TMS Safety Survey - With DCC and H-Coil

Survey Flow
Standard: Informed Consent (2 Questions)

Branch: New Branch
If
   If Do you consent to participate in this study? Yes, I consent to participate in this study. Is Selected

Standard: Coil Types Block (1 Question)

Branch: New Branch
If
   If We are interested in the safety of TMS. In what follows, we will ask you to provide numbers that... Round coils and/or flat figure-8 coils Is Selected

Standard: Standard Types (9 Questions)

Branch: New Branch
If
   If We are interested in the safety of TMS. In what follows, we will ask you to provide numbers that... Double-cone coils Is Selected

Standard: DCC Block (9 Questions)

Branch: New Branch
If
   If We are interested in the safety of TMS. In what follows, we will ask you to provide numbers that... H-coils Is Selected

Standard: H-Coil (9 Questions)

Standard: Seizure Descriptions (13 Questions)
Standard: Pregnancy Testing Policy (2 Questions)
Standard: Other Serious Adverse Events (2 Questions)
Block: Identifying Information (6 Questions)
Standard: Additional Feedback (1 Question)

Branch: New Branch
If
   If Do you consent to participate in this study? No, I do not consent to participate in this study. Is Selected

EndSurvey:
Q1 You are being invited to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please take the time to read the following information carefully. Please ask the researcher if there is anything that is not clear or if you need more information.

**Purpose of the research:**
Our goal is to calculate the frequency of seizures and other serious adverse events from transcranial magnetic stimulation.

**Study Procedures:**
In this study you will be asked to provide information about
- the setting in which you administer TMS
- the number of sessions of TMS you have conducted at your site in the past five years (2012-2016)
- how many of these sessions involved elevated risk because the patient or research subject had risk factors identified by the 2009 safety guidelines
- how many of these sessions involved elevated risk because the stimulation parameters exceeded the 2009 safety guidelines
- the number of seizures patients or healthy individuals have experienced during or immediately after receiving TMS at your site in the past five years (2012-2016)
- information about cases where seizures occurred
- any other serious adverse effects during or after TMS at your site in the past five years (2012-2016)
- how serious adverse events were handled by staff

Your total expected time commitment for this study depends largely on how long it will take to obtain the above information. For those who have this information ready to hand, we believe the questionnaire will take approximately 15 to 30 minutes to complete. For those who do not have this information ready, we believe that compiling this information will take an additional 15 to 30 minutes.

**Benefit and Risk:**
The only risks associated with participating in the study are the risks associated with operating a desktop computer, and the risk of a breach of confidentiality and consequent damage to your reputation should it be revealed that TMS from your group has resulted in seizures or other serious adverse events. See the section below on confidentiality for precautions that will be taken to minimize this risk.

You will not receive any direct benefit from your participating. You may also draw satisfaction from the knowledge that information generated by this study will help regulatory bodies make informed decisions about the conditions under which TMS can be conducted safely.
**Confidentiality:**
All records from this study will be kept confidential. Your responses will be kept private, and we will not include any information that will make it possible to identify you in any report we might publish.
Research records will be stored securely in a locked cabinet and/or on password-protected computers. The research team will be the only party that will have access to your data.

**Compensation:**
You will not be paid for your participation in this experiment. Your participation in this study is purely voluntary.

**Who to contact with questions:**
PRINCIPAL INVESTIGATOR:
Diana Tamir
Peretsman-Scully Hall
Department of Psychology
dtamir@princeton.edu

2. If you have questions regarding your rights as a research subject, or if problems arise which you do not feel you can discuss with the Investigator, please contact the Institutional Review Board at:

Office of Research Integrity and Assurance
Human Research Protection Program
Assistant Director
Phone: (609) 258-0865
Email: irb@princeton.edu

Q2 Do you consent to participate in this study?

- Yes, I consent to participate in this study. (1)
- No, I do not consent to participate in this study. (2)

End of Block: Informed Consent

Start of Block: Coil Types Block

Q3 We are interested in the safety of TMS. In what follows, we will ask you to provide numbers that will allow us to calculate the risk of seizure due to TMS. Before we ask you to provide these numbers, we need to know what coils you use to conduct TMS. As you know, TMS can be
conducted with at least four different coil types: round coils, flat figure-8 coils, double-cone coils, and Hesed coils (H-coils). Which coils have you used in administering TMS? (You may select multiple options.)

☐ Round coils and/or flat figure-8 coils (1)

☐ Double-cone coils (3)

☐ H-coils (4)

End of Block: Coil Types Block

Start of Block: Standard Types

Q4 On this page, we ask you to provide numbers that will allow us to calculate the risk of seizure due to TMS using round coils and/or flat figure-8 coils. Please read the following carefully before answering the questions below.

Q5
As you know, the risk associated with TMS has two sources. First, risk may be elevated by medications or other biological factors involving the patient or research subject. Second, risk may be elevated by the use of novel equipment or stimulation protocols that go beyond established safety guidelines. In what follows, we refer to the first type of risk as subject-risk and the second type of risk as protocol-risk. We are interested in investigating the safety of TMS studies with different levels of subject-risk and protocol-risk.

For our purposes, TMS of a particular patient or research subject carried elevated subject-risk when any of following conditions were met:

a) The participant had a personal history of epilepsy (untreated patents with one or a few past episodes), or treated patients
b) The participant had a vascular, traumatic, humoral, infectious, or metabolic lesion of the brain, even without history of seizure, and without anticonvulsant medication
c) The participant was taking drugs that potentially lower seizure threshold without concomitant administration of anticonvulsant drugs which potentially protect against seizure occurrence
d) The participant experienced sleep deprivation or alcoholism
e) The participant had implanted brain electrodes (cortical or deep-brain electrodes)
f) The participant was pregnant
g) The participant had severe or recent heart disease
For our purposes, TMS of a particular patient or research subject carried elevated protocol-risk when the following condition was met:

-Delivery parameters (intensity, frequency, train length, or intertrain duration) exceeded the established safety limits reported in the following tables (Rossi et al., 2009):

Q6

Please answer the questions below. Please note that these questions pertain only to TMS that your lab or treatment center has administered. While it is permissible to estimate the numbers we request, we will ask you to specify the source/precision of your answer.
Q7 In the last five years (2012-2016), how many sessions of TMS has your group conducted using only round coils and/or flat figure-8 coils? Please report a number for each of the following types of TMS at each of the different levels of risk.
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<thead>
<tr>
<th></th>
<th>Elevated Subject-Risk (1)</th>
<th>Elevated Protocol-Risk (2)</th>
<th>Elevated Subject-Risk AND Elevated Protocol-Risk (3)</th>
<th>No Elevated Risk (4)</th>
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</table>
Q8 Are the numbers reported in response to the previous question estimates, or are they sums based on exact records?

- Estimates (1)
- Sums based on exact records (2)
Q9 In the last five years (2012-2016), how many times has a patient or research subject experienced a seizure during or immediately following TMS from your group using only round coils and/or flat figure-8 coils? Please report a number for each of the following types of TMS at each of the different levels of risk.
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Q10 Are the numbers reported in response to the previous question estimates, or are they sums based on exact records?

- Estimates (1)
- Sums based on exact records (2)
Q11 In the last five years (2012-2016), how many times has a patient or research subject experienced evoked activity, such as MEPs or twitching, which persisted after the end of TMS from your group using only round coils and/or flat figure-8 coils? Please report a number for each of the following types of TMS at each of the different levels of risk.
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Q12 Are the numbers reported in response to the previous question estimates, or are they sums based on exact records?

- Estimates (1)
- Sums based on exact records (2)

End of Block: Standard Types

Start of Block: DCC Block

Q13 On this page, we ask you to provide numbers that will allow us to calculate the risk of seizure due to TMS using double-cone coils. Please read the following carefully before answering the questions below.

Q14 As you know, the risk associated with TMS has two sources. First, risk may be elevated by medications or other biological factors involving the patient or research subject. Second, risk may be elevated by the use of novel equipment or stimulation protocols that go beyond established safety guidelines. In what follows, we refer to the first type of risk as subject-risk and the second type of risk as protocol-risk. We are interested in investigating the safety of TMS studies with different levels of subject-risk and protocol-risk.

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c) The participant was taking drugs that potentially lower seizure threshold without concomitant administration of anticonvulsant drugs which potentially protect against seizure occurrence
d) The participant experienced sleep deprivation or alcoholism
e) The participant had implanted brain electrodes (cortical or deep-brain electrodes)
f) The participant was pregnant
g) The participant had severe or recent heart disease

For our purposes, TMS of a particular patient or research subject carried elevated protocol-risk when the following condition was met:

-Delivery parameters (intensity, frequency, train length, or intertrain duration) exceeded the established safety limits reported in the following tables (Rossi et al., 2009):

Q15

Please answer the questions below. Please note that these questions pertain only to TMS that your lab or treatment center has administered. While it is permissible to estimate the numbers we request, we will ask you to specify the source/precision of your answer.
Q16 In the last five years (2012-2016), how many sessions of TMS has your group conducted using a double-cone coil? Please report a number for each of the following types of TMS at each of the different levels of risk.
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<th></th>
<th>Elevated Subject-Risk (1)</th>
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Q17 Are the numbers reported in response to the previous question estimates, or are they sums based on exact records?

- Estimates (1)
- Sums based on exact records (2)
Q18 In the last five years (2012-2016), how many times has a patient or research subject experienced a seizure during or immediately following TMS from your group using a double-cone coil? Please report a number for each of the following types of TMS at each of the different levels of risk.
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Q19 Are the numbers reported in response to the previous question estimates, or are they sums based on exact records?

- Estimates (1)
- Sums based on exact records (2)
Q20 In the last five years (2012-2016), how many times has a patient or research subject experienced evoked activity, such as MEPs or twitching, which persisted after the end of TMS from your group using a double-cone coil? Please report a number for each of the following types of TMS at each of the different levels of risk.
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Q21 Are the numbers reported in response to the previous question estimates, or are they sums based on exact records?

○ Estimates (1)

○ Sums based on exact records (2)

End of Block: DCC Block

Start of Block: H-Coil

Q22 On this page, we ask you to provide numbers that will allow us to calculate the risk of seizure due to TMS using Hesed coils (H-coils). Please read the following carefully before answering the questions below.

Q23 As you know, the risk associated with TMS has two sources. First, risk may be elevated by medications or other biological factors involving the patient or research subject. Second, risk may be elevated by the use of novel equipment or stimulation protocols that go beyond established safety guidelines. In what follows, we refer to the first type of risk as subject-risk and the second type of risk as protocol-risk. We are interested in investigating the safety of TMS studies with different levels of subject-risk and protocol-risk.

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For our purposes, TMS of a particular patient or research subject carried elevated protocol-risk when the following condition was met:

-Delivery parameters (intensity, frequency, train length, or intertrain duration) exceeded the established safety limits reported in the following tables (Rossi et al., 2009):

Q24

Please answer the questions below. Please note that these questions pertain only to TMS that your lab or treatment center has administered. While it is permissible to estimate the numbers we request, we will ask you to specify the source/precision of your answer.
Q25 In the last five years (2012-2016), how many sessions of TMS has your group conducted using an H-coil? Please report a number for each of the following types of TMS at each of the different levels of risk.
<table>
<thead>
<tr>
<th>Elevation of Subject-Risk</th>
<th>Elevated Protocol-Risk (2)</th>
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Q26 Are the numbers reported in response to the previous question estimates, or are they sums based on exact records?

- Estimates (1)
- Sums based on exact records (2)
Q27 In the last five years (2012-2016), how many times has a patient or research subject experienced a seizure during or immediately following TMS from your group using an H-coil? Please report a number for each of the following types of TMS at each of the different levels of risk.
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- Estimates (1)
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Q29 In the last five years (2012-2016), how many times has a patient or research subject experienced evoked activity, such as MEPs or twitching, which persisted after the end of TMS from your group using an H-coil? Please report a number for each of the following types of TMS at each of the different levels of risk.
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Q30 Are the numbers reported in response to the previous question estimates, or are they sums based on exact records?

- Estimates (1)
- Sums based on exact records (2)

End of Block: H-Coil

Start of Block: Seizure Descriptions

Q31 If you reported any seizures on any of the previous pages, please describe them below. For each seizure, please include the type of seizure (generalized vs. partial), stimulation parameters (intensity, frequency, and train duration), coil type, and stimulation site. If the person who experienced the seizure had any diagnoses or risk factors, was taking any medications, or had any prior history receiving TMS, please describe these in detail. Please also describe the qualifications of the person who was administering the TMS when the seizure occurred. Lastly, please indicate whether this seizure has been published or otherwise reported publicly.

We ask that you do not include any information that could identify the person who experienced the seizure.
Q32 Please describe Seizure #1.

- Type of Seizure (1) ________________________________________________
- Stimulation Parameters (2) __________________________________________
- Coil Type (3) _____________________________________________________
- Stimulation Site (4) ________________________________________________
- Diagnoses (5) _____________________________________________________
- Risk Factors (6) ___________________________________________________
- Medications (7) ___________________________________________________
- TMS History (8) ___________________________________________________
- Qualifications of Operator (9) _______________________________________
- Published or Reported Publicly? (10) _________________________________
Q33 Please describe Seizure #2.

○ Type of Seizure (1) ________________________________________________

○ Stimulation Parameters (2) ________________________________________________

○ Coil Type (3) ________________________________________________

○ Stimulation Site (4) ________________________________________________

○ Diagnoses (5) ________________________________________________

○ Risk Factors (6) ________________________________________________

○ Medications (7) ________________________________________________

○ TMS History (8) ________________________________________________

○ Qualifications of Operator (9) ________________________________________________

○ Published or Reported Publicly? (10) ________________________________________________
Q34 Please describe Seizure #3.

- Type of Seizure (1) __________________________________________________________
- Stimulation Parameters (2) __________________________________________________
- Coil Type (3) _____________________________________________________________
- Stimulation Site (4) _______________________________________________________  
- Diagnoses (5) _____________________________________________________________
- Risk Factors (6) __________________________________________________________
- Medications (7) __________________________________________________________
- TMS History (8) __________________________________________________________
- Qualifications of Operator (9) ______________________________________________
- Published or Reported Publicly? (10) ________________________________________
Q35 Please describe Seizure #4.

- Type of Seizure (1) ________________________________________________
- Stimulation Parameters (2) __________________________________________
- Coil Type (3) ______________________________________________________
- Stimulation Site (4) ________________________________________________
- Diagnoses (5) ______________________________________________________
- Risk Factors (6) ____________________________________________________
- Medications (7) ____________________________________________________
- TMS History (8) ____________________________________________________
- Qualifications of Operator (9) ________________________________________
- Published or Reported Publicly? (10) __________________________________
Q36 Please describe Seizure #5.

- Type of Seizure (1) ________________________________________________
- Stimulation Parameters (2) _________________________________________
- Coil Type (3) _____________________________________________________
- Stimulation Site (4) _______________________________________________
- Diagnoses (5) _____________________________________________________
- Risk Factors (6) ___________________________________________________
- Medications (7) ___________________________________________________
- TMS History (8) ___________________________________________________
- Qualifications of Operator (9) _______________________________________
- Published or Reported Publicly? (10) _________________________________

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Q37 Please describe Seizure #6.

- Type of Seizure (1) ________________________________________________
- Stimulation Parameters (2) __________________________________________
- Coil Type (3) ________________________________
- Stimulation Site (4) ________________________________________________
- Diagnoses (5) _____________________________________________________
- Risk Factors (6) ___________________________________________________
- Medications (7) ___________________________________________________
- TMS History (8) ___________________________________________________
- Qualifications of Operator (9) ________________________________
- Published or Reported Publicly? (10) ________________________________
Q38 Please describe Seizure #7.

- Type of Seizure (1) ________________________________
- Stimulation Parameters (2) ________________________________
- Coil Type (3) ________________________________
- Stimulation Site (4) ________________________________
- Diagnoses (5) ________________________________
- Risk Factors (6) ________________________________
- Medications (7) ________________________________
- TMS History (8) ________________________________
- Qualifications of Operator (9) ________________________________
- Published or Reported Publicly? (10) ________________________________
Q39 Please describe Seizure #8.

☐ Type of Seizure (1) ________________________________________________

☐ Stimulation Parameters (2) ________________________________________________

☐ Coil Type (3) ________________________________________________

☐ Stimulation Site (4) ________________________________________________

☐ Diagnoses (5) ________________________________________________

☐ Risk Factors (6) ________________________________________________

☐ Medications (7) ________________________________________________

☐ TMS History (8) ________________________________________________

☐ Qualifications of Operator (9)

________________________________________________

☐ Published or Reported Publicly? (10)

________________________________________________
Q40 Please describe Seizure #9.

- Type of Seizure (1) ________________________________
- Stimulation Parameters (2) ________________________________
- Coil Type (3) ________________________________
- Stimulation Site (4) ________________________________
- Diagnoses (5) ________________________________
- Risk Factors (6) ________________________________
- Medications (7) ________________________________
- TMS History (8) ________________________________
- Qualifications of Operator (9) ________________________________
- Published or Reported Publicly? (10) ________________________________
Q41 Please describe Seizure #10.

- Type of Seizure (1) ________________________________________________
- Stimulation Parameters (2) ________________________________________________
- Coil Type (3) ________________________________________________
- Stimulation Site (4) ________________________________________________
- Diagnoses (5) ________________________________________________
- Risk Factors (6) ________________________________________________
- Medications (7) ________________________________________________
- TMS History (8) ________________________________________________
- Qualifications of Operator (9)
- Published or Reported Publicly? (10)

Q42 If you reported more than 10 seizures, please describe any additional seizures here.

________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________

Q43 If any of these seizures took place in a non-clinic setting, please describe how these seizures were handled.

________________________________________________________________
Q44 Some institutions require a pregnancy test before every rTMS session with women of childbearing potential. Does your group conduct a pregnancy test before every rTMS session with women of childbearing potential? Or does your group conduct a pregnancy test once before the entire rTMS study or treatment?

- Before every rTMS session (1)
- Once before the entire rTMS study or treatment (2)
- Neither (3)

Q45 How many pregnant individuals has your group treated?
Q47 If these adverse events occurred in a non-clinic setting, please describe how they were handled.

________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________

End of Block: Other Serious Adverse Events

Start of Block: Identifying Information

Q48 Please answer the questions below. We are asking for identifying information only so we may validate the information provided in the survey and eliminate any redundant information provided by different individuals. We will not share this information with anyone, and any information we publish or share with other researchers will be entirely decoupled from any identifying information you provide us.

Q49 What is your name?
________________________________________________________________

Q50 What is your e-mail address?
________________________________________________________________
Q51 What is the name of the lab or treatment center whose TMS safety data you are reporting?

________________________________________________________________

Q52 Please check the following boxes if you would like us to acknowledge you or your group in eventual publications. (No identifying information will be associated with the specific data you provide us.)

☐ Yes, I would like to be acknowledged in eventual publications. (1)

☐ Yes, I would like my group to be acknowledged in eventual publications. (2)

Q53 Where is your group administering TMS? Please check all that apply.

*Please note: For this survey, we define a clinic as a health care facility with advanced life-support (injectable medications, intubation, etc.) on site.

☐ Clinic (1)

☐ Non-clinic setting near a clinic with a specific coverage arrangement (2)

☐ Non-clinic setting with a physician or other licensed independent practitioner (LIP) in the room (3)

☐ Non-clinic setting with a physician or other licensed independent practitioner (LIP) on the premises (4)

☐ Non-clinic setting without a physician or other licensed independent practitioner (LIP) on the premises (5)
Q54 Do you have any other comments, questions, or concerns?

________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________