Attachment F- HSRB Documentation

Masterson, Kathy J. (CDC/NIOSH/OD)

From: NIOSH HSRB Office (CDC)

Wednesday, October 26, 2011 3:27 PM Sent: To: Ellison, Chris (CDC/NIOSH/DCAS)

Toraason, Mark A. (CDC/NIOSH/DART); Trout, Douglas (CDC/NIOSH/DSHEFS); Hinnefeld, Cc:

Stuart L. (CDC/NIOSH/DCAS); Sundin, David S. (CDC/NIOSH/DCAS); Neton, Jim

(CDC/NIOSH/DCAS)

Subject: HSRB 11-DCAS-NR01 "Energy Employees...Dose Reconstruction..." Re-Confirmation Non-

Research Determination 10/26/11 EllisonC

Importance: High

Chris, thank you for contacting HSRB Office.

Effective 10/26/2011, I have assigned the below described 2011 Re-Confirmation of Non-Research activity HSRB/IRB number/title HSRB 11-DCAS-NR01 "Energy Employees Occupational Illness Compensation Program Act Dose Reconstruction Interviews and Forms.* This is a re-confirmation of 2009 Non-Research Determination HSRB 09-OCAS-NR01 approved 1/22/2009.

Thank you, Chris.

Kathy.

Kathy Masterson, CIP NIOSH HSRB Administrator

Human Subjects Review Board (HSRB-IRB)

Office of the Director

National Institute for Occupational Safety and Health

Centers for Disease Control and Prevention (CDC)

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CDC/NIOSH HSRB INTRAnet Link: http://inside.niosh.cdc.gov/hsrb/default.htm CDC/NIOSH HSRB INTERnet Link: http://www.cdc.gov/niosh/pgms/HSRB/

From: Toraason, Mark A. (CDC/NIOSH/DART) Sent: Wednesday, October 26, 2011 1:55 PM

To: Ellison, Chris (CDC/NIOSH/DCAS)

Cc: Trout, Douglas (CDC/NIOSH/DSHEPS); Masterson, Kathy J. (CDC/NIOSH/OD); NIOSH HSRB Office (CDC) Subject: RE: DCAS 10/26/11 Request Reconfirmation of Previous Non-Research Determ HSRB 09-OCAS-NR01:

On January 21, 2009, your program, DCAS (formally OCAS) requested from the NIOSH IRB HSRB a human subjects research/non-research determination for the activity "Energy Employees Occupational Illness Compensation Program act Dose Reconstruction Interviews and Forms" The NIOSH IRB HSRB determined that your activity of obtaining exposure information from energy employees to determined possible compensation did not meet the DHHS 45CFR 46.102(d) definition of research. This is because the intent of your activity is not to contribute to generalizable knowledge. The activity was determined to be human subjects non-research not requiring IRB review.

You are now requesting a renewed human subjects research/non-research determination for this activity. You have indicated that the activity conducted under "The Energy Employees Occupational Illness Compensation Program Act" has not changed. The activity remains human subjects non-research and does not require IRB review.

Kathy Masterson will assign a new HSRB non-research number to this activity.

Mark Toraason, Ph.D.

IRB Chair, HRPP Director

From: NIOSH HSRB Office (CDC)

Sent: Wednesday, October 26, 2011 10:54 AM

To: Ellison, Chris (CDC/NIOSH/DCAS)

Cc: Toraason, Mark A. (CDC/NIOSH/DART); Trout, Douglas (CDC/NIOSH/DSHEFS); Masterson, Kathy J. (CDC/NIOSH/OD)

Subject: DCAS 10/26/11 Request Reconfirmation of Previous Non-Research Determ HSRB 09-OCAS-NR01;

Importance: High

Hello Chris,

All is well and thank you for your E-mail. You have requested a reconfirmation of previous Non-Research
Determination HSRB 09-OCAS-NR01 (attached below). I have cc'd Mark Torasson (Chair HSRB-IRB) here as he or Doug Trout, Co-Chair HSRB-IRB, are the ones to make NIOSH HSRB-IRB Research/Non-Research Determinations. If Mark reconfirms this non-changed activity as non-research, I will assign a new 2011 number using DCAS in the nomenclature and send same to you for your records.

Thank you, Chris.

Kathy.

Kathy Masterson, CIP NIOSH HSRB Administrator **Human Subjects Review Board** Office of the Director

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From: Ellison, Chris (CDC/NIOSH/DCAS) Sent: Wednesday, October 26, 2011 10:22 AM To: Masterson, Kathy J. (CDC/NIOSH/OD) Subject: HSRB Question/Assistance

Good morning Kathy!

I hope all is well. I have several questions I hope you can help me with. DCAS has a set of interview questions and a form that we use with our claimants. The items are up for OMB renewal and one of the items that needs updated is the statement of non-determination by HSRB. The HSRB renewal is for item HSRB 09-OCAS-NR01. There are no changes to either item. I have enclosed the document that I have from the last time. Sorry but it is the only copy of the document I have and it is a little to read.

If you can please assist me in what steps I need to take, I would greatly appreciate it.

Chris Ellison

Acting Deputy Director Division of Compensation Analysis and Support National Institute for Occupational Safety and Health

