CAUTION: This diagram does not apply to 1) prospective collection of human tissue that involves human subject contact, 2) FDA-regulated research, and 3) research involving prisoners. All of these must be reviewed either by Full Committee or Expedited Review.

Data and/or specimens have personal identifiers

Data and/or specimens are coded and identifiers* are kept separately

Data and/or specimens are de-identified*

Do the PI or Co-Investigators on the study have access to the “key” to link back to the identifiers*?

Yes

No

Human subjects

Not human subjects

See the conditions that must be met.

The data and/or specimens are pre-existing*, and the information is recorded in a manner that subjects cannot be identified directly or through identifiers* linked to the subject.

No

Yes

Expedited Review or Full Committee

Exempt Certification

Conditions:
The coded data and/or specimens were not collected specifically for the current proposed research project, and one or more of the following apply:
1. The key to decipher the code is destroyed before researcher begins, or
2. PI and holder of the key enter into an agreement prohibiting the release of the key under any circumstances, or
3. There are IRB-approved written policies for the repository or data management that prohibit the release of the key.

Important Note: If these are not applicable then the coded data or specimens are considered human subjects.

Refer also to the PI Self-Certification Form

See also OHRP Guidance on Research Involving Coded Private Information or Biological Specimens

Definitions:

Obtaining - is defined as receiving or accessing data or biological specimens.

Identifiers – Any of the 18 Protected Health Identifiers (PHI). IMPORTANT EXCEPTION: The data or biological specimens may include a limited set of data including all elements of dates and geographical codes (zip codes) as long as the individuals identity cannot be ascertained. See page 2 of the Self Certification for Determining Whether Human Subjects Are Involved in Research for additional information about identifiers.

Pre-existing - means collected (i.e., on the shelf) prior to the research for a purpose other than the proposed research. It includes data or specimens collected during research and/or non-research activities.
**PI SELF-CERTIFICATION FOR DETERMINING WHETHER RESEARCH USING CODED PRIVATE INFORMATION (DATA) OR BIOLOGICAL SPECIMENS INVOLVES HUMAN SUBJECTS**

<table>
<thead>
<tr>
<th>Principal Investigator Name</th>
<th>Degree(s)</th>
<th>University Title</th>
<th>Campus Phone #</th>
</tr>
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<tbody>
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<table>
<thead>
<tr>
<th>Department</th>
<th>Campus Mailing Address</th>
<th>Mail Code</th>
<th>e-Mail Address</th>
</tr>
</thead>
<tbody>
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<td></td>
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</tbody>
</table>

**Important notes:** 1) If you check any of the boxes that are asterisked (*), then your project must be submitted to the IRB for either exempt certification or expedited review. 2) Answer Section A or B, not both. 3) Additional instructions for completing this form are on page 2.

**Section A. CONDITIONS THAT MUST BE MET FOR CODED PRIVATE INFORMATION (DATA) OR BIOLOGICAL SPECIMENS NOT TO BE CONSIDERED HUMAN SUBJECTS RESEARCH**

1. Were the data or specimens collected or will they be collected specifically for the current proposed research project? ☐ No ☐ Yes*

2. Is your research covered by the FDA? ☐ No ☐ Yes*

   **Important note:** Some research involving coded private information or specimens may be subject to Food and Drug Administration regulations. For example, for device research, a subject is also an individual on whose specimen a device is used (21 CFR 812.3(p)).

3. Do the data and/or specimens include personally identifying information (PII)? ☐ No ☐ Yes*

   **Important Note:** Information or specimens contain personally identifying information (PII) when they can be linked to specific individuals by the UCLA investigator(s), whether directly or indirectly through coding systems. See page 2 of this form for definition of personally identifying information.

4. Will the UCLA investigator ever have access to personally identifying information associated with the data and/or specimens? ☐ No ☐ Yes*

5. If you answered “no” to question #4 above, indicate how the personally identifying identifiable information associated with the records/data/specimens will be protected. Check all that apply.

   a. The key to decipher the code will be destroyed before the data or specimens are provided to the UCLA investigator.
   b. The UCLA investigator and holder of the key will enter into an agreement prohibiting the release of the key to the UCLA investigator under any circumstances.
   c. IRB-approved written policies for the repository or data management prohibit the release of the key.
   d. Neither the UCLA investigator nor the source possesses the identifiers.
   e. A third party “honest broker” holds the identifiers.
   f. The identifiers are maintained at the source only. There is a firewall between the source and the researcher so that the personally identifying information will never be given to the UCLA investigator.

**Section B. PUBLICLY AVAILABLE DATA AND/OR SPECIMENS**

Are the data and/or specimens you will study publicly available? ☐ No* ☐ Yes

If the data and/or specimens are publicly available, then your project does not meet the definition of “human subjects research.” Therefore, neither IRB review nor certification of exemption from IRB review is required. However, note that the term “publicly available” is restricted to mean that the general public can obtain the data/biological specimens. Sources are not considered “publicly available” if access to the data/specimen source is limited to researchers. Please also review OPRS/HRPP Guidance 42: Research Involving Public Use Data Files for more detailed guidance.

**Section C. Principal Investigator’s Certification**

I certify that the information provided in this application is complete and correct.

______________________________
Printed Name of PI

______________________________
Signature of PI                         Date
INSTRUCTIONS for Completing the

SELF-CERTIFICATION FOR DETERMINING WHETHER HUMAN SUBJECTS ARE INVOLVED IN RESEARCH when obtaining coded private information (data) and/or biological specimens

• Complete either Section A or Section B, as appropriate. Your responses to the questions in the form will help you determine if the proposed use of coded private information (data) and/or biological specimens in your project meets the definition of a human subject. If not, the project does not require either Certification of Exempt from IRB Review or IRB review.
• The decision tree Determining Whether Human Subjects Are Involved in Research When Obtaining Private Information and/or Human Biological Specimens may also help you make this determination.
• See also "Guidance on Research Involving Coded Private Information or Biological Specimens" on the DHHS Office for Human Research Protection website.
• See also OPRS/HRPP Policy 2: Determining Which Research Activities Require UCLA IRB Review.
• This form should be locked so that you can tab from one section to the next. If you are having any problems with this, click on View, then Toolbars, then Forms and then the Lock Icon to lock or unlock the form.

• If you need documentation for funding agencies, administrators, or collaborators, this self-certification form is provided for your use. The PI should maintain copies of this in the research files. Do not submit this form to the UCLA IRB.

• If you have questions about how to use this form contact the OPRS at (310) 825-7122 or e-mail: gcirb@oprs.ucla.edu.

• For purposes of this certification Personally Identifying Information (PII) includes either or both of the following:

Protected Health Identifiers (PHI): An individual’s personal and health information that is created, received, or maintained by a health care provider or health plan and includes at least one of the 18 personal identifiers listed below in association with the health information:
- Name
- Postal address
- All elements of dates except year
- Telephone number
- Fax number
- Email address
- URL address
- IP address
- Social security number
- Account numbers
- License numbers
- Medical record number
- Health plan beneficiary #
- Device identifiers and their serial numbers
- Vehicle identifiers and serial number
- Biometric identifiers (finger and voice prints)
- Full face photos and other comparable images
- Any other unique identifying number, code, or characteristic

Personal Identifying Information: Information about an individual which includes any of the identifiers below:
- Name
- Postal address
- All elements of dates except year
- Telephone number
- Fax number
- Email address
- URL address
- IP address
- Social security number
- Account number, credit or debit card number, in combination with any required security code, access code or password that would permit access to an individual’s financial account
- Driver’s License numbers or California or other identification card number
- Device identifiers and their serial numbers
- Vehicle identifiers and serial number
- Biometric identifiers (finger and voice prints)
- Full face photos and other comparable images
- Any other unique identifying number, code, or characteristic (e.g., student identification number)
CERTIFICATION OF EXEMPT

General Instructions

Certification of Exemption: Exempt categories of research are defined by the Department of Health and Human Services (DHHS) regulations for protection of human subjects in 45 CFR 46.101 (see Exemption Categories below). If an investigator believes his or her study qualifies for certification of exemption from Institutional Review Board (IRB) review, then a Certification of Exemption form must be completed and submitted to the OPRS HRPP office for review and certification. Federal guidance and University policy do not allow investigators to make this determination on their own.

Two Forms and Exempt Categories List
There are two types of certification of exemption forms:

- Certification of Exemption Form â€“ Categories 1, 2, 3, 5 and 6 is primarily for research that is being conducted in educational settings involving normal educational practices and research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observations of public behavior.

- Certification of Exemption Form â€“ Category 4 is for research which involves analysis of pre-existing data or biological specimens.

- Click on this Exempt Categories link for additional explanation of what may be submitted as exempt at UCLA.

Filling Out the Certification of Exemption Forms

- Review the Exemption Categories list before filling out the Certification of Exempt form. This list will help you make an initial determination as to whether your proposed research falls under one or more of the exemption categories.

- Be sure to use the appropriate form once you determine that your research may qualify for certification of exempt.

- Save the form immediately, before filling it out. After saving it, start Word (or other word-processing program) and open the form from within that program (i.e., do not open it from your desktop).

- Type your answers in the blank, un-shaded areas below questions. Do not alter the text and formatting of the form itself.

- Use clear, jargon-free language, understandable to persons outside of your research field.

- Complete all applicable sections of the application. The funding section must be completed. The Principal Investigator must sign the form.

- Complete the on-line Human Subject Research training. All investigators and faculty sponsors must complete this training before the research can be certified exempt. The on-line certification course is available as a link from the Human Research section of the OPRS Home Page.

- If you have any questions, please contact: Wendy Brunt, Administrator; Email: wbrunt@oprsl.ucla.edu; Call: 310- 825-4810; Fax: 310-794-9565.

- Important Note to Researcher: Before implementing any changes to the certified exempt protocol, the changes require re-certification of this study. Click here for a link to the Checklist for Submitting Amendments to Exempt Protocols.
Certification of Exemption

List of Exemption Categories

Important Notes:
• None of these exemption categories apply to research involving prisoners.
• Categories 1-5 do not apply to FDA regulated research.
• The following types of research do not qualify for exemption from UCLA IRB review:
  - Research involving deception
  - Research involving access to UCLA medical records
  - Research involving the use of human embryonic stem cells and human embryonic germ cells

Exempt status applies to research activities in which the only involvement of human subjects will be in one or more of the following categories:

Exemption Category #1:
Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
(i) research on regular and special education instructional strategies, or
(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exemption Category #2:
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

The above exemption category applies to research with children as follows:
• Research involving the use of educational tests is exempt;
• Research involving survey or interview procedures is not exempt;
• Research involving observations of public behavior is exempt only when the investigator does not participate in the observed activities.

Exemption Category #3:
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under category (2), if:
(i) The human subjects are elected or appointed public officials or candidates for public office; or
(ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Exemption Category #4:
Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Exemption Category #5:
Research and demonstration projects that are conducted by or subject to the approval of federal department or agency heads, and that are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs;
(ii) Procedures for obtaining benefits or services under those programs;
(iii) Possible changes in or alternatives to those programs or procedures; or
(iv) Possible changes in methods or levels of payment for benefits or services under those programs.

**Exemption Category #6:**
Taste and food quality evaluation and consumer acceptance studies,
(i) if wholesome foods without additives are consumed, or
(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental containment at or below the level found to be safe, by the FDA or approved by the EPA or the Food Safety and Inspection Service of the USDA.
EXPEDITED REVIEW REFERENCE TOOL

Research activities that (1) present no more than minimal risk\(^1\) to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure (authorized by 45 CFR 46.110 and 21 CFR 56.110) rather than by full committee review.

This document is intended for reference by investigators when completing Part 2, question 2 of the (HS-1) Application for the Involvement of Human Participants in Social Behavioral & Educational Research (SBER) and Health Services Research (HSR): "Indicate which level of IRB review you are requesting."

Please note that because all applications received by the OPRS are screened to determine the appropriate IRB level of review, if you identify the category incorrectly but the study does qualify for expedited review, the OPRS will apply the correct category.

EXPEDITED REVIEW CATEGORIES

<table>
<thead>
<tr>
<th>Expedited Category 2</th>
<th>Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:</th>
</tr>
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<tbody>
<tr>
<td>(a)</td>
<td>from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or</td>
</tr>
<tr>
<td>(b)</td>
<td>from other adults and children(^2), considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.</td>
</tr>
</tbody>
</table>

| Expedited Category 3 | Prospective collection of biological specimens for research purposes by noninvasive means.* |

| Expedited Category 4 | Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.* |

| Expedited Category 5 | Research involving materials (data, documents, records, or specimens) that have been collected; or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).* |

| Expedited Category 6 | Collection of data from voice, video, digital, or image recordings made for research purposes. |

| Expedited Category 7 | Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.* |

| Expedited Category 1 | Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. |

**Important Note:** This category is listed last rather than first because it is the least frequently applied.

\(^1\) **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(i)).

\(^2\) See [DHHS website](https://www.hhs.gov) for a more detailed description for and examples of the categories that are asterisked.

UCLA OPRS/HRPP Expedited Review Reference Tool
Version 4/7/2009
ADDITIONAL INFORMATION FOR EVALUATING EXPEDITED REVIEW CATEGORIES

1. For a complete description of each expedited review category with examples for most, refer to the DHHS website at [http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm).

2. The categories in this list apply regardless of the age of subjects, except as noted.

3. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

4. The expedited review procedure may not be used for classified research involving human subjects.

5. The standard requirements for informed consent (or its waiver or alteration) apply regardless of the type of review--expedited or Full Committee--conducted by the IRB.

6. The above categories pertain to both initial and continuing IRB review.
University of California, Los Angeles

CONSENT TO PARTICIPATE IN RESEARCH

[Insert title of the study.]

You are asked to participate in a research study conducted by [insert names and degrees of Principal Investigator—Faculty Sponsor as appropriate], and associates from the [insert department affiliation], at the University of California, Los Angeles. You were selected as a possible participant in this study because [explain why the potential participant is eligible to participate]. Your participation in this research study is voluntary.

Why is this study being done?

[Using a language that is easily understandable by the participants in the study and avoiding jargon and technical terms state what the study is designed to assess or establish - in approximately 2 sentences]

What will happen if I take part in this research study?

If you volunteer to participate in this study, the researcher will ask you to do the following:

[List and describe the procedures/tests/activities and their frequency chronologically using simple language, short sentences and short paragraphs. Use bullets or number the paragraphs as appropriate. If there are questionnaires or interviews, describe types of questions. Specify location of the study activities, if appropriate. If the study will include experimental and non-experimental procedures, please specify which procedures are experimental.]

How long will I be in the research study?

[Short-term/simple study:] Participation in the study will take a total of about XX hours [over a period of XX days/weeks].
[Long-term/complex study:] You will be asked to XXX every XXX for [months, weeks/until a certain event]. [When appropriate, state that the study will involve long-term follow-up and specify time frames and requirements of follow-up].

Are there any potential risks or discomforts that I can expect from this study?

[List and describe any reasonable foreseeable risks, discomforts, inconveniences, and how these will be managed. If there are significant physical or psychological risks to participation that might cause the researcher to end the participant's participation in the study, please describe them. If there are no anticipated risks or discomforts, please state "There are no anticipated risks or discomforts."]

UCLA IRB Number: 
Expiration Date:
Are there any potential benefits if I participate?

I may benefit from the study ... [Describe benefits to participants expected from the research. If the participants will not directly benefit from participation, please state, "You will not directly benefit from your participation in the research."]

The results of the research may ... [Describe the potential benefits, if any, to science or society expected from the research.]

Alternatives to participation

NOTE: If the research does not involve treatment (e.g., behavioral therapy), and the subject population will not be recruited from IRB-approved student subject pools, this section is NOT required.

If the research includes treatment, please describe any appropriate alternative therapeutic, diagnostic, or preventive procedures that should be considered before the subjects decide whether or not to participate in the study. If applicable, explain why these procedures are being withheld. If there are no efficacious alternatives, state that an alternative is not to participate in the study.

Will I receive any payment if I participate in this study?

You will receive ... [describe amount of payment and how and when payment will be received.] [If participant will not receive payment, say "you will receive no payment for your participation."]

Will information about me and my participation be kept confidential?

Any information that is obtained in connection with this study and that can identify you will remain confidential. It will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of ... [describe coding procedures and plans to safeguard data, including where data will be kept, who will have access to it, etc.]

• Withdrawal of participation by the investigator

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. If (describe include examples of the circumstances in which you would withdraw subjects from participation in the research), you may have to drop out, even if you would like to continue. The investigator will make the decision and let you know if it is not possible for you to continue. The decision may be made (include if applicable: either to protect your health and safety, or) because (explain).

What are my rights if I take part in this study?

You may withdraw your consent at any time and discontinue participation without penalty or loss of benefits to which you were otherwise entitled.
You can choose whether or not you want to be in this study. If you volunteer to be in this study, you may leave the study at any time without consequences of any kind. You are not waiving any of your legal rights if you choose to be in this research study. You may refuse to answer any questions that you do not want to answer and still remain in the study.

**Who can answer questions I might have about this study?**

In the event of a research related injury, please immediately contact one of the researchers listed below. If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact the [add the name of the PI and faculty sponsor as appropriate] at [phone number(s)—add postal and/or email address if appropriate].

If you wish to ask questions about your rights as a research participant or if you wish to voice any problems or concerns you may have about the study to someone other than the researchers, please call the Office for Protection of Research Subjects at (310) 825-7122 or write to Office for Protection of Research Subjects, UCLA, 11000 Kinross Avenue, Suite 102, Box 951694, Los Angeles, CA 90095-1694.

**SIGNATURE OF STUDY PARTICIPANT**

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

______________________________
Name of Participant

______________________________  __________________________
Signature of Participant  Date

**SIGNATURE OF PERSON OBTAINING CONSENT**

In my judgment the participant is voluntarily and knowingly giving informed consent and possesses the legal capacity to give informed consent to participate in this research study.

______________________________  __________________________
Name of Person Obtaining Consent  Contact Number

______________________________  __________________________
Signature of Person Obtaining Consent  Date
# Administrative Review for Human Research Studies Not Being Conducted by a UCLA Principal Investigator But Accessing UCLA Facilities, Patients or Personnel (Faculty, Staff, or Students)

**INSTRUCTIONS FOR USE:**

- Non-UCLA investigators involved in human research that seek to access any UCLA facilities, patients or personnel (faculty, staff or students) must complete this form and submit it to the UCLA IRB for a determination of whether proposed research involving human subjects falls within the UCLA IRB jurisdiction and/or whether UCLA is engaged in the research. Either case requires UCLA IRB review and approval or certification of exemption from IRB review.
- Submit one copy of the completed and signed form to the OPRS by 1) mail or deliver to the OPRS/IRB office at 11000 Kinross Avenue, Suite 102, Box 951694, Los Angeles, CA 90095-1694, or 2) fax to (310) 794-9565, or e-mail to gcirb@oprs.ucla.edu. You will be notified by e-mail of the results of this review.
- Call 310-825-7122 if you have any questions.

## Principal Investigator:

<table>
<thead>
<tr>
<th>Name and degree</th>
<th>Institution</th>
<th>Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mailing Address</td>
<td>Phone Number</td>
<td>E-mail Address</td>
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</table>

## Contact Person:

<table>
<thead>
<tr>
<th>Name and degree</th>
<th>Institution</th>
<th>Department</th>
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</thead>
<tbody>
<tr>
<td>Mailing Address</td>
<td>Phone Number</td>
<td>E-mail Address</td>
</tr>
</tbody>
</table>

## Study Title:

**All Researchers Involved in Study Who Will Be Working With UCLA Facilities, Patients, or Personnel:**

<table>
<thead>
<tr>
<th>Name and Degree/Institution</th>
<th>List the UCLA Site(s) and Specific Location(s):</th>
<th>End Date of UCLA Involvement:</th>
</tr>
</thead>
</table>

## Provide a Brief Description of the Study:


## Describe How UCLA Facilities, Patients, Employees Will Be Involved in the Study:


## Describe the Subject Population and the Recruitment and Consent of Subjects:


## Include the Following Information About the PI’s Institution:

1. Has this study been reviewed and approved by a duly constituted IRB?  
   - Yes  
   - No

2. If yes, please provide the name of the Institution:  
   - 
   - a. What is the PI’s relationship to the institution?  
     - 
   - b. Please provide the following with this application, as appropriate. Check all that apply.  
     - Local IRB Approval  
     - Local IRB Protocol  
     - Local IRB Approved Consent Form  
     - Questionnaire, Survey or Interview Outline

3. If no, please provide in the space below the justification as to why local IRB approval was not received.  
   - Note: Without appropriate IRB approval it may not be possible to involve UCLA facilities and subjects.  
   - 

## Funding Source(s):  

**Review Type:**
<table>
<thead>
<tr>
<th>Principal Investigator's Certification:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• I certify that the information provided in this application is complete and correct.</td>
</tr>
<tr>
<td>• I certify that I will follow my IRB Approved Protocol.</td>
</tr>
<tr>
<td>• I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the human subjects who are directly or indirectly involved in this project.</td>
</tr>
<tr>
<td>• I will comply with all applicable federal, state and local laws regarding the protection of human subjects in research.</td>
</tr>
<tr>
<td>• I will ensure that the personnel performing this study are qualified and adhere to the provisions of this IRB-certified protocol.</td>
</tr>
<tr>
<td>• I will not modify this protocol or any attached materials without first submitting an amendment to the previously approved protocol and receiving subsequent IRB approval as well as review at UCLA.</td>
</tr>
</tbody>
</table>

Principal Investigator's Signature ____________ Date ____________

<table>
<thead>
<tr>
<th>UCLA Department or Clinic Head, as appropriate:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• I am aware of the proposed research and the level of involvement with the departmental faculty, staff, students, and or facilities.</td>
</tr>
<tr>
<td>• I agree that this researcher can assess our clinic, personnel or patients as described in the proposal.</td>
</tr>
</tbody>
</table>

UCLA Department or Clinic Head Signature ____________ Date ____________

*******************************************************************************

UCLA OPRS Administrative Review Determination

UCLA Office for Protection of Research Subjects (OPRS) Administrative Review Determination

<table>
<thead>
<tr>
<th>UCLA IRB review or certification of exemption from UCLA IRB review is required</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Authorized Signature ____________ Date ____________

******************************************************************************* STOP

If full committee review was required at the PI's Institution or if there are any questions or concerns raised during the OPRS administrative review, the UCLA OPRS Director may also be required to review and approve this research. The OPRS will arrange this process.

UCLA OPRS Director Review and Approval:

Authorized Signature ____________ Date ____________

Sponsor Name: ________