University of Maryland College Park Institutional Review Board IRB Initial Application - Part 1

Last edited by: Michel Boudreaux Last edited on: April 7, 2025 [click for checklist] Full Expedited

N/A 🔽

[2313444-1] Wildfire Exposures in Colorado

Answer all questions on this form completely, include attachments and obtain signatures of Co-Investigators and your department IRB Liaison prior to final submission on IRBNet.

I. Principal Investigator			
Name:	Michel Boudreaux	Status:	Faculty
Department:	HLSA- Health Services Administration		
Phone:	2023944412	Email:	mhb@umd.edu
Address:	SPH Building, 4200 Valley Drive, College Park MD 20742		

II. Faculty Advisor

Note: A faculty advisor is required if the PI is a student resident or fellow and the Faculty Advisor MUST sign this package through IRBNet.

Name:				
Department:				
Phone:		Email:		
Address:				
III. Co-Invest	igators			N/A 🗖
Note: All co-in	vestigators MUST sign th	is package through IRBNet		
Name:	Rebecca Gourevitch			
Department:	HLSA- Health Services Administration			
Phone:	301-405-2438	Email:	rgourevi@umd.edu	
Address:	4200 Valley Drive Colle	ge Park MD 20742		

Name:	Maranna Yoder		
Department:	ECON- Economics		
Phone:	301-405-2438	Email:	maranna@umd.edu
Address:	4200 Valley Drive College Park MD 20742		

Name: Marcos Fabian

Department:	PUAF- Public Affairs			
Phone:	301-405-2438	Email:	mfbnco@umd.edu	
Address:	4200 Valley Drive College Park MD 20742			
Name:	Sunjung Yoon			
Department:	HLSA- Health Services Administration			
Phone:	301-405-2438	Email:	<sy527@umd.edu></sy527@umd.edu>	
Address:	4200 Valley Drive College Park MD 20742			

IV. Funding Information

N/A 🗖

Note: A copy of the awarded grant application (minus budgetary information) must be provided.

Status	Funding Type	Sponsor Name	ORAA #	COI	
Awarded	Federal Government	National Institutes of Health	unknown	No	
Funding T	itle: Wildfires and Infant Health				

V. Project Information

Lay Summary:

The goal of this project is to study the effect of wildfire exposures (smoke and local fire activity) on the health, health service use, and health care costs of people in Colorado.

Requested Review Path:

- 🗖 Full
- Expedited
- Exempt

Projected Completion Date: 04/07/2030

Research Category:

- Faculty or Staff Research
- Graduate Student Research
- Student/Faculty Collaboration
- Undergraduate Student Research
- Dther:

Academic Committee Review:

- Yes Masters committee
- Yes Dissertation committee
- No additional academic review required

Participant Incentives:

- 🗖 Cash
- Check
- Raffle/ Lottery:
- Extra Credit/ Course Credit:
- 🗖 Gift:
- Food:
- D Other:
- Not Applicable

VI. Performance Sites

Performance Sites Engaged in Human Subject Research:

(where the research will be conducted)

- UMCP Campus: School of Public Health
- University of Maryland Extension:
- Campus Health Center
- Universities at Shady Grove:
- Schools:
- Prison/Jail:
- Other:

Is this an international study?

- Yes [complete Section 10 of Initial Application Part 2]
- 🔽 No
- If yes: International Sites:

VII. Subject Information

Targeted Populations:

- Normal adult/healthy persons
- Cognitively impaired persons

- Economically disadvantaged persons
- Educationally disadvantaged persons
- Elderly/aged persons
- Hospital patients or outpatients
- Illiterate persons
- Individuals with physical disabilities
- Minority group(s)
- Minors/children [inclusion of anyone under 18 requires a Parental Consent Form]
- ☐ Non-English speakers
- Pregnant women
- Prisoners
- Students (non-minors)
- ☐ UMCP employees
- Other special characteristics and special populations:

Informed Consent Process:

- Informed consent will be obtained from subjects and documented with a signed, written consent form
- Informed consent will be obtained from subjects, but no signed consent form will be used. This includes oral consent and implied consent (e.g., completing a survey). [please see the Requesting a Waiver of Informed Consent Guidance]
- Fully informed consent will not be obtained from all subjects. This includes deception, withholding information, etc.

[please see the Requesting a Waiver of Informed Consent Guidance]

Will you be collecting health information from or as a HIPAA covered entity?

(See the HIPAA section of the IRB website for more information and additional resources.)

- No
- Yes, data are de-identified or constitute a limited data set.
- Yes, subject's authorization will be obtained or a waiver or alteration of authorization will be requested. [complete IRB Form HIPAA]

VIII. Research Procedures

Research Procedures:

- Records review retrospective
- Records review prospective
- Education research
- Behavioral experiments
- Behavioral observation

- Questionnaires/surveys
- Interviews
- Audiotaping/videotaping
- The Internet
- Deception [describe debriefing process in Section 7 of Initial Application Part 2]
- Cancer Interventions (health promotion, implementation, etc.)
- ☐ None of the above

Biomedical Procedures:

- Tissue banking
- Biopsy
- Blood draw:
- Use of pre-existing tissues
- Clinical tests
- Radiology
- Radiation/X-ray/DEXA
- fMRI [use IRB fMRI templates]
- Pregnancy screening
- EKG
- 🗖 EEG
- Genetic analysis
- None of the above

IX. Assurances and Signatures

Assurances

This research, once approved, is subject to continuing review and approval by the IRB. The principal investigator will maintain records of this research according to IRB guidelines. If these conditions are not met, approval of this research could be suspended or terminated.

Electronic signatures certify that:

- The signatory agrees that he or she is aware of the policies on research involving participants of the University of Maryland College Park and will safeguard the rights, dignity, and privacy of all participants.
- The information provided in this application form is correct.
- The principal investigator will seek and obtain prior written approval from the IRB for any substantive modification in the proposal, including but not limited to changes in cooperating investigators/ agencies as well as changes in procedures.
- Unexpected or otherwise significant adverse events in the course of this study which may affect the risks and benefits to participation will be reported to the IRB.

• The research will not be initiated and subjects cannot be recruited until <u>final written approval</u> is granted.

The following signatures are required for new project submissions:

- Principal Investigator
- Co-Investigator(s)
- IRB Liaison (click here for list)

INSTRUCTIONS TO RESEARCHERS

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Now that you have completed this document, check your work, attach all appropriate documents, electronically sign and submit your work. Based on your responses, the following additional documentation must be included with this package before submission. Upload additional documentation in the Designer.

Documents available in the IRBNet Forms and Templates Library:

No additional documents from the Library are required for this project.

Additional required documentation:

- Grant application for any awarded funding
- Parental Consent Form
- Request for Consent Waiver

If you have any questions, please refer to the guidelines in the IRBNet Forms and Templates Library or contact irb@umd.edu.