

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.

## 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 <u>ncicirbcontact@emmes.com</u>.

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:	
	Click on the boxes below:

$\square$ *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 <u>ncicirbcontact@emmes.com</u> .	
Submit	

User Number: 325179

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