

CONSENT FORM

Adverse Event Reporting Project

CONSENT TO BE A RESEARCH PARTICIPANT

PURPOSE AND BACKGROUND

Suzanne Morrissey, PhD, Associate Professor of Anthropology at Whitman College in Walla Walla, Washington, is aiding in the creation of a Safety Database with the Peoples Organization of Community Acupuncture (POCA). The purpose of POCA's Safety Database is to gather data about adverse events that occur while an individual is practicing or receiving acupuncture. POCA is developing this resource to advance our understanding of acupuncture; to help the profession evolve and be more responsible by giving us a way to learn from our mistakes; to support POCA by gathering data to prove that community acupuncture is safe; and, to improve best practices and improve our safety record.

Participation in the survey is voluntary, confidential and anonymous. If you are willing to be contacted in the future about your survey responses, you can choose to provide your name and contact information. You are under no obligation to identify yourself and are asked to not identify the people with whom you work, treat with acupuncture, or receive acupuncture from.

PROCEDURES

- 1) Participants will be recruited through POCA newsletters and online forums, POCA Tech student training sites, POCA patient networks (e.g., clinic flyers, word of mouth, referrals from acupuncture providers), and the voluntary participation of acupuncturists or their patients who are not affiliated POCA.
- 2) If you are willing to consider participation in the project, you will be directed to a website that explains the value of voluntary reporting of medical errors in acupuncture. From there you will be given a link to the project survey.
- 3) If you choose to participate in the project, you will follow the link to the survey and complete the survey.
- 4) Once a month all responses will be downloaded and the results will be analyzed by project administrators for emerging trends.

RISKS OR DISCOMFORTS

- 1) Because the purpose of collecting data is to use it to improve safety procedures, discussion of safety events that happen in conjunction with analyzing the data involve the risk of the acupuncturist involved being identified based on the circumstances of the event, and this identification could affect the acupuncturist's reputation/employability.
- 2) In order to minimize the risk of respondents being identified, we have elected to use the SurveyMonkey survey platform. SurveyMonkey employs an inhouse team of security experts to identify security issues and prevent information breaches. They are equipped to maintain a secure environment for our survey and response data. We have restricted administrative access to the full survey response data and only allow the approved research team members to access identifying information. Anonymized data will be available for more general or student research. All responses will be password protected and administrators will be encouraged to use strong passwords.
- 3) In the event that unapproved access (direct or remote) was gained to the server it is possible that the attacker could gain access to identifying information about the respondents if they have chosen to provide their contact information. In the event that a data breach were to occur we will contact any respondents that have chosen to provide contact information and give them the opportunity to have their responses removed from the database.

D. BENEFITS

There will be no direct benefit to you for participating in this study. However, the information that you provide will help educate audiences about the safety of acupuncture while also identifying the possibility of practice errors that can be improved and prevented if known.

Acupuncture Adverse Events and Error Reporting

At the end of this report you will have the option of identifying yourself for follow up contact if you choose. While filling out this report *please respect the privacy of others and do not identify anyone but yourself*. Information that identifies others will be stricken from the report and will not be used.

1. Are you a(n):

- Acupuncturist or other healthcare provider
- Acupuncture student
- Patient

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2. This incident occurred as a result of:

- a treatment that I gave to this patient.
- a treatment that a clinic coworker gave to this patient.
- a treatment that a practitioner gave to this patient at a clinic where I do not work.
- a treatment that occurred in our clinic, but we're unsure which provider's treatment caused the issue.
- an environmental factor that may not be related to a specific treatment (TDP lamp, lost needle, allergic reaction, etc.)

3. Did this treatment consist of the NADA Protocol and nothing more?

(The NADA protocol is a standardized prescription of ear points which may be delivered by providers other than licensed acupuncturists, often in detox or mental health settings)

- Yes
- No

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4. This incident occurred durring the course of a treatment that:

- I received.
- Someone I know received.

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5. Describe the incident:

- needle left in
- lost needle - for example, a needle which fell out and which was found later in clothing
- stuck by a stray needle
- bruising
- bleeding
- dizziness
- fainting
- infection
- symptoms worse
- psychoemotional trigger
- adverse herbal reaction
- redness or soreness at site
- organ puncture
- Other (please specify)

6. When did the signs and symptoms appear?

- during the treatment
- immediately after treatment
- 24 hours later
- more than 24 hours later
- not relevant
- Other (please specify)

7. The treatment included:

- Acupuncture
- Ear Acupuncture
- Cupping
- Gua Sha
- Herbs
- Massage (Tui Na, Shiatsu, or other)
- Plum Flower/ Seven Star Needle
- Bleeding Therapy
- Other (please specify)

8. Was this the patient's first treatment with this practitioner?

- Yes
- No

9. If appropriate, please share more information about the treatment. If you are a practitioner include location of treatment/point(s) used. (Please enter points as LU10 not Lung 10.)

10. When was the treatment?

Date

11. Where was this treatment given

City/Town	<input type="text"/>
State/Province	<input type="text"/>
ZIP/Postal Code	<input type="text"/>
Country	<input type="text"/>

12. Did the patient seek medical treatment as a result of this incident?

Yes

No

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Medical Treatment

13. What type of medical treatment did the patient require?

Applied basic first aid

Returned to the same acupuncturist/ practitioner for follow up care

Visited another medical practitioner

Visited the emergency room

Was hospitalized

Other (please specify)

14. The patient's signs and/or symptoms are now:

Better

Worse

Same

Don't know

Not relevant

15. Do you think that any aspect of the practitioner's technique or equipment could have contributed to this incident?

- Needle size
- Brand of needle
- Strong needle stimulation
- Depth of needle insertion
- Angle of needle insertion
- Point location
- Use of electrical stimulation
- Other (please specify)

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Patient Information

16. The patient identifies as:

- Male
- Female
- Nonbinary/genderqueer
- Transgender
- Don't Know
- Self identify as:

17. Age:

18. What other treatment(s) was the patient receiving at the time of this incident?

- Prescribed medication
- Physical Therapy
- Chiropractic or Osteopathic adjustments
- Massage Therapy
- Self-prescribed supplements
- Trigger point/Dry needling
- Emotional counseling
- Other (please specify)

19. Is there any aspect of the the patient's health history or reaction to the treatment in general which led you to expect an adverse reaction?

- fragile skin
- metal allergy
- poor hygiene
- pregnancy
- previous vasovagal response to needles
- trauma history (or specific reports about traumatic events)
- Other (please specify)

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20. Do you have safety procedures in place that are intended to prevent this type of incident?

- yes
- no

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21. If yes, what are they?

- counting needles in and out
- asking patients to help check to ensure all needles are removed after treatment
- swabbing with alcohol
- not swabbing with alcohol
- sweeping floor with magnet
- oblique or shallow insertion of points
- distal acupuncture/avoidance of points over organs
- avoidance of contra indicated points
- trauma-informed clinic procedures
- Other (please explain)

22. If yes, do you have thoughts about why these procedures did not prevent this incident?

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Contact Information

As researchers concerned with the safety practices in the acupuncture profession it may be valuable for us to be able to contact you with follow up questions about your adverse event. To do so we need your consent to contact you and your contact information.

Providing this information is voluntary and not required to submit a report.

We have made a reasonable effort to ensure that your report and any identifying information that you choose to submit remain private. We will not share it with anyone who is not a part of our research team and it will not be used for any other purpose except to contact you for follow up.

However, the world is full of nefarious people with resources and technological ability. It is possible, however unlikely, that your report could be made public. It is our duty as researchers to inform you of this possibility.

If you feel that exposure of your identifying information in association with this report could cause you to become unemployable, face criminal charges, or otherwise damage your personal or professional reputation, please answer no to the following question and don't provide any contact information.

23. Can we contact you about this event? (Optional)

Yes

No

24. Contact information (Optional)

Name	<input type="text"/>
Company	<input type="text"/>
Address	<input type="text"/>
Address 2	<input type="text"/>
City/Town	<input type="text"/>
State/Province	<input type="text"/>
ZIP/Postal Code	<input type="text"/>
Country	<input type="text"/>
Email Address	<input type="text"/>
Phone Number	<input type="text"/>

Acupuncture Adverse Events and Error Reporting

Thanks!

Thank you for taking the time to report this adverse event. You have made a valuable contribution to the study of safety in the acupuncture profession. If you have time, please answer these three questions about this process. Your answers will help us improve, but are not required.

25. Is there anything that we didn't ask you about this event, that you would like to share?

26. How could we improve this adverse event reporting form?

27. Any other comments or information you would like to provide?