

COLUMBIA UNIVERSITY
MEDICAL CENTERInstitutional Review Board
(CU IRB)
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New York, New York 10032
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May 10, 2007

Steven Shea, MD
Department of Medicine-General Medicine
General Medicine
Ph 9 East 105www.cumc.columbia.edu/dept/iri

Re: **IRB Continuing Review Approval**
Protocol #: AAAA7791

Title: **Multi-Ethnic Study of Atherosclerosis**
Approval Date: April 25, 2007 **Expiration Date: April 24, 2008**

Dear Dr. Shea:

On April 25, 2007, the renewal for the above-mentioned study was reviewed and approved at a convened meeting of Columbia University Medical Center Institutional Review Board IRB #2.

During the approval period, all subjects enrolled not only must provide voluntary informed consent to participate in the study, but also must sign a copy of the appropriate stamped consent document(s). A copy of the consent document(s) must be given to the subjects for their record.

INVESTIGATOR PLEASE NOTE:

Questions related to the protocol:

Please submit a modification to address the following:

- 1) As per CUMC policy all study personnel are required to complete GCP and HIPAA research training before they are approved to participate in the conduct of a research project. Study team member, Milka Monegro, is required to complete GCP and HIPAA research training as per CUMC policy. The required exams can be accessed through the RASCAL website www.rascal.columbia.edu click on testing center exam TC0005 for the GCP exam and TC0019 for the HIPAA research exam.
- 2) Since this project includes the collection of bodily materials Hazardous Materials, Appendix C requires completion. Please complete Appendix C in RASCAL in order to facilitate IBC review.
- 3) There is a discrepancy in the number of subjects enrolled to date and the total expected to participate. Last year's renewal indicates target enrollment at this site = 1500, with 1354 accrued to date at this site. This year's renewal indicates target enrollment at this site = 1200 with 1102 accrued to date at this site. The cumulative number accrued to date cannot decrease from one year to the next. Please reconcile and clarify the number of subjects enrolled, the number remaining on study, and the number expected to be enrolled in the upcoming year. Also, it appears that the local enrollment has been exceeded by 90 subjects. Please provide a justification for this overenrollment.
- 4) An annual summary of adverse events is required but has not been attached and no explanation is provided. If there are no adverse events, this should be indicated in the Oversight Monitoring section of this renewal, which requires completion.
- 5) Three funding sources are listed: NIH, EPA & HEI. Current Progress Report is not attached and no explanation is provided. Again, an explanation of why the progress reports are not attached should be indicated in the Oversight Monitoring section of this renewal, which is blank.

Questions related to the informed consent form: for additional quartz filter sampling

Please submit a modification to address the following:

- 1) HEI Quartz consent form Potential Risks and Discomforts section: The IRB has deactivated this consent form and will reactivate the document upon receipt of the modification to address the above concerns as well as the following: The consent form indicates that the air monitoring equipment can fall from the window, and that this could pose a risk of injury to person or property. Can you provide the IRB with more information pertaining to the device (i.e., a picture of the device, along with the dimensions and installation instructions?). Will coordinators be trained in installing the device? If so, who will conduct the training? Who is liable if the device falls from the window and hits a passerby? What is the actual risk of that happening?

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The following study materials were approved:

- 1) The following questionnaires attached in RASCAL on 04/05/07: FU8 MESA Form Packet_03282007.pdf, FU8 Family Form Packet_03282007.pdf, FU8 New Recruit Form Packet_03282007.pdf, FollowUp Questionnaire 3-14-07.pdf.
- 2) The following questionnaires attached in RASCAL on 11/21/06: FORM Participant Tracking Log v2_3.pdf, FORM Participant FollowUp Log v2_3.pdf, FORM Participant Contact Log v2_2.pdf.
- 3) The following questionnaires attached in RASCAL on 09/25/06: Spanish MESA Air Questionnaire 9-06-06.pdf, Spanish Air Residential Quest 4-20-06.pdf, Spanish Air Neighborhood Quest 9-9-05.pdf, Spanish Dairy Time & Location w-HispSTAMP9-07-06.pdf, Spanish Air Infiltration Questionnaire6-21-06.pdf, Spanish Air Family Screening Recruitment 09-06-06.pdf, Spanish Air Columbia Screening Recruitment 09-05-06.pdf.
- 4) Letter - FollowUp 8 Cover Letter 3-14-07.pdf [attached in RASCAL on 04/05/07].
- 5) Reminder - FollowUpAppointmentReminder 3-14-07.pdf [attached in RASCAL on 04/05/07].
- 6) Consent - Spanish RNA Consent Form 3-22-07.pdf [attached in RASCAL on 04/05/07].
- 7) Reminders attached in RASCAL on 04/05/07: MESAAirampling Reminder OutInPersonal.doc, MESAAir Sampling Reminder OutIn.doc, MESAAir Sampling Reminder Out.doc.
- 8) Contact scripts attached in RASCAL on 04/05/07: MESAAir Monitoring Contact Scripts OutInPer.doc, MESAAir Monitoring Contact Scripts OutIn.doc, MESAAir Monitoring Contact Scripts Out.doc.
- 9) Letter - MESA Air Post Letter 102405.doc [attached in RASCAL on 04/05/07].
- 10) Letter - Thank You Letter02202007.doc [attached in RASCAL on 03/12/07].
- 11) Consent - Clean RNA MESA Consent Form 3-22-07.doc [attached in RASCAL on 03/22/07].
- 12) Consent - Spanish MESA Exam 4 Consent.pdf [attached in RASCAL on 02/14/07].
- 13) Consent - CLEAN EXAM 4 CONSENT 11-24-07.doc [attached in RASCAL on 01/24/07].
- 14) Reminder - Spanish Reminder Letters & Guides for AIR Sampling.pdf [attached in RASCAL on 12/20/06].
- 15) Consent - Passivel sampling_NYC.doc [attached in RASCAL on 12/20/06].
- 16) Letter - MESA Air Post Letter2 111706.doc [attached in RASCAL on 12/20/06].
- 17) Consent - Personal sampling_Rockland.doc [attached in RASCAL on 10/12/06].
- 18) Consent - Personal sampling_NYC.doc [attached in RASCAL on 10/12/06].
- 19) Letter - Spanish Air Invitation letter Air w-HTC 09-07-06.pdf [attached in RASCAL on 09/25/06].
- 20) Questionnaire - F7-General Health10052006.pdf [attached in RASCAL on 10/11/06].
- 21) Questionnaire - Spanish Follow-up 7.pdf [attached in RASCAL on 08/10/06].
- 22) Questionnaire - TelephoneQuestionnaire_PhoneScripts.doc [attached in RASCAL on 08/09/06].
- 23) Questionnaire - Mailed Air Questionnaires cover letter (MESA).doc [attached in RASCAL on 08/09/06].
- 24) Cover letter - Consent form cover letter.doc [attached in RASCAL on 08/09/06].
- 25) Letter - MESA Air invitation letter.doc [attached in RASCAL on 07/28/06].
- 26) Letter - air reschedule letter Eng (1).doc [attached in RASCAL on 08/09/06].
- 27) Screening - Air-Family Siblings Screening_English.pdf [attached in RASCAL on 08/09/06].
- 28) Letter - Mailed Air Questionnaires cover letter (MESA Family).doc [attached in RASCAL on 08/09/06].
- 29) Questionnaires attached in RASCAL on 07/28/06: Residential History Questionnaire_English.pdf, Neighborhood Questionnaire_English.pdf, MESA AIR Questionnaire_English.pdf.
- 30) Screening - MESA Air Columbia Screening E.pdf [attached in RASCAL on 07/28/06].
- 31) Reception - MESA Air Clinic Reception 7.18.06.pdf [attached in RASCAL on 07/28/06].
- 32) Observation form - Air_Technician_Observation_Form_v1_1.pdf [attached in RASCAL on 07/28/06].
- 33) Personal time - Air_Personal_Time-Loc_v2_2_6_06_2006.pdf [attached in RASCAL on 06/07/06].
- 34) Questionnaire - Follow-up 7 Packet 2_27_2006.pdf [attached in RASCAL on 06/07/06].
- 35) Consent - Spanish MESA Fam New R w-HRC.pdf [attached in RASCAL on 02/14/06].
- 36) Consent - Spanish MESA Fam Sib w-HRC.pdf [attached in RASCAL on 02/14/06].
- 37) Consent - Spanish MESA Air w-HRC.pdf [attached in RASCAL on 02/14/06].
- 38) Consent forms attached in RASCAL on 01/10/06: CLEAN MESA FAMILY NEW RECRUITS CONSENT + Air Pollution 01-10-06.doc, CLEAN MESA FAMILY SIB CONSENT + Air Pollution 01-10-06.doc, CLEAN MESA AIR New Recruits 01-10-06.doc.

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- 39) Reception form - V4_Cover020806.pdf [attached in RASCAL on 02/14/07].
- 40) Reminder - AIR Reminder clinic visit.doc [attached in RASCAL on 01/11/06].
- 41) Letter - Inner Imaging letter.pdf [attached in RASCAL on 01/11/06].
- 42) Results - Lab Results Template 11-28-05.Doc [attached in RASCAL on 01/09/06].
- 43) Tracking - F6-Tracking.pdf [attached in RASCAL on 01/09/06].
- 44) Exam report - V4 CT Examination Report 10-13-05.pdf [attached in RASCAL on 01/09/06].
- 45) Ultrasound - V4 Ultrasound IMT 10-27-2005.pdf [attached in RASCAL on 01/09/06].
- 46) Phlebotomy - MESA Air Phlebotomy.pdf [attached in RASCAL on 09/29/05].
- 47) Tracking - SpanishTracking Events (participants).pdf [attached in RASCAL on 09/29/05].
- 48) Phlebotomy - Spanish V4 Phlebotomy.pdf [attached in RASCAL on 09/29/05].
- 49) Reminder - Spanish Reminder Appointment Letter.pdf [attached in RASCAL on 09/29/05].
- 50) Questionnaire - Spanish Follow-up 6 phone call.pdf [attached in RASCAL on 09/29/05].
- 51) Questionnaire - Spanish Air Health and Life.pdf [attached in RASCAL on 09/29/05].
- 52) Letter - Letters for participants.pdf [attached in RASCAL on 09/29/05].
- 53) Consent - MESA Lung Consent Forms.zip [attached in RASCAL on 09/28/05].
- 54) Form - V4 Processing Form 8-24-05.pdf [attached in RASCAL on 08/24/05].
- 55) Phlebotomy - V4 Phlebotomy 8-24-05.pdf [attached in RASCAL on 08/24/05].
- 56) Tracking - Tracking events (participants).doc [attached in RASCAL on 08/24/05].
- 57) Reminders attached in RASCAL on 08/24/05: Reminder letters Follow-up.pdf,Reminder Follo-up phone call.doc, Reminder clinic visit Exam 4.doc.
- 58) Invitation - NEW invitation to exam 4.doc [attached in RASCAL on 08/24/05].
- 59) Questionnaires attached 08/23/05: FU6 packet 6-22-05.pdf, Health & Life.pdf, Spanish New Recruits Clinic forms w HRRC.pdf, Spanish MESA Fam Sibling Recruitment Air w HRRC.pdf, Spanish MESA Exam 4 Clinic Forms w HRRC stamp.pdf, Spanish General Health FU 6 w HRRC.pdf.
- 60) Form - Medication form-new.pdf [attached in RASCAL on 08/23/05].
- 61) Questionnaires attached on 07/27/05: Exam4 Forms Packet 6-9-05.pdf, AIR Personal History.pdf.
- 62) Consent - MESA Family Parent-Proband Consent w-HRC stamp.pdf [attached in RASCAL on 06/27/05].
- 63) Letter - MESA Air Invitation letters (2) w-HRC stamp.pdf [attached in RASCAL on 06/27/05].
- 64) Letter - MESA Air Participant Invitation Letter Pollution 04-11-05.doc [attached in RASCAL on 05/25/05].
- 65) Questionnaires attached in RASCAL on 05/05/05: Air New Recruit Clinic Forms 4-13-05.pdf, AIR Family Sibling Screening and Recruitment040405.pdf.
- 66) Cue cards - CueCards - Air Pollution.pdf [attached in RASCAL on 05/05/05].
- 67) Cue cards - Cue Card #5 Time Sheetfinal.pdf [attached in RASCAL on 05/05/05].
- 68) Results - CLEAN PartPhysResultsLetterTemplate.doc [attached in RASCAL on 05/05/05].
- 69) Letter - MESA Events-Letters.pdf [attached in RASCAL on 05/04/05].
- 70) Questionnaire - MESA Events 6-28-04.pdf [attached in RASCAL on 05/04/05].
- 71) Form - SpirometryCompletionform-Spanish.pdf [attached in RASCAL on 05/04/05].
- 72) Supplement - SpirometryQuestionnaireSupplement -Spanish.pdf [attached in RASCAL 11/30/04].
- 73) Results - Family Result Letters 10-19-04.pdf [attached in RASCAL on 10/19/04].
- 74) Questionnaire - CleanSpanishSpirometryQuestionnaire.pdf [attached in RASCAL on 10/08/04].
- 75) Questionnaire - SpirometryQuestionnaireSupp 8-4-04l.pdf [attached in RASCAL on 09/07/04].
- 76) Questionnaire - Spirometry Questionnaire 08-10-04.pdf [attached in RASCAL on 08/13/04].
- 77) Form - Spirometry Completion Form 08-11-04.pdf [attached in RASCAL on 08/13/04].

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Any proposed changes in the protocol must be immediately submitted to the IRB for review and approval prior to implementation, unless such a change is necessary to avoid immediate harm to the participants. Additionally, any serious and unexpected adverse events or other problems that involve risks to subjects must be reported to the IRB in accordance with the CUMC IRB AE Reporting Policy, dated April 13, 2004. All submissions for modifications and adverse events must be submitted through RASCAL.

Renewal applications should be submitted 60 days before the expiration date of this study through RASCAL. Failure to obtain renewal of your study prior to the expiration date will require discontinuance of all research activities for this study, including enrollment of new subjects. You must inform the IRB in writing when your study has been completed.

If you have any questions, please call Madeline Peyton at 212-342-0157 or Lauren Privitera at 212-342-0948. Columbia University appreciates your commitment towards the ethical conduct of human research.

Sincerely,



Lauren Privitera, CIP
Team #2 Manager
Columbia University Medical Center IRB
IRB/taw

Enc: Mesa Consent Forms, Spanish Consent Forms, Questionnaires, Recruitment flyers, phone scripts.