IRB Approval Letters

THE UNIVERSITY OF TEXAS
MD ANDERSON
CANCER CENTER

DATE: APR 07, 2009

TO: Lewis Foxhall M.D.
223

FROM: IRB Coordinator
Office of Protocol Research
Unit 574

SUBJECT: Continuing Review Contingency Met
Continuing Review of Protocol DR07-0819

Title: Assessing Problem Areas in Referrals in Chronic Hematologic Malignancies and Developing Interventions to Address Them

The M.D. Anderson Cancer Center Institutional Review Board (MDACC IRB4) chair or designee approved the above named and numbered protocol since the CONTINGENCY outlined by the committee at the DEC 18,2008 meeting has been met as of MAR 30, 2009.

All research related activities may continue for another 365 days from DEC 18,2008.

If you have any questions regarding this matter, please call the Office of Protocol Research at (713)792-2933 or send an email to IRB CONTINUING REVIEW@mdanderson.org.

Thank you for your cooperation.

THE UNIVERSITY of TEXAS
HEALTH SCIENCE CENTER AT HOUSTON

The Committee for the Protection of Human Subjects
Office of Research Support Committees

6410 Fannin, Suite 1100
Houston, TX 77030

Leona Bartholomew, EdD
UT-H - SPH - Health Prom & Behavioral Sci

NOTICE OF CONTINUING REVIEW APPROVAL December 23, 2008

HSC-SPH-07-0187 - *Assessing Problem Areas in Referrals for Chronic Hematological Malignancies and Developing Interventions to Address Them*

PI: Leona Bartholomew, EdD

PROVISOS: Unless otherwise noted, this approval relates to the research to be conducted under the above referenced title and/or to any associated materials considered at this meeting, e.g. study documents, informed consents, etc.

NOTE: If this study meets the federal registration requirements and this is an investigator-initiated study, or if the PI is the study sponsor or holds the IND/IDE applicable to this study, and no one else has registered this trial on the national registry, you are required to register this trial on the national registry at www.clinicaltrials.gov in order to publish results in any of the key peer-reviewed journals. For further information contact Gena Monroe at 713-500-7903.

APPROVED:	By Expedited Review and Approval	
REVIEW DATE:	December 22, 2008	
APPROVAL DATE:	December 23, 2008	**EXPIRATION DATE**: 11/30/2009
CHAIRPERSON:	Anne Dougherty, M.D.	

Upon review, the CPHS finds that this research is being conducted in accord with its guidelines and with the methods agreed upon by the principal investigator (PI) and approved by the Committee. This approval, subject to any listed provisions and contingent upon compliance with the following stipulations, will expire as noted above:

CHANGES: The PI must receive approval from the CPHS before initiating any changes, including those required by the sponsor, which would affect human subjects, e.g. changes in methods or procedures, numbers or kinds of human subjects, or revisions to the informed consent document or procedures. The addition of co-investigators must also receive approval from the CPHS. ALL PROTOCOL REVISIONS MUST BE SUBMITTED TO THE SPONSOR OF THE RESEARCH.

INFORMED CONSENT: Informed consent must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to instruct the designee in

the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document. Attached is the approved and validated informed consent form. You must discard all previous informed consent documents being used and replace them with this stamped validated version. **Please note that only copies of the appropriately dated, stamped approved informed consent form can be used when obtaining consent.**

UNANTICIPATED RISK OR HARM, OR ADVERSE DRUG REACTIONS: The PI will immediately inform the CPHS of any unanticipated problems involving risks to subjects or others, of any serious harm to subjects, and of any adverse drug reactions.

RECORDS: The PI will maintain adequate records, including signed consent documents if required, in a manner which ensures subject confidentiality.

DANA-FARBER/PARTNERS CANCER CARE

Office for Human Research Studies
Dana Farber Cancer Institute
20 Overland Street
Boston, MA 02115
(617) 632-3029

Continuing Review: Notification of IRB Approval/Activation

DFCI Legacy #: 07-303

Date: 10/23/2008

To: Gregory Abel, MD, MPH

From: DFCI OHRS

Title of Protocol:	Referals for Chronic Hematological Malignancies: A PCP Survey
IRB Continuing Review #:	1
IRB Review Type:	Expedited 8(b) Continuing review of research previously approved by IRB where no subjects have been enrolled and no additional risks have been identified. 9 - Continuing review of research not under an IND or IDE where categories 2-8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
IRB Approval Date:	10/23/2008
IRB Expiration Date:	10/23/2009

This Project has been reviewed and approved by the DFCI IRB, Assurance # FWA00001121. During the review of this Project, the IRB specifically considered (i) the risks and anticipated benefits, if any, to subjects; (ii) the selection of subjects; (iii) the procedures for securing and documenting informed consent; (iv) the safety of subjects; and (v) the privacy of subjects and confidentiality of the data.

As Principal Investigator you are responsible for the following:

1. Submission in writing of any and all changes to this project (e.g., protocol, recruitment materials, consent form, study completion, etc.) to the IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB within 24 hours.
2. Submission in writing of any and all adverse event(s) that occur during the course of this project in accordance with the IRB's policy on adverse event reporting.
3. Submission in writing of any and all unanticipated problems involving risks to subjects or others.
4. Use of only IRB approved copies of the consent form(s), questionnaire(s), letter(s), advertisement(s), etc. in your research. Do not use expired consent forms.
5. Informing all physicians listed on the project of changes, adverse events, and unanticipated problems.

The IRB can and will terminate projects that are not in compliance with these requirements. Direct questions, correspondence and forms (e.g., continuing reviews, amendments, adverse events, safety reports) to OHRS, 617-632-3029.

cc:
Gregory A Abel, MD, MPH
Lysa Magazu