Appendix D

Human Subjects Review Board Approval

TO: Naomi G. Swanson, Ph.D.
Through: Director, DART_____(C-22)
Chief, OSHEF_____ (C-24)

Report of NIOSH HSRB

NIOSH Protocol HSRB 02-DART-05XP "Work Organization Predictors of Depression in Women"

October 17, 2007

General Comments and IRB Actions

I have reviewed your request to continue protocol HSRB 02-DART-05XP "Work Organization Predictors of Depression in Women" using the expedited criteria outlined in 45 CFR 46.110 (7) and (8) (a) categories and have determined that the study still involves no more than minimal risk to subjects and that no additional risks have been identified since the last review. This protocol is granted approval for another year (10/9/2008). However, if you make any substantive changes to the protocol, or if any adverse reactions occur in any study participants, please notify me immediately.

Protocol Issues - None
Consent Form Issues - None
Addenda Issues (Scripts, questionnaires, brochures, etc.) - None

End of report
Cherie F. Estill, M.S., P.E., Chair, NIOSH HSRB

IRB ID Number: 10787

Office of Research Protection and Ethics
Institutional Review Board Notice of Approval
Federalwide Assurance No. 3331

Title of Study: Work Organization Health and Well-being Study
RTI Project Number: 0207171.330 **RTI Proposal Number** (if no Project Number)
Project Leader: Kathleen Considine
Project Team Member Contact (if different from Project Leader):
Source of Funding for this Study: NIOSH
Date Submitted to IRB: 04-13-07

Level of Review *(check one)*:
Full ☐, IRB Meeting Date: N/A
Expedited ☒, category: 9: Cont. Rev. minimal risk research

Type of Review *(check one)*:
- ☐ Preliminary review (Do not involve human subjects or data until pretest or full study is approved.)
- ☐ Pretest/Pilot Test
- ☐ Full Implementation
- ☐ Amendment, describe:
- ☐ Add study site(s):
- ☒ Renewal
- ☐ Study Closure

IRB Approval of Special Conditions *(check all that apply)*:
- ☐ Waiver of Signed Informed Consent/Parental Permission
- ☐ Participation of Pregnant Women (**Worksheet B** submitted by project team)
- ☐ Participation of Prisoners (**Worksheet C** submitted by project team)
- ☐ Participation of Minors (**Worksheet D** submitted by project team)
- ☐ IRB Agreement of Nonsignificant Risk Device Study Determination

Please note the following requirements:
- If **unexpected problems** or **adverse events** occur, the project team must notify the IRB.
- If there are **changes** in study procedures or protocol or any data collection materials (brochures, letters, questionnaires, etc.) the project team must notify the IRB before they are implemented.
- The project team is required to apply for **continuing review** as long as the study is active, which includes participation of human subjects or possession of human data or specimens.

Expiration Date of IRB Approval: **April 28, 2008**
(No human subjects research can occur after this date without continuing review and approval.)

Wendy Visscher
Signature - IRB Member or Chair

4-17-07
Date of IRB Approval

Wendy A. Visscher, PhD
Name - IRB Member or Chair (print or type)

☒ Copy sent to project leader
☒ Entered into MIS

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