Sample text for an Institution with a Federalwide Assurance (FWA) to rely on the IRB/IEC of another institution (institutions may use this sample as a guide to develop their own agreement).


Name of Institution or Organization Providing IRB Review (Institution/Organization A):
___Medstar Health Research Institute- Georgetown University Oncology Institutional Review Board

IRB Registration #: 0002119___ Federalwide Assurance (FWA) #, if any: FWA00001080

Name of Institution Relying on the Designated IRB (Institution B): University if Maryland, College Park

FWA #: FWA00005856

The Officials signing below agree that University if Maryland, College Park may rely on the designated IRB for review and continuing oversight of its human subjects research described below: (check one)

(____) This agreement applies to all human subjects research covered by Institution B’s FWA.

(____) This agreement is limited to the following specific protocol(s):

Name of Research Project: ___Today’s Truth Research Brings Hope________________________
Name of Principal Investigator: ___Sandra M. Swain, M.D_________________________
Sponsor or Funding Agency: __NIH/NCMHHD___ Award Number, if any: ___RC1MD004185___

(____) Other (describe):

The review performed by the designated IRB will meet the human subject protection requirements of Institution B’s OHRP-approved FWA. The IRB at Institution/Organization A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB’s determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (Institution/Organization A):
Sheila Zimmmer* Date: 12/1/10
Print Full Name: Sheila Chen Zimmmer* Institutional Title: Sr. Associate VP for Regulatory Affairs

NOTE: The IRB of Institution A must be designated on the OHRP-approved FWA for Institution B.

Signature of Signatory Official (Institution B):
Mary Ann Ottinger Date: 4/28/11
Print Full Name: Mary Ann Ottinger Institutional Title: Associate VP for Compliance and Policy
TO: MHRI-GU Oncology IRB

FROM: Kathryn Bailey, Regulatory Coordinator
On Behalf of Sandra M. Swain, MD

DATE: October 27, 2010

IRB #: 2009-465

PI: Sandra M. Swain, MD

SPONSOR: Investigator-Initiated – Sandra M. Swain, MD
Today’s Truth: Research Brings Hope

ACTION: Amendment 3 version October 25, 2010; IRB Authorization for University of Maryland
Addition of Deliya Banda as a sub-investigator; patient flyer—expedited review

Please find attached the following for the above study:

1. IRB Authorization for the University of Maryland
2. Financial disclosure – Deliya Banda
3. CV – Deliya Banda
4. PEER # 091215006
5. Patient Poster – attached
7. Protocol version October, 2010 – tracked
8. Amendment cover letter

There is no change to the ICF. This amendment includes a flyer and details that the site will collect information regarding what type of insurance the study participants have.

The IRB at Maryland IRB has agreed to recognize the MHRI-GU IRB as the IRB of Record for this study, and will rely on the MHRI-GU IRB for review and continuing oversight of this study. The University of Maryland will sign and keep this on file after Ms. Banda has both parties’ signatures.

If there are any further questions, please feel free to contact me.

Thank you.
MedStar Health Research Institute-Georgetown University Oncology Institutional Review Board

Date: November 18, 2010

To: Sandra Swain, MD
Washington Cancer Institute
110 Irving St NW C-2149
Washington, DC 20010

From: Melissa Lewis
Project Coordinator
Institutional Review Board

Title: Today's Truth Research Brings Hope

IRB#: 2009-465

Annual Approval Date: May 26, 2010

Expiration Date: May 25, 2011

Action: Expedited Amendment/Modification
Protocol Amendment 3 dated October 25, 2010
Addition of Deliya Banda as a sub-investigator
Recruitment Flyer

The revisions as referenced above to your protocol were recommended for approval through expedited review by Dr. Vinay Gupta, the Chair of the Institutional Review Board or the designee, on November 10, 2010.

This is to inform you that you may continue your project.

Please remember to:
1. Seek and obtain prior approval for any modifications to the approved protocol.
2. Promptly report any unexpected or otherwise significant adverse effects encountered in the course of this study to the Institutional Review Board within 7 calendar days. This includes information obtained from sources outside MedStar Health Research Institute and Georgetown University that reveals previously unknown risks from the procedures, drugs or devices used in this study.

30016
CC: Bailey, Kathryn

CC: IRB file
The only University of Maryland is myself.
Name: Deliya R. Banda
Role: Sub-Investigator
Responsibilities: All aspects of study coordination, data collection, patient recruitment, patient interviews and manuscript development.

Please let me know if this is sufficient.
Thanks
~ Deliya

On Fri, Jan 28, 2011 at 8:14 AM, Tykisha Bell <tbell@umresearch.umd.edu> wrote:

In the review of your paper I did not see your write up listing the names, roles and responsibilities of each investigator from University of Maryland on the project. Please email me this information.

Best regards,

Tykisha Bell, M.B.A.
IRB Assistant Manager
Institutional Review Board Office
University of Maryland, College Park
Lee building Room # 0101
College Park, MD 20742-5121
301-405-7326 (voice)
301-314-1475 (fax)
tbell@umresearch.umd.edu
http://www.umresearch.umd.edu/IRB

>>> <Deliya.R.Banda@Medstar.net> 1/25/2011 5:00 PM >>>

Good Afternoon Tykisha,
I just wanted to confirm that I dropped off the documentation you requested below, at your office yesterday. I was told at the front desk that it would be sent off for the required signatures from UMD IRB after which we will