

## **CONSENT TO PARTICIPATE IN RESEARCH**

# **The Effectiveness of Guided Self-Help Administered Integrative Interventions in the Prevention and Management of Environmental Illnesses**

**Science and Public Policy Institute  
Comparative Effectiveness Research Program**

**Washington, D.C.**

**October 2009**

## INVITATION TO PARTICIPATE

You are invited to participate in a research study of the effectiveness of guided self-help administered custom interventions for the prevention and management of environmental illness as well as enhancing overall wellness. A secondary goal of this research is to gather scientific data that can be used as evidence to support health insurance coverage for illnesses that are influenced adversely by a range of environmental exposures.

You have been invited to participate in this study because:

- You suffer from one of the following illnesses which derive from environmentally induced cell-membrane damage: Autism, Electro-Hypersensitivity (EHS), Multiple Chemical Sensitivities (MCS), attention-deficit conditions, Post-Traumatic Stress Disorder (PTSD), anxiety disorders and sleep problems;
- You suffer from another environmental illness not listed above that you have been diagnosed with;
- You believe that treatment for other conditions from which you suffer is compromised by adverse environmental influences;
- You are the parent of a young person who suffers from one of the environmental illness conditions defined herein;
- You have expressed an interest in following healthful adaptation protocols as a means for prevention of environmental illness;
- You have expressed an interest in following healthful adaptation protocols as a means for enhancing your wellness.

This work is being conducted under the auspices of the non-profit Science and Public Policy Institute, Comparative Effectiveness Research Program, based in Washington, D.C.<sup>1</sup> The Principal Investigator for this study is Dr. George L. Carlo.<sup>2</sup>

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<sup>1</sup> *The non-profit Science and Public Policy Institute (SPPI) was established in 1989 in Washington, D.C.. The mission of SPPI is to provide guidance to government agencies and the public on complex issues where science can be applied to assist in making informed public health, public policy and individual health protection decisions. SPPI has provided guidance on myriad issues including occupational health hazards, environmental and ecological damage, Agent Orange, abandoned hazardous waste sites, anti-viral treatments, food safety, smoking cessation, indoor air quality standards, silicone breast implants, electro-magnetic field exposures, clinical research criteria, and nanotechnology. Note that the Science and Public Policy Institute name has been used by other political entities located in states outside of the District of Columbia. SPPI is not affiliated with any of those entities and does not endorse their positions.*

<sup>2</sup> *Dr. George Carlo is Chairman of SPPI, a position he has held since 1989. Over the past thirty years, he has been at the forefront of researching and developing strategies for managing environmental illness. He was among the first scientists on the scene at the infamous Love Canal chemical crisis in Niagara Falls, New York in 1978 that lead to the Superfund law addressing hazards from abandoned hazardous waste sites. He was integral in writing the enabling legislation that established the Agency for Toxic*

Research assistants, who will be identified to you through the course of the study as you encounter them, will carry out all major tasks in the work. The study design has been peer-reviewed and approved by the SPPI internal Institutional Review Board.

The study will enlist participants from around the world from October 6, 2009 through April 6, 2010. The data collection phase will cease October 6, 2010, and the final report will be completed within four months following the cessation of data collection. A summary of the final report will be made available to participants upon request.

Your participation in this study is entirely voluntary.

It is anticipated that benefits derived from the services received through the course of the study will be variable from participant to participant. Benefits to society of this research include the provision of data that will enhance the possibility of insurance coverage for the integrative interventions applied to the environmental illnesses for prevention, management and wellness encompassed within the study as well as lay groundwork for coverage of other interventions aimed at preventing, treating and otherwise managing environmental illness.

You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate. Contact information for such queries is presented on page 17 of this document.

## **BACKGROUND AND PURPOSE OF THE STUDY**

A primary purpose of health science research, be it descriptive, clinical, epidemiological, or experiments done in the laboratory, has always been to learn enough about a disease process to be able to manage and control it. In today's society, another layer of complexity for disease prevention, treatment and control has emerged because of the soaring costs of health care around the world. Thus, the ability to pay for interventions that are integral to managing diseases has become an important variable that is a determinant of favorable outcomes. Those who have

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*Substances and Disease Registry within the Department of Health and Human Services, a primary group addressing the effects of environmental contaminants. He served for ten years on the U.S. Congress' Office of Technology Assessment Agent Orange Advisory Panel, providing advice to Viet Nam Veteran's suffering from the effects of the dioxin-laced defoliant program. During the 1990s, he headed Wireless Technology Research, the world's largest program to date addressing the health impacts of wireless technology related electro-magnetic radiation. Among his more than 200 peer-reviewed publications are papers addressing environmentally caused reproductive effects, infertility, tumors, cancer, electro-sensitivity, Autism, and multiple chemical sensitivities. He has training in pathology, epidemiology, medical science and law, and over the past thirty years has served on the medical and research faculties of the State University of New York at Buffalo, the University of Arkansas and the George Washington University.*

means of payment have access to quality care at a rate higher than those who do not have means. For most people, insurance coverage and other third-party payment structures have become integral to their receiving quality health care.

A critical component of third party coverage is the definition of what are appropriate interventions that warrant coverage. The basis for these definitions is rapidly evolving; however, it has become very clear that ‘evidence-based’ interventions – meaning those interventions for which there is rigorous scientific support – will continue to be those favored by third party payers. For example, under evolving new laws in the United States regarding the delivery of health care, ‘evidence-based’ interventions are advised. Only those interventions studied under scientifically rigorous protocols addressing outcomes that can be incorporated into ‘comparative effectiveness research’ become candidates for payer reimbursement under both private and public health care insurance.

As new knowledge emerges, clinical observations continue to be important tools for verifying, modifying and focusing research so that those who are suffering can be helped. However, gross clinical observations, patient testimonials and other *ad hoc* claims of efficacy have not been historically persuasive and are unlikely to be considered in the future as proper scientific evidence. In addition, environmental illness conditions are complicated, with diverse symptom patterns and arrays of interventions that work for some people and not for others. Standard double-blind placebo-controlled studies are not appropriate for these types of conditions because those models are based on interventions thought to have universal applicability. Environmental illness is much more complicated and new scientific approaches are needed for properly assessing environmental illness management.

The research that you are being asked to participate in addresses this need and provides important data within the health science framework that can lead to broader third party coverage of interventions for difficult environmental illnesses that currently are paid only by patients who are treated, and not by third party payers. Self-payment for these conditions causes considerable financial and quality of life hardship among those already suffering health compromise.

The scientific goal of this research is to test both the delivery system and outcome effectiveness of a series of guided self-help, customized protocols for prevention and management of oxidative stress-induced cell-membrane mediated environmental illnesses using integrative pathways defined by current and emerging science. For those not ill, wellness enhancement is encompassed in the research for them.

Outcome measures for the delivery system effectiveness will be multiple, and include:

- Ease of use of self-administered evaluation instruments
- Understandability of primary, secondary and tertiary intervention tools
- Ease of use of the intervention protocols and pathways
- Thresholds for meaningful interaction with study 'guides'
- Accessibility of interventions in terms of cost

Outcome measures for the effectiveness of the intervention protocols will be multiple, and include:

- Self-assessed symptom improvement
- Self-assessed quality of life improvement
- Where appropriate, laboratory marker longitudinal evaluation
- Other objective measures of health and wellness

The results of this effectiveness research will be compared, both qualitatively and quantitatively, with similar outcomes from parallel studies of the same protocols, administered through walk-in clinics and centers, as well as website enabled delivery. Those comparative studies of the other delivery systems are expected to commence in early 2010.

### **Environmental Illness: Relevant Science**

Traditionally, categorization of environmental illness has been limited to Multiple Chemical Sensitivities, Electro-Hypersensitivity and other conditions with diverse and non-specific symptoms thought to be 'idiopathic'. However, new research makes it clear that influences of the environment on illness go far beyond this limited number of conditions. In its simplest definition, environmental illness is any condition for which the cause has not been shown to be genetic, and environmental science has now evolved to a content complexity that supports that simple definition.

All environmental exposures – including external insults from air, water and electro-magnetic fields as well as internal insults from ingested foods and pharmaceuticals – provoke cell membrane level adaptive responses. Mal-adaptation leads to disease; constructive adaptation tends toward resistance and immunity. Differences in adaptive capacity define why everyone who smokes does not develop lung cancer and why everyone who diets does not lose weight. The key is that the complex interplay of genetics and environment, including epigenetic mechanisms, synergies and effect modifications, defines adaptive capacity and therefore defines disease, illness, wellness and self-realization.

Following from this new knowledge, it is clear that environmental illness in today's world is more pervasive than generally acknowledged. Autism – now estimated by the U.S. Centers for Disease Control to occur in 1 of every 91 births,

conditions such as ADHD and ADD, Post-Traumatic Stress Disorder, anxiety disorders and sleep problems all have significant environmental components. Most cancers, birth defects, reproductive problems and infertility are considered to have some environmental etiology. Heart disease, diabetes and circulatory system problems are related largely to internal environmental insults derivative of dietary practices. All told, more than half of all illnesses being treated everyday in North America, Europe and Asia can be classified as environmental to some degree.

Prevention, treatment and management of these conditions are difficult and success rates, irrespective of the public relations efforts of treatment providers proclaiming dramatic cures, are low. One reason is that consideration of the fundamental Bio-Energetic Loop (BEL) that underscores the organism-environment interaction is missing in most treatment and management protocols. The complexity of these conditions makes it important from a favorable outcome perspective that integrative interventions, which support traditional treatments by enhancing bio-medical availability, are encouraged and paid for in standard treatment coverage.

### **The Bio-Energetic Loop (BEL): Relevant Science**

Energy potential differences across cell membranes have long been known to play important roles in cell structure and function. As biological knowledge has evolved, it has also become clear that virtually all reactions in physiology are the result of energy transfer, including making and breaking of ionic or covalent bonds, free radical reactions, and osmosis. Thanks to the work of luminaries such as Drs. Fritz Popp and Bruce Lipton we now understand that light energy in the form of bio-photons are also integral to organism physiology and that the cell membrane is the focal point for cellular environmental monitoring. In addition, research shows that energy potentials across cell membranes are variable over time, depending on whether a cell is in a parasympathetic (relaxed) functional state or in a sympathetic (stressed) reactive state. When the cell is effectively 'relaxed' the energy potential and resultant kinetic energy is greater than when the cell is 'stressed'. These collective findings have been critical to understanding the BEL.

Individual cells function in coordination with neighboring cells. The means of effecting this coordination is intercellular communication. We now know that intercellular communication is achieved through at least two distinct types of reactions. The first is an energetic communication that is bio-photon based. The second is biochemically mediated through gap junctions and connexins, depending on the type of cell. Most important is that the combination of light energy and chemical energy transfer makes intercellular communication effectively instantaneous.

The Bio-Energetic Loop (see figure below) is the means through which any external or internal environmental stimulus is able to instantaneously cause a cell membrane level reaction under certain circumstances defined by the characteristics of the person at a specific point in time. In short, the BEL is the connection between cells and the environment. Cells communicating with each other to effectuate joint function form tissues. Cells and tissues communicating with each other to effectuate joint function form organs. Organs communicating and functioning together form organ systems. Organ systems working together define the organism or in this case, the person.

At each level of coordination is a transfer of energy that effectuates a transition of cell membrane energy potential to kinetic energy. The sum-total of the kinetic energy scaling from cells to tissues to organs to organ systems to the organism forms a bio-energetic field that radiates a distance away from the corpus or body of the organism. This supra-organism or bio-field can be measured and in most cases it radiates from six inches to about three feet, depending on variables including the person's health status, activity and level of sympathetic stress. Internally, the bio-field reaches across the digestive and excretory tracts.<sup>3</sup>

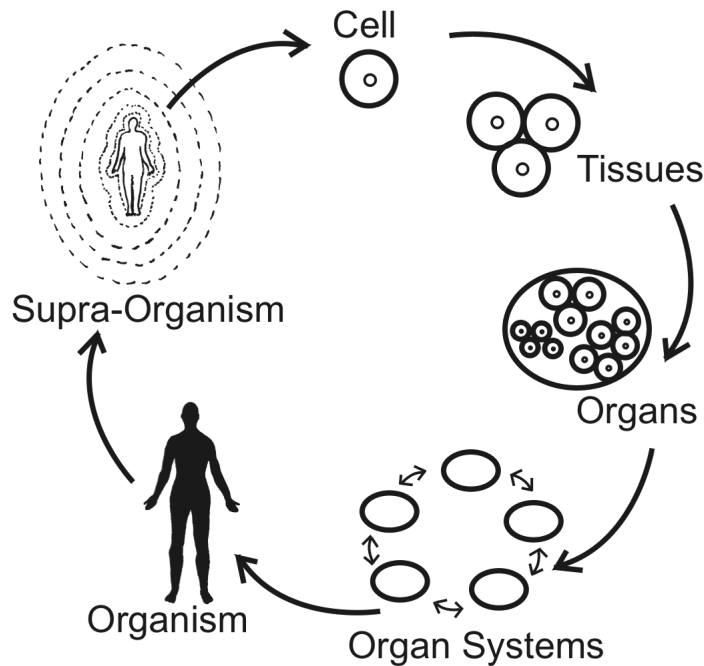
Evolutionarily, the BEL is a multi-level protective system for the organism, with the ultimate protection aimed at keeping individual cells from being damaged. The first line of defense or the first level point of adaptive response is the bio-field – both external and internal. For example, a bio-field response explains why people can 'feel the energy change' in a room when an argument ensues (external bio-field reaction) and why people feel queasy in their stomach when they see something that makes them nervous (internal bio-field reaction). The purpose of this reaction is to provoke in the organism (person) a 'protective response', usually an avoidance response.

If there is no avoidance response provoked by the bio-field level warning, then the organ systems take over – for example, initiating an adrenalin release provoking cardiac and circulatory system changes to facilitate 'fight or flight'. The protective layers scale down to the individual cell, where lipid peroxidase and related reactions effectively close cell membrane ion channels as the last line of defense. The protective cascade is a continuum where each insult impacts the entire BEL to varying degrees.

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<sup>3</sup> From an embryonic development perspective, the digestive and excretory tracts are 'external' to the organism, the result of internal folding of ectoderm and endoderm. Thus, it follows that the bio-field is the result of cumulative energy radiating outward.

## Bio-energetic Loop



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### Using the BEL in Treatment, Prevention and Wellness.

The key to applying knowledge of the BEL in preventing, treating and managing environmental illness is in understanding that the BEL defines what level of the organism can be accessed with an intervention at a given time. The BEL determines the bio-medical availability of all preventive, wellness and therapeutic interventions. Whether an intervention is physical, chemical or biological, the organism's initial response is protection against a potential environmental insult. Thus, with any intervention, the BEL protective cascade is initiated. In addition, residual environmental insults present at the time an intervention is introduced play a role in determining the level of access within the organism.

For example, successful treatment and management of conditions such as Autism, MCS and EHS require elimination of both chemicals (including fragrances) and electromagnetic fields from the person's environment as well as other sympathetic stressors while the interventions are introduced. Cell membranes are the site of the operative pathology, and to reverse these conditions, cell membranes need to be accessed. If the person is in an environment where the bio-field

avoidance response is not possible, organ systems and organ protections prevent efficient cell membrane access. Ingestible supplements to increase cellular energy, for example, would not be taken up by cells because cell membrane sympathetic stress reactions would reduce cell membrane permeability.

As a practical matter, addressing interventions over time from the outer layers of the BEL to the inner layers has shown the most promise in efficiently managing environmental illness. Outer layer interventions include many integrative approaches including acupuncture, network chiropractic, standard chiropractic, massage therapy, homeopathy, and Reiki. After a period of time, inner layer interventions such as nutraceuticals, probiotics and other medicines can efficiently be added and made bio-medically available to do their jobs. The goal is to achieve bio-energetic balance throughout the course of intervention and this is best achieved by using the BEL as a roadmap to intervention choices. The BEL roadmap approach is incorporated within this research study.

### **Guided Self-Help versus Clinical Supervision.**

Many people who knowingly suffer from environmental illnesses face difficult challenges in the traditional western health care delivery system. These challenges include difficulty in establishing diagnoses as well as the absence of understanding among many clinicians about environmental causes and influences on disease. As such, many with these conditions seek out information on the Internet and other easy-to-access sources to become informed so that they can treat themselves or, in the case of parents, treat their children. Unfortunately, much of the information easily accessed is unfiltered, not peer reviewed, and many times fraudulent or otherwise misleading as it is offered to sell products and services. Nonetheless, with no where else to turn, far too many of these patients expend personal resources to exhaustion out of desperation to help themselves while seeing very little health and quality of life improvements for their efforts.

Many others are not aware that their symptoms and health challenges are environmentally induced and many times receive treatments and medications that are contraindicated for environmental illness. In these cases, the 'wrong medicine' serves to exacerbate discomfort and symptoms.

An important part of the research you are being asked to participate in relates to empowering those of you who are able to assimilate and then use intervention information on your own to help manage environmental illness. Studies and clinical experience over the past five years show that in all age demographics, especially the under 50 age group, a significant proportion of people prefer to be empowered to help themselves with regard to their health rather than depend exclusively on advice from clinicians. Successful interventions leading to illness recovery and risk management occur under both self-help and clinic-based

delivery mechanisms; however, it is believed that higher levels of efficacy are achieved when the patient or person sustaining the interventions are in a program consistent with their comfort levels and belief systems. There are many variations of health intervention delivery, including: visiting a clinic or clinician and receiving advice and guidance under their direction; visiting a self-help website and following iterative advice offered there; and ordered conveyance of fundamental, but scientifically rigorous, information for application to guided self-help. This research is addressing the third option delivery system that is the most 'hands-off', self-empowering in terms of direction, and resource conservative in terms of health care costs.

## STUDY PROCEDURES

This study focuses primarily on the minimal direction, guided self-help system for delivering interventions customized to the needs of each individual participant. Each participant will be lead through the study process over the subsequent months by a 'guide' who will serve mainly in the capacity of a coach. The 'guides' are charged with helping the participant through the identified intervention pathway by providing choices for the participant and will endeavor to offer minimal direction. One purpose of the study is to identify minimal needs for direct interaction between a 'guide' and the participant so that the most resource-efficient procedures can be identified in the study.

Prior to enrollment in the study, and then during the process of the study itself, eligibility evaluations will be made for each participant to determine whether or not there is a high probability that the guided self-help approach will be successful for the individual participant. In cases where either the initial evaluation or later evaluations suggest that guided self-help is not likely to glean favorable outcomes for the participant, the participant will be offered two choices:

- The opportunity to identify a clinician with whom they would like to work and having the delivery of the interventions coordinated through that clinician.<sup>4</sup>
- The opportunity to be placed on a study list for one of the subsequent studies planned using other delivery systems for the protocol pathways: website based or clinical center based.

If you volunteer to participate in this study and you are determined to be eligible, you will be asked to do the following things:

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<sup>4</sup> Because there are health benefits associated with participation, it is the policy of SPPI to not deny those opportunities for wellness to anyone. Study personnel will provide recommendations of clinicians and will also work with new clinicians interested in the subject matter. The costs of these, as the others involved in the study, will be borne jointly by SPPI (professional services) and the participant (interventions).

- Complete evaluation questionnaires at the beginning of the study under the supervision of a 'study guide'. A 'study guide' is the member of the research team responsible for seeing you through the study processes over the length of the study. The primary function of the 'guide' is to lead you through the process that has been defined as the protocol for this study. 'Guides' are not medical personnel and will not be able to provide recommendations. They will provide choices for you, the participant, to decide upon.
- Use your best efforts to follow intervention protocol pathways that derive from the questionnaires that you will complete through the study. Your 'guide' will contact you monthly to provide updates on your intervention pathway choices and progress. You can contact your 'guide' at your need.
- Pay for the services that are administered to you through the study to the best of your ability.<sup>5</sup>
- Participate to the best of your ability in discussing and choosing specific interventions that are defined in your intervention protocols
- Complete evaluation questionnaires during the study and at the end of the study, explaining the things in the study that worked best and those that did not.
- Complete evaluation questionnaires during the study and at the end of the study, explaining your progress or lack of progress toward feeling better.

The design of this study is descriptive in nature, meaning that specific null hypotheses defined *a priori* are not being employed. Specific null hypotheses for testing will be defined *a posteriori* based on the extent and the nature of the data gathered. Thus, participants in this study will not be defined to treatment and control groups ahead of time. There are no placebos being used in the research. Each participant will be afforded the opportunity to glean the full range of benefits encompassed within the intervention protocols being employed.

The study endeavors to define the most likely successful protocol pathway for each participant and comparisons will be made between groups of people who self-select by virtue of the intervention choices they make based on understanding, finances and other factors, throughout the research study. Participants will be thus placed into different protocol content groups for statistical analysis.<sup>6</sup> There is no

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<sup>5</sup> Choices with respect to which interventions are employed are left to the participant. Thus, the participant is integrally involved in determining the course of care and the cost of care, which is a reality for most people as they seek out all types of health care. The analyses at the end of the study will address personal financial means as variables determinative of favorable and unfavorable health outcomes.

<sup>6</sup> Self-selection into protocol groups will be reflective of financial means, willingness to follow the protocols, and other 'real-world' variables that contribute to the quantification of outcome effectiveness.

manipulation of interventions or protocols for the benefit of the study at the expense of participants.

## POTENTIAL RISKS AND DISCOMFORTS

The study is designed to empower choices among participants from recommended protocol pathways based on questionnaires and in some cases, laboratory tests, administered throughout the study. Each participant is, in effect, under his or her own care by design of the study and therefore has control over determining comfort levels with each intervention, including their cost.

Intervention choices for prevention, wellness enhancement and illness management in the study will be integrative and customized to the participant, based on iterative queries including Medical Risk Assessments and Intervention Pathway Evaluations. The customized integrative choices include:

- Neurological re-balancing tools such as acupuncture, massage, chiropractic, yoga, meditation, prayer and other energy medicine techniques as support, biological preparation and enhancement of bio-medical availability of subsequent intervention steps.
- Environmental exposure controls such as use of headsets on cell phones, mitigation tools for eliminating sources of electro-magnetic fields, altering electrical and power circuits and otherwise clearing sleeping areas, elimination of smells and fragrances in living space, and mitigation of environmental insults including mold and microbes.
- Applied Behavioral Analysis (ABA), Cognitive Behavioral Therapy (CBT), and other symptom management interventions.
- Nutraceuticals, probiotics and other medicines addressing underlying pathology that can be ingested as either sprays or capsules.<sup>7</sup>

There are no identified special risks associated with these interventions beyond those derived from individual preference and choice. The decision to use any, all or none of the interventions offered is left completely to the participant. In cases where the participant has questions or concerns about an intervention option, 'guides' will facilitate seeking out answers to those questions for the participant.

## ANTICIPATED BENEFITS TO PARTICIPANTS

The intervention protocols and integrative pathways being studied in this research have been used clinically in varying degree over the past several years around the world in assisting those with the various types of environmental illness encompassed within this work. The arrays of interventions are uniquely convergent

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<sup>7</sup> Use of prescription medications will derive from consultation with and agreement of each participant's personal physician.

in addressing the common underlying pathology in these conditions of cell-membrane oxidative stress. Many people who have followed various versions of the protocols have seen reversals of their symptoms and improvements in their conditions. Some of these reversals have been dramatic. Others who have used the protocols have not accrued such strong benefits. The purpose of the study in this regard is to allow the 'data to speak' in terms of the effectiveness and the efficiency of the protocols and pathways as well as the guided self-help delivery system.

### **ANTICIPATED BENEFITS TO SOCIETY**

Environmental illness presents difficult challenges for medical professionals. Many times, traditional interventions worsen some of the oxidative stress reactions induced by environmental insult and thus exacerbate symptoms. In addition, many of the alternative or integrative intervention tools that have shown promise in managing environmental illness are not covered by insurance and therefore out of the range of options for many people who do not have means to pay for additional care. This creates a health care inequity, the burden of which falls on those underserved and underprivileged. Your participation in this study will help balance this inequity.

Health care is moving strongly toward 'evidence-based' interventions and 'best practices' designations based on comparative effectiveness research as key parts of determining insurance coverage eligibility. Integrative medicine approaches to these types of diseases are very difficult to study and for that lack of data, are sometimes denigrated as non-science or quackery. The work encompassed in this study is designed to produce 'evidence' consistent with the criteria used by private and public health care payers in deciding what is covered and what is not. Providing such data will level the playing field for integrative choices, hopefully leading to insurance coverage for the interventions being studied and other similar interventions aimed at preventing and managing environmental illness.

### **FINANCIAL ASPECTS AND OBLIGATIONS**

This study is not funded at the present time by any outside sponsor. However, this work is critically important in terms of addressing the emerging health care burden of environmental illness and no one who meets the eligibility requirements will be denied participation. In addition, the research is time-sensitive in terms of the opportunities presented by current efforts for health care reform to present new data into the decision-making process. These considerations have led SPPI to commence this study in lieu of waiting for other government or private sector funding. Therefore, the costs of the study are jointly borne by the non-profit SPPI and the participants. SPPI is covering the scientific aspects of the work with its contribution of resources. Collaboratively, each participant will contribute, either directly or indirectly, a participation fee that covers the

professional services you will receive in the study process over the 12-month study period.

It is possible that your insurance will pay for some or all of the interventions and tests you will receive if you participate in this research. Conversely, your insurance may not cover any of the costs at all. That is because many insurance companies, HMOs, and health benefits plans do not cover experimental programs or do not recognize the conditions being considered in this research as compensable. In any case, the research team will do its best to help achieve insurance coverage for your participation.

The charges you will have to pay, either through insurance coverage, through a benefactor or personally, will be as follows:

- \$600 participation fee that covers your initial and ongoing questionnaire-based evaluations and other costs associated with your enrollment in the study and following your progress throughout<sup>8</sup>
- Standard costs for treatments such as acupuncture, massage, chiropractic, ABA, CBT and other integrative interventions that might be part of your customized pathway
- Professional assessment of the need for and purchase of intervention tools such as fragrance-free soaps, lotions, deodorants, laundry detergents, furnishings, linens, cell phone headsets, electrical shielding materials or devices, and non-toxic remediation of mold and mildew.
- Purchase of intervention tools such as fragrance-free soaps, lotions, deodorants, laundry detergents, cell phone headsets, electrical kill-switches or filters and remediation of mold and mildew.
- In cases where necessary, laboratory tests
- Nutraceuticals, probiotics and other medicines that range in cost from \$40 to \$60 per month at the early stages of the study and up to \$150 per month at the late stages of the study

Those who wish to participate in the study but do not currently have the financial means to cover their contribution to their participation are offered two options:

- Option 1: make progress payments toward the participation fee, and once that amount has been reached, you will be invited into the active study pool so long as the study is still in the phase of admitting new participants.

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<sup>8</sup> Protocol pathways addressing Autism and related conditions in children include interventions aimed concurrently at mother and child. As such, the participation fee for the second and other subsequent participants is reduced by fifty percent.

- Option 2: be placed on a study eligibility waiting list in order of the date of receiving your signed agreement to participate.<sup>9</sup> The SPPI will actively seek out benefactors to cover the costs of individuals so challenged, and those on the waiting list will be notified when funding for their participation is secured and they will be entered into the study at that time so long as the study is still in the phase of admitting new participants.<sup>10</sup>

It is estimated that the total cost, combined insurance reimbursed and out-of-pocket, for persons participating through the full length of the study will on average be approximately \$2,500. Payments to the study can be made via PayPal, credit card or check. Checks will be cleared through online monitoring, and information required for that process is required.

### PRIVACY AND CONFIDENTIALITY

The only people who will know that you are a research subject are members of the research team and if appropriate your clinician. No information about you, or provided by you during the research, will be disclosed to others without your written permission. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audio tape recordings of you will be used for educational purposes, your identify will be protected or disguised.

### PROCEDURE TO INITIATE PARTICPATION

Once you have decided that you wish to participate in this research, please follow these steps:

- Sign the **Signature Page** below and send the original page to: *Environmental Illness Research Study, 1075 Sheree Drive, Grand Island, New York 14072*
- Retain the remained of this document for your records
- Notify Sharon Yates of your decision to participate via e-mail at: [Directyates@aol.com](mailto:Directyates@aol.com) or by phone at: 866-620-4459
- Indicate what your preferred method of contact will be: e-mail or telephone

Upon receipt of your voice or e-mail notification, the study team will contact you and the study process will commence.

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<sup>9</sup> Basic financial information will be asked for to help determine financial means and needs.

<sup>10</sup> It is important for the scientific integrity of the study that all participants are situated as similarly as possible in terms of financial coverage as they move through the study. Those who are funded by a specific benefactor will have a defined amount of funds dedicated to their participation so they too will have to choose which interventions are applied based on there affordability.

## SIGNATURE PAGE

I have read (or someone has read to me) and understand the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form. I understand that the study team is not responsible for the decisions that I make through the course of the study and I agree to hold the Science and Public Policy Institute and the research team harmless for any discomfort I encounter through participation.

**BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH AS IT IS DESCRIBED AND TO COMPLY WITH ITS PROCEDURES.**

\_\_\_\_\_  
Name of Subject

\_\_\_\_\_  
Name of Legal Representative (if applicable)

\_\_\_\_\_  
Signature of Subject or Legal Representative

\_\_\_\_\_  
Date

Subject Mailing Address: \_\_\_\_\_

Subject E-mail Address: \_\_\_\_\_

Subject Phone Number: \_\_\_\_\_

### INVESTIGATOR OR INVESTIGATOR REPRESENTATIVE

I have explained the research to the subject or his/her legal representative and answered all of his/her questions.

\_\_\_\_\_  
Name of Investigator or Representative

\_\_\_\_\_  
Signature of Investigator or Representative

\_\_\_\_\_  
Date

## **RESEARCH TEAM CONTACT INFORMATION**

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Grand Island, New York 14072**