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.

<u>Important Note:</u> 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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