Treatments are given every 10 weeks while using arginine. However, with the treatment following the return of severe symptoms, the symptoms will likely disappear or considerably lessen, after which time you will generally have been successfully treated for the viral component of your illness.

Warning: *Patients who stop EPD after having had an adverse reaction to one of the first 1-3 treatments may be at risk for considerable worsening of symptoms for up to a year or longer. Considering this, it is assumed you will make a commitment to a minimum of 6 treatments when you start EPD, to avoid this possibility. (However, children under 12 years of age – and rarely adults – could require less than a total of 6 treatments of EPD immunotherapy to receive long-term or permanent benefits).*

Allergy testing on the skin may cause you to not feel well for several days after testing. Also you may experience swelling of several of the test sites, or even mild hives, for which you can take an antihistamine. Severe or even fatal reactions have also been known to occur from skin testing, but these are rare and have not occurred with proper testing methods. Bruising and/or pain may occur after a blood test (venipuncture).

Results of EPD trials have been published, and a list of these references are available from this office. EPD has shown apparent benefit for use in the treatment of a considerable number of medical conditions not treatable by any other method of immunotherapy, such as hyperactivity, ulcerative colitis, rheumatoid arthritis, chronic fatigue, moderately severe adverse reactions to chemicals and other medical conditions.

PREGNANCY:

EPD immunotherapy is considered to be investigational in the USA. In nearly 30 years' use in the U.K. and elsewhere, EPD has never been associated with any known birth defect, and has been used during pregnancy. However, we and Dr. McEwen legally must advise EPD not be given during pregnancy. We must advise you that the effects of EPD if used during pregnancy must be considered uncertain. Should you chose to continue EPD when you are pregnant, your signature on this consent form hereby unconditionally releases Dr. «LASTNAME», Dr. Shrader, Dr. McEwen, GLCCM and all other parties involved in your treatment with EPD immunotherapy from any and all liability which might occur as a result of any real or theoretical adverse effects of EPD on mother or child during pregnancy or after birth. *Should you become pregnant during EPD therapy and wish to discontinue EPD, you are free to terminate therapy at any time.*

IF YOU HAVE QUESTIONS OR AN EMERGENCY:

Dr. «LASTNAME» or his/her staff will be available to assist you whenever possible, and during office hours. The doctor can be reached at his/her office, at home if he/she has a listed phone number, or you can call the _____ Hospital emergency room at _____ in an emergency.

FREE TO DECLINE:

You are free to decline participation in this study, or to withdraw consent and discontinue participation at any time and for any reason without prejudice to yourself (see

NO COMPENSATION TO PARTICIPANTS

No compensation will be provided by the investigator or other party, except by your insurance company as their usual reimbursement for your testing and treatment.

I understand that the Great Lakes College of Clinical Medicine has no policy to medically treat or compensate any patient for physical injuries incurred as a result in participating in biomedical or behavioral research, or in this study.

I also understand that Dr. «LASTNAME» or his/her staff have no policy to compensate patients for physical or other injuries incurred as the result of participating in this study, or in biomedical or behavioral research, except as specified by «STATE» State Malpractice Insurance law.

CONFIDENTIALITY:

All personal patient records and data will remain strictly confidential to Dr. «LASTNAME» and his/her staff. However, your records and data may be reviewed by Dr. W. A. Shrader, Jr. or his designee, the EPD Study Office and Dr. L.H. McEwen of London, England. For your safety, the Institutional Review Board of the Great Lakes College of Clinical Medicine and the FDA have the authority to inspect and review your medical records or the study data at any time. This data will eventually be combined for publication with data from other participants, and will be presented and/or published alone or combined. You will be notified of any changes to this consent and may withdraw your consent if you wish.

COPY OF THIS CONSENT FORM:

You may have a copy of this consent form at any time.

COSTS:

The costs of testing and treatment with EPD will be reviewed with you, and a written estimate of all costs involved will be given to you, or will be available. Medical insurance may not cover EPD immunotherapy itself or the nutritional supplements required as an adjunct to EPD, but it should cover office visits and allergy testing as it usually would any similar services.

WARRANTIES:

No warranties expressed or implied are made for the safety of the nutrients, medications, EPD itself or other products provided or required by this study.

WAIVER OF LIABILITY:

I, _____, and Dr. «LASTNAME» (additional investigator) grant a waiver of liability to the FDA and to the Great Lakes College of Clinical Medicine and its Institutional Review Board.

PERMISSION TO PUBLISH:

I give my permission to publish the results of this investigational medical research project.

DATE OF SIGNATURE: _____

PATIENT'S NAME: _____ PATIENT'S SIGNATURE: _____

WITNESS'S SIGNATURE: _____

NOTE: If you experience what you feel are severe problems with EPD, and your physician is unable to address them, or you have not made your physician aware that you have had problems, please notify *in writing*: Dr. W.A. Shrader, Jr., principal (co-ordinating) investigator, 141 Paseo de Peralta, Santa Fe, NM 87501.