- **Form 2L: Facilitated Review Acceptance Form**
  The instructions on this website form were revised to be more clear and easier to understand for the public. No additional burden to the public is foreseen.

Text deleted	Text added
"indicated below and is requesting the CIRB to be"	"Submission of this Facilitated Review Acceptance Form (FRAF) is mandatory to indicate to the CIRB that your IRB has conducted a facilitated review for this study. Once the CIRB Operations Office confirms receipt of this FRAF, the CIRB is the IRB responsible for review of the study"
"submit it electronically by clicking on the 'Submit' button at the bottom	Step 1. Complete this form Step 2. Click "Next" once form is completed… Step 3. Review information on confirmation page… Step 4. Once you click "Submit," your browser will automatically take you back to the main page… Step 5. You, and everyone whose email you include on this form, will receive… Important Note: a separate FRAF must be submitted for every study when facilitated review is conducted.
"Institution IRB Name" "Local IRB Chair Name" "Local IRB Contact Email"	"Name of Local IRB" Name of Person Submitting the FRAF Email for Person Submitting the FRAF
"Local IRB Contact Name" "Additional recipient of this acknowledgement Email" "I confirm that all the information provided is correct"	
Our institution has reviewed and accepts the responsibilities outlined in the "Division of Responsibilities" between the Central IRB and Participating Local Institutions" handout"	

cancer.gov

The Central Institutional Review Board Initiative
in consultation with OHRP

Facilitated Review Acceptance Form

OMB#: 0925 – 0625 Expiry Date: 01/31/2014

STATEMENT OF CONFIDENTIALITY

Collection of this information is authorized under 42 USC 285a. Your participation is completely voluntary. You are subject to no penalty if you choose not to provide all or any part of the requested information. Data collected as part of the NCI CIRB review is confidential 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 held in confidence 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 (0925-0625*). Do not return the completed form to this address.

Submission of this Facilitated Review Acceptance Form (FRAF) is mandatory to indicate to the CIRB that your IRB has conducted a facilitated review for this study. Once the CIRB Operations Office confirms receipt of this FRAF, the CIRB is the IRB responsible for review of the study.

Step 1: Complete this form.

Step 2: Click "Next" once the form is completed and you will be taken to a confirmation page.

Step 3: Review information on the confirmation page and click "Submit" if information is correct. If changes are required, click "Go Back" and you will be returned to this form.

Step 4: Once you click "Submit", your browser will automatically take you back to the main page of the Participant's Area of the CIRB website.

Step 5: You, and everyone whose email you include on this form, will receive an email from the CIRB Operations Office confirming receipt of the FRAF.

Important Note: A separate FRAF must be submitted for every study when a facilitated review is conducted.

Study ID:	COG-ARST0531
Study Title:	Randomized Study of Vincristine, Dactinomycin and Cyclophosphamide (VAC) versus VAC Alternating with Vincristine and Irinotecan (VI) for Patients with Intermediate-Risk Rhabdomyosarcoma (RMS): A Groupwide Phase
Name of Local IRB:	Select from the List
Local IRB Registration Number:	
Institution's FWA Number:	FWA00005287
Name of Person Submitting the FRAF:	Michelle Stickler

Email for Person Submitting the FRAF: mcstickler@vcu.edu

Enter email addresses of additional people to receive the confirmation email. Use a semicolon (;) to separate email addresses.

Our IRB has performed a facilitated review of study COG-ARST0531 and requests the CIRB to be the IRB responsible for review of this study.

Please check ONE of the following options:

- ○ This is the first time COG-ARST0531 will be opened at our institution.

OR

- ○ COG-ARST0531 was previously opened through our local IRB however by submitting this form we are indicating that we want to transfer this study so the CIRB will be the IRB responsible for review. Once we receive the confirmation email that the Facilitated Review Acceptance Form has been received by the CIRB Operations Office, we will document the transfer of this study to the CIRB in our regulatory file.

Date FRAF Submitted to CIRB: 3/10/2011

If you have any questions or are having any difficulty completing this form, please call the NCI CIRB Helpdesk at 888-657-3711 or email ncicirbcontact@emmes.com.

NEXT

User Number: 370486

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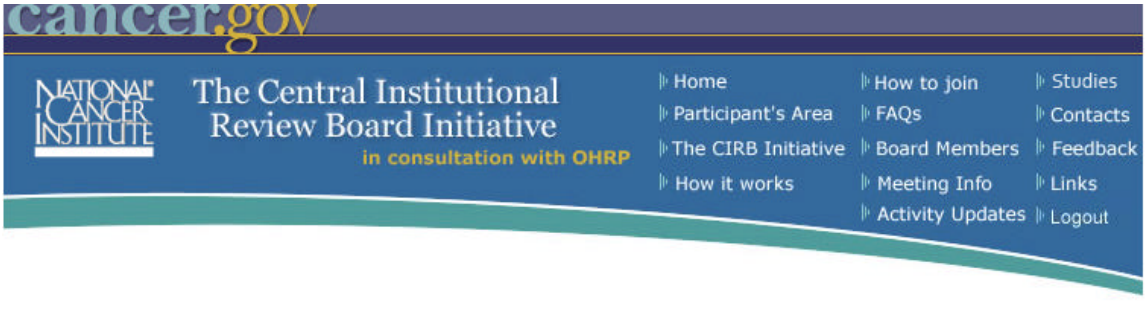

Facilitated Review Acceptance Form

OMB#: 0925 – 0625 Expiry Date: 1/31/2014

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Facilitated Review Acceptance Form

Local Institution IRB Office Staff:

Submission of this Facilitated Review Acceptance Form indicates to the CIRB that your IRB has conducted a facilitated review for the study indicated below and is requesting the CIRB to be the IRB of record for this study.

Your institution will be added to the distribution list for the bimonthly Study Activity Update. The Study Activity Update provides local IRBs with a listing of all recent study-specific postings on the CIRB website. Postings include new studies, amendments to current studies, adverse events, acknowledgement of notifications or announcements received from the Cooperative Groups, etc.

Please complete this form and submit it electronically by clicking on the 'Submit' button at the bottom of the form.

Everyone whose email is listed on this form will receive an acknowledgement email along with a copy of this form. Hard copies of the form and the acknowledgement should be kept in your institution's study file per your local procedures.

Please note - Facilitated Review Acceptance Forms are study specific so a separate form must be submitted for each study for which your IRB accepts facilitated review.

If you have any questions or are having any difficulty completing this form, please call the NCI CIRB Helpdesk at 888-657-3711 or email ncicirbcontact@emmes.com.

Fields marked with * are required.

Study ID:	ACOSOG-Z1031
Study Title:	A Randomized Phase III Trial Comparing 16 to 18 Weeks of Neoadjuvant Exemestane (25 mg daily), Letrozole (2.5 mg), or Anastrozole (1 mg) in Postmenopausal Women with Clinical Stage II and III Estrogen Receptor Positive Breast Cancer
Institution IRB Name:	Tufts Medical Center
*Institution's FWA #:	FWA
*Local IRB Registration #:	IRB
*Local IRB Chair Name:	
*Local IRB Contact Name:	Julie Morelli Novak
*Local IRB Contact Email:	jmorelli@tuftsmedicalcenter.org
Additional recipients of this acknowledgement Email:	

Use semicolon (;) character to separate email addresses.

Click on the boxes below:

☐ *Our IRB has performed a facilitated review of study ACOSOG-Z1031 and requests the CIRB to be the IRB of record for this study.

Please check ONE of the following options:

○ This is the first time ACOSOG-Z1031 will be opened at our institution.

OR

○ ACOSOG-Z1031 was previously opened through our local IRB however by submitting this form we are indicating that we want to transfer this study so the CIRB will be the IRB of Record. Once we receive the confirmation email that the Facilitated Review Acceptance Form has been received by the CIRB Operations Office, we will document the transfer of this study to the CIRB in our regulatory file.

☐ *I confirm that all the information provided is correct.

☐ *Our institution has reviewed and accepts the responsibilities outlined in the "Division of Responsibilities between the Central IRB and Participating Local Institutions" handout.

Date Submitted to CIRB: 7/30/2010

If you have any questions or are having any difficulty completing this form, please call the NCI CIRB Helpdesk at 888-657-3711 or email ncicirbcontact@emmes.com.

Submit

User Number: 325179

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