

Version: 6.0

Application Version Date: 10/1/2013

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1. Project Identification and Abstract

1.1. * Type of Submission:

 Research Protocol or Study on Human Subjects

 Grant/Contract Only

 Facilitated Review (NCI CIRB)

 USC/CHLA Collaborative Review

 Use of Humanitarian Use Device (Not Research)

 Ceded Review (Utilize approval by an outside IRB)

1.2. * Full Title of Research Protocol

A Multicenter, Randomized, Double-Blind, Parallel Group, Active-Controlled Study to Evaluate the Efficacy and Safety of [REDACTED] Compared to [REDACTED] on Morbidity and Mortality in Patients with Chronic Heart Failure and Reduced Ejection Fraction [REDACTED]

1.3. * Short Title

[REDACTED]

1.4. Abstract: Provide a simple explanation of the study and briefly address (in 1 to 2 sentences) each of the following points: rationale; intervention; objectives or purpose; study population or sample characteristics; study methodology; description of study arms (if appropriate); study endpoints or outcomes; follow-up; statistics and plans for analysis.

Background/Rationale: Chronic heart failure (CHF) is a major public health problem characterized by significant mortality, frequent hospitalizations, and poor quality of life, with an overall prevalence that is increasing throughout the world. Therapies targeted at improving outcomes in HF with a low ejection fraction (EF) have been well studied over the past two decades, leading to improvement in survival as well as a decrease in morbidity with ACE inhibitors, angiotensin receptor blockers (ARBs), beta blockers, and mineralocorticoid antagonists. However, despite these advances, overall 50% of patients die within 4 yrs. and 40% of patients admitted to the hospital with HF die or are readmitted within 1 yr. Data from this study are intended to be used to support a worldwide registration submission of [REDACTED] for treatment of pts. with CHF and reduced EF. Objectives/Purpose: The purpose of this study is to evaluate the effect of [REDACTED] 200 mg BID compared to [REDACTED] 10 mg BID, in addition to conventional HF treatment, in delaying time to first occurrence of either CV death or HF hospitalization events in pts. with stable CHF NYHA classes II-IV and reduced EF (less than or equal to 35%). The primary objective is to test if [REDACTED] is superior to [REDACTED] in delaying time to first occurrence of the composite endpoint, which is defined as either CV death or HF hospitalization, in pts. with CHF and reduced EF. Study Population/Sample Characteristics: The study population will consist of pts. with CHF (NYHA II-IV), aged 18 yrs. or older with EF less than or equal to 35%. Eligible pts. will be on a stable dose of an ACE or an ARB for at least 4 wks. before entering the study. Study Methodology: This study is a randomized, double-blind, double-dummy, parallel-group, active-controlled, two-arm, long-term trial to compare [REDACTED] to [REDACTED] in CV mortality and morbidity reduction in pts. with stable CHF and reduced EF. Pts. will enter a single-blind active run-in period ranging from 5 - 10 wks. in which they will receive [REDACTED] 10 mg BID, followed by [REDACTED] 100 mg BID, and then [REDACTED] 200 mg BID. Pts. who tolerate the target dose of [REDACTED] (10 mg BID) and the target dose of [REDACTED] (200 mg BID) for at least 2 wks. will then be randomized in equal allocations to receive [REDACTED] 200 mg BID OR [REDACTED] 10 mg BID during the double-blind period. Description of Study Arms: Pts. who are eligible for randomization will be assigned to one of the following two treatment arms in a 1:1 ratio [REDACTED] 200 mg BID [REDACTED] 10 mg BID. Study Endpoints/Outcomes: The primary composite endpoint consists of the following components: CV Death HF Hospitalization. The target number of primary composite endpoint events is 2410. Secondary endpoints are: HF symptoms and physical limitation clinical summary score of KCCQ All-cause mortality Composite renal endpoint Intervention/Follow-Up: The study consists of two main periods: a single-blind run-in period, which will last ranging from 5 - 10 wks. and a double-blind randomized treatment period, which is projected to last up to 43 mos. The trial will be event-driven and all randomized pts. will remain in the trial until either the targeted number of pts. with primary events has been reached or the trial is terminated prematurely at the recommendation of the Data Monitoring Committee when pre-specified early-stopping criteria for efficacy or safety criteria are met. Statistics/Plans for

Analysis:Populations for analysis include the full analysis set which consists of all randomized pts. with the exception for those pts. who have not been qualified for randomization and have not received study drug, but have been inadvertently randomized into the study; the safety population which consists of all randomized pts. who received at least one dose of study drug; and the pre-protocol population which consists of the pts. who do not have major deviations from the protocol procedures in the double-blind study stage.

1.5. * Select which IRB you are requesting review from:

USC-Health Sciences (HSC)

2. Study Personnel

2.1. Study Personnel and their roles:

	Last Name	First Name	Organization	Study Role	Certifications	Obtain Consent
View			CARDIOVASCULAR MEDICINE	Principal Investigator		yes
View			CARDIOVASCULAR MEDICINE	Study Contact Person		
View			CARDIOVASCULAR MEDICINE	Co-Investigator		yes
View			CLINICAL PHARMACY AND PHARMACEUTICAL ECONOMICS AND POLICY	Co-Investigator		yes
View			CARDIOVASCULAR MEDICINE	Co-Investigator		yes
View			CARDIOVASCULAR MEDICINE	Regulatory Personnel		no
View			CARDIOVASCULAR MEDICINE	Research Assistant or Associate		no
View			Volunteer	Research Coordinator		no
View			CARDIOVASCULAR MEDICINE	Research Coordinator		no
View			HEALTH BEHAVIOR RESEARCH (IPR)	Research Coordinator		no

2.2. Is the Principal Investigator a student, resident, fellow, other trainee, or visiting scholar at USC/CHLA?

Yes No

2.3. If there are any individual collaborators from other institutions, check here:

2.4. Does this study require Cancer Center Committee (CIC) approval?

Yes No

2.4.1. Are Cancer Patients Involved? Yes No

2.5. Specify the group/organization who has reviewed this study for scientific merit:

FDA; CRU Scientific Review Panel

3. Required Department Approvals (for a study already submitted to the IRB)*This screen indicates the division/department approvals received once the proposal has been submitted.***3.1. Pending Division/Department Approvals:**

Name Division/Department Parent Campus

There are no items to display

3.2. Received Division/Department Approvals:

Name	Division/Department	Parent Campus
CLINICAL PHARMACY AND PHARMACEUTICAL ECONOMICS AND POLICY	Department	USC-Health Sciences (HSC)
CARDIOVASCULAR MEDICINE	Division	USC-Health Sciences (HSC)
MEDICINE	Department	USC-Health Sciences (HSC)

3a.3. Other campus committees, services or departments that need to review and approve this protocol:

Committee Name Committee Chair Approval Memo

There are no items to display

3a.4. Will the research be conducted through the CTU? Yes No**4. Funding Information****4.1. * What existing, planned, or pending support will be used for this study? (check all that apply)**

- Cooperative Group (SWOG, COG, RTOG, etc.)
- CTSI
- Department of Defense (DOD) Funds
- Departmental/Institutional Funds
- Federal Grant/Contract
- Foundation Grant/Contract
- Industry**
- Intramural/Internal Grant
- Residual Funds
- State or Local Grant/Contract
- Subcontract from another institution
- No Funding
- Other

4.3. This study has the following clinical trial from the TRUE2 system:

Name

4.4. Add the details of each source of funding for this study.

Sponsor	Principal Investigator	Type of Funding
[REDACTED]	[REDACTED]	[REDACTED]

View

5. Type of Study Review**5.1. Select the type of review that you are requesting for this study:** Full Committee Review Expedited Review Exempt Review Coded Specimens/Data**5.2. Attach the protocol here. For simple, investigator-initiated studies, a separate protocol may not be necessary. However, larger, complex, or multi-site studies require a fully developed protocol. If you have questions contact the IRB office to discuss.**

name	Version	Modified
[REDACTED] Study Protocol, June 14, 2011 History	0.01	3/19/2012 2:55 PM
[REDACTED] Study Protocol, Version 4, dated 03-07-2013 (tracked changes) History	0.01	4/1/2013 11:27 AM
[REDACTED] Study Protocol, Version 4, dated 03-07-2013 (clean) History	0.02	4/1/2013 11:28 AM

5.3. Attach the sponsor's template informed consent here.

name	Version	Modified
Sponsor-generated [REDACTED] Study ICF Template History	0.01	4/19/2012 8:44 AM

5.4. If any study documents are password protected, enter the passwords here.**5.5. If there is a sponsor protocol number associated with this file, specify it here:**

[REDACTED]

6. Study Location(s)**6.1. Select the locations where this study will be conducted by the USC/CHLA investigator(s) (check all that apply):** HSC - Health Sciences Associated Locations UPC - University Park Associated Locations CHLA**6.2. Are there other sites besides USC/CHLA involved in the research?** Yes No**6.3. Is USC/CHLA the coordinating site or are there sites where USC/CHLA is conducting the study?** Yes No**6a. HSC Location(s)***This screen is required if you indicated HSC - Health Sciences Associated Locations (Question 6.1.)***6a.1. Locations that recruitment, consent, and/or study procedures will be performed: (check all that apply)**

Location
<input checked="" type="checkbox"/> LAC+USC Medical Center
<input type="checkbox"/> LAC+USC Emergency Dept
<input checked="" type="checkbox"/> LAC+USC Outpatient Clinics

- LAC+USC 5P21 Building
- Keck Hospital of USC Facilities**
- USC Norris Comprehensive Cancer Center Facilities
- Keck School of Medicine of USC
- USC Eye Institute
- USC Healthcare Consultation Center I or II**
- USC Center for Health Professions (CHP)
- USC School of Dentistry
- El Monte Comprehensive Health Center *
- H. Claude Hudson Comprehensive Center *
- Roybal Comprehensive Health Center *
- Verdugo Hills Hospital
- Other location (e.g., subjects home, community)

6a.2. Describe other location(s):

6a.3. If you are conducting this research in an LAC+USC location, specify the room numbers:

CCU and Cardiology Outpatient Clinic

6a.4. If you are conducting this research at a location marked with an asterisk "", attach a letter of approval from the medical director.**

name	Version	Modified
There are no items to display		

9. Methods and Procedures - Selected Descriptors/Community Engaged Research

Note: The list of items below IS NOT an all-inclusive list of methods and procedures available to investigators. The list only includes items that will trigger additional questions specific to areas of research or are necessary for the review process.

9.1. This study will involve: (check all that apply)

- Prospective collection of data/specimens
- Use of existing or retrospective data/specimens

9.2. Study Procedures: (check all that apply)

- Audio/Video Recordings or Photographs
- Behavioral Observations and/or Behavioral Experimentation
- Behavioral Interventions
- Deception
- Interview/Focus Groups
- Population-based Field Study
- Psychophysiological Testing
- Surveys/Questionnaires/Psychometric Testing
- Anatomic Pathology Specimens
- Approved/Investigational Devices
- Approved/Investigational Drugs and Biologics
- Biohazardous Substances
- Controlled Substances
- Creation of a Data or Tissue Repository

- Emergency Research (with exception from informed consent requirements)
- Gene Transfer Study
- Heritable Genetic Specimens or Germ Line
- Magnetic Resonance Imaging (MRI) or ultrasound other than clinically indicated
- Radiation Exposure Other Than Clinically Indicated Tests and/or Therapy (e.g. x-ray, CT, DEXA, radiation therapy, etc.)
- Stem Cell Research
- Substance Abuse Treatment (with medication)
- Venipuncture

9.3. Does this project involve FDA regulated drugs, biologics, or devices where USC/CHLA faculty have submitted the IND/IDE and will be considered the sponsor/investigator?

Yes No

9.4. Will data from this study be submitted to the NIH Genome-Wide Association Studies (GWAS) data repository?

Yes No

9.5. Does your study involve community-engaged research (community-engaged research addresses community needs and involves the community in research plan, conduct of study, etc)?

Yes No

10. Characteristics of the Study Subject Population

10.1. What is the maximum number of subjects you plan to recruit for this site? (Integer values only)

7

10.1.1. If this is a multi-site study, indicate the projected total subject accrual. (Integer values only)

7980

10.1.2. If necessary, provide further explanation of accrual goals for all subject populations.

Up to 7980 participants will take part in this study at about 1200 centers both in and outside the U.S.

10.2. Describe the inclusion criteria for enrollment. (HSC: Refer to specific sections of the protocol/grant, if applicable)

Please refer to Section 5.1 of the attached [REDACTED] protocol for information regarding study inclusion criteria.

10.3. Describe the exclusion criteria for enrollment. (HSC: Refer to specific sections of the protocol/grant, if applicable)

Please refer to Section 5.2 of the attached [REDACTED] protocol for information regarding study exclusion criteria.

10.3.1. If there are any age, ethnic, language, or gender-based exclusion criteria, please provide justification.

Participants must be over the age of 18 years old and pregnant and lactating women may not take part in the study.

11. Research Objectives and Background

11.1. Describe the specific objectives or aims of the study and hypotheses or research questions. (HSC: refer to

specific sections of the protocol/grant, if applicable)

Please refer to Section 3 of the attached [REDACTED] protocol for a description of the specific objectives or aims of the study.

- 11.2. Provide a summary of the background of the study, and explain how this research will contribute to existing knowledge. Describe previous work that provides a basis to show that the proposed research can be carried out without undue risk to human subjects. Include relevant citations. (HSC: refer to specific sections of the protocol/grant, if applicable)**

Please refer to Section 1 of the attached [REDACTED] protocol for a summary of the background of the study.

12. Methods and Procedures - Prospective Studies

- 12.1. Describe in detail the design and methodology of the study. Provide a detailed description of the planned data collection, specific outcomes, and criteria for evaluation and endpoint definition. If applicable, include information on stratification or randomization plans. Include the frequency and duration of each activity and the total length of subject participation. Identify and distinguish between those procedures that are standard of care and those that are experimental. (Refer to specific sections of the protocol/grant, if applicable. Describe any differences between the protocol and the local site.)**

Please refer to Section 4 of the attached [REDACTED] protocol for a description of the design and methodology of the study.

- 12.1.2. Provide a detailed description of the planned data collection, specific outcomes, and criteria for evaluation and endpoint definition. (Refer to specific sections of the protocol/grant, if applicable. This is a deprecated field - only used for existing studies. It used to be question 12.2.)**

Please refer to Sections 7.4 and 9.2 of the attached [REDACTED] protocol for a description of the planned data collection, specific outcomes and criteria for evaluation and endpoint definition.

- 12.2. Describe the statistical considerations for the study, how the sample size was determined, and how the results will be analyzed, if applicable. (Refer to specific sections of the protocol/grant, if applicable)**

Please refer to Section 10 of the attached [REDACTED] protocol for a description of the statistical considerations for the study.

17. Methods and Procedures - Drug and Biologic Information

This screen is required if you indicated the use of Approved or Investigational Drugs and Biologics (Question 9.2.)

- 17.1. Fill in an entry for all drugs and biologics that will be administered in this study.**

	Drug Name	FDA Approved for this indication	IND# or N/A	IND Holder	Supplied By
View	[REDACTED]	yes			[REDACTED]
View	[REDACTED]	no	[REDACTED]	[REDACTED]	[REDACTED]

- 17.2. Describe where the drugs/biologics will be stored, how they will be secured, and how the inventory will be managed.**

Study medications will be stored and maintained by the IDS pharmacy.

- 17.3. Attach a copy of the Investigators Drug Brochure and/or package insert for each IND agent and any other study medications.**

name	Version	Modified
[REDACTED] Investigator's Brochure Edition 11, release date 13-Mar-2012- Table of Changes History	0.01	12/4/2012 4:11 PM
[REDACTED] Investigator's Brochure Edition 11, release date 13-Mar- 2012 History	0.02	12/4/2012 4:11 PM
[REDACTED] Investigator Brochure, Edition 11, 3-13-12 History	0.01	3/29/2012 10:13 AM

Investigator Brochure, Edition 12, dated March 27, 2013 History	0.01	5/22/2013 8:59 AM
Package Insert for [REDACTED] History	0.01	5/23/2012 2:35 PM
Investigator Brochure, Edition 19, dated 1-20-2009 History	0.01	5/23/2012 2:36 PM

21. Methods and Procedures - Surveys/Questionnaires/Psychometric Testing

This screen is required if you indicated the use of Surveys, Questionnaires, or Psychometric Testing (Question 9.2.)

21.1. List all of the measures/instruments that will be used for this study and attach copies below. Explain the purpose of the measures and indicate if any have been previously validated.

The KCCQ is a self-administered questionnaire containing 23 items, covering physical function, clinical symptoms, social function, self-efficacy and knowledge, and QQuality of Life. The KCCQ will be completed at Visits 5, 9, 10, 11, 14, 17, and at end of study.

The EQ-5D is an instrument used to assess the current health status of pts. It consists of five domains and one visual analogue scale that assesses morbidity, self-care, usual activity, pain, and anxiety and depression of pts.

The EQ-5D will completed at Visits 5, 9, 10, 11, 14, 17 and at end of study.

21.2. Attach copies of all measures/instruments that will be used for this study.

name	Version Modified	
EQ-5D History	0.01	3/19/2012 4:05 PM
EQ-5D - Spanish Version History	0.01	3/19/2012 4:05 PM
Kansas City Cardiomyopathy Questionnaire History	0.01	3/19/2012 4:04 PM
Kansas City Cardiomyopathy Questionnaire - Spanish Version History	0.01	3/19/2012 4:04 PM

22. Special Subject Populations

22.1. Indicate any vulnerable subject populations you intend or expect to enroll in the research: (check all that apply)

- Normal Volunteers
- Employees or Students
- Adults not Competent to Consent (or likely to lose the capacity to consent during the study)
- Non-English Speaking Populations**
- Minors (subjects under 18 years of age)
- Pregnant Women / Human Fetuses
- Neonates (infants under 30 days old)
- Prisoners/Detainees
- Wards
- None of the above

22d. Special Subject Populations - Non-English Speaking Subjects

This screen is required if you indicated you will be recruiting non-English speaking subjects (Question 22.1.)

22d.1. Describe how you will communicate with non-English speaking participants. (check all that apply)

- The use of interpreters
- Translated informed consent documents
- Translated short forms
- Other

22d.1.1 Please explain:

For Spanish-speaking participants, a translator will be provided. Through an appropriate translator, the study purpose and procedures, the informed consent, and the participant's involvement in the study will be explained. Potential participants will be given ample time to read the informed consent form and ask questions. In addition, a Spanish translation of the informed consent form will be provided for potential participants who are Spanish-speaking only.

When there is a need for consenting a potential participant who is not fluent in English or Spanish, a written short form informed consent will be used to obtain consent in conjunction with the written IRB-approved English version of the informed consent form.

The short form in the participant's language from the IRB website will be used. In addition, a translator will be used to translate the IRB-approved English version of the consent form to the potential participant in a language understandable to the participant. The entire consent process will also be witnessed by an individual who is fluent in both English and the language understandable to the study participant.

22d.2. If the study will likely include subjects and families for whom Spanish is the primary language, the consent documents must be translated into Spanish. Select the method of translation.

- Investigator will provide the IRB with a translation of the approved consent form
- Request that the IRB office translate (HSIRB Only)

22d.3. If the research will primarily include subjects who speak a language other than English or Spanish, the informed consent documents should be translated into that language. Indicate the languages and method of translation.

Language Translation Method

There are no items to display

23. Study Resources**23.1. Describe the time the investigators have available to conduct and complete the research and justify that it is sufficient. Please check-off the items that apply to this study.**

- Employed interns, residents, fellows, or postdocs with dedicated time to conduct this research.
- Employed faculty and or staff with dedicated time to conduct this research.
- Students with dedicated time as part of their training to conduct this research.
- Volunteers
- Other

23.1.1. Please specify:

will designate a portion of her time to the conduct of this research study. If for some reason she is out of the office and/or unavailable, she has designated as a co-investigators who can be reached for study related matters/inquiries.

23.2. Describe the staff and justify their qualifications. Please check-off the items that apply to this study.

- All biomedical investigators are privileged and credentialed to perform the study activities in the study locations.
- All study staff are trained and credentialed to perform the duties assigned to them.
- All study staff have fulfilled the training mandated by their respective departments or institutions.
- Other

23.2.1. Please specify:

_____ is the Nurse Coordinator who works on studies with _____. A portion of her time has been designated toward subject recruitment and retention as well as regulatory management for this study.

_____ is the Research Coordinator for _____, _____ is the research assistant for _____. A portion of their time is designated toward management of all regulatory documents as well as data collection and documentation for this study.

23.3. Describe the study facilities and justify they are adequate.

The USC University Hospital is a private research and teaching hospital with a fully staffed cardiac catheterization lab. Interventional Cardiology maintains offices in the USC University Hospital and Healthcare Consultation Center II with sufficient office space and computer equipment to accommodate this study.

LAC+USC Medical Center is a county and teaching hospital with a fully staffed cardiac catheterization lab. _____ performs interventional cases on an at least weekly basis in this facility. Subjects enrolled in this study at LAC+USC Medical Center will be followed at the Healthcare Consultation Center II which has sufficient office space and computer equipment to accommodate this study.

23.4. Describe how staff and others will receive necessary information and training to assist in the conduct of this study.

The investigator will ensure that all study staff have been properly trained on the protocol for the _____ study and that human subjects training certification is current for all study staff.

23.5 Describe the method(s) by which subjects will be identified, eligibility will be determined, and by whom.

(deprecated field, used to be 23.1- only used for existing studies)

Patients of the Division of Cardiovascular Medicine who have chronic heart failure with reduced EF and meet protocol inclusion criteria will be approached for possible study participation. These are patients seen under usual clinical circumstances by the investigators and would be treated regardless of enrollment in the study. _____ also accepts patient referrals from other physicians.

24. Subject Recruitment and Informed Consent**24.1. Recruitment Tools that will be used by the local site (check a box only if your site will control the use or distribution of the recruitment tool):** (check ALL that apply)

- E-mail/Electronic Mailing List
- Brochure
- Flyers
- Letters
- Newspaper/Magazine Advertisements
- Radio/Television Announcements
- Subject or Participant Pool
- Telephone Scripts
- Verbal (Personal Solicitation)**
- Website / Social Media Outlets
- Other
- None of the above

24.1.2. Describe how you will be obtaining contact information:

24.1.3. Describe in detail all recruitment strategies for each participant group (including controls) involved in this study. Explain who will approach the participants, how and when the participants will be approached, and what will be said. (deprecated field, used to be 24.3 - only used for existing studies)

The subject population of interest for the [REDACTED] study includes current patients of the cardiology service. [REDACTED] and the co-investigators have daily contact with such patients which allows access to this population for recruitment purposes. Potential participants will be educated on the purpose of the study including their role and responsibilities and invited to participate. It will be explained and clarified that study participation is voluntary and that a decision not to participate will not affect an individual's regular care.

24.2. Attach copies of all recruitment tools that will be used by the local site. (Do not attach any advertising or recruitment materials that will not be used at the local site or under control of the local site.)

name Version Modified

There are no items to display

24.3. Informed Consent and Waivers:

Check the type(s) of consent or waiver of consent planned for this study: (check ALL that apply)

- Written/signed consent (participants will sign an informed consent document)**
- An information sheet will be provided and/or verbal consent obtained
- Waiver of consent (participants will not be asked to sign a consent document or be given an information sheet)
- Alteration of the elements of consent (participants will sign a consent document, but one or more of the basic required elements of consent will be altered or waived)

24.7. Attach copies of the informed consent documents(s), information sheets, and any statements of new information/findings or consent addenda (as applicable) that will be used in this study. This set should also contain any assent or parental permission documents that will be used.

name	Version	Modified
[REDACTED] IC Clean History	0.02	8/6/2012 8:56 AM
Site-specific [REDACTED] Study ICF following Sponsor Approval - 4-19-12 History	0.01	4/19/2012 9:01 AM
SNIF #1 07.16.13 Clean.doc History	0.03	7/22/2013 8:46 AM

[IRB Informed Consent Templates and Forms](#)

Personnel from section 2.1 obtaining consent/permission/assent:

Last Name	First Name	Organization	Study Role	Certifications	Obtain Consent
[REDACTED]	[REDACTED]	CARDIOVASCULAR MEDICINE	Principal Investigator		yes
[REDACTED]	[REDACTED]	CARDIOVASCULAR MEDICINE	Co-Investigator		yes
[REDACTED]	[REDACTED]	CLINICAL PHARMACY AND PHARMACEUTICAL ECONOMICS AND POLICY	Co-Investigator		yes
[REDACTED]	[REDACTED]	CARDIOVASCULAR MEDICINE	Co-Investigator		yes

If the above list is incomplete or incorrect, please navigate to item 2.1 and make your changes there.

24.8. Describe the circumstances and location of the process of recruitment and consent: (check ALL that apply)

- In a private area**
- In a waiting room, open ward, group, or public setting
- Online, over the telephone, by mail, or via fax
- Other

24.9. Describe how you will assess the individual's comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating. (check ALL that apply)

An assessment tool will be used. (attach a copy of the tool below)

This will be verbally assessed. Individuals will be asked to answer the following questions (as applicable):

(1) What are you being asked to do? (2) What question is this study trying to answer? (3) What are the potential risks of participating in this study? (4) How often will you need to come in for study visits? (5) What is the difference between participating in this study and your standard medical care? (6) What should you do if you decide to withdraw from the study?

Other (specify below)

24.10. Describe all measures that will be taken during the recruitment and consent process to ensure that individuals have adequate time to consider participation and to safeguard against potential coercion and undue influence: (check ALL that apply)

They will not be forced, threatened or coerced in any way to participate in this research, and no undue influence or other form of constraint will be used to recruit individuals to participate in this research or to retain currently enrolled subjects. (Note: "Coercion" is the use or threat of the use of force to gain compliance. "Undue influence" is when an individual who is in a position of authority (e.g., physician, teacher, employer) exerts inappropriate or excessive manipulation to gain power and compliance over a vulnerable individual (potential research subject). "Constraint" means force, obligation or pressure.)

They will not be punished or denied something which they would normally receive (e.g., threatening to withdraw health services to which an individual would otherwise be entitled) if they choose not to participate in this research or choose to withdraw early from participation.

They will be given an adequate amount of time to consider participation in the study relative to the initiation of study procedures.

The information presented to individuals during recruitment and consent will reflect that provided in the informed consent document/informed consent script.

The recruitment and consent process will not promise them a certainty of cure or benefit beyond what is outlined in the informed consent document/informed consent script.

The recruitment and consent process will take place in an area in which it is possible to maintain privacy and confidentiality.

They will be given the opportunity to take the informed consent document home in order to discuss participation with their family, friends and/or others before making a definitive decision.

They will receive payment for their participation, but the amount of payment will be commensurate with their participation (not an inducement for participation), and receipt of the payment will not be contingent upon the individual's completion of the study. (Note: The specific method, schedule and amount of payment must be outlined in the payment section of the application.)

Other (explain below)

24.10.2. Describe the consent process. Discuss when and where the consent process will take place relative to the initiation of the study procedures. Describe how prospective participants/families will be permitted to discuss their participation with others before signing the consent form. Describe the steps taken to provide the prospective participant sufficient opportunity to consider whether or not to participate in the study. If more than one consent form will be used in the study, explain when and how each form will be used to obtain consent from participants. (deprecated field, used to be 30.2 - only used for existing studies)

Discussion regarding the study may occur with a potential participant when he/she is identified in the hospital setting or in the clinic post-hospital discharge. Potential participants will be consented in clinical areas where families can also participate in the consenting process. After the study purpose and procedures have been explained, including risks, benefits and alternatives to treatment, individuals will be given time to read the consent and have any questions answered.

25. Financial Obligation and Compensation

You may not update the question below because it has been locked by the contract administrator. Any changes must be made by the contract administrator.

25.1. Financial Obligation: Describe who pays for financial obligations that the subject may incur as a result of

participating in the study.

-
- All costs are paid by the sponsor or funding agency.
-
- Research costs are paid by the sponsor or funding agency. Other costs are the responsibility of the participants and/or their healthcare plans.**
-
- All costs are the responsibility of the participants and/or their healthcare plans.
-
- Study drug will be provided but not the costs of preparation or administration, which will be the responsibility of the participants and/or their healthcare plans.
-
- All costs are covered by the department/division.
-
- There are no financial obligations related to participation.
-
- Other

25.1.A. Consent Text: The following financial obligation statement must be contained in the informed consents for this study: (edit only as necessary. If your study has a contract, this language must be consistent with the contract language)

You and/or your health plan or insurance company will not be expected to pay for any of the procedures, study medications, or tests that are required as part of this study. You and/or your health plan/insurance company will still be responsible for the cost of your usual ongoing medical care, including procedures and medications that your study doctor or regular doctor require as part of your usual medical care. You will also be responsible for any co-payments and deductibles that are standard for your health plan/insurance coverage. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. If you have any questions, please ask the study doctor or a member of the study staff.

25.2. Payment for Participation: Describe how much, if any, financial or other form of compensation will be provided to the subject/family. Describe the requisite conditions that must be fulfilled to receive full or partial compensation. Describe the proposed method of timing and disbursement. If children are involved, please specifically address how the compensation will be distributed to children.

Participants will not be paid for taking part in this study.

You may not update the question below because it has been locked by the contract administrator. Any changes must be made by the contract administrator.

25.3. Research-Related Injury and Compensation for Injury: For studies of greater than minimal risk, if participants require care, medical services, or psychological services as a consequence of the research, who will provide this care? If applicable, describe who will pay for research-related injuries.

Medical and/or psychological care/treatment will be offered. In addition:

-
- Costs for medical care from research-related injuries will be paid by the sponsor or funding agency.
-
- Costs for medical care from research-related injuries will be the responsibility of the participants and/or their healthcare plans.
-
- Other**

25.3.1. If other is selected, please specify:

It is important that you tell the study doctor, [REDACTED] if you feel that you have been injured because of taking part in this study. You can tell the study doctor in person or call her at [REDACTED].

If you require medical care/treatment as a result of injury arising from your participation in this study, emergency medical care/treatment will be provided. [REDACTED] will pay for all of the reasonable medical bills for injuries directly related to the study medications that are not covered by your private insurance company or third party payor (excluding any government health benefit programs in which case [REDACTED] will pay for all of the reasonable medical bills) and/or non-standard of care properly performed procedure required by this study. No other form of compensation will be provided for injuries resulting from your personal conduct or participation in activities outside of the scope of this study. No financial compensation will be provided for such things as

lost wages, disability or discomfort, losses claimed by spouses or family members, or medical expenses due to treatment of any underlying or unrelated condition.

█ is not responsible for the negligence or actions of the study doctor or staff. █ is not responsible for problems caused by your failure to follow the research study instructions, including attending all follow-up visits. However, by signing this form you have not given up any of your legal rights.

26. Participant Privacy and Data Confidentiality

- 26.1. Privacy Protections:** Privacy is a participant's ability to control how other people see, touch, or obtain information about his/her self. Violations of privacy can involve circumstances such as being photographed or videotaped without consent, being asked personal questions in a public setting, being seen without clothing, being observed while conducting personal behavior, or disclosing information about abortions, HIV status, or illegal drug use.

Select the provisions to protect the privacy of the individual during screening, consenting, and conduct of the research: (check ALL that apply)

- Research procedures will be conducted in person in a private setting.**
- Data will be captured and reviewed in a private setting.**
- Only authorized research study personnel will be present during research related activities.**
- The collection of information about participants is limited to the amount necessary to achieve aims of the research.**
- Participants will not be approached in a setting or location that may constitute an invasion of privacy or could potentially stigmatize them.**
- Other (specify below)

- 26.2. Confidentiality Precautions:** Confidentiality is an extension of the concept of privacy; it refers to the participant's understanding of, and agreement to, the ways identifiable information will be collected, stored, and shared. Identifiable information can be printed information, electronic information, or visual information such as photographs.

How will the research data/specimens be recorded? (check ALL that apply)

- Data and/or specimens will be directly labeled with personal identifying information. (Identifiable)
- Data and/or specimens will be labeled with a code that the research team can link to personal identifying information. (Coded)**
- Data and/or specimens will not be labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information. (Anonymous)
- Other (explain below)

- 26.3. How will the research data and/or specimens be protected against inappropriate use or disclosure?** (check ALL that apply)

- Locked office**
- Locked storage unit
- Restricted access to authorized study personnel**
- Secure computer/laptop**
- Individual ID plus password protection**
- Encryption of digital data**
- Network Restrictions**
- Security software (firewall, antivirus, anti-intrusion) is installed and regularly updated in all servers, workstations, laptops, and other devices used in the study**
- Restrictions on copying study related materials**
- Destruction of source data immediately after data collection (to preserve anonymity of participants)
- Audio and/or video recordings will be transcribed and then will be destroyed
- Audio and/or video recordings will be modified to eliminate the possibility that study participants could be identified

- Photos or images will be modified to eliminate the possibility that study participants could be identified
- Study personnel will sign statements agreeing to protect security and confidentiality of study information**
- Access rights are terminated when authorized study personnel leave the study**
- Not Applicable
- Other (specify below)

26.4. Will coded or identified data and/or specimens be released to a third party (external to USC/CHLA)?

Yes No

26.4.1. Specify what data and/or specimens will be released, to whom (the individuals and/or agencies), and why.

Information may be released to [REDACTED] (sponsor) including data monitoring committees, and as required by law, representatives of government organizations (including the FDA), review boards and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research. The study participant's name and other identifying information will be removed from any records that are released by the site.

This study site will also make medical and study records available to the sponsor's clinical monitor for periodic inspection. A monitor designated by [REDACTED] will visit the site according to the sponsor's standard operating procedures for site monitoring and review participant records to verify that all records and files are up to date and compliant with all protocol requirements and FDA regulations.

26.5. What will happen to the research data and/or specimens at the conclusion of the study? (check ALL that apply)

- Direct identifiers and/or the key to the codes will be destroyed upon completion of the research (all data/specimens will be stripped of identifying information and/or the key to codes destroyed, paper documents shredded, electronic files purged, electronic media securely erased).
- Retained for study record keeping purposes per institutional policy.
- Retained by the investigator for future research use.
- Retained for future research use (create data or tissue repository/bank).
- Restricted use data will be destroyed or returned to the source.
- No direct or indirect identifiers are being collected. The anonymous data and/or specimens will be retained at the discretion of the investigator.
- This research is a clinical trial conducted under FDA regulations. Direct identifiers and/or the key to the codes will be destroyed as directed by the sponsor (IND/IDE holder) in accordance with FDA regulations.**
- Other (specify below)

26.6. Do you have, or plan to apply for, a DHHS issued Certificate of Confidentiality for this study?

Yes No

27. Risk/Benefit Assessment - Risks

27.1. Risks, Discomforts and Potential Harms: Describe the risks associated with each research intervention. Include consideration of physical, psychological, social, and other factors. (check all that apply)

- Discrimination based on genetic findings.
- Some people may find it upsetting to learn that they have certain mutations or errors in genes that could lead to future health problems for themselves or their children.
- Some of the questions may make the participant feel uneasy or embarrassed.**
- There is a small risk that people who are not connected with this study will learn a participant's identity or their personal information.**

The participants are providing highly sensitive, personal information in this study. If people not connected with the

- study learn this information, they could have problems getting a new job, keeping their current job, finding housing, or getting insurance (health, disability, or life insurance). In highly unlikely situations, they could be charged with a crime.

Biomedical risks, including drug, device, biologics, radiation, surgery or other research procedures (please specify).

The research includes the risk or disclosure that a participant may engage in self-harm or attempt suicide.

Venipuncture risks including: mild discomfort (or pain), bruising and swelling around the puncture site, dizziness or fainting, or infection (rare).

Other (specify below)

27.1.1. Describe the biomedical or other possible risks and discomforts participants could experience during this study: (HSC: refer to specific sections of the protocol, grant, investigator's brochure or product labeling, if applicable)

Please refer to Section 8.0 of the attached [REDACTED] protocol for risks, discomforts, and potential harms associated with the study.

Please also refer to the Investigators Brochure, Edition 12, dated March 27, 2013.

27.2. Describe the precautions that will be taken to minimize risks/harms. (check all that apply)

We will use our best efforts to keep the findings in this study as confidential as possible.

Subjects can choose to skip or stop answering any questions that make them uncomfortable.

Data will be coded and identity stored separate from data.

Data will be collected anonymously.

Biomedical precautions, including precautions relating to drugs, devices, biologics, radiation, surgery or other research procedures (please specify).

Venipuncture by individuals certified and privileged to perform the procedure.

Other (specify below)

27.2.1. Other precautions (including biomedical precautions) that will be taken to minimize risks/harms include: (HSC: refer to specific sections of the protocol/grant, if applicable)

Please refer to Section 8.0 of the attached [REDACTED] protocol for risks, discomforts, and potential harms associated with the study.

27.3. Who will monitor the research for the safety of the participants? (check all that apply)

The USC/CHLA Principal Investigator (or designee)

A USC/CHLA Data Safety Monitoring Committee/Board

A Non-USC/CHLA Data Safety Monitoring Committee/Board

The Sponsor/Funding Agency

Other (specify below)

27.3.1. Other Data Safety Monitoring Plan: Describe who will monitor the studies for the safety of the participants (investigators, sponsor, independent monitor, DSMB, etc). Provide a plan (monitoring provisions) which may include information on: the type of data or events to be captured, who is responsible for monitoring data related to unanticipated problems and adverse events, time frames for reporting adverse events and unanticipated problems to the monitoring entity, the frequency of assessments of data / events captured by monitoring, specific triggers or stopping rules that dictate when an action is required, and procedures for communicating to the IRB, sponsor, investigator, and other appropriate officials the outcome of the reviews by the monitoring entity.

Please refer to Section 8.4 of the attached [REDACTED] protocol for a description of the data safety monitoring plan.

27.3.2. All Reportable Events or unanticipated problems will be submitted to the IRB in compliance with USC/CHLA policy, Federal/state regulations, and sponsor requirements (as applicable).

27.3.3. How often will the DSMB/DSMC meet?

Every six months

Once a year

Other frequency (specify)

27.3.3.1. Other Frequency for the DSMB/DSMC meetings:

The frequency of the DSMB meetings is described in the Data Monitoring Committee Charter.

28. Risk/Benefit Analysis - Potential Benefits and Alternatives

28.1. Describe any potential for direct benefits to participants in the study: (check all that apply)

- There are no direct benefits to some or all of the research participants**
- Improvement in some or all of participants' symptoms
- Improvement in some or all of participants' survival or longevity
- Information gained from testing or monitoring procedures
- Provision of drug or device
- Reduced side effects
- Other (explain below)

28.2. Describe potential benefits to society, if any. (check all that apply)

- The advancement of knowledge**
- A new treatment or therapy for the condition under study**
- None
- Other (explain below)

28.3. What are the alternatives to participation? (check all that apply)

- Not participating**
- Continue current medical care for their condition**
- Participation in other research studies**
- Palliative care
- No treatment or therapy
- Participate in other subject pool activities
- Other (specify below)

28.4. Risks in relation to benefits:

- The potential benefits to the research participants justify exposure of the participants to the risks.**
- The potential benefits to humanity justify exposure of the participants to the risks.
- Other (specify below)

35. Is the HIPAA Privacy Rule Applicable?

35.1. Do you intend to access, review, collect, use or disclose protected health information (PHI) in your research?

Answer yes if you intend to do any of the following:

- Look at medical records (paper or electronic) to identify potential research participants
- Look at clinic logs to identify potential research participants
- Record demographic information obtained from medical records (paper or electronic)
- Record health information obtained from medical records (paper or electronic)
- Obtain information from laboratory reports, pathology reports, radiology reports or images, or other reports from medical or mental health testing and treatment
- Obtain information from medical billing records
- Record or use medical record numbers or other information that could be used to identify an individual (review the list of HIPAA identifiers below)

Yes **No**

35.2. Do you intend to record data that contains any of the 18 elements defined by HIPAA as identifiers (listed below), in your research?

Yes No

- Name/Initials
- Street address, city*, county*, precinct*, zip code*, or equivalent geocodes*
- All elements of dates (except year) directly related to an individual (date of birth, admission date, discharge date, date of death)*
- Elements of date, including year, for persons 90 or older
- Telephone number
- Fax number
- Electronic mail address
- Social Security Number
- Medical record number
- Health plan identification number
- Account number
- Certificate/license number
- Vehicle identifiers and serial numbers, including license plate number
- Device identifiers and serial number
- Web addresses (URLs); Internet IP addresses
- Biometric identifiers, including finger and voice print
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic, or code*

35.3. Are you going to record only the personal identifiers marked with an asterisk (*)? If so, you may be able to obtain or use such health information from a healthcare provider for research purposes without an authorization. Under the HIPAA Privacy Rule, this data constitutes a limited data set. If you are creating or obtaining a limited data set, you must complete a Data Use Agreement. Attach a copy of the signed Data Use Agreement below.

name	Version	Modified
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There are no items to display

[USC Template Data Use Agreement](#)

36. HIPAA Analysis

This screen is only required if you indicated HIPAA is applicable by answering "yes" to Question 35.1.

36.1. If you are using or accessing protected health information in order to identify potential participants, indicate if these activities fall under the rules for Activities Preparatory to Research, if you will be applying for a Partial Waiver of HIPAA Authorization for the purposes of screening and recruiting, or if neither option applies.

- (CHLA Only) Activities Preparatory to Research
- Partial Waiver of HIPAA Authorization for screening, recruiting, and identifying participants**
- None of the Above

36.2. If you are using or accessing protected health information to conduct the research, please select whether you will be obtaining authorization from the participant or requesting a Full Waiver of HIPAA Authorization.

- Obtaining HIPAA authorization from participant**
- Full Waiver of HIPAA Authorization

36.2.1. If you are obtaining authorization from the participant, attach the HIPAA authorization forms here (USC Only). Please [click here](#) to download the HIPAA Authorization template forms from OPRS.

name	Version	Modified
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38. Partial Waiver of HIPAA Authorization

This screen is required only if HIPAA is applicable and you indicated you are requesting a Partial Waiver of HIPAA Authorization (Question 36.1.)

If you are applying for a partial waiver of authorization for the purposes of screening, recruitment, and subject identification, provide justification per 45 CFR 164.

38.1. How will you protect PHI (Protected Health Information) from improper use and disclosure? (check all that apply)

PHI will be used only for the purposes of assessing eligibility and identifying potential participants.

All source and research documents containing PHI will be stored and maintained in a locked/password protected area accessible only to study staff.

Study data will be coded or de-identified prior to being sent outside the study team.

Other

38.2. How will you destroy identifiers at the earliest opportunity consistent with the conduct of the research? (check all that apply)

No identifiers or links to identifiers will be recorded during the data collection process.

Direct Identifiers will be maintained only until the study is completed. After that, the identifiers will be shredded and electronic records purged.

The link between study participants and study ID numbers will be destroyed (shredded/purged) when study activities are complete.

The FDA requires that the records be retained for two years following marketing approval for the drug/device or discontinuation of the investigation. After that, the identifiers will be shredded and or purged.

The NIH requires that the records be retained for three years following the completion of the study. After that, the identifiers will be shredded and/or purged.

Other

38.3. By checking the "I Agree" box you are providing assurance that PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.

I Agree

38.4. The research could not practicably be conducted without the requested waiver or alteration because: (check all that apply)

PHI is required to identify potential participants who meet the eligibility criteria.

Other

38.5. The research could not practicably be conducted without access to and use of the PHI because: (check all that apply)

PHI is required to identify potential participants who meet the eligibility criteria.

During the recruitment process, PHI is needed in order to contact potential participants.

Other

38.6. By checking the "I Agree" box you are providing assurance that PHI requested will be the minimum amount necessary to conduct the research or meet the research objectives.

I Agree

38.x. Explain how the use of and disclosure of the information presents no more than minimal risk to the privacy of the individual. (deprecated field, used to be 38.1 - only used for existing studies)

This is a request for a limited waiver to review medical record information to assess potential eligibility before

approaching a potential participant regarding study participation. All efforts will be made to respect and protect the privacy of the individual.

39. Conflict Of Interest Information

39.1. Does the **Investigator**, **Research Personnel** or **Close Relation** have an **ownership interest** (any equity in a non-publicly traded company, regardless of value, or stock, stock options or warrants, in a publicly traded company of \$5,000 or more excluding mutual funds) in:

- The sponsor of the research; or
- An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or
- An entity that has an economic interest in the research.

Yes No

39.2. Does the **Investigator**, **Research Personnel** or **Close Relation** have a **management role** (such as director, officer, scientific, or technical appointment), or any other role with significant decision-making authority, in:

- The sponsor of the research; or
- An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or
- An entity that has an economic interest in the research.

Yes No

39.3. Did the **Investigator**, **Research Personnel** or **Close Relation** receive in the last twelve months or does the Investigator, Research Personnel or Close Relation expect to receive in the next twelve months any payments for **services** (such as speakers fees, payments for consulting, participation on an advisory board, or assistance with protocol design) from

- The sponsor of the research; or
- An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or
- An entity that has an economic interest in the research.

This does not include salary for services as an investigator/staff on the research study. Also excluded are payments from the federal government for services performed (i.e. peer review, study section participation, seminars, lectures, or service on advisory committees).

Yes No

39.4. Does the **Investigator**, **Research Personnel** or **Close Relation** personally receive **intellectual property rights** (e.g. patents, copyrights, or royalties) directly from:

- The sponsor of the research; or
- An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or
- An entity that has an economic interest in the research.

This does not include royalties paid directly from USC

Yes No

39.5. **To the investigator's knowledge, does the Institution have financial and or intellectual property interests in the sponsor or the products used in this project?** *An institutional conflict may occur when a financial interest of the University has the potential to bias the outcome of research conducted by its employees or students or to create an unacceptable risk to human subjects.*

Yes No

40. Additional Supporting Documents

40.1. **Attach any other documents that have not been specifically requested in previous questions, but are needed for IRB review.**

name	Version	Modified
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There are no items to display

40.2. **If there is any additional information that you wish to communicate about the study include it below. Please note, this section should not be used instead of the standard application items.**

99. Instructions for Submission

You have reached the end of the application. When you are sure of the content, the following steps may be taken to submit your application for review.

1. Click the "**Finish**" button on the top or bottom application navigator bar to return to the workspace.
2. Use the SmartForm Progress Calculator to determine that all sections of the application are filled out correctly.
3. Use the "**Send Study Ready Notification**" activity to send an email to the Principal Investigator and Co-Investigators with instructions for reviewing and submitting the application.
4. **All listed Co-Investigators (indicated in item 2.1.) must use the "Agree to Participate" activity and answer yes.**
5. Once all the Co-Investigators have agreed to participate, the **Principal Investigator** (indicated in item 2.1.) can submit the application by using the "**Submit Application to _____**", where _____ indicates the IRB you are submitting to.
6. The PI will have to check the PI endorsement box. The PI will also have to check the student endorsement box if it is applicable.
7. The application is submitted. The state indicator in the top left of the workspace will no longer display Pre Submission.
8. The PI and Study Contact Person will receive an email confirming the application has been submitted.

4.4. Funding Source

Please enter the fields below and click 'OK' when done.

4.4.1. *** Name of Sponsor:**

4.4.2. *** Named Principal Investigator:**

4.4.3. **Institution awarded the grant-award:**

4.4.4. **Grant-award number provided by the Sponsor:**

4.4.5. **Title of the Funding Project, if applicable:**

4.4.6. *** Type of Funding:**

4.4.7. **Attach a copy of the proposal/contract/grant with the project budget.** (salary information need not be displayed or included.)

name	Version	Modified
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There are no items to display

17.1 Drug/Biologic Entry

Please enter the fields below and click 'OK' when done.

17.1.1. * Drug/Biologic Name:

[REDACTED]

17.1.2 * The FDA Investigational New Drug (IND) Status of the drug or biological:

(An IND is a request for authorization from the Food and Drug Administration to administer an investigational drug or biological product to humans.)

The drug/biologic has an IND

as evidenced by:

Attach the document:

name	Version	Modified
There are no items to display		

There are no items to display

Please ensure that the protocol with the IND number is uploaded at item 4.2

IND Number:

IND Holder:

The IND application has been submitted

The investigation is believed to be exempt from FDA regulations

17.1.3. * FDA Approved for marketing for this indication?

Yes No

17.1.4. * Supplied By:

[REDACTED]

Drug/Biologic Entry

Please enter the fields below and click 'OK' when done.

17.1.1. * Drug/Biologic Name:

[REDACTED]

17.1.2 * The FDA Investigational New Drug (IND) Status of the drug or biological:

(An IND is a request for authorization from the Food and Drug Administration to administer an investigational drug or biological product to humans.)

The drug/biologic has an IND

as evidenced by:

Communication from the Sponsor or FDA with the IND number

Attach the document:

name	Version	Modified
Site Invitation Letter	0.01	3/29/2012 1:38 PM

Site Invitation Letter 0.01 3/29/2012 1:38 PM

Please ensure that the protocol with the IND number is uploaded at item 4.2

IND Number:

[REDACTED]

IND Holder:

[REDACTED]

The IND application has been submitted

Enter the Date the IND application was submitted:

The investigation is believed to be exempt from FDA regulations

Permitted exemptions from the IND regulations:

The clinical investigation of a drug product that is lawfully marketed [21 CFR 312.2(b)(1)]:

Name

There are no items to display

The clinical investigation involves in vitro diagnostic biological products [21 CFR 312.2(b)(2)] where:

Name

There are no items to display

The investigation involves a drug intended solely for tests in vitro or in laboratory research animals [21 CFR 312.2(b)(3)].

The clinical investigation involves use of a placebo AND the investigation does not otherwise require submission of an IND [21 CFR 312.2(b)(5)].

FDA determination of exemption. The research has been submitted to the FDA who determined in writing that an IND is not required.

Attach correspondence with FDA determination:

17.1.3. * FDA Approved for marketing for this indication?

Yes No

17.1.4. * Supplied By:

[REDACTED]