

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	Storgion, Stephanie A	Yes	02/20/2009	03/12/2009
Secondary Reviewer	Ackerman, Terrence F	Yes	03/10/2009	03/10/2009

Date:

03/10/2009

Principal Investigator:

John Sample

05-0000-FB

Study Title:

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

Treating Obesity

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								Date Submitted

History	Print	Open	Type		Document Name	Version	into Workflow
	<input type="checkbox"/>		Submission Form		Form 2a: Change Request & Amendments	Version 2.2	04/21/2009 10:38 AM CDT
	<input type="checkbox"/>		Submission Form		PI Response to Review	Version 2.1	04/21/2009 10:38 AM CDT
Submission Attachments below:							
	<input type="checkbox"/>		Application		Form 1: Study Application	Version 1.3	04/21/2009 10:38 AM CDT
	<input type="checkbox"/>		Consent (English)	<input type="checkbox"/>	Patient Consent Form	Version 1.4	04/21/2009 10:38 AM CDT
	<input type="checkbox"/>		Document - a. Master Protocol	<input type="checkbox"/>	Project Descriptors	Version 1.4	04/21/2009 10:38 AM CDT

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

(700) Full Board Revision

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			Document - a. Master Protocol		Project Descriptors	Version 1.4	04/21/2009 10:38 AM CDT

Do proposed revisions in study procedures/personnel unfavorably alter the risk-benefit ratio for the study?

- Yes
 No
 Not applicable, because no revisions are being proposed in study procedures/personnel

If yes, please explain in what specific ways the proposed revisions unfavorably alter the risk-benefit ratio for the study:

The changes enhance the risk-benefit ratio by reducing the risks to the fetuses of pregnant subjects.

Are additional changes beyond any proposed revisions in study procedures/personnel necessary in order to maintain an acceptable risk-benefit ratio and/or minimize risks to the subjects?

- Yes
 No

If yes, please explain what additional changes are necessary in order to maintain an acceptable risk-benefit ratio and/or minimize risks to subjects:

Are proposed revisions in the informed consent disclosure/process acceptable?

- Yes
 No
 Not applicable, because no revisions are being proposed in the informed consent disclosure/process
 Not applicable, because informed consent has been waived for the study

Are additional changes beyond any proposed revisions in the informed consent disclosure/process necessary?

- Yes
 No
 Not applicable, because informed consent has been waived for the study

If yes, please explain what additional changes are necessary in the informed consent disclosure/process:

Are any additional issues regarding protection for the rights and welfare of human subjects raised by the proposed revisions in the study?

- Yes
 No

If yes, please enumerate these additional issues below:

RECOMMENDATION

- Approve the study revisions without modification
 Approve the study revisions after minor administrative changes
 Defer approval of the study revisions pending substantive changes
 Disapprove the study revisions
 Incomplete submission

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

(2000) Close Form**Have you completed your review?**

- Yes No Date the Review was completed: 03/10/2009

THE ELECTRONIC SIGNATURE HAS BEEN APPLIED

by Terrence F Ackerman

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