



INSTITUTIONAL REVIEW BOARD

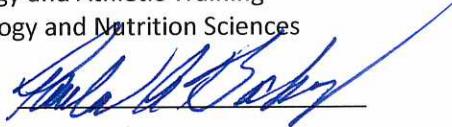
for the Protection of Human Subjects in Research

FWA 00000078

Research & Creative Scholarship
Interdisciplinary Science Building 104
University of Montana
Missoula, MT 59812
Phone 406-243-6672

Date: June 16, 2021

To: Dr. John Quindry, Integrative Physiology and Athletic Training
Dr. Graham McGinnis, UNLV - Kinesiology and Nutrition Sciences

From: Paula A. Baker, IRB Chair and Manager 

RE: IRB #83-21: "The Effects of Circadian Rhythm Disruption on the Inflammatory Response to Particulate Matter Exposure from Woodsmoke"

All conditions have been satisfactorily met, and your IRB proposal #83-21, "The Effects of Circadian Rhythm Disruption on the Inflammatory Response to Particulate Matter Exposure from Woodsmoke," has been **APPROVED** under **Full Committee Review** by the Institutional Review Board in accordance with the Code of Federal Regulations, 45 CFR 46. Please review and retain the attached documents with your project file.

All consent forms and flyers used for this project must be date-stamped and signed by the IRB. **Use the PDF sent with this approval notice as a "master" from which to make copies.**

Amendments: Any changes to the approved protocol, including the addition of any new research team members, must be reviewed and approved by the IRB **before** being made. Amendment requests must be submitted using [Form RA-110](#).

Unanticipated or Adverse Events: You are required to timely notify the IRB if any unanticipated or adverse events occur during the study, if you experience an increased risk to the participants, or if you have participants withdraw from the study or register complaints about the study. Use [Form RA-111](#).

Continuation: Federal regulation and University of Montana IRB policy require you to file an annual Continuation Report ([Form RA-109](#)) for studies under full committee review. You must file the report within 30 days prior to the expiration date, which is **June 15, 2022**. *Tip: Put a reminder on your calendar now.* A study that has expired is no longer in compliance with federal or University IRB policy, and all project work must cease immediately.

Study Completion or Closure: Finally, you are also required to file a Closure Report ([Form RA-109](#)) when the study is completed or if the study is abandoned. See the directions on the form.

This approval only applies to this specific project and may not be extended to any other projects, no matter how similar. Separate IRB applications must be submitted for each separate project.

Procedure for Sponsored Projects: If your project is funded, even via a sub-award, it is now your responsibility to notify your sponsored programs specialist in the Office of Sponsored Programs (OSP) of this IRB approval. Please provide them with the IRB number and date of approval. You may simply forward this approval email with the attachment(s).

Please contact the IRB office with any questions at (406) 243-6672 or email irb@umontana.edu.



UNIVERSITY OF MONTANA
Institutional Review Board (IRB)
for the Protection of Human Subjects in Research

IRB Protocol No.:

83-21

APPLICATION FOR IRB REVIEW

At the University of Montana (UM), the Institutional Review Board (IRB) is the institutional review body responsible for oversight of all research activities involving human subjects as outlined in the U.S. Department of Health and Human Services' Office of Human Research Protections.

Instructions: A separate application must be submitted for each project. Email the completed form as a Word document to IRB@umontana.edu, or submit a hardcopy (no staples) to the IRB office in the Interdisciplinary Science Building, room 104. Student applications must be accompanied by email authorization by the supervising faculty member or a signed hard copy. *All fields must be completed. If an item does not apply to this project, write in: N/A. Questions? Call the IRB office at 243-6672.*

1. Administrative Information

Project Title: The effects of circadian rhythm disruption on the inflammatory response to particulate matter exposure from woodsmoke	
Principal Investigator: Dr. John Quindry	UM Position: Professor
Department: IPAT	Office location: McGill Hall 102
Work Phone: (406) 243-4268	Cell Phone:

2. Human Subjects Protection Training (All researchers, including faculty supervisors for student projects, must be listed below and have completed a self-study course on protection of human research subjects within the last three years and be able to supply the "Certificate(s) of Completion" upon request. If you need to add rows for more people, use the Additional Researchers Addendum.

All Research Team Members (list yourself first)	PI	CO-PI	Faculty Supervisor	Research Assistant	DATE COMPLETED IRB-approved Course mm/dd/yyyy
Name: John Quindry, PhD Email: john.quindry@umontana.edu	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9/17/2018
Name: Graham McGinnis Email: graham.mcginnis@unlv.edu	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1/30/2018 6/4/2021
Name: Cassie Williamson-Reisdorph Email: cassie.reisdorph@umontana.edu	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	08/28/2018
Name: Joe Sol Email: joseph.sol@umconnect.umt.edu	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	3/30/2021

3. Project Funding (If federally funded, additional requirements may apply.)

Is grant application currently under review at a grant funding agency? <input checked="" type="checkbox"/> Yes (If yes, cite sponsor on ICF if applicable) <input type="checkbox"/> No	Has grant proposal received approval and funding? <input checked="" type="checkbox"/> Yes (If yes, cite sponsor on ICF if applicable) <input type="checkbox"/> No				
Agency	Grant No.	e-Prop #	Start Date	End Date	PI on grant
USFS	funded, ongoing	2021-302	8/6/18	3/23/23	John Quindry
INBRE	funded, being finalized	pending	3/1/2021	2/28/2023	Graham McGinnis, John Quindry

For UM-IRB Use Only

IRB Determination:

Not Human Subjects Research
Approved by Exempt Review, Category # _____
Approved by Expedited Review, Category # _____
Full IRB Determination
 Approved (see Note to PI)
 Conditional Approval (see memo) - IRB Chair Signature/Date: *P. Baker 5/25/2021*
 Conditions Met (see Note to PI)
 Resubmit Proposal (see memo)
 Disapproved (see memo)

Note to PI: Use any attached IRB-approved forms (signed/dated) as "masters" when preparing copies. Notify the IRB if any significant changes or unanticipated events occur. Failure to follow these directions constitutes non-compliance with UM policy.

P. Baker 5/25/2021

Risk Level: Minor increase over Minimal

Final Approval by IRB Chair/Manager: *P. Baker*

Date: 6/16/2021 Expires: 6/15/2022

SUBJECT INFORMATION AND INFORMED CONSENT

Study Title: The effects of circadian rhythm disruption on the inflammatory response to particulate matter exposure from woodsmoke

Sponsor: United States Department of Agriculture Forest Service and the National Institutes of Health
Montana INBRE program

Investigator(s):

John Quindry, Ph.D. (406) 243-4268
Graham McGinnis, Ph.D. (702) 895-4626
Cassie Williamson-Reisdorph, MS (406) 243-4268
Joe Sol, MS (406) 243-4268

Please read the following information carefully and feel free to ask questions. This consent form may contain words that are new to you. Only sign the final page when you are satisfied and the procedures and risks have been sufficiently explained.

Inclusion criteria: This research study requires that you meet the following criteria:

- You must be a male between the ages of 18 and 50 years old
- You must be a non-smoker (of any substance) within the last 12 months
- You must be able to cycle continuously at a moderate intensity for 45 minutes
- Be an 'Intermediate Chronotype.' (Not morning larks or night owls)

Exclusion criteria:

- Having a history of chronic lung disease, asthma, or Covid-19 with diagnosed lung involvement within the last year
- Having had a previous adverse reaction to environmental smoke exposure
- Having had orthopedic limitations that would limit your ability to exercise
- Having been diagnosed with cardiovascular or metabolic diseases
- Having been diagnosed with disordered sleep or sleep apnea
- Having traveled overnight outside of this time zone within the two weeks before participation, and the three weeks during the scheduled testing
- Having Covid-19 symptoms or having been exposed to someone with symptoms in the last week

Purpose: The purpose of this study is to better understand the effects of sleep deprivation and exercise during heavy woodsmoke inhalation on your cardiovascular and respiratory system (heart and lungs). To evaluate these things, we will have you perform two exercise trials on a stationary cycle while breathing a controlled amount of woodsmoke generated in our lab facility. In order to examine the influence of sleep restriction (good sleep vs. bad sleep) you will report to one exercise trial well rested, while in the other trial you will be instructed to go to sleep late and wake up early. To understand the overall stress imposed on you, we will examine your heart using a Fitbit monitor and a heart rate monitor. We will examine your lungs with a breathing test and will examine hormonal, inflammation, and circadian rhythm (time of day) biomarkers from blood, saliva, and breath moisture ("exhaled breath condensate") collected before and after exercise.

Procedures: You will be asked to participate in three visits (i.e., Baseline Testing and Exercise Inhalation Trials 1 and 2) over a 3-week period. Baseline Testing will be performed to determine eligibility for the study (e.g., your cardio fitness level). Baseline Testing will also be used to determine the moderate-intensity exercise bicycle setting for Exercise Inhalation Trials 1 & 2.

The University of Montana IRB
Expiration Date <u>6-15-2022</u>
Date Approved <u>6-16-2021</u>
Chair/Admin <u>P. Lohr</u>

Before all visits, you will be asked to avoid eating or consuming any beverage other than water for 12 hours prior to testing (including alcohol and caffeinated beverages). As a general rule with morning testing of this nature, you will be tested following an overnight fast (water is acceptable).

Baseline Testing (015 McGill Hall, ~ 1.5 hours): Upon arrival, the details of the study will be explained to you and you will be given the opportunity to provide informed consent to participate in this study. For this process, you will be asked to complete several forms called the **PAR-Q-plus** (physical activity readiness questionnaire which determines exercise readiness), the **MEQ** (morningness-eveningness questionnaire which assesses your waking/sleeping preferences) and the **MCTQ** (Munich chronotype questionnaire which determines your actual waking/sleeping habits). If you qualify for this investigation after the completion of these forms you will then have the opportunity to sign the informed consent document.

Next you will undergo testing to determine your body composition (lean vs. fat tissue) and your cardio fitness ("maximal oxygen consumption, $VO_{2\max}$ ") on a bicycle ergometer. The body composition test will measure your percentage of body fat via an underwater weighing test. The test will begin with the recording of your height and weight while wearing a bathing suit. Then, you will submerge yourself in a tank of warm water (similar to a hot tub) and hold your breath for four seconds while your weight is recorded. This procedure will be repeated until three consistent measurements are obtained. This test will take up to 30 minutes, and a nose clip will be provided.

Next, you will perform a maximal intensity bicycling test, called a " $VO_{2\max}$ test". The $VO_{2\max}$ test will take approximately 45 minutes, including 20 minutes of preparation, 10-20 minutes of cycling exercise, and 5 minutes of recovery. The results of the $VO_{2\max}$ test indicate your cardiovascular fitness level and determine eligibility for full study participation. Exercise intensity (cycling resistance/power) will gradually increase until you reach a maximal effort. During the test, the amount of oxygen used during exercise will be measured using a facemask that covers your nose and mouth. Study participation in the Exercise Inhalation Trials 1&2 requires that you have a $VO_{2\max}$ test result that exceeds 40 ml/kg/min (the ability to run approximately 7 mph for 45 minutes, or bicycle 16-17 mph for 45 minutes). During the $VO_{2\max}$ test, heart rate will be measured using an elastic chest strap and heart rate monitor worn under your shirt.

Following the completion of Baseline Testing, if $VO_{2\max}$ test inclusion criteria are met, scheduling will be completed for Exercise Inhalation Trials 1&2 (with each of these trials being separated by at least one week), and you will be equipped with a Fitbit Charge 3 fitness tracker and a Polar Heart Rate Monitor. The Fitbit is worn throughout the study (~3 weeks) like a watch, and it measures your patterns of activity and sleep over the study period. Note that if you are uncomfortable wearing the Fitbit watch (e.g., you're concerned it will get snagged during an activity), you may take it off. The Polar heart rate monitor will be worn the night before your 2 Exercise Inhalation Trials (~12 hours prior) and for 24 hours after these moderate-intensity exercise sessions. You will also be provided with a cheek swab sample collection kit (described below) to collect cells from the inside of your cheeks on a Q-tip. Finally, you will be given a paper copy of a sleep diary to manually record when you go to sleep and when you wake during the testing period.

Exercise Inhalation Trials 1&2 – (Inhalation and Pulmonary Physiology Core within Center for Environmental Health, 061 in the basement of the Skaggs Building ~ 3.5 hours each). As described below, these research trials are identical with the exception for the amount of sleep you receive prior to the trial:

After the Baseline Testing, we will provide you with a cheek swab kit to take home with you containing material for at-home sample collection leading up to each trial. In this kit, you will have an instruction manual, 4 small tubes with a sample stabilization buffer, and 4 small brushes that you will use to brush the inside of your cheek. At 4 specific times leading up to the experimental tests (12:00 noon the day before, 6:00 pm the day before, 12:00 midnight the night before, and 6:00 am the day of testing), you will use the brush to gently scrape the inside of the cheek for approximately 30 seconds, and carefully place the brush in

the tube, submerging it in sample stabilization buffer, and sealing the tube. You should avoid consuming anything other than water for at least 30 minutes prior to sample collection. Sample collection should not cause any irritation of the cheek. Importantly, cheek swab collection at midnight should be performed with minimal exposure to light. Cheek cells will be used to measure the expression of genes related to your sleep/circadian rhythm.

The night before your laboratory visit, you will undergo either 1) a 'normal' night of sleep, with an approximately 8-hour sleep opportunity from 10:00 pm to 6:00 am, or 2) a 'restricted' night of sleep (approximately 4-hours), where you go to sleep at 12:00 midnight and set an alarm to wake at 4:00 am.

At each visit, you will be asked to 1) provide pre-trial samples (blood and exhaled breath condensate), 2) undergo baseline lung function measurements, 3) put on a heart rate monitor (chest strap) to be worn during the visit and for 24-hours post visit, and 4) baseline cardiovascular function measurements. Additional details for each of these tests is provided below.

You will then be asked to cycle at a moderate intensity while exposed to air that contains wood smoke (particulate at a diameter of 2.5 μm ; roughly the size of a pollen molecule, and at concentration of 250 $\mu\text{g}/\text{m}^3$) after a night of normal sleep (~8 hours) or restricted sleep (~4 hours). Both trials will occur for a period of 45 minutes. The exercise intensity will equate to 70% $\text{VO}_{2\text{max}}$, an intensity that you will recognize as being of moderate intensity. Wood smoke will be delivered directly using a modified mask respirator to make it more comfortable. You will be allowed to consume water at 15-minutes and 30-minutes during each exercise trial. The amount of water consumed will be recorded and matched between Exercise Inhalation Trials 1&2.

Measurement of smoke concentration will be confirmed using an air particulate counting device called a DustTrak II (Model 8530), which makes sure you don't inhale too much smoke. Delivery of smoke within the exposure chamber will occur through a modified breathing mask attached to you through a mouthpiece. Other aspects of air quality, including temperature, humidity, carbon monoxide, and carbon dioxide in the exposure chamber and exercise room will be monitored with a device called a Q-Trak. Immediately after the 45-minute exercise trials, you will be asked to provide another blood and exhaled breath condensate sample and complete another lung and cardiovascular function test. 90 minutes after the completion of the exercise trial, a third set of tests and another blood and exhaled breath condensate sample will be collected.

The total time commitment will be approximately 1.5 hours for Baseline Testing, and approximately 3.5 hours on both Exercise Inhalation Trials 1&2, for a total of ~8 hours total time during the 3-week testing period.

Tests 1-5 below will be completed immediately before, after, and 90-minutes after the exposure to wood smoke on Days 2-3:

- 1) **Lung Function Tests** - You will be asked to inhale fully and then forcibly exhale into a device called a spirometer to collect measurements of lung function (vital capacity, forced expiratory volume, maximal voluntary ventilation). This test will be performed between 2-3 times.
- 2) **Cardiovascular Function Tests** - You will be asked to sit or lay quietly in a dark room while connected to a device that monitors your heart rate, rhythm, and heart rate variability. Afterwards, an automated device will record blood pressure in your arm and leg. As this test is conducted, a research assistant will gently place a "transducer" (a soft probe that will measure blood pulses with each heartbeat) over your carotid artery (the artery in your neck), the major blood vessel in your neck. All of these tests are completely painless and can be performed while you lie on a padded table.
- 3) **Exhaled Breath Moisture ("Exhaled Breath Condensate", EBC)** - You will be asked to exhale normally into a five-foot-long section of 3/4" diameter plastic tubing while seated. The length of the

tubing goes through an ice bath (0 degrees Celsius) to cool the exhaled air and allow for liquid collection. While wearing a nose clip, you will breathe in room air and exhale into a mouthpiece (with spit trap) that is attached to the tube, which has a one-way valve on both ends of the tube. After 10 minutes of exhaling into the tube, researchers will collect the tube containing the EBC sample (~3 mL) for analysis. At a later time, your EBC samples will be analyzed to determine whether smoke exposure during exercise resulted in increased inflammatory molecules present in your lung alveolar fluid.

- 4) **Blood Samples** - From the 3 blood draws conducted per exercise trial, approximately 30 milliliters (3x 10 ml or 3 tablespoons total) of blood will be taken from a vein in your arm (alternating arms as needed). Blood will be drawn before exercise, immediately after exercise, and 90-minutes after the conclusion of exercise (1 tube of blood at each blood draw). At a later time, your stored blood samples will be analyzed to determine whether smoke exposure during exercise resulted in increased inflammatory molecules circulating in your blood.
- 5) **Saliva Samples** - Saliva samples will be collected prior to and 90-minutes post exercise to monitor biomarkers in your saliva. Using a saliva collection tube (Salivette®Cortisol, SARSTEDT AG&Co. Germany), you will chew on a small cotton swab for 60 seconds and place it into the tube. Collection tubes will then be spun in a centrifuge to collect the saliva sample in the tube and the sample will be stored for analysis of biomarkers at a later date.

Risks/Discomforts:

- 1) Exercise related risks and discomforts - Mild discomfort may result during and after the exercise sessions. These discomforts may include shortness of breath, tired or sore legs, nausea and possibility of vomiting. Muscle soreness could occur after the exercise; however, it should not persist beyond a day or two. Certain changes in body function can occur following exercise, some of which are normal, and others are abnormal. Normal occurrences include mild symptoms of dehydration such as headache and general fatigue. Abnormal changes that may occur include alterations in blood pressure, heart rate, heart rhythm (as might be observed clinically on an ECG), or extreme shortness of breath. Very rare instances of heart attack have occurred following exercise. During any of the exercise performed for this study, should abnormal symptoms occur, such as chest discomfort, unusual shortness of breath or other abnormal findings develop, the exercise physiologist conducting the research will terminate the test. These symptoms could include moderate to severe angina (chest pain), increased dizziness, shortness of breath, fatigue or your desire to stop. If you experience these symptoms, please inform study personnel immediately.
- 2) Smoke inhalation risks and discomforts - During the Exercise Inhalation Trials, we will expose you to air containing moderate smoke particulate (250 $\mu\text{g}/\text{m}^3$, smaller than a dust particle) after a night of normal sleep (~8 hours) or restricted sleep (~4 hours). The total smoke exposure you experience is a combination of the particulate concentration, the number of breaths, and the depth of breath taken. During exercise at 70% of maximal intensity, you will take more breaths and deeper breaths while exposed to smoky air. For these reasons, the total smoke particulate exposure during your moderate dose exposure trial (250 $\mu\text{g}/\text{m}^3$, categorized as being on the threshold between "Very Unhealthy" and "Hazardous" by the U.S. Environmental Protection Agency) and is comparable to non-exercise exposures where one breathes several hours (3-6 hours) of smoky air created while not exercising. The moderate dose of wood smoke particulate (250 $\mu\text{g}/\text{m}^3$) used in this study is consistent with several other human exposure wood smoke studies of this type (using exercise + wood smoke) and are also reported in published scientific literature.
- 3) A wood smoke exposure study reported that the discomfort from smoke was minimal with exposure at 250 $\mu\text{g}/\text{m}^3$. The most prevalent symptom reported was a mild increase in eye irritation in 10 of 13

subjects. A slight increase in nose irritation was reported by 5 of 13 subjects, and 6 subjects reported the smell of wood smoke to be somewhat unpleasant. These subjects were exposed to similar concentrations of particulate matter for four hours, so the discomfort experienced should be comparable. The modified mask used in this study covers just the nose and mouth, and therefore should not result in eye irritation. Based on a wealth of related research, there is no evidence that comparable doses of smoke exposure result in lasting effects to one's health or wellbeing. A research assistant will be constantly monitoring both the particulate matter content and your signs of discomfort during all trials.

- 4) Risk and discomforts related to pulmonary function testing, exhaled breath condensate, and blood draw - You may experience discomfort when performing the pulmonary test and exhaled breath condensate tests due to the breathing requirements of these techniques. When blood samples are obtained for the study, you may feel a slight sting or pinch in your arm, you may suffer a small bruise, and there is a very slight possibility of infection. Should you notice unusual redness, bruising, or swelling at the blood sampling site, you should seek medical attention and contact John Quindry or Graham McGinnis.
- 5) Risks associated with acute sleep restriction and cheek swab sample collection – You may experience mild, transient symptoms following acute sleep restriction including fatigue and drowsiness. However, these symptoms should be reversed after a single night of 'recovery' sleep. Cheek swab collection should not induce any irritation. If so, you should contact John Quindry or Graham McGinnis.
- 6) Risks associated with Covid-19 transmission have been minimized by having you review a CDC Covid-19 questionnaire prior to each data collection session. Researchers will also adhere to this practice, canceling all data collection when anyone is symptomatic for Covid-19. Moreover, we will not resume data collection until both participants and researchers are confirmed as Covid-19 free/recovered. Daily temperature and symptom checks will be performed during data collection as an added measure to minimize risk. Moreover, social distancing and personal protective equipment will be used according to CDC recommendations during data collection. A HEPA filtration device will be used to clean air around you while you exercise, and your trial will be separated from other participants by a standard amount of time to ensure removal of potentially contaminated air.
- 7) Fitbit and Polar heart rate monitor devices may accumulate moisture producing skin irritation, a rash, or other skin discomfort. In order to minimize this risk, you will be provided with wearables that have been cleaned with alcohol and dried prior to your use. You will also be instructed on how to clean the devices while they are in your possession for this study. Finally, if you should experience any skin irritation, remove the wearable device and contact John Quindry or Graham McGinnis. As a last consideration, the Fitbit device may get caught while being physically active (e.g., snagging while doing yard work). If this becomes a concern, please remove the device and contact John Quindry or Graham McGinnis with questions or concerns.

You will be informed of any new findings that may affect your decision to remain in the study.

Benefits: As an incentive for participating in this study, you will receive information on your physical fitness ($VO_{2\max}$) and body composition. Also, this research may provide useful insight into how poor sleep may impact exposure to wood smoke and affect an individual's cardiovascular and respiratory systems. This information may be useful for those who work as wildland firefighters, others who perform strenuous activity while exposed to wood smoke, and those members of the general public that are exposed to wood smoke. Note that while blood work and gene expression analysis will be performed, these results will not be returned as a study benefit.

Confidentiality: Your records will be kept confidential and will not be released without your consent except as required by law. Your identity as a participant in this study will be kept private. The intended outcome of this research is a published manuscript in a scientific journal. Should that occur, your name will not be used in any publications or presentations about this research. To achieve this level of privacy, you will be randomly assigned an identification number at the beginning of the study and all questionnaire responses and data collected will be labeled with this assigned number. The signed informed consent forms and the key linking the identification number to your name and contact number will be under the control of the John Quindry or Graham McGinnis and kept separately in a locked file cabinet. After the completion of the study, the key linking identifying personal information to their respective identification number will be destroyed. A separate sheet containing only the contact information with no identification numbers will be kept until data analysis is complete. Separately, you will be given the opportunity to consent or decline the change to have your photograph used in presentations or publications associated with this research.

Voluntary Participation/Withdrawal: You may refuse to take part, or you may withdraw from the study at any time without penalty or loss of benefits to which you are normally entitled. If you choose to withdraw, please notify Dr. John Quindry or Dr. Graham McGinnis (contact information below) as soon as possible.

Compensation for Injury: In the event that you are injured as a result of this research you should individually seek appropriate medical treatment. If the injury is caused by the negligence of the University of Montana or any of its employees, you may be entitled to reimbursement or compensation pursuant to the Comprehensive State Insurance Plan established by the Department of Administration under the authority of M.C.A., Title 2, Chapter 9. In the event of a claim for such injury, further information may be obtained from the University's Risk Manager (406-243-2700; michele.wheeler@umontana.edu) or the Office of Legal Counsel (406-243-4742; legalcounsel@umontana.edu). (Reviewed by University Legal Counsel, May 9, 2013)

Future research: Data and biological specimens collected during this investigation may be used for future investigations. In this regard, all your data will be anonymized (containing no identifiable links to your identity or private information).

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Questions: You may wish to discuss this with others before you agree to take part in this study. If you have any questions about the research now or during the study, please contact Dr. John Quindry, PhD at (406) 243-4268 (john.quindry@mso.umt.edu) or Dr. Graham McGinnis at (702) 895-4626 (graham.mcginnis@unlv.edu). If you have any questions regarding your rights as a research subject, you may contact the UM Institutional Review Board (IRB) at (406) 243-6672.

Statement of Your Consent: I have read the above description of this research study. I have been informed of the risks and benefits involved, and all my questions have been answered to my satisfaction. Furthermore, I have been assured that any future questions I may have will also be answered by a member of the research team. I voluntarily agree to take part in this study. I understand I will receive a copy of this consent form.

Printed Name of Subject

Subject's Signature

Date

Statement of Consent to be Photographed:

I consent to use of my photograph in presentations related to this study.

The University of Montana IRB
Expiration Date <u>6-15-2022</u>
Date Approved <u>6-16-2021</u>
Chair/Admin 

I understand that if photographs are used for presentations of any kind, names or other identifying information will not be associated with them.

Subject's Signature

Date

The University of Montana IRB
Expiration Date <u>6-15-2022</u>
Date Approved <u>6-16-2021</u>
Chair/Admin <u>J. B. Bach</u>

SEEKING PARTICIPANTS FOR EXERCISE RESEARCH STUDY



Research Study Examining Woodsmoke Inhalation and Sleep Deprivation While Cycling

Seeking individuals:

- Males 18-50 years old, Covid-19 free (vaccinated)
- Able to cycle continuously for 45 minutes
- Non-smoker (any substance) for 12 months
- No history of cardiovascular disease, metabolic disease, asthma, or disordered sleep
- Have not experienced adverse reactions to environmental smoke
- Free of orthopedic limitations that would limit exercise ability
- Be neither a "morning lark" nor a "night owl"

Benefits:

- Body composition testing
- Cardiorespiratory fitness testing (VO_{2max})

For more information, please contact:

Dr. John Quindry
(406) 243-4268
John.quindry@mso.umt.edu

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