OMB#: 0925 – xxxx **Expiry Date: xx/xx/xxxx**

STATEMENT OF CONFIDENTIALITY

Collection of this information is authorized under 42 USC 285a. While your participation is completely voluntary, to participate in the NCI CIRB, completion of this form is required. Data collected as part of the NCI CIRB review is private and protected by law. Under the provisions of Section 301d of the Public Health Service Act, no information that could permit identification of a participating individual may be released. All such information will be kept private under the Privacy Act and will be presented only in statistical or summary form.

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx*). Do not return the completed form to this address.

Study Review Responsibility Transfer Form

Submission of this Study Review Responsibility Transfer Form indicates that the CIRB is no longer the IRB responsible for review of this study. This is a two-step process. Step 1 is to complete this form. Step 2 is to confirm the information and submit.

Step 1: Complete this form.

A: Click "Next" once the form is completed and you will be taken to the confirmation page.
Note: If you wish to transfer more than one study, a separate request must be made for each study being transferred.

Fields marked with * are required.

*Study Number: Select from the List

Study Title:

*Name of Local IRB: Select from the List

*Institution's FWA Number Auto-populate

*Local IRB Registration Number Auto-populate

☐ Click this box if there are study participants enrolled at a site covered by this IRB. If so, upload a copy of the IRB approval letter. NOTE: Your IRB must have approved the study via local procedures before transfer so there is no lapse in IRB oversight of the study.

*Upload IRB Approval Letter:

☐ Click this box if there are no study participants enrolled at a site covered by this IRB. NOTE: Proof that the study is open is not required since there are no participants enrolled.

If you have any questions, call the NCI CIRB Helpdesk at 888-657-3711 or email ncicirbcontact@emmes.com.

NEXT BUTTON

If you wish to return to the Facilitated Review Submission Report, click the ‘Go Back” button (all information entered will be lost). GO BACK BUTTON

Review of Information and Submission of Study Review Responsibility Transfer Form

Review, Revise if necessary, and Submit

Study Number: CALGB-80303

Study Title: "A Randomized Phase III Trial of Gemcitabine Plus Bevacizumab (NSC #704865 IND# 7921) versus Gemcitabine Plus Placebo in Patients with Advanced Pancreatic Cancer"

Name of IRB: Missouri Baptist Medical Center

Institution's FWA Number: FWA00001234

Local IRB Registration Number: IRB00001234

Study participants are enrolled.
OR
Study participants are not enrolled.

IRB Approval Letter if applicable: C:\Documents and Settings\lcovington\Desktop\transcript.doc

After your review, select the appropriate option below:

If you want to change any information, click on "Go Back".
['Go Back' Button]

OR

If the information is correct, click the Submit button. You will receive an email confirming the request.

['Submit' Button]

AUTOMATICALLY GENERATED EMAIL UPON CLICKING SUBMIT ON THE CONFIRMATION PAGE. NO GREETING IS NECESSARY.

SUBJECT LINE: NCI CIRB Acknowledgement of the Submission of the Study Review Responsibility Transfer Form

Your request has been transmitted to the CIRB Operations Office. Within the next 10 days, you will receive an email from the CIRB Operations Office confirming that this transfer has been entered into the system or a telephone call to resolve any outstanding issues.

If you have any questions, call the NCI CIRB Helpdesk at 888-657-3711 or email ncicirbcontact@emmes.com

Study Number: CALGB-80303

Study Title: "A Randomized Phase III Trial of Gemcitabine Plus Bevacizumab (NSC #704865 IND# 7921) versus Gemcitabine Plus Placebo in Patients with Advanced Pancreatic Cancer"

Name of IRB: Missouri Baptist Medical Center

Institution’s FWA Number: FWA00001234

Local IRB Registration Number: IRB00001234

Study participants are enrolled.
OR
Study participants are not enrolled.

IRB Approval Letter: C:\Documents and Settings\lcovington\Desktop\transcript.doc

AUTOMATICALLY GENERATED INTERNAL EMAIL ONLY

Subject: Study Review Responsibility Transfer Request for Study (Study ID)
Sent: Day of week, Month DD, YYYY Time
From: CTIS
To: ncicirbcontact@emmes.com
Attachment: IRB Approval Letter

Study Review Responsibility Transfer Request

Greetings,

A study review responsibility transfer request has been submitted by <person submitting transfer first name> < person submitting transfer last name> (email < person submitting transfer email address>) for Study: (Study ID) – (Study Title):

Next steps:
Review the attached IRB Approval Letter to ensure it is complete and accurate for those studies with participants enrolled. NOTE: if there are no participants enrolled there will be no IRB Approval Letter.
Go to CIRB website and complete the CIRB Operations Office Confirmation page for the protocol-specific transfer request.
Create a CHAD ticket once the review is complete. Select the Category as "Transfer of Review Responsibility".
Complete the CHAD ticket and send the final email with the information provided in INTERNAL EMAIL 2.
Close the CHAD ticket within the next 3 days.
An email will be sent from CIRB website submitter that the transfer has been accepted.
A request to complete a survey specific to the SRRTF will be provided to users.

To confirm the Transfer Request click here <link to CIRB Operations Staff Confirmation page>

Study Number: CALGB-80303

Study Title: "A Randomized Phase III Trial of Gemcitabine Plus Bevacizumab (NSC #704865 IND# 7921) versus Gemcitabine Plus Placebo in Patients with Advanced Pancreatic Cancer"

Name of IRB: Missouri Baptist Medical Center

Institution's FWA Number: FWA00001234

Local IRB Registration Number: IRB00001234

Study participants are enrolled. OR Study participants are not enrolled.

IRB Approval Letter: C:\Documents and Settings\lcovington\Desktop\transcript.doc (as attachment)

CIRB Operations Office Confirmation

Please confirm that the submitted IRB Approval Letter is complete and accurate and that this study may be transferred to the designated IRB.

Study Number: (Study ID)
Study Title: (Study Title)
Name of Local IRB: (IRB Name)
Study Status: (Study Status) Participants are enrolled. OR Participants are not enrolled.
IRB Approval Letter: (File Name)

☐ *The study review responsibility transfer request is completed.
SUBMIT BUTTON

INTERNAL EMAIL 2

Subject: Study Review Responsibility Transfer Completed
Sent: Day of week, Month DD, YYYY Time
From: CTIS
To: <person approving transfer email>
cc: ncicirbcontact@emmes.com
Attachment: IRB Approval Letter

Study Review Responsibility Transfer Request Approval Notice

Greetings,

You have approved the study transfer of review responsibility to (Institution name, City, State) for (Study ID).

Please complete the appropriate CHAD ticket with the following email.

EXTERNAL EMAIL

To: < person submitting transfer email address>
cc: ncicirbcontact@emmes.com; ctsurego ffice@ecogchair.org; plus any additional addresses indicated

Subject Line: Study Review Responsibility Transfer Completed

Dear IRB Contact Person:

The NCI CIRB Operations Office has completed the Study Review Responsibility Transfer to (Institutio n name, City, State) for (Study ID).

As of today, the CIRB is no longer the reviewing IRB for this study.

If you have any questions, contact the NCI CIRB Helpdesk at ncicirbcontact@emmes.com or by phone at 1-888-657-3711.