

**HUMAN RESEARCH
CONSENT FORM
(Spiritual Groups)**

Title of the Study: A longitudinal study of spiritual engagement, self-transcendence, and human flourishing.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

The Institutional Review Board at California Pacific Medical Center wishes you to know: Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of both the procedures to be followed in the medical experiment, as well as any drug to be used in the experiment.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of the signed and dated written consent form when one is required.
10. 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.

If you have questions regarding a research study, the researcher or his/her assistant will be glad to answer them. You may seek information from the Institutional Review Board--established for the protection of volunteers in research projects--by calling (415) 600-3688 Monday through Friday, between 9:00 a.m. and 4:00 p.m.

Participant's Signature or legal representative if appropriate

Date



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**CALIFORNIA PACIFIC MEDICAL CENTER
CONSENT TO ACT AS A RESEARCH PARTICIPANT**

The Principal Investigators are Cassandra Vieten, Ph.D., and John Astin, Ph.D.

A. WHAT IS THE PURPOSE OF THIS STUDY?

You have been asked to participate in a research study because you are a member of a spiritual practice community. The purpose of this research study is to determine how different levels of involvement in a spiritual practice community and engagement in spiritual practices are related to physical, emotional, psychological, and spiritual well-being over a one-year period.

B. HOW MANY PEOPLE WILL PARTICIPATE?

About 320 participants will take part in this study at California Pacific Medical Center.

C. HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for 12 months. You will be asked to complete assessments *seven* times over the course of 12 months.

D. WHAT WILL HAPPEN TO ME DURING THIS STUDY?

If you volunteer to participate in this study, we would ask you to do the following:

- 1.) You will be asked to respond to online questionnaires about your spiritual practice, your physical health and general well-being at four times over the course of the study. These measures should take about 30-45 minutes to complete each time.
- 2.) Three times during the year, you will be asked to phone in to a call center every day for one week to answer a brief set of questions about how your day has gone. If we do not hear from you by a certain time each day, we will call you at numbers you provide to request that you answer this brief set of questions. The questions should take about 5 minutes to answer each day.
- 3.) You will be asked to provide the names and contact information for two people who know where you are most of the time, even if you move or change your

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email address or phone number, and to give us permission to contact them to help us find you if we are unable to reach you at any of the measurement points.

- 4.) You will be asked to provide the name and contact information for one person with whom you have regular contact and whose opinion you trust who would be willing to answer some questions *about you* at the beginning and end of your participation in the study. They will be asked some of the same questions you will be asked, but will be instructed to answer those questions about you. You will be provided with a copy of the questions that will be asked of this person prior to selecting that individual to participate in the study.

E. WHAT ARE THE RISKS OF THIS STUDY?

The primary risks to participating in this study are loss of privacy and expenditure of time. In addition, you may find the questionnaires boring, distressing, or otherwise uncomfortable. Some of the questions may make you upset, but you are free to decline to answer any questions you do not wish to, or to stop the questionnaire at any time.

Participation in research will involve a loss of privacy, but information about you will be handled as confidentially as possible. Your personal identifying information will be kept separately from the answers you give on the questionnaires, and your personal identifying information will not be kept on the internet. Your name will not be used in any published reports about this study. For more information, please see Section I, "How Confidential Are My Records" of this consent document.

If you are aware now that you do not wish to participate in any part of the assessments, you should not enroll. However, once you have enrolled, you may withdraw from the study, and may refuse to answer any question or refuse to participate in any study activity at any time. If you become distressed by any questionnaire, or assessment in a way that is not resolved by speaking with the principal investigator (Dr. Vieten), or if you would rather speak with someone not involved with the study, a psychologist will be made available for a consultation and will make a recommendation or referral if the issue is not resolved. The study will pay for one session with the psychologist should this be necessary.

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F. WHAT ARE THE POTENTIAL BENEFITS TO ME AND OTHERS?

There may be no direct benefit to you from participation in this study. However, it is hoped that the information gained from the study will contribute to our understanding of how engagement in spiritual communities and practices is related to health and well-being.

While we will offer compensation for your participation in the study it is not a benefit of the study.

G. WHAT OTHER ALTERNATIVES OR TREATMENT OPTIONS ARE AVAILABLE TO ME?

You are free to choose not to participate in this study.

H. WHAT HAPPENS IF I AM INJURED OR HARMED IN SOME WAY BY THIS STUDY?

You have been advised that California Pacific Medical Center and the Investigators have no special program to provide compensation if injury occurs during the study. If you are injured or made ill as a result of participation in this study, treatment will be made available. Because insurance companies may not pay for research-related costs, they may not pay for an injury resulting from your participation in this study. Any costs not paid by your insurance company will be your responsibility. **In the event of a research-related injury, you should contact Dr. Cassandra Vieten at 415-600-6574. This is a 24-hour number.**

I. HOW CONFIDENTIAL ARE MY RECORDS?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may become aware of your participation in this study. For example, federal government regulatory agencies and the sponsor, Duke University and the California Pacific Medical Center Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. If we write a report or article about this study, we will describe the study results in a summarized manner so that you cannot be identified.

An authorization describing how health information about you may be used and to whom it will be disclosed by the principal investigator and the research team will be provided to you. Federal

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and state law requires that patients must give authorization for use of their protected health information in order to participate in this research study. Please refer to the attached "Patient Authorization for the Use and Disclosure of Protected Health Information for Research" form.

J. IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. You may also refuse to answer any questions you don't want to answer and still remain in the study. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

K. WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will be compensated \$100 at the end of the year, once you have completed all of the study assessments in a timely manner and/or as long as you stay enrolled in the study. If you choose to discontinue participation in the study and do not complete all study measurements, you will not be compensated for partial participation.

L. WHO IS FUNDING THIS STUDY?

Duke University is funding this research study. This means that California Pacific Medical Center is receiving payments from Duke University to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or an increase in salary from Duke University for conducting this study.

M. WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

N. WILL I RECEIVE NEW INFORMATION ABOUT THE STUDY WHILE PARTICIPATING?

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

O. EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

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A copy of the Experimental Subject's Bill of Rights and a copy of this consent form will be given to you for your own use.

P. WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Nina Fry, MA at (415) 600-5772; Cassandra Vieten, Ph.D. at 415-600-5772 or John Astin, PhD at 415-600-1624.

Should you have any questions about your rights as a research participant, you may call the Institutional Review Board which is concerned with protection of volunteers in research projects, between 9 a.m. and 4 p.m., Monday through Friday, at (415) 600-3688 or by writing: California Pacific Medical Center Research Institute (CPMCRI) Institutional Review Board Office, P.O. Box 7999, SF CA 94120.

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SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE

I have read (or someone has read to me) 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 consent form; the Subject's Experimental Bill of Rights; and a copy of the Authorization for the Use and Disclosure of Protected Health Information for Research form.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

Participant's Name **Date**

Participant's Signature **Date**

**Name and Signature of Legally Authorized Representative
(if appropriate)** **Date**

Name and Signature of Person Conducting Consent Discussion **Date**

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**PATIENT AUTHORIZATION FOR THE USE AND DISCLOSURE
OF PROTECTED HEALTH INFORMATION FOR RESEARCH**

Part I. Patient Authorization for the Use and Disclosure of Protected Health Information (PHI) for Research Purposes

Principal Investigator: Cassandra Vieten, Ph.D. and John Astin, Ph.D.

Phone: 415-600-5772

Address of Principal Investigator: 2200 Webster Street, Room 345,
San Francisco, CA 94115

Authorization Expiration Date: 2/1/2015

Protected Health Information (PHI) is any health information including medical records, mental health records, billing records, survey data, and demographic data that is identified to you. By signing below, you are authorizing the Principal Investigator and the research team to collect, store, use and disclose the PHI described below. You are also authorizing the Principal Investigator and research team to request copies of your medical and/or billing records from the providers listed.

Your authorization is required for participation in the research study. You may revoke your authorization at any time. We will discontinue collecting, using or disclosing your information except as required to maintain the integrity of the research study or as required by law. For example, we may need to use your information to document why you have withdrawn from the study, for compliance reporting purposes, or to report adverse events.

During the research study, your research team will look at the following information:

- Billing records for healthcare services
- Medical records
- Lab, pathology and/or radiology results
- Mental Health records
- Previous Research records
- Questionnaires and interviews
- Other (specify):

Date prepared: 07/28/2008

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During the research study, your research team may disclose your PHI to the following individuals or organizations:

- California Pacific Medical Center Institutional Review Board for oversight purposes
- Study sponsor:
- Contract research organization (CRO):
- Office for Human Research Protections (OHRP); Food and Drug Administration (FDA); or National Institutes of Health (NIH) for safety, efficacy, and compliance reports. Also included are other federal or state agencies that have authority over the research project or other governmental offices as required by law.
- Statistician for data analysis
- Outside lab for specimen processing
- A data safety monitoring board, if applicable
- Others (list all that apply):

During the research study, we may request copies of your PHI from the following sources (list all that apply):

Name:

Address:

Name:

Address:

California Pacific Medical Center is required by State and Federal laws to protect your information. California law prohibits the recipient from making further disclosure of your health information unless the recipient obtains another authorization from you or unless the disclosure is required or permitted by law. This protection does not extend to recipients outside the state of California. There is always the possibility that your information could be disclosed to a party that is not required to protect its confidentiality. Your identity will not be revealed in any publication that may result from this study.

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RESEARCH SUBJECT'S STATEMENT:

I hereby authorize the Principal Investigator listed above and the research team to use and disclose my protected health information as described above for research purposes.

Signature

Date

If conservator or individual authorized to make health decisions on behalf of the Research Subject, state relationship to Research Subject: _____

If this box is checked and initialed, I authorize the Principal Investigator named above to obtain copies of any of my medical records needed for purposes of the research while I am enrolled in this study.
_____ (Research subject's initials)

If this box is checked and initialed, I acknowledge that my right to access my health information pertaining to the research study will be suspended until the study is concluded.
_____ (Research subject's initials)

