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#: For IRB Office Use Only

Lead Researcher Name: Kathleen M. Hoff, MSN, RN, CCRN
Study Title: Clinicians perceptions of dying and death in the critical care setting

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.

End of life care is an universal healthcare concern for medical providers worldwide. National healthcare organizations and current reviews on end of life care indicate there are disparities in providing quality and comfortable end of life care. It is estimated one in five Americans will die after receiving care in the intensive care area. It has been identified that 20% of all deaths in America that occur in the intensive setting may be marked with suffering from physical and emotional pain. As an important endeavor to improve quality of care for adult critical care patients who may die in the intensive care setting, a study of health care team member’s perceptions and personal experiences with end of life care will be conducted.

The study plan is to conduct a pre and post-test questionnaire prior to and after the implementation of a clinical algorithm developed that provides optimal guidelines to assist health professionals in the removal of mechanical ventilation (RMV) from the dying critical care patient. Critical and comprehensive review, analysis, and integration of national recommendations, other published data, and recommendations from University of California, Irvine (UCI) expert medical staff has been obtained to create the RMV guideline.

Given the fact that disparities in providing optimal care for the dying critical care patient are
identified, evaluating health care professional’s knowledge and experience and developing evidenced-based clinical algorithm and guidelines can decrease obstacles or barriers and increase support. Obtaining valid pre and post education and clinical experiences responses from health processional’s perception is a good method to facilitate a “good death process” (Hale, et al, 2010).

REFERENCE:

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.

End of life care is not a new concept for health professionals and the need to improve quality of dying and death within the intensive care unit is well supported in the literature. Many leading organizations such as the World Healthcare Organization (WHO), Robert Woods Johnson Foundation, American College of Surgeons, and the American Association of Critical Care Nurses indicate improved end of life care is essential and a priority for healthcare professionals. According to Treece (2006) a large number of patient deaths in the United States occur in the intensive care unit (ICU) or after a stay in the ICU. One in five Americans will die after receiving medical care with in an intensive care setting (Nelson et al, 2006). The most common causes of death in the critical care setting are cancer, sepsis, acute respiratory distress syndrome, and complications of trauma. The mortality rate for these populations is between 52 to 60 % (Angus et al., 2004).

The literature supports the need for improved end of life care but acknowledges a lack of consensus of concerning a good death experience among critical care providers (Rocker, 2003). Numerous studies have shown that most ICU deaths are preceded by removal of mechanical ventilation. Given that the Interdisciplinary Team (IDT) is charged with the responsibility for quality and compassionate end of life care, it is imperative to identify and analyze the perceptions of these health care providers concerning ICU death experiences.

The purpose of this study is to obtain the IDT’s perceptions with the dying critical care patient to improve the quality of end of life care in the critical care setting. The results of the questionnaire will be analyzed to assess the IDT’s interpretation of the patient’s end of life care since critical care physicians, nurses and respiratory therapists are in the frontline position to care for the dying patient.

Beckstrand and Kirchhoff (2005) contacted a study of critical care nurses and found that when death occurs in the critical care unit is often unnatural. Critical care nurses are an essential part of the IDT and they are in the position to see a variety of patient death experiences. They indicated that besides providing quality and comfortable care to the dying patient, critical care nurses noted
that caring for the patient and the family was one of the most stressful and painful events. The nurses reported obstacles and lack of support were factors that affected end of life care.

Levy (2005) compared perceptions of the quality and death in the ICU from nurses, resident physicians, attending physicians, and family members. They found perceptions of dying and death in the ICU varies considerably between this IDT members. They recommend further studies are needed to explain the differences and determine the usefulness of the Quality of Dying and Death questionnaire (QODD) to assess and improve end of life care in the ICU.

The review of current literature indicated that evaluating health professional’s perceptions and the development of organizational recommendations for end of life care in the critical care setting is essential. The universal priority for critical care patients at the end of life is to evaluate the health professionals’ perceptions and experiences of providing care at end of life. The results of this perception study have the potential to improve the quality of end of life care in the ICU.

Objective:
Describe the IDT’s perceptions and experiences with the dying critical care patient to improve the quality of end of life care in the critical care setting.

REFERENCES


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.

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**Lead Researcher:**
Kathleen Hoff

Kathleen M. Hoff, RN, MSN, CCRN, FNP – BC
Surgical intensive care unit critical care educator at UCI Medical Center. She will be responsible for the educational evaluations, competencies, and continuous guidance for patient care management. K. Hoff has served on numerous committees including nursing standards, critical care professional practice council, magnet planning, and as the policy and procedure coordinator. K. Hoff contributed to current evidenced-based nursing practice as a clinical staff nurse and a nurse educator. K. Hoff will be the lead researcher, coordinating the study process.

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**Co-Researcher(s):**
Ruth A. Mulnard, DNSc, RN, CNRN, CIP, FAAN, Associate Professor and Associate Director of the Program in Nursing Science. Dr. Mulnard is an experienced clinical researcher and serves as a faculty consultant to the Nursing Quality and Research Council at UCIMC to assist clinical nurses with the research process. Dr. Mulnard will serve as the Faculty Sponsor for this research project, and will provide oversight and guidance for the conduct and management of this project.

Michael E. Lekawa, MD, Associate Clinical Professor and Chief of the Division of Trauma and Surgical Critical Care has participated in several prior investigational studies at UCIMC as Principal Investigator, including studies related to the treatment of patients with trauma. Dr. Lekawa has conducted many critical care and trauma related studies over the last 7 years. For this study, he will assist in identifying appropriate subjects and monitor the progression of data collection.

Cristobal Barrios, MD is a clinical instructor in the Trauma/Critical Care Division of the Department of Surgery at the University of California Irvine (UCI). His fellowship in Trauma/Critical Care was completed at UCI. His general surgery training was completed at the University of Arizona (Tucson, Arizona). Dr. Barrios will assist in identifying appropriate subjects and monitor the progression of data collection.

Maurice Espinoza RN, MSN, CS
Adult critical care clinical nurse specialist at UCI Medical Center. His usual duties include assessing the ongoing learning needs and maintaining up-to-date competencies and skills for the nursing staff. He is involved in areas of clinical practice, education, consultation, and research. For this study, Maurice will be facilitating completion of the survey using an electronic version via email. This will be achieved by converting the survey to electronic format using Survey Monkey. This electronic version will be emailed to potential participants. Maurice will be available for all questions in completing the survey. He will also tabulate the results. In addition, he will be assisting in nursing education implementation and helping to facilitate physician
**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.

Category 2: Research involving the use of survey procedures. Although identifiers will be maintained to allow linkage within subjects of the pre and post-test questionnaire data, once the data set is complete, identifiers will be discarded, leaving a de-identified dataset.

**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.*
1. Study Chronology:
   a. Baseline survey “The Quality of Dying and Death (QODD) Questionnaire”
   b. Educate and implement Clinical Algorithm: Removal of Mechanical Ventilation, End of Life care (RMV).
   c. Re-survey 6 months after the algorithm is implemented of participants who had completed initial baseline survey.
   d. Each participant can complete a pre and post survey only once. The post survey will be completed 6 months after education.

2. Photographs: NA

3. Privacy: Participants can complete the survey at their own convenience. This can occur at the Medical Center or any private computer.

The goal of this project is to conduct a healthcare questionnaire of their perceptions of dying patient’s experience at the end of life in the Intensive Care Unit (ICU). The Quality of Dying and Death (QODD) Questionnaire for health professionals - a survey instrument, will be used to measure the critical care interdisciplinary team (IDT) member’s perceptions of quality of care at the end of life. The QODD has been identified as a validated quality of dying and death measurement tool (Downey, et al, 2010). It is the most frequent used tool to study end of life care (Hales, 2010). Permission has been obtained by the University of Washington to use the 3.2 version of the QODD instrument.

The IDT will include attending physicians, fellow or chief resident physicians, and resident physicians, critical care nurses, and respiratory therapists within all adult critical care services at UCI Medical Center.

The QODD questionnaire will be completed by participants electronically. Participants will be contacted via email and the survey will be completed through Survey Monkey. In completing the questionnaire, participants will be asked to reflect about their experiences they have had during the time he/she was in the ICU and how they think these experiences affected the quality of their patient's dying and death. The survey will be obtained prior to (pre-test) and after (post-test) end of life education has been delivered surrounding implementation of a Care at End of Life; Removal of Mechanical Ventilation (RMV) algorithm. No other education, in regards to procedures, evaluation, or guidance will be included. The participants will be sent an electronic message via e-mail. The estimated time to complete the QODD is approximately 10 to 15 minutes.

**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. N/A

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): N/A
[ ] Individual level data from an established data repository (specify): N/A
[ ] Other (specify): N/A

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.

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.

The estimated number of participants is 950. The participant groups include 600 physicians, 300 registered critical nurses, and 50 respiratory therapists. The approximate number of participants was derived from the UC Healthcare electronic directory. The study population is gender and age neutral.

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.

Physicians, fellow or chief resident physicians and resident physicians, critical care nurses, and respiratory therapist within adult critical care services at UCI Medical Center.

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.**

[ X ] Other Methods:  Participants will be contacted via email and the survey will be completed through Survey Monkey.
  - **Complete Question 6B.**

**B. Recruitment Process**

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).

Email distribution list will be obtained through the adult critical care services. This email list includes physicians, nurses, and respiratory therapists. This distribution list is available to all UC employees and is kept on secured servers. No external emails will be used for this study (yahoo, etc.).

**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.*

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**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.**

- [X] 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.**

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No study team members will directly approach study participants to complete the survey. There is a small potential that some study team members may have a pre-existing relationship with some survey participants but only Maurice Espinoza will have access to participants personal information. This information will be kept confidential and will be de-identified.

Since there is virtually no risk involved in completing this on-line questionnaire at two separate time points, we will not obtain written consent to participate in this study, which would create an unnecessary identifier (signature of the participant). Instead, we will achieve verbal consent by including the basic elements of informed consent in the introduction section of the questionnaire, allowing participants to make an informed decision about participating in this research study. Content will include the right to refuse to participate. If the participants refuse, the survey will terminate at that question. If the participant agrees to complete the survey, they will be prompted to complete the survey. Once the post-test data is collected and the data collection time points have been linked, identifiers will be removed and discarded from the dataset.

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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.

[ X ] No compensation will be provided to subjects.

OR

**SECTION 9: CONFIDENTIALITY OF RESEARCH DATA**

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

[ ] No subject identifiers are obtained.

[ X ] Names and other subject identifying information are obtained but are not shared with anyone except the study staff. Once the dataset has been linked for the two data collection time points, all identifiers will be removed from the dataset and discarded.

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

[ ] Other (specify): <Type here>

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.

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<thead>
<tr>
<th></th>
<th>Anonymous or de-identified data only (i.e., no code key)</th>
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<tbody>
<tr>
<td>X</td>
<td>Coded data with the code key kept in separate location. <strong>Key destroyed upon completion of the research</strong> or (specify):</td>
</tr>
<tr>
<td></td>
<td>Coded data with the code key kept in separate location. Key maintained beyond the completion of the research.</td>
</tr>
<tr>
<td></td>
<td>Data includes subject identifiable information. <strong>Note: If electronic record/file, encryption software is required.</strong></td>
</tr>
</tbody>
</table>

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)

|   |Not applicable – No subject identifiers will be collected. |
|   |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. |
| X |Destroy once data collection is completed |
|   |Destroy after publication/presentation |
|   |Maintain indefinitely for future research |
|   |Maintain for future research (specify time frame, e.g., 3 months, etc.): |
|   |Other (specify): |

OR

4. If audio or video recordings will be collected, specify the **timeframe for the transcription and/or destruction of the audio and video recordings.**

5. If photographs will be collected, specify the **timeframe destruction of photographs**

| X |Not applicable – No audio/video recordings or photographs will be collected. |
|   |Audio or video recordings transcribed; specify time frame: |
|   |Audio or video recordings destroyed; specify time frame: |
|   |Audio or video recordings maintained indefinitely |
|   |Photographs destroyed; specify time frame: |
|   |Photographs maintained indefinitely |

**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

1. Will investigators have interaction or intervention with subjects? [ ] YES [ ] NO

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)? [ ] YES [ ] NO

3. Will investigators collect subject identifiers or have access to a code key linking subjects’ identities to the data or biospecimens? [ ] YES [ ] NO

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.

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):  
[ ] 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):  

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.)

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.

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,
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>