

UTHSC Institutional Review Board Form

Reviewer's Comment Form

Reviewer's Name:

Alfred P Kraus

List of Reviewers:

Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed
Primary Reviewer	Kraus, Alfred P	Yes	03/12/2009	03/17/2009

Date:

03/15/2009

Principal Investigator:

Thomas Sample PI
07-0000-FB

Study Title:

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

A Twelve-Month, Open-Label, ...

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
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							Workflow
			Submission Form		PI Response to Review	Version 2.0	03/23/2009 12:47 PM CST
			Submission Form		Form 3: Continuing Review Submission Form	Version cont-1.1	03/23/2009 12:47 PM CST
Submission Attachments below:							
			Consent (English)		ICF revised clean 3/20/2009	Version 5.0	03/23/2009 12:47 PM CST
			Consent (English)		ICF track changes form 3 (3/20/2009)	Version 5.0	03/23/2009 12:47 PM CST
			Consent (English)		Informed Consent clean yearly renewal <i>* This consent was part of this submission.</i>	Version 5.0	03/11/2009 08:55 AM 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

(500) Full Board Continuation

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6) Viewing Previous Submission Forms (such as revisions, adverse events, and data safety monitoring reports)

You may wish to view previous submission forms while considering this continuation application.

From the IRB Assistant menu, click Meeting Agenda.

Choose the assigned meeting date.

Locate the section identified as Continuation-FB.










Open the submission you are assigned to review.

Directly beneath the IRB number and the PI name, click on the Submission Forms tab.

Click on the type of forms you wish to view.

Contents of Submission:

Print selected item(s)

Show History	Print	Open	Type		Document Name	Version	Date Submitted into Workflow
	<input type="checkbox"/>		Submission Form		PI Response to Review	Version 2.0	03/23/2009 12:47 PM CST
	<input type="checkbox"/>		Submission Form		Form 3: Continuing Review Submission Form	Version cont-1.1	03/23/2009 12:47 PM CST
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	<input type="checkbox"/>		Consent (English)		Informed Consent clean yearly renewal <i>* This consent was part of this submission.</i>	Version 5.0	03/11/2009 08:55 AM CST

Does any of the information provided in the application suggest that the risk-benefit ratio for the study has become less favorable?

- Yes
 No

If yes, please explain how the risk-benefit ratio has become less favorable:

Does any of the information provided in the application suggest that changes are required in study procedures in

order to maintain an acceptable risk-benefit ratio and/or to minimize risks to the subjects?

- Yes
 No

If yes, please enumerate specific changes that are required in the protocol procedures:

Does any of the information provided in the application suggest that changes should be made in the informed consent disclosure/process for new subjects?

- Yes
 No
 Not applicable, waiver of consent granted for this study
 Not applicable, enrollment closed

If yes, please describe appropriate changes in the informed consent disclosure/process:

Does any of the information provided in the application suggest that new information should be provided to current subjects to determine their willingness to continue participation?

- Yes
 No
 Not applicable, waiver of consent granted for this study
 Not applicable, all subjects have completed research interventions

If yes, please describe what new information should be provided to current subjects:

Does any of the information provided in the application suggest that additional information should be provided to former subjects in the study?

- Yes
 No
 Not applicable, waiver of consent granted for this study

If yes, please describe what additional information should be provided to former subjects:

Based on the study's progress as reported in the application, is it true that subjects have been recruited without regard (as applicable) to gender, race, or ethnic status?

- Yes
 No

If no, please specify how recruitment of subjects should be revised if the study is still open to enrollment:

Are any additional issues regarding protection for the rights and welfare of human subjects raised by the information provided in the continuation application?

- Yes
 No

If yes, please enumerate these additional issues below:

RECOMMENDATION

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

Incomplete submission

If the recommendation is for approval, please indicate the length of time and/or other conditions which should limit the period for which re-approval of the study is granted:

- One Year
- 3 months
- 6 months
- 9 months
- Other conditions

If other conditions are checked, please specify these conditions below:

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: 03/17/2009

THE ELECTRONIC SIGNATURE HAS BEEN APPLIED

by Alfred P Kraus

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