Attachment M

NIOSH IRB Approval Letter

Effective 9/30/2013, this is your official notice that your protocol **amendment** request re HSRB 10-DRDS-01 "An Investigation of Lung Health at an Indium-Tin Oxide Production Facility" has been **approved**. Below for your files is your amendment approval report and attached is your signed application for amendment. The next review date for your protocol is 4/9/2014.

General Comments and IRB Actions

I have reviewed your request to amend HSRB 10-DRDS-01 "An Investigation of Lung Health at an Indium-Tin Oxide Production Facility" using the expedited criteria outlined in 45 CFR 46.110 (b) (2) category in that it involves minor changes to a previously approved protocol; and that no additional risks have been identified since the last review. The revised protocol and consent documents (dated 9/30/2013) will serve as the documents of record for this study. The next review date for this protocol is 4/9/2014. This amendment is approved. 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 incidents need to be reported to NIOSH IRB by phone or E-mail within 2 working days; and reported formally [send CDC form 0.1254 + 0.1379] within 2 weeks.

If you choose to make changes to your approved protocol, the changes must be reviewed and approved prior to implementation by submitting via hard copy CDC forms 0.1379 (signature page), 0.1252 (amendment request), 0.1370 (non CDC collaborator, if have), a clean copy of the revised protocol and a highlighted copy (track changes or pen/ink) of the revised protocol (all changes highlighted). Electronic submission of your amendment request may facilitate review, but it is not required. The general procedure for requesting annual continuing review is to send 45-60 days prior to renewal date completed hard copy forms CDC 0.1379 (signature page), 0.1251 (continuing review request), 0.1370 (non CDC collaborator, if have), a copy of your current consent form (if consenting or recruiting currently). An electronic submission of your continuing review may facilitate review, but it is not required.

Protocol Issues, Consent Form Issues, Addenda Issues – None.

End of report
Mark A. Toraason, Ph.D., Chair, NIOSH IRB (HSRB)