

Gilsenan, Michael

From: Jim Miller [jmiller@health.nyc.gov]
Sent: Tuesday, June 11, 2002 3:56 PM
To: Nancy Jeffery
Cc: Gilsenan, Michael; Callahan.Kathy@epamail.epa.gov; Jessica Leighton
Subject: IRB application for background study



IRB



Consent Form.doc



IRB cover letter.doc

Application_draft.doc

Attached for your review and comment, please find a

revised IRB application for the background study (thanks to all who provided comments). All sections of the application have been completed, although in some areas the answer to a question is shown by underlining one of the possible answers (the hard copy is clearer). I am also attaching the consent form, modeled on the ATSDR/NYC study, and the cover letter (in which an expedited review, typically 3 days, is requested).

As soon as the application, cover letter, and consent form are finalized, they can be packaged with the scope of work (received), building/apartment questionnaire (received), and CVs for Carol and Nancy (to be received), and submitted to the IRB.

APPLICATION
to
CONDUCT RESEARCH WITH HUMAN SUBJECTS
at the
NEW YORK CITY DEPARTMENT OF HEALTH

Principal Investigator: Carol Lynes
Job Title: Environmental Scientist
Affiliation: United States Environmental Protection Agency, Region 2
Address: Edison, NJ
Telephone: 732-321-6760
Fax: 732-321-6616
E-mail: lynes.carol@epa.gov

For office use only

IRB # _____ - _____
V. S. Log # _____ - _____

Other IRB approvals:

Agencies: _____

Date of approval: ____ / ____ / ____

Attach copies & related correspondence

/ here if pending: ☐

Study Title: Determining Background Levels of Contaminants of Potential Concern in New York City

Funding Source: Federal Emergency Management Agency

Grant #

Background of the Study: The collapse and subsequent fires at the World Trade Center site created a large amount of dust. Some of this dust was deposited inside apartments. Components of the dust may have included dioxin, lead, polycyclic aromatic hydrocarbons (PAHs), ceramic fibers, fibrous glass, asbestos, and silica.

Objectives (*List specific aims, study questions, & hypotheses*): The purpose of this study is to implement indoor sampling to collect settled and airborne dust samples for analysis to determine the concentrations of seven (7) Contaminants Of Potential Concern (COPC): dioxin, lead, PAHs, ceramic fibers, fibrous glass, asbestos, and silica. Sampling will be conducted in fourteen (14) buildings in midtown and upper Manhattan, i.e., areas unaffected by the airborne dust and plume that emanated from the World Trade Center (WTC) site. The level of contaminants in these apartments will be compared with levels found in apartments impacted by the WTC collapse. The contaminant levels found in midtown and upper Manhattan will serve as a background level of these materials in New York City and will help determine whether the cleaning of apartments in lower Manhattan has resulted in levels of COPC exposure comparable to background levels in midtown and upper Manhattan.

Design: A questionnaire will be completed for each residential unit and common area regarding general building characteristics, cleaning practices, and type and recent service history for the heating, ventilation, and air conditioning (HVAC) system. A contractor retained by the United States Environmental Protection Agency (EPA) shall transport portable air, microvacuum cleaner, and wipe sampling devices to sample locations, assemble the instruments, program the instruments, perform verifications (calibrations as specified in the QAPP), install filters and operate the instruments for sampling. An oscillating fan will operate during the sampling. Most residential unit sampling will be completed during a single 10-hour visit, but an additional visit(s) may be necessary. The contractor shall remain at each site for the entire sampling event. Residents will be free to come and go at will, but will be requested not to smoke, burn candles or incense, fry foods or perform any other activities that produce smoke inside their apartment during sampling. The contractor shall remove and properly package and store the samples for transport, and disassemble the sampling instruments. The contractor shall properly package the samples for shipment/transport to the EPA contracted laboratory specified on chain-of-custody forms. Samples will be analyzed at an EPA-contracted certified laboratory. Test results will be provided to residents and building owners. A final report of sampling results reported by street address will be a public document. No information on exact sampling locations (i.e., tenant names and apartment numbers) will be made public.

Target Population/Sample: The EPA contractor will visit a total of 14 buildings for this project. Ten of the buildings will be

located north of 79th Street in Manhattan, and these buildings have not previously been sampled. Four additional buildings, that were part of an earlier investigation (IRB Protocol Number 01-062), will be asked to participate in this study. In each building, two residential units and one common area will be sampled.

Recruitment Method: The New York City Department of Housing Preservation and Development (HPD) has prepared a list of 60 buildings north of 79th Street which match the 5 major residential building types in the vicinity of the WTC site. The 5 major types of residential buildings are turn-of-the-century tenements, post-1920 non-doorman mid rises, high-rise co-ops, lofts, and high-rise condos. Twelve (12) buildings have been identified in each category, and recruitment will begin with the first listed building in each category and selection will continue until two buildings with a willing building owner and two tenants are identified in each building type. Four additional buildings, that were part of an earlier investigation (IRB Protocol Number 01-062), will be asked to participate in this study.

Study Site(s): See Target Population/Sample above.

Study Procedures: Sample collection will be conducted using established sampling methods and laboratory analysis will be conducted by a certified laboratory.

Planned Analysis and Use of Data: The results obtained from these 28 apartments and 14 common areas will be compared with results from buildings that are closer to the WTC site. The measurements obtained in this study will provide a range of background levels of COPCs in New York City.

Is there an intervention or interaction with a living person that would not be occurring or would be occurring in some other fashion, but for this research?

Yes No

Will identifiable private data/information be obtained for this research in any form directly or indirectly associable with the individual?

Yes No

Number of participants to be enrolled: The residents of 28 apartments and the owners (if different) of 14 buildings will be enrolled.

Study Population (*Please check all that apply*): The residents of 28 apartments and the owners of 14 buildings (if different from the residents) will be the study population. It is anticipated that this population will include families with children/adolescents and elderly persons.

☒ <u>children/adolescents</u>	☐ terminally ill	☐ cognitively impaired
☐ pregnant women	☐ prisoners	☐ mentally ill or disabled
☐ fetuses/in vitro fertilization	☐ DOH or other employees	☐ clinical population (<i>specify</i> _____)
☒ <u>elderly</u>	☐ healthy volunteers	☐ other _____

List inclusion & exclusion criteria. Justify the exclusion of 1)pregnant women or women of child-bearing potential, 2)people above or under a certain age limit, or 3) a blanket exclusion of any specified group. Inclusion criteria are residence in a selected building and willingness to participate in the study. There are no exclusion criteria.

Provide statistical justification for the number of participants to be enrolled (summarize or attach power analysis if applicable): The 28 apartments and 14 common areas will provide a range of background levels for the 7 COPCs in 5

residential building types that correspond to the major types of residential buildings impacted by the WTC collapse.

Are investigators involved in subjects' clinical care or counseling? ☐ No ☐ *Yes—explain:*

Who will be recruiting subjects? researcher/research staff other: _____

How will the person(s) recruiting subjects be paid? recruitment activities part of regular job responsibilities
no payment
other: _____

Provide dates for projected timeline: Recruitment/enrollment: June 2002

Data collection, including intervention & follow-up: June-July 2002 sample collection

Study Completion: August 2002

Duration of participation by individual participant: [12 weeks] [___ months] [___ years] _____

Most sampling will be completed in a single 10-hour day. Test results will be made available approximately 10 weeks after sample collection.

Study Methods and Instrumentation:

Paste your recruitment script, questionnaire, eligibility screener, capacity screener, data abstraction form, medical records abstraction form, and any other study instrumentation at the end of this application form.

Qualifications of Key personnel:

Paste the curriculum vitae of the principal investigator, project director, and all other key personnel to the end of this form. Anyone whose name or job title is responsible for ensuring protocol adherence, quality assurance, and safety and confidentiality of subjects is considered key.

Human Subjects Training Certificates of Key Personnel:

Scan and paste (or attach) your human subjects training certificate to the end of this form.

Human Subjects Concerns:

Explain physical, psychological, social and economic risks associated with study participation: Participants will have sampling equipment and an oscillating fan present in their apartment for 1-2 days, up to 10 hours/day. They will be requested to refrain from cleaning and activities that produce smoke during the sampling. It is anticipated that low levels of some COPCs, e.g., lead, will be detected in some of the background apartments. Some residents may be surprised or upset to learn of the constituents of the urban environment.

Explain measures you will take to protect subjects from these risks. Participants will not be required to remain at home during the sampling. Sampling personnel will remain at the site throughout the entire sampling period. DOH staff will be available to answer any questions that arise from test results.

Explain the confidentiality and data security risks associated with the study. Failure to maintain confidentiality of test results would create the potential for an apartment to be identified as having had a COPC detected in a particular apartment.

Explain measures you will take to protect subject confidentiality and data security. Sample results for specific apartments will not be made public.

Does your study have a data safety monitoring board or other monitoring mechanisms? None (/ check if applicable)

Consent Form:

Paste your consent form to the end of this application. Remember to include separate consents or forms for the drawing, storage, and future testing of blood (if possible specifying type of test to be performed), special protections for any genetic tests

that are planned or may be performed in the future, and provide assurances about the disclosure of test results to patients and others (e.g., their designated clinician). Fully disclose all aspects of study participation, follow-up, and communication of results to subjects. Explain procedures such as collection of specimens, photography, videography or audiotaping, retrospective or prospective medical record review.

Explain anticipated benefits (if any).

Explain the costs and any reimbursements of study participation.

Explain that study participation will not affect the subject's rights to receive any other care that he/she was otherwise entitled to at the site.

Explain that consent must be freely and voluntarily given, and that persons may refuse or withdraw without penalty. Do not include any exculpatory language in the consent form.

Other languages (specify) None

Attach translated consent form if applicable.

Is FDA-regulated product involved? ☐ No ☐ Yes

IND/IDE number & date: _____ / ____ / ____

If pending, date requested: ____ / ____ / ____

☐ Include Investigator Brochure

DOH Involvement Please check all that apply:

☐ **data provision** (specify data & source[s]):

☐ **funding** identify mechanism:

☐ **subject recruitment** explain: DOH staff will assist EPA in notifying and explaining test results to building owners and residents.

☐ **use of DOH facilities** specify facility & activity that will take place:

☐ **staff participation in research activities** specify staff & describe activities, including specific consultation responsibilities

Nancy Jeffery, Director, Environmental and Occupational Disease Epidemiology, will oversee DOH involvement in this study, including supervision of any DOH staff who participate. DOH's primary responsibility will be to help interpret the health significance of any COPCs that are detected.

☐ **other** describe:

Signature of Principal Investigator: _____ Date: ____ / ____ / ____

I approve the research plan described in this application.

Signature of Program Director or

Assistant/Associate Commissioner: _____ Date: ____ / ____ / ____

Signature of Deputy Commissioner: _____ Date: ____ / ____ / ____
_____ Date: ____ / ____ / ____

***Follow instructions on pasting or attaching protocol, consent forms, and other required elements of this application.**



Consent for Release of Information and Access to Property for Environmental Sampling

The United States Environmental Protection Agency (EPA) and the New York City Department of Health (DOH) are conducting an investigation to determine the level, if any, of seven substances (dioxin, lead, polycyclic aromatic hydrocarbons, ceramic fibers, fibrous glass, asbestos, and silica) in the air and in settled dust in residential buildings in upper Manhattan. Residential buildings in lower Manhattan, especially those close to the World Trade Center (WTC) site, may have these seven substances present at elevated levels because of the WTC collapse. Determining the amount of these seven substances in upper Manhattan will establish the background levels of these substances in New York City. Participation in this investigation is voluntary. Your participation will help to determine whether the cleaning of apartments in lower Manhattan has reduced the level of these substances to the background level.

This investigation involves collecting indoor environmental samples (air and settled surface dust) from your property. Sample collection will be conducted by persons authorized by EPA, and will be done with a small vacuum cleaner, by wiping various surfaces, and by an air pump with an attached filter. An oscillating fan will run throughout the sampling period to maintain air circulation.

Sample collection will probably be completed in a single 10-hour day, but an additional visit(s) may be needed. Sampling personnel shall remain at each site for the entire sampling event. You will be free to come and go at will, and when you are present during the sampling, you may freely move about your home. You will be requested not to smoke, burn candles or incense, fry foods or perform any other activities that produce smoke. You will be requested not to do any cleaning during the day when sampling is taking place.

You have the right to request photo identification from all persons who gain access to your property for the purpose of sample collection.

Results

Upon completion of this investigation, EPA and DOH will prepare a written report that discusses the findings. The report will be available to the public but will not contain your name or your apartment number.

EPA and DOH will provide your test results and an explanation of their significance to you. Individual test results will not be made available to the public. Copies of test results will be provided to each apartment where sampling has occurred, and to the building owner (when the owner is different than the resident). Individual test results may be shared with other local, State, and Federal health or environmental agencies. Confidentiality will be protected according to local, State, and Federal laws.

Consent for Sharing of Test Results

I consent to having my test results shared with other local, State, and Federal health or environmental agencies.

Signature of Resident _____ Date

Signature of Property Owner (if different than resident) _____ Date

Directions: if you do not understand the description of the investigation, please ask questions. If you agree to participate, please sign the consent form below.

Consent for Access to Property

Resident's name (print) _____

Telephone number (____) _____

Description of Property (address) _____

I hereby consent to employees of EPA and parties authorized by EPA, to enter and have reasonable access to the above described property for the collection of environmental samples.

I am the property owner, or an individual having authorization of the property owner to make this access agreement. This written permission is given by me voluntarily with full knowledge of my right to refuse and with threats or promises of any kind.

Signature of Resident Date

Signature of Property Owner (if different than resident) Date

Signature of Witness Date

Please direct any questions or concerns about this sampling to Carol Lynes,
Environmental Scientist, at the United States Environmental Protection Agency at
732-321-6760.



THE CITY OF NEW YORK DEPARTMENT OF HEALTH

Michael R. Bloomberg
Mayor

Thomas R. Frieden, M.D., M.P.H.
Commissioner

nyc.gov/health

June 13, 2002

Dr. Lucia Torian
Acting Chair
NYCDOH Institutional Review Board
125 Worth Street, Room 620
New York, NY 10013

Dear Dr. Torian:

The overall objective of this sampling is to provide results upon which public health agencies can determine the potential for environmental exposures and possible health effects from the WTC building collapse. The initial (2001) study protocol (IRB Protocol Number 01-062) included sampling of contaminants of potential concern in 30 residential apartments in lower Manhattan that may have been impacted by dust fallout from the WTC collapse, and sampling of 4 "background" apartments (for comparison purposes) from locations north of 57th Street that were not significantly impacted by the dust fallout.

The purpose of the current study is to identify 10 additional and suitable "background" buildings north of 79th Street in Manhattan, and to sample these buildings along with re-sampling the original 4 background buildings for levels of the seven contaminants of concern. This new sampling will provide a more robust set of background environmental data to compare with data obtained from lower Manhattan, and thus significantly enhance our assessment of potential environmental exposures and possible health effects associated with the WTC building collapse.

I am requesting that this project be given an expedited review by the IRB. Carol Lynes from the Environmental Protection Agency will be the Principal Investigator on this project, and Nancy Jeffery, Director, Environmental and Occupational Disease Epidemiology, will oversee DOH involvement in this study.

Sincerely,

Benjamin A. Mojica, MD, MPH
Deputy Commissioner of Health