

PROTOCOL NARRATIVE FOR EXEMPT RESEARCH

University of California, Irvine Institutional Review Board

Version: January 2010



IMPORTANT TIME SAVER: THIS FORM SHOULD BE USED ONLY IF THE RESEARCH CAN BE CATEGORIZED AS EXEMPT RESEARCH.

TO VERIFY THAT THE PROPOSED RESEARCH MEETS ONE OF THE EXEMPTION CATEGORIES PLEASE REVIEW THE [EXEMPT CATEGORY](#) DESCRIPTIONS.

IF THE RESEARCH CANNOT BE CATEGORIZED AS EXEMPT, PLEASE COMPLETE THE [PROTOCOL NARRATIVE FOR EXPEDITED/FULL COMMITTEE RESEARCH](#).

IMPORTANT: CAREFULLY READ THE INSTRUCTIONS FOR EACH SECTION BEFORE COMPLETING THE PROTOCOL NARRATIVE.

NEED HELP? CONTACT THE [HRP STAFF](#) FOR ASSISTANCE

HS#: 2012-8972

For IRB Office Use Only

Lead Researcher Name: William C. Thompson

Study Title: Evidence, inference and bias in WMD forensics

NON-TECHNICAL SUMMARY

Provide a non-technical summary of the proposed research project. The summary should include a brief statement of the **purpose of the research** and a brief description of the **procedure(s) involving human subjects**. *This summary should not exceed ¼ page.*

The proposed research project is one component of a large study funded by the UC Laboratory Fees Research Program. The overall project concerns the use and misuse of forensic science evidence in investigations of alleged terrorism. The particular component for which I am seeking approval here is three jury simulation studies that examine how lay people evaluate statistical and probabilistic evidence in criminal investigations. All three studies have previously been reviewed and approved by the UCI IRB to run with participants recruited from the Orange County Courthouse (under Protocol 2006-5148). All that is being proposed here is to run the same studies using participants recruited in a different manner.

Human subjects will be recruited using Amazon's Mechanical Turk (www.mturk.com). Participation will be limited to US citizens over age 18 who speak English using a screening process incorporated into Mechanical Turk. Participants in Mechanical Turk (Turkers) will be offered a small financial incentive (less than 50 cents) to participate in an online study. They will be given a brief disclosure describing the study, but (because they will be participating anonymously and the study poses no risks), they will not be asked to sign a consent form. Instead they will indicate their consent by clicking a hyperlink, which will

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take them to a website containing the study materials.

At the study website, all respondents will be asked a series of screening questions to ascertain that they are human beings and not “bots” programmed to respond to surveys. Weeding out of robotic respondents is a necessary step for assuring the validity of online research of this type. Respondents who do not respond in a manner indicating they are human will be dropped from the study and will not be paid. For example, respondents will be given a question like the following:

Sometimes people write programs called “bots” to respond to surveys of this type. Because we want responses from human beings, rather than computer programs, we ask you, if you are a human, to skip the next question—just don’t answer it.

1. *What are you?*
 - a. *A human being*
 - b. *An intelligent animal*
 - c. *A computer program*
 - d. *A non-human alien from another planet*

It has been shown that “bots” answer such questions and humans do not—accordingly, any respondent who answers such a question (regardless of the answer given) will be dropped from the study and will not be paid.

Human respondents will read a summary of evidence in a criminal case and will be asked to give their opinion about it. Key parts of the evidence, involving forensic science, will be varied experimentally to test how participants’ evaluations are affected by the way the evidence is characterized and presented. After giving opinions about the case, such as whether the accused person is likely to be guilty, and how strong or weak various aspects of the case are, participants will be asked to provide (anonymously) some basic demographic information about themselves. They will then be thanked for participating. Any participant who successfully completes the screening question and examines the materials will be given a code that allows them to be paid through the Mechanical Turk payment system. Respondents need not complete the entire study nor respond to all questions in order to be paid—they need only pass the screening question and open the pages of the survey containing the stimulus materials. But any who decide to terminate their participation before even looking at the study materials will not be paid.

SECTION 1: PURPOSE OF THE RESEARCH

1. Describe the **purpose of the research** project and state the **overall objectives, specific aims, hypotheses** (or research question) and **scientific or scholarly rationale** for performing the study.
2. Clearly identify the **primary outcome(s) and key factor(s) of interest**, as applicable.

The purpose of the proposed study is to determine whether respondents recruited through Mechanical Turk respond in the same way as respondents recruited in more traditional ways. This information will be helpful in assessing whether Mechanical Turk is an appropriate source for future jury simulation studies.

SECTION 2: ROLES AND EXPERTISE OF THE STUDY TEAM

List all study team members below.

1. Identify each **member's position** (e.g., Associate Professor, graduate or undergraduate student) and **department**, and describe his or her **qualifications, level of training and expertise**. Include information about relevant licenses/medical privileges, as applicable.
2. Describe each team member's **specific role and responsibility** on the study.
3. **Faculty Sponsors** - list as Co-Researchers and describe their role on the project; include oversight responsibilities for the research study.
4. Explain who will have **access to subject identifiable data**.
5. Indicate who will be **involved in recruitment, informed consent process, research procedures/interventions, and analysis of data**.

Lead Researcher:

William C. Thompson, Professor, will run the studies and, at this point, will be the sole person with access to the data. As additional study personnel are added, this protocol will be modified to indicate their participation.



IMPORTANT TIME SAVER: If requesting [Exempt Registration under Category 4](#) ONLY, complete the non-technical summary, [Sections 1-2](#) and [Sections 10-11](#).

SECTION 3: EXEMPT CATEGORY JUSTIFICATION

If you are requesting Exempt Registration per Category(ies) 1-3 or 5, provide a **brief justification** for why the research **meets each applicable Exempt category**.

***Note:** Research involving prisoners is not eligible for Exempt Registration. Also, research involving children may only be Exempt under Category 1; or under Category 2 if the research involves only educational tests or observation without direct interaction by the researchers.*

This study falls under Exempt Category 2 because it involves anonymous survey-type stimuli that pose no foreseeable risks to participants. No information that could be used to identify a participant is collected.

SECTION 4: RESEARCH METHODOLOGY/STUDY PROCEDURES FOR EXEMPTION

A. Study Design and Procedures

1. Provide a detailed chronological description of all **study activities** (e.g., pilot testing, recruitment, screening, [intervention/interaction](#)/data collection, and follow-up) and **procedures**.
 - a. Indicate how much **time will be required of the subjects**, per visit and in total for the study.
 - b. Indicate the **setting** where each **procedure will take place**/be administered (e.g. via telephone, sent via email, online, classroom). ***Note:** If any of the procedures will take place at off-campus location (e.g., educational institutions, businesses,*

organizations, etc) Letters of Permission are required.

- c. If a procedure will be completed more than once (e.g., pre and post survey), indicate **how many times** and the **time span** between administrations.
2. If study procedures include collecting **photographs, or audio/video recording**, specify whether any subject identifiable will be collected and describe which identifiers will, if any.
3. Describe how the **subject's privacy will be protected** during the research procedures.
Note: *This is not the same as confidentiality (see the [Privacy and Confidentiality web page](#)).*
4. Be sure to submit **data collection instruments** for review with your e-IRB Application (e.g., measures, questionnaires, interview questions, observational tool, etc.). **Note:** *If the instrument is still being developed, submit a draft with this application. The final version of the data collection instrument must be submitted to the IRB via an eMOD request before you begin data collection.*

People who participate in Mechanical Turk, Amazon's online marketplace for human intelligence tasks, will see a notice inviting participation in a jury simulation study. They will be offered a small financial incentive (less than 50 cents) to participate. Participation will be limited to those with IP addresses in the United States. Those who indicate their interest by clicking on the task will see a brief disclosure statement describing the study. If they decide to participate they will click a link labeled "I would like to participate" which will take them to another website, where the study materials are will be posted. It will take subjects approximately 15-20 minutes to read the stimulus materials and respond to questions. Participation will be entirely anonymous. Participants will need to enter an Amazon Turk ID number in order to receive payment for the study, but there will be no way for the researcher to link any particular Turk ID number to specific responses, nor will there be any easy way for the researcher to link a Turk ID number with any particular individual (Amazon maintains this information but does not make it publicly available).



IMPORTANT TIME SAVER: Complete Part B ONLY if you are requesting permission to review student academic records.

B. Student Academic Records Review

1. Specify the **types/source of records/data** that will be reviewed by selecting the appropriate bracket(s) below.
2. If you will **manually extract research** data from academic records, upload a **Data Extraction Sheet** when you submit your e-IRB application (i.e. the document used to record the information). **Note:** *The application will be considered incomplete until this is submitted.*

- School Records (specify): [<Type here>](#)
- Individual level data from an established data repository (specify): [<Type here>](#)
- Other (specify): [<Type here>](#)

3. Specify how the **records/data will be obtained**, and whether the data are **publicly available**.
4. Submit a copy of the **School or School District Permission Letter** to access the academic records with your e-IRB Application. **Note:** *Since official student records will be accessed for research purposes, the letter of permission must address how Title 34 of the Code of Federal Regulations Part 99 - **Family Educational Rights and Privacy Act (FERPA)** applies to this research.*

<Type here>

5. Specify how the **data are identified** when they are made available to the study team. Please indicate by marking the appropriate bracket(s) below.

- i) No Identifier (i.e., neither the researcher nor the source providing the data can identify a student based upon information provided with the data)
- ii) Indirect Identifier* (i.e., an assigned code will be kept which could be used by the investigator or the source providing data to identify a student, such as a tracking code used by the source.)
- iii) Direct Identifier (i.e., student name, address, social security number, academic record number, etc. will be attached to data)

***If ii is checked above**, specify whether the study team will be given access to the code.

- Yes, the study team will have access to the link between the tracking code and subject identities.
- No, the study team will not have access to the link between the code and subject identities.

SECTION 5: SUBJECTS

A. Number of Subjects

1. Indicate the maximum number of subjects to be **recruited/consented** on this UCI protocol. This is the number of potential subjects you may recruit in order to get your sample—not just the number who actually participate in the study.
2. For studies where multiple groups of subjects will be evaluated, please **provide a breakdown per group** (e.g., controls vs. experimental subjects; children vs. adults).
3. For **Mail/Internet surveys** include the number of people directly solicited.
4. For **academic records review**, specify the maximum number of records that will be reviewed to compile the data necessary to address the research question or the maximum number of individuals that will comprise the dataset.

1200

B. Subject Populations

1. Describe the **characteristics** of the proposed subject population. At a minimum include information about the age and gender of the study population.
2. Describe **different subject groups** (e.g., students and teachers) **separately**.

The proposed subject population is English-speaking adults who live in the United States. They will be sampled from participants in Amazon's Mechanical Turk. The solicitation posted on Mechanical Turk will invite participation from US residents aged 18 or over who read English. Participants will be asked

to verify that they meet those criteria before participating. Only those with US IP addresses will be able to participate. Mechanical Turk provides no easy way to screen out individuals under 18 who claim to be older. Participants will be asked anonymously to state their age and data from those indicate an age under 18 will not be used. In any event, there is nothing in the stimulus materials that would be harmful to a juvenile old enough to contrive a way to read them.

SECTION 6: RECRUITMENT METHODS AND PROCESS

A. Recruitment Methods

Please check **all** applicable recruitment methods that apply to the study. Place an “X” in the bracket [] next to the recruitment method.

- [] UCI IRB approved advertisements, flyers, notices, and/or media will be used to recruit subjects. **Submit advertisements for IRB approval.**
- Passive Recruitment - Potential subjects initiate contact with the study team.
 - **Complete Question 6B - Explain where recruitment materials will be posted.**

- [] The study team will recruit potential subjects who are unknown to them (e.g., convenience sampling, use of social networks, direct approach in public situations, random digit dialing, etc.)
- Active Recruitment – Researchers contact potential subjects.
 - **Complete Question 6B.**

- [] The UCI Social Sciences human subject pool will be used. **Submit the Social Science Human Subject Pool Recruitment Advertisement for IRB approval.**
- Passive Recruitment - Potential subjects initiate contact with the study team.
 - **Skip to Section 7.**

- [] Study team members will contact potential subjects who have provided permission to be contacted for participation in future research studies.
- Active Recruitment – Researchers contact potential subjects.
 - **Complete Question 6B – Explain when and how these individuals granted permission for future contact; provide the IRB protocol numbers, if applicable.**

- [] Study team members will approach their own patients, students, employees for participation in the study.
- Active Recruitment – Researchers contact potential subjects.
 - **Complete Question 6B.**

- [xx] Other Methods: [<Amazon’s Mechanical Turk>](#)
- **Complete Question 6B.**

B. Recruitment Process

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1. Based on the methods checked above, describe and provide **details of the recruitment process** (i.e. when, where, by whom and how potential subjects will be approached).
2. If you will recruit by **mail, e-mail, or phone**, explain how potential subjects' **contact information will be obtained**.
3. If active recruitment methods will be used, explain how the individual's **privacy will be protected**. **Note: This is not the same as confidentiality (see the [Privacy and Confidentiality web page](#)).**

People who participate in Mechanical Turk, Amazon's online marketplace for human intelligence tasks, will see a notice inviting participation in a jury simulation study. They will be offered a small financial incentive (less than 50 cents) to participate. Participation will be limited to those with IP addresses in the United States.

SECTION 7: INFORMED CONSENT PROCESS

1. If there will be contact with subjects*, then specify **how consent will be obtained** and **describe the specific steps** for obtaining informed consent (e.g. a study information sheet used to obtain verbal consent, an introductory paragraph included on the data collection instrument, a telephone script used, etc.).
2. Include information about **when and where** consent will take place and the **length of time** subjects will be given to decide whether they wish to participate.
3. If study team members will approach their own patients, students, or employees for participation in the study, then explain what precautions will be taken to **minimize potential undue influence or coercion**, and **how compromised objectivity will be avoided**.
4. If children are involved in this study, please describe the **parental permission** process and the **child assent** process.
5. Be sure to **submit the consent/assent document(s)** with your e-IRB Application.
6. If this study involves the creation, use, or disclosure of Protected Health Information (PHI), specify the process for **obtaining HIPAA Authorization**.

***Note: Mail/Internet surveys constitute subject contact.**

Check all that apply:

- N/A** – There will be no direct subject contact. No consent process will take place. **Explain why consent is not required.**
- Written (signed) consent will not be obtained** - Informed consent, parental permission and/or child assent will be obtained from subjects, as applicable. **Explain how this will be obtained.**
- Written (signed) informed consent will be obtained** – Signed informed consent, parental permission, and/or assent will be obtained from subjects, as applicable. **Describe the informed consent process. Note: Signed informed consent is infrequently required when conducting Exempt research.**

Participants will read consent disclosure text, which will appear on the Mechanical Turk website (see attached).

You are invited to participate in a jury simulation study designed by researchers at the University

of California, Irvine. Participating in this research is completely voluntary, and you may withdraw at any time. You will be asked to read a description of the evidence in a criminal case and give your opinion about it. The case you will read about will either be a murder or a rape. Although the crime in question was violent, you will not be asked to view any violent or graphic images. You will read descriptions of testimony offered by key witnesses and will use your best judgment to decide whether the defendant is guilty or not guilty. You will give your assessment of the strengths and weaknesses of the evidence. You will also be asked to provide some basic demographic information about yourself, such as your age, occupation, and level of education. Your answers will be completely anonymous and will not be linked in any way to your Amazon ID number. The study takes about 20 minutes and pays xx cents.

This study is open to United States citizens over the age of 18 who can read English. If you do not fall in those categories, please do not participate. In order to be paid, you will need to answer some basic questions about the materials (designed to make sure you are an actual human being who has looked at the materials, rather than a “bot”). If you answer those questions successfully, you will receive a code number that you will enter below to obtain credit for participating. If you want to skip any of the questions that ask about your opinions or your background, that’s okay, although we hope you will answer them all.

The study poses no risk to you (other than the risk of wasting some of your time) and offers no benefits. You will be compensated a nominal payment of xx cents for your time as a result of participating in this research. But most people find it interesting, and the study may provide useful information about the way people evaluate evidence in jury trials.

The lead researcher for this study is Prof. William C. Thompson, Department of Criminology, Law & Society, University of California, Irvine, Ca. 92697. If you have concerns about the study you may contact him by email at William.thompson@uci.edu. If you are unable to reach Prof. Thompson, or you have concerns or complaints about the research, or questions about your rights as a research subject, please contact UCI’s Office of Research Administration by phone, (949) 824-6662, by e-mail at IRB@rgs.uci.edu or at Research Park – 5171 California Ave, Ste 150; Irvine, CA 92697-7600.

If you would like to participate, please click on the following link, which will take you to the study:

[I want to participate]

7. **Non-English Speaking Participants:** In order to consent subjects who are unable to read and speak English, the English version of the consent form must be translated into appropriate languages once IRB approval is granted.

Check all that apply:

[X] Not applicable - Only individuals who can read and speak English are eligible for this study.

[] The English version of the consent form will be translated into appropriate languages for non-English speaking subjects once IRB approval is granted. An interpreter will be involved in the consenting process. **Note: The IRB must officially stamp the translated consent forms.**

SECTION 8: PARTICIPANT COMPENSATION

1. If subjects will be compensated for their participation, provide detailed information about the **amount and the method/terms of payment** (e.g., money; check; extra credit; gift certificate).
2. Describe the **schedule of compensation** (e.g., at end of study; after each session/visit).

Note: *Compensation should be offered on a prorated basis when the research involves multiple sessions.*

No compensation will be provided to subjects.

OR

Subjects will receive a nominal compensation of less than fifty cents through the Mechanical Turk payment system. Subjects who view the research materials and successfully answer question designed to distinguish them from “bots” will receive a code that they can enter at the Mechanical Turk website to receive payment. The exact amount of the payment will be determined experimentally by trying various amounts between 10 cents and 50 cents to see how the amount offered affects participation rate.

SECTION 9: CONFIDENTIALITY OF RESEARCH DATA

1. Explain how the collected data will be **identified**.

No subject identifiers are obtained.

Names and other subject identifying information are obtained but are not shared with anyone except the study staff

Names and other subject identifying information are obtained and potentially used in publications/presentations. **Note:** *This may require written consent.*

Other (specify): *<Subjects must enter an Amazon ID number at the Mechanical Turk website to obtain payment, but that ID number will not be linked to any of their responses in the study. They will respond anonymously to the experiment, which will be hosted on a website external to Amazon. They will then receive a code that they can enter with their ID at the Mechanical Turk website to receive payment. >*

2. Explain the manner in which the **data will be stored**.

Note: *If the research data includes subject identifiable information the storage devices or research files must be encrypted. Avoid storing subject identifiable data on portable devices (such as laptop computers, digital cameras, portable hard drives including flash drives, USB memory sticks, iPods or similar storage devices) as these devices are particularly susceptible to loss or theft.*

Anonymous or de-identified data only (i.e., no code key)

Coded data with the code key kept in separate location. Key destroyed upon completion of the research or (specify):

Coded data with the code key kept in separate location. Key maintained beyond the completion of the research.

<p><input type="checkbox"/> Data includes subject identifiable information. Note: <i>If electronic record/file, encryption software is required.</i></p>
<p>3. Explain how long subject identifiable research data will be retained. The data may include a code with a separate code key or the data may include subject identifiers (hard copy documents, computer files, recordings, biospecimens)</p>
<p><input checked="" type="checkbox"/> Not applicable – No subject identifiers will be collected.</p> <p><input type="checkbox"/> Research records will be retained for seven years after all children enrolled in the study reach the age of majority [age 18 in California] as this study includes children.</p> <p><input type="checkbox"/> Destroy once data collection is completed</p> <p><input type="checkbox"/> Destroy after publication/presentation</p> <p><input type="checkbox"/> Maintain indefinitely for future research</p> <p><input type="checkbox"/> Maintain for future research (specify time frame, e.g., 3 months, etc.): <input type="text" value="<Type here>"/></p> <p><input type="checkbox"/> Other (specify): <input type="text" value="<Type here>"/></p>
<p>4. If audio or video recordings will be collected, specify the timeframe for the transcription and/or destruction of the audio and video recordings.</p> <p>5. If photographs will be collected, specify the timeframe destruction of photographs</p>
<p><input checked="" type="checkbox"/> Not applicable – No audio/video recordings or photographs will be collected.</p> <p><input type="checkbox"/> Audio or video recordings transcribed; specify time frame: <input type="text" value="<Type here>"/></p> <p><input type="checkbox"/> Audio or video recordings destroyed; specify time frame: <input type="text" value="<Type here>"/></p> <p><input type="checkbox"/> Audio or video recordings maintained indefinitely</p> <p><input type="checkbox"/> Photographs destroyed; specify time frame: <input type="text" value="<Type here>"/></p> <p><input type="checkbox"/> Photographs maintained indefinitely</p>

 **IMPORTANT TIME SAVER: ONLY COMPLETE Sections 10-11 if you are requesting Exempt Registration under Category 4. OTHERWISE STOP, YOU HAVE COMPLETED THE PROTOCOL NARRATIVE.**

Note: If you will not have access to subject identifiers or the code key that links ID numbers and subject identifiers, this activity may not constitute human subjects research. You should submit a request for [Determination of Non-Human Subjects Research](#).

SECTION 10: BIOSPECIMENS/CHARTS/RECORDS/DATASETS

A. Exempt Category 4 Eligibility

<p>1. Will investigators have interaction or intervention with subjects? <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>2. Will investigators collect information that does not currently exist? (i.e., biospecimens that are not currently on the shelf or information from records that does not already exist as of the date of submission of this protocol)? <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>3. Will investigators collect subject identifiers or have access to a code key linking subjects' identities to the data or biospecimens? <input type="checkbox"/> YES <input type="checkbox"/> NO</p>
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Note: If you answer YES to any of the above three questions, your protocol does not qualify as Exempt research under Category 4. If another Exempt category does not apply complete the Protocol Narrative for Expedited/Full Committee Research.

B. Number of Biospecimens/Charts/Records/Datasets

Specify the **maximum number of records or biospecimens that will be reviewed/analyzed** to compile the data necessary to address the research question **or the maximum number of individuals that will comprise the dataset.**

<Type here>



IMPORTANT TIME SAVER: Complete Part C ONLY if you are requesting permission to study biospecimens.

C. Description of Biospecimens

1. Specify the **type(s) of human biospecimens** that will be studied:

<Type here>

- 2. Specify the **source of the biospecimens and** whether the biospecimens were originally **collected solely for research purposes.**
- 3. If the biospecimens were originally collected for research purposes, please **submit a copy of the IRB Approval Notice and Consent Form for the original collection** of these specimens with the e-IRB Application.

<Type here>

4. Specify how the **biospecimens are identified** when they are made available to the study team. Please indicate by marking the appropriate bracket(s) below.

- i) No Identifier (i.e., neither the researcher nor the source providing the data can identify a subject based upon information provided with the biospecimens.)
- ii) Indirect Identifier (i.e., an assigned code will be kept which could be used by the investigator or the source providing biospecimens to identify a subject, such as a tracking code used by the source.)
- iii) Direct Identifier** (i.e., subject name, address, social security number, medical record number, etc. will be attached to biospecimens)

If ii is checked above, specify whether the study team will be given access to the key code.

Yes, the study team will have access to the code key linking the code and subject

identities**

- No, the study team will not have access to the code key linking the code and subject identities

****Note:** *If direct identifiers will be used or the study team will have access to the code key, the research does not qualify for [Exempt Registration under Category 4](#). If another Exempt category does not apply complete the [Protocol Narrative for Expedited/Full Committee Research](#).*



IMPORTANT TIME SAVER: Complete Part D ONLY if you are requesting permission to study existing data, charts, or records.

D. Description of Charts/Records/Datasets

1. Specify the **types/sources of records/data** that will be reviewed by selecting the appropriate box below (e.g., census, medical).
2. Please be sure to submit a copy of the **Data Extraction Sheet** that will be used to collect the data for this study (i.e. the document used to record the information)) with the e-IRB Application.

Note: *If direct identifiers will be collected on the data abstraction sheet (e.g., medical record number, name), or the study team will have access to the code key linking the code to the subjects' identities, the research does not qualify for Exempt Registration. STOP completing this form and complete the [Protocol Narrative for Expedited or Full Committee Review](#).*

- UCI Medical Records
 Individual level data from an established data bank or repository (specify): [<Type here>](#)
 Publicly available information (i.e. DMV, US Census)
 NCI SEER (Surveillance Epidemiology and End Results)
 Data Sets not including any of the [18 Protected Health Identifiers](#)
 Other (specify): [<Type here>](#)

3. Provide a description of **how** the appropriate **records/data** for study will be **provided** to the study team. (e.g. the Investigator will ask the Medical Records Department to provide specific charts and/or de-identified data; the Investigator will review his/her own charts and abstract data directly from those charts; the Investigator will be provided an already existing, de-identified data set, etc.)

[<Type here>](#)

4. Specify whether the information is **publicly available**.
5. Explain whether the data was originally collected **solely for research purposes**.
6. If the records/data were originally collected for research purposes, please **submit a copy of the IRB Approval Notice and Consent Form for the original collection** of this information with the e-IRB Application.

[<Type here>](#)

7. Specify how the **data is identified** when it is **recorded** by the study team. Please indicate by marking the appropriate bracket(s) below.

- i) No Identifier (i.e., neither the researcher nor the source providing the data can identify a subject based upon information provided with the data)
- ii) Indirect Identifier (i.e., an assigned code will be kept which could be used by the investigator or the source providing data to identify a subject, such as a tracking code used by the source.)
- iii) Direct Identifier** (i.e., subject name, address, social security number, medical record number, etc. will be attached to data)

If ii is checked above, specify whether the study team will be given access to the code.

- Yes, the study team will have access to the link between the tracking code and subject identities.**
- No, the study team will not have access to the link between the code and subject identities.

****Note:** *Unless the information is publicly available, if direct identifiers will be used, or the study team will have access to the code key linking the code to the subjects' identities, the research does not qualify for Exempt Registration. STOP completing this form and instead complete the [Protocol Narrative for Expedited or Full Committee Review](#).*

SECTION 11: RESEARCH METHODOLOGY/STUDY PROCEDURES

A. Study Design and Procedures

1. Provide a detailed chronological description of all **study procedures**.
2. Describe how the **subject's privacy will be protected** during the research procedures (i.e., during data extraction procedures).

<Type here>