

UTHSC Institutional Review Board Form

Reviewer's Comment Form

Reviewer's Name:

Terrence F Ackerman

List of Reviewers:

Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed
Primary Reviewer	Ackerman, Terrence F	Yes	04/01/2009	04/08/2009

Date:

04/08/2009

Principal Investigator:
John Sample
09-00000-FB
Study Title:

Please click on "Save and Continue to the Next Section."

OZF Component - Minimum Five Year Follow-up

Instructions for Electronic Review

1) Contents of Submission

View "Contents of Submission" below. Look in the 3rd column at "Type." The Submission Form is at the top and below it are the attachments. [Make sure the Pop-Up blocker is turned off.]

2) Attachments

Under attachments, you will see 'Study Application' and other attachments (such as Consent Form, Protocol, Investigators Brochure). To the left of each of those other documents (not the Study Application), click on "Open" and save the document to your desktop. [HINT: You must have the Pop-Up Blocker turned off in order to open a document.] Then go to your desktop, open the document and minimize it.

3) Study Application

Once all other attachments are minimized, open the Study Application (or other form you are reviewing).

Click on "Entire View of Application" (or "Section View of Application" if you prefer) and scroll down the form, reading the PI's answers.

4) Notes Icon

As you scroll down, look in the right margin for the "Notes" icon. Clicking on this icon allows you to write notes in the margin of the section you are reading. Notice, the icon changes once notes are associated with a section. This allows you to glance at a section and know whether notes have been added pertaining to that section.










5) Attachments Minimized

You may wish to view a document that you have minimized while evaluating the PI's answers on the application. Click on the minimized document to examine its content and then minimize it again when you have finished. You may also make margin notes in the section of the application that relates to the document.

Contents of Submission:

Print selected item(s)

Show History	Print	Open	Type	Document Name	Version	Date Submitted into Workflow

<input type="checkbox"/>		Submission Form		Routing Form for Form 1: Initial Review Submission Form * This form was part of this submission.	Version 1.0	03/30/2009 01:56 PM CST
Submission Attachments below:						
<input type="checkbox"/>		Application		Form 1: Study Application * This application was part of this submission.	Version 1.0	03/30/2009 01:56 PM CST
<input type="checkbox"/>		Consent (English)	<input type="checkbox"/>	090330 THA Verbal Consent * This consent was part of this submission.	Version 1.0	03/30/2009 01:56 PM CST
<input type="checkbox"/>		Consent (English)	<input type="checkbox"/>	090318 THA ICF * This consent was part of this submission.	Version 1.0	03/30/2009 01:56 PM CST
<input type="checkbox"/>		Document - h. Surveys/Questionnaires/Data Collection Instruments	<input type="checkbox"/>	090330 THA Telephone Follow-Up Questions * This document was part of this submission.	Version 1.0	03/30/2009 01:56 PM CST
<input type="checkbox"/>		Document - h. Surveys/Questionnaires/Data Collection Instruments	<input type="checkbox"/>	090317 Evaluation * This document was part of this submission.	Version 1.0	03/30/2009 01:56 PM CST
<input type="checkbox"/>		Document - h. Surveys/Questionnaires/Data Collection Instruments	<input type="checkbox"/>	090317 Index * This document was part of this submission.	Version 1.0	03/30/2009 01:56 PM CST
<input type="checkbox"/>		Document - i. Recruitment Materials	<input type="checkbox"/>	090330 Mailing Letter * This document was part of this submission.	Version 1.0	03/30/2009 01:56 PM CST
<input type="checkbox"/>		Document - i. Recruitment Materials	<input type="checkbox"/>	090330 Telephone Script * This document was part of this submission.	Version 1.0	03/30/2009 01:56 PM CST

Please choose the type of review and then click on "Save and Continue to the Next Section."

- New full board application
- New expedited application
- New exempt application
- Full board continuation
- Expedited continuation
- Full board revision
- Expedited revision
- Exempt revision
- Unanticipated problem, including adverse event & protocol deviation
- Recruitment material
- Termination

- HIPAA authorization waiver or alteration request
- Revised investigator's brochure
- Data Safety Monitoring Report
- Miscellaneous

Re: Study Application

The Study Application (Form 1) covers 20 general topics, in order, 1 through 20. A topic may have one section or many sections where questions regarding that topic are asked of the investigator.

Topics:

- 1 General Study Information
- 2 Study Status (exempt or expedited) and Synopsis
- 3 Purpose, Background and Current Status of Work in Field
- 4 Drug or Device Information
- 5 Site
- 6 Population, Duration and Inclusion Exclusion Criteria
- 7 Subject Selection
- 8 Procedures
- 9 Risks
- 10 AE's and Data Monitoring
- 11 Risk Benefit Assessment
- 12 Alternatives to Participation
- 13 Confidentiality
- 14 Reimbursements and Incentives
- 15 Financial Obligations
- 16 Injury
- 17 Conflict of Interest
- 18 Informed Consent
- 19 HIPAA
- 20 References and Information

When looking at a section in the Study Application, prior to the title of the section is the topic # (1-20) followed by the section number in parentheses. For example: 2 (925) Synopsis

Note: After initial study approval, when changes occur, the PI creates a new version of the Study Application (Form 1) and updates the new version to reflect the changes. The new version is submitted with the change request form.

(150) Risk Benefit Assessment

Are the inclusion/exclusion criteria appropriate for the study and do they assure that risks to subjects are minimized?

- Yes.
- No.

If no, please list specific concerns and/or recommendations for changes below:

For studies involving the administration and evaluation of a treatment, is it correct that no subjects are significantly disadvantaged with respect to treatment of their condition by participation in the study?

- Yes.
- No.
- Not Applicable. No treatment is being administered as part of this study.

If no, please list specific concerns or recommendations for changes below:

Are the screening and monitoring procedures used in the study sufficient to assure that the risks to subjects are minimized?

- Yes.
 No.

If no, please list specific concerns or recommendations for changes below:

Leaving aside any treatments administered in the study, are the risks of procedures performed solely for research purposes sufficiently low to be justified by the anticipated benefits of the knowledge to be gained?

- Yes.
 No.
 Not Applicable. No study procedures are performed solely for research purposes.

If no, please list specific concerns and/or recommendations for changes below:

Given the nature of the risks associated with study participation, are the goals of this study sufficiently important to justify the use of human subjects?

- Yes.
 No.

If no, please list specific concerns and/or recommendations for changes below:

Are the statistical considerations outlined in the study protocol (sample size, endpoints, planned analyses, etc.) satisfactory?

- Yes.
 No.
 Not applicable.

If no, please list specific concerns and/or recommendations for changes below:

(160) Information Disclosed

Does the informed consent disclosure adequately reflect the application and master protocol in addressing the following items of information?

Element of Informed Consent	Status
1. A statement that the study involves research	Yes
2. An explanation of the purposes of the research	Yes
3. The expected duration of the subject's participation	Yes
4. The approximate number of subjects locally and in aggregate	Yes
5. A description of the procedures that will be followed	No
6. Identification of any procedures being performed only because the subject is participating in a research study	Yes
7. Delineation of any foreseeable risks or discomforts for subjects	No
8. An explanation of whether there may be currently unforeseeable risks	Yes
9. A statement that subjects will be apprised of new information that may affect their willingness to continue participation	Yes

10. A description of any potential benefits for the subject	Yes
11. An explanation of any potential benefits of the study for society	Yes
12. Disclosure of alternatives to participation	Yes
13. A description of protections for the confidentiality of subject records	Yes
14. An explanation of the availability of compensation for injury	Yes
15. Clarification of whether treatment for injury is available and who will provide it	Yes
16. An explanation of whom to notify in the event of a research-related injury	Yes
17. A description of whom to contact to answer questions about the research	Yes
18. Identification of whom to contact to answer questions about the rights of research subjects	Yes
19. An explanation of whether subjects will be paid for participation	Yes
20. Clarification of whether subjects will incur additional costs related to their participation	No
21. An explanation of the conditions under which a subject's participation may be terminated	Yes
22. A statement that participation is voluntary and that refusal to participate or withdrawal will involve no loss of benefits to which the subject is otherwise entitled	Yes

For each item above answered "no," please list specific concerns and/or recommendations for changes below:

(170) Informed Consent Questions

Do the plans for documenting the consent of subjects/LARs satisfy federal regulations and local IRB requirements?

- Yes.
 No.
 Not applicable. A waiver of informed consent and/or a waiver of written documentation of consent is being sought for this study.

If no, please list specific concerns and/or recommendations for changes below:

If subjects/LARs are being paid for participation, do the reimbursements for expenses and/or incentive payments avoid the problem of constituting an undue inducement?

- Yes
 No
 Not applicable. No payments are being offered in the study.

If no, please list specific concerns and/or recommendations for changes below:

If the investigator is proposing to include incompetent subjects in the study, are there satisfactory reasons for including them?

- Yes
 No
 Not applicable. There is no plan to include incompetent subjects.

If no, please list specific concerns and/or recommendations for changes below:

If incompetent subjects are participating in the study, are satisfactory plans in place for securing their assent if they are capable of providing assent?

- Yes
 No
 Not applicable. There is no plan to include incompetent subjects, none will be capable of providing assent, or the applicant has requested a waiver of consent.

If no, please list specific concerns and/or recommendations for changes below:

(180) Waiver or Alteration of Consent

If no waiver or alteration of consent was requested, click save and continue.

- Waiver or alteration of consent was not requested.
 Waiver or alteration of consent is being requested.

If waiver or alteration of consent is being requested, are the conditions for waiver or alteration of consent as specified in the federal regulations fully satisfied?

Conditions for Waiver or alteration:

The research involves no more than minimal risk

- Yes
 No

The waiver or alteration will not adversely affect the rights and welfare of the subjects

- Yes
 No

The study cannot practicably be carried out without the waiver or alteration

- Yes
 No

Where appropriate, subjects will be provided with additional information about the research after participation

- Yes
 No
 Not applicable

For each condition answered "no," please list specific concerns and/or recommendations for changes below:

(185) HIPAA - PHI

Did the principal investigator make a request to use PHI without the subject's authorization?

- Yes
 No

Click save and continue

(190) Additional Issues

Are the plans for monitoring unanticipated problems (including adverse events) and accumulating data appropriate to the nature and degree of risk posed by study participation?

- Yes
 No

If no, please list specific concerns and/or recommendations below:

Will subjects be recruited without regard (as appropriate) to gender, race and ethnic status?

- Yes
 No

If no, please list specific concerns and/or recommendations for changes below:

If the research involves vulnerable subjects, are appropriate safeguards in place to assure that their rights and welfare are adequately protected?

- Yes
 No
 Not applicable. Vulnerable subjects are not included in the proposed study.

If no, please list specific concerns and/or recommendations for changes below:

Have all pertinent issues regarding protection for the rights and welfare of human subjects been adequately addressed in the application?

- Yes
 No

If no, please list specific concerns and/or recommendations for changes below:

(195) Reviewer Recommendations

RECOMMENDATION

- Approve after minor administrative revisions
 Defer approval until substantive revisions have been made
 Approve without modification
 Disapprove
 Incomplete submission

If the recommendation is for deferral or disapproval, please enumerate the primary reasons below:

Comments listed from study application and attached documents.

Rank

Reference

Item Number

No Comments have been entered.

(2000) Close Form

Have you completed your review?

- Yes No Date the Review was completed: 04/08/2009

THE ELECTRONIC SIGNATURE HAS BEEN APPLIED

by Terrence F Ackerman

Please click on "Form Completed -- Click here to close the Form."