Version Date: 12/20/2005

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).

Institutional Review Board (IRB)/Independent Ethics Committee (IEC) Authorization Agreement

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

IRB Registration #: 00002119____ 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.

(_X__) 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 Zimmet Date: 12/1/10

Print Full Name: Sheila Cohen Zimmet 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: 1/28/11

Print Full Name: Mary Ann Ottinger Institutional Title: Associate VP for Compliance and Policy

MedStar Health
Research Institute

Advancing Health Through Research

☐ Noted
☑ Approved
☐ Approved
☐ Approved
☐ Approved

DATE: 10/10/10
w/modifications:
Exempt
Expedited

☐ Disapproved

Chair, Institutional Review Board

EA 30016

TO: MHRI-GU Oncology IRB

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

Kathryn Bailey 10/27/10

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**
6. **Protocol version October 25, 2010 – clean**
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

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

Tykisha Bell - Re: 2009-465 : IRB approval for dissertation substudy?

From: Deliya Banda <dbanda@umd.edu>
To: Tykisha Bell <tbell@umresearch.umd.edu>
Date: 1/28/2011 8:37 AM
Subject: Re: 2009-465 : IRB approval for dissertation substudy?
CC: "Deliya.R.Banda@medstar.net" <Deliya.R.Banda@medstar.net>, "nikpayp@georgetown.edu" <nikpayp@georgetown.edu>, "Kathryn.Bailey@medstar.net" <Kathryn.Bailey@medstar.net>, "wci.regulatory@medstar.net" <wci.regulatory@medstar.net>

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