

**PROJECT**    **Evaluation of Post-Exposure Sauna**  
**TITLE:**     **Treatment of Firefighters – A Pilot Study**

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**STUDY PROTOCOL**

**NCT NUMBER: NCT03429348**

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## 1) Background

Firefighters are at increased risk of cancer, and both inhalation and dermal routes contribute to overall exposure to carcinogens, including polycyclic aromatic hydrocarbons (PAHs). PAHs can be measured in urine samples so urine sampling has been shown to be a good measurement of exposure to toxicants.

Training fires are performed as part of fire suppression continuing education and/or training events scheduled by fire departments to review or present new departmental concepts in fire suppression activities under closely monitored safety conditions. The National Fire Protection Agency (NFPA) requires fire department to annually test active firefighters for competency in fire suppression. This can be done using training fires.

Two types of structure training fires are flashover and burn room fires. Flashover training fires are fires that simulate the transitional phase of a structure fire between the growth stage and the fully developed stage of a fire. During a flashover, ignition of the room contents are ignited at once, includes smoke, and the entire space is consumed by fire. Burn room training fires simulate fires that burn wood, straw, excelsior, hay, wood pallets, generating enough heat for fire training purposes.

After fighting a fire, the standard operating procedures for fire department require a post-fire rehabilitation to prevent the risk of injury that may result from extended field operations under adverse conditions. At the Fire Department, the rehabilitation consists of: 1) assessment of vital signs; 2) revitalization p rest, hydration, refreshments, and temperature regulation; 3) medical evaluation and treatment of injuries, if needed; 4) transportation for those requiring treatment at medical facilities, and 5) reassignment as needed.

Sauna post-fire incident exposure detoxification was performed post 9-11 and studied in research published in 2006 by Cecchini, etal., (article attached) but the results of the study are incomplete and were not controlled. Crinnion, 2007, as director of the Environmental Medicine Center of Excellence at the Southwest College of Naturopathic Medicine in Tempe, Arizona, summarized that saunas, "...can be used very effectively for certain cardiovascular problems and as a means to enhance the mobilization of fat-soluble xenobiotics. When saunas are used to reduce blood pressure and enhance blood flow and cardiac functioning, only short sauna sessions (15 minutes) are necessary.

A traditional sauna generates heat by heating rocks to heat the air, adding in steam to heat the skin, and generally operate at 180-190 deg F. An infrared sauna uses light to create heat that warms your body directly without warming the air and operate at lower temperatures, 110-140 deg F. A Mayo Clinic Consumer Health report by Dr. Brent A Bauer, MD, accessed 12/21/2017 (attached) reported "...no adverse effects have been reported with infrared saunas."

The purpose of the current study is to determine if treatment in an infrared sauna: a) affects absorption of PAHs as measured by urinary metabolites; and b) changes core body temperature and heart rate. Infrared exposure from the sauna treatment is expected to increase the core body temperature, which may have a detrimental effect on the firefighter performance; heart rate will be used as a measurement of stress. There is sparse literature concerning the subject of using infrared sauna as a post-exposure treatment.

## 2) Purpose

The purpose of the current study is to determine if post-fire training exercise treatment in an infrared sauna as compared to the standard post-fire treatment:

- a) Affects absorption of PAHs as measured by urinary metabolites. (Aim 1)
- b) Changes core body temperature and heart rate. (Aim2)

These two aims will be achieved by the following objectives:

- a. Coordinating with the Fire Department to recruit and consent firefighters scheduled for training fires to participate
- b. Obtaining 12 hour pre and post-fire urine samples, along with dermal samples.
- c. Monitoring core body temperature and heart rate at baseline, during fire response, and for 8 hours after
- d. Splitting the post-fire post-standard Rehab firefighters into 2 groups: no additional treatment group or sauna rehab group.
- e. Answering a survey to gather demographic information and information about recent exposures that might affect the results of the urine results and information about their participation in the fire

The results of the biological samples may tell us if sauna post-fire rehab is an effective means for increasing the body's removal of toxic chemicals during post-fire rehab with less than a 102 degree core body temperature increase.

## 3) Lay Summary (approximately 400 words)

The fire department chosen is a career fire department with approx. 260 active firefighters on staff. They respond to fire incidents and other medical emergencies in a 184 square mile area. They train recruits to become firefighters and annually proving drill training in various skills, such as live fire training. Following live fire responses (including training fires) their standard operating procedure includes a rehabilitation requirement to insure that no firefighter will be permitted to continue emergency operations beyond safe levels of physical or mental exertion (rehab).

They would like to add the use of a sauna post-fire response to their rehab SOP and have supported the UA study team lead by Dr. Jeff Burgess to compare a chemical commonly excreted after firefighting to compare the value of adding sauna to rehab post-fire and monitoring the heart rate and temperature using a core body temperature/heart rate monitor data recorder. Urine will be collected for 12 hours immediately before the scheduled training fire and for 12 hours afterwards.

The core body temperature/heart rate monitor works by having the firefighter swallow a sensor shaped like a pill that the data recorder senses the temperature. The pill passes thru the gut and is removed with bowel movement, approximately in 24 hours, depending on the normal excretion timing of the person. A Polar heart rate belt that is worn around the body in the chest area and records the heart rate/pulse of the person wearing it. The firefighter will swallow the sensor and put on the Polar heart rate belt and the UA study team will start the data recorder before the firefighter enters the training fire and will continue to wear it for up to 8 hours afterwards.

After the fire, the firefighter will perform the standard rehab. During this time, the UA study team will randomly select half of the firefighters to and additional sauna rehab and the other half of the firefighters to no additional rehab. Dermal (skin) wipe samples will be taken off the calf, arm, and neck before the fire, before standard rehab, and after sauna/no additional treatment.

If it is available, a personal air monitor will be worn to assess the air quality in the fire. A post-fire survey will be administered to gather demographic information, pre-fire exposure information, job duties in the training fire, and other information.

The UA study team will perform the urine PAH-OH analysis, download the air monitor data (if performed), results of the surveys, skin wipe analysis (if performed) , and download and compare the core body temperature and heart rate data between the sauna rehab and the no additional treatment groups.

#### **4) Setting of the Human Research**

The recruitment, consenting, and training fire exercises will take place at the fire department's main office, stations, and training centers used to train firefighters to respond to live-fires. The University of Arizona (UA) study team will be responsible for recruiting and consenting interested firefighters and in collecting samples and surveys before and after the training fire. The fire department personnel are responsible for the training and safety of the firefighters with regard to the fire training exercise. At the University of Arizona, data and sample analysis and manuscript writing will be done at Drachman Hall, Office 317C or A241, at the Medical Research Building Lab 130, or Keating Building, Lab 402. The UA study team are trained in human subjects protection, sample collection, processing, transportation, and analysis.

#### **5) Resources available to conduct the Human Research**

The fire department has fire training for both flashover and burn room fires as standard operating training exercises. Making space available to the UA study team to recruit, consent, and collect samples has not caused undue problems to their department as is evidenced in their support letter.

The supplies needed for the UA study team's research will be funded by the PI's fixed price complete account, or alternate sources as determined by the PI.

The sauna already belongs to the fire department and it is NOT being purchased for this research.

#### **6) Study Population**

The study will seek participation from the fire department firefighters assigned or soon to be assigned to a training fire exercise. To test the best type of training fire exercise (flashover or burn room) we will need four for each group; this is referred to as Stage 1 in section 1, page 3 of this document. They may be the same firefighters or different, depending on the fire department schedule and the firefighters consent preferences.

After the training fire type is chosen (flashover or burn-room) up to 24 firefighters already scheduled to participate in a training fire as part of their continuing education will be selected as participants in the study exercise referred to as Stage 2 involving urine collection, skin wipes, core body temperature monitoring, survey collection, etc. They will be selected based on the availability of the UA study team to be present during their training fire exercise and their consent preferences. This group of 20-up to 24 firefighters may consist of the same firefighters who participated in the Stage 1

fire(s) or may be different, depending on the fire department training fire schedules and the firefighters consent preferences.

The fire department employees can be included in the study if they:

- 1) Are employed as an active fire responder by the fire department
- 2) Are scheduled for a training fire exercise by the fire department in the next year.
- 3) Are currently a non-smoker (including cigarettes, cigars and e-cigarettes)
- 4) Cannot have any contraindications to the core temp pill, which are:
  - a. Do you weigh less than eighty (80) pounds?
  - b. Do you have any known or suspected obstructive disease of the gastrointestinal tract, including but not limited to diverticulitis and inflammatory bowel disease?
  - c. Do you exhibit or have a history of disorders or impairment of the gag reflex?
  - d. Have you had a previous gastrointestinal surgery?
  - e. Do you have any diseases or disorders of the esophagus?
  - f. Will you be undergoing Nuclear Magnetic Resonance (NMR) or MRI scanning less than 3 days after swallowing the sensor?
  - g. Do you have a low motility disorder of the gastrointestinal tract including but not limited to ileus?
  - h. Do you have a cardiac pacemaker or other implanted electromedical device?
  - i. Do you have a swallowing disorder? (problems swallowing)

In order to insure we have enough firefighters consented for the scheduled training fires, we will plan to consent more than 24 firefighters, requesting approval for up to 40 firefighters. There is no power analysis planned for the recruitment of the firefighters.

## **7) Recruitment Methods and Consenting Process**

- a. Recruitment Process: We will recruit using a recruiting flyer that may be distributed at the fire department's main office, stations, newsletters, and list-serves.
- b. Informed Consent:

We will consent firefighters, individually, who are interested in participating in a private area prior to the training fire exercise. Consent will be a written version, signed by the firefighter and administered by the UA study team who are well versed in the proper consenting process. The consenting process may be over the phone to facilitate urine collection prior to the training day. If consent is obtained over the phone, a signature will be obtained, in person, prior to the firefighter turning in the urine sample, or otherwise participating in any part of the research. Each page of the consent form will be individually discussed with the firefighter and will provide the firefighter with an opportunity to ask questions. Coercion and undue influence will be avoided by ensuring the voluntary nature of this study is stressed. Additionally, no supervisors will be involved in the consenting process.

As a condition of employment, all fire department firefighters are adults, fluent in English so all information and consenting materials will be presented in English. Only non-smoking firefighters (including cigarettes, cigars and e-cigarettes) will be recruited, to minimize smoke exposure not associated with live-fire training.

## 8) Research procedures involved in the Human Research

**Stage 1:** An initial four firefighters will be evaluated for change in PAHs associated with standard fire department flashover training to determine if urinary PAH metabolites increase following exposure, comparing baseline urine samples before training to a repeat sample collected after cessation of training. If a significant increase is not seen, then repeat testing with four additional firefighters will be completed using alternate burn room training fire. Prior to starting the training fire, the subjects will provide a 12-hour pre-fire urine sample, swallow a core temperature probe and wear a monitor and heart rate belt for recording both their core temperature and heart rate. In addition, dermal wipes will be collected prior to the training fire. Firefighters may wear a personal air monitor to capture the quality of the air during the training exercise. Post-fire dermal wipe samples will be collected after the firefighter removes turnout gear. Post-fire 12 hour urine samples will be collected in the same manner as the pre-fire urine samples. Subjects will also be asked to complete the exposure assessment survey. Specific procedures as explained in more detail below.

**Stage 2:** Once a measurable increase in post-fire urinary PAH has been documented, the associated training fire (flashover training or burn room training), testing will be carried out in up to 24 subjects. Urine, core temperature, heart rate, dermal wipe and air monitoring samples will be collected as in Stage 1 collection.

In addition, following the standard rehab, the firefighters will be randomly selected to either sauna-treatment or no additional treatment as explained in the “Sampling Protocol Timeline” below.

### The Sampling Protocol Timeline for the Stage 1 and Stage 2 training fires:

1. Beginning of sampling period: The UA study team will meet each firefighter at the training fire facility prior to beginning their training fire. Firefighters will have already been consented and their contraindications forms completed at an earlier date as described in the “Informed Consent” and “Risks to Subjects” sections. The UA study team will read the contraindicated form to the participant one more time to confirm that they have not experienced any of the contraindications. If they answer ‘yes’ to any of the contraindications, they will be excluded from the study. If the firefighter consented by phone, the consent form will be signed by the firefighter before continuing.
2. If the firefighter answered ‘no’ to all contraindications, the UA study team will instruct the firefighter to swallow the core thermo pill (the sensor will pass through the body and excreted with their normal bowel movement at the subject’s normal rate of motility, which is typically 24-36 hours).
3. The UA study team will accept the urine sample collection the firefighter began collecting approximately 12 hours before the anticipated start of the fire. If one of the 12 hour urine samples has not yet been collected by the firefighter, a “zero” hour baseline sample will be collected at the time of the scheduled training.
4. The Polar heart rate belt will be donned by the firefighter and three dermal skin wipes (calf, arm, and neck) will be collected prior to the firefighter donning the turnout gear.

5. When the fire department personnel say that it is time for the firefighter to don their turnout gear, the UA study team will turn on the core body/heart rate monitor data recorder. Next, the UA study team will place the core body/heart rate monitor data recorder in the firefighter's inner pocket of their turnout jacket. The UA study team will make sure the data is recording by pressing the "run" button to see that it registers a digital reading. After the firefighter is in full gear, the placement of the heart rate monitor/data recorder will be accessed for firefighter activity safety (not impeding movement) and a personal air monitor may be attached to the outside of the turnout gear jacket in an unobtrusive location.
6. The firefighter will enter the training fire room as instructed by standard fire department protocol for the standard period of time for participation in the training fire. Following cessation of the training fire, the subjects will follow their standard fire department procedures for post-fire treatment (rehab).
7. The UA study team will remove the personal air monitor from the firefighter's turnout jacket (if applicable). The firefighters will remove their turnout gear at this time. The heart rate/core body temperature monitor data recorder will be transferred from the turnout jacket inner pocket to a pants pocket. A dermal wipe (a gauze pad moistened with alcohol) of the left calf, arm, and neck will be obtained prior to cleaning their skin with their standard rehab baby wipes (part of the standard fire department procedures for post-fire treatment.)
8. **(For Stage 2 fires only)** The subjects will then be randomized to either an infrared sauna treatment, or no additional treatment following their fire department protocols. The firefighters will be randomized by the UA study team as such: Firefighters will pull a piece of paper out of a helmet; if it says "sauna" they will participate in the sauna treatment. If it is blank, they will participate in no additional post-fire treatment. "Sauna treatment" consists of a firefighter entering the sauna for 20 minutes as soon as the fire department has completed their standard rehab.
9. Following the sauna treatment or no additional treatment time period, dermal wipes of the left calf, arm, and neck will be repeated and the subjects will complete a survey and return to work. The dermal wipe samples will be transported under Arizona Department of Transportation guidelines for transportation of samples to the University of Arizona.
10. Core temperature and heart rate will continue to be monitored for up to 8 hours after training scenario. At the end of the 8 hour period, the firefighter will turn the monitor off by pressing the "stop" button and the "On/Off" button.
11. The subjects will collect all their urine after the fire training for a period of up to 12 hours in the same manner that urine was collected prior to the fire training.
12. *End of sampling period:* At the end of the sampling period, the UA study team will, again, meet the firefighters at the fire department to collect the data recorder/heart rate monitor data recorder, Polar Heart Rate belt, and urine samples.
13. The urine will be stored at the Medical Research Building at -80 deg C until analyzed for urinary PAH metabolites and potentially other toxicants from the fire, and, dependent on the available budget, similar evaluations may be carried out on the skin wipes. The core

temperature and heart rate data will be downloaded from the data recorder onto a password protected computers and will be analyzed for comparison to the pre-fire data. The personal air monitors will be downloaded in the same manner and analyzed for air quality.

We would like to take pictures during the activities such as wearing the monitors, performing skin wipes, going into or coming out of the training fires or sauna, including cleaning up gear, for possible use in manuscripts, presentations, posters, and/or brochures to present a visual description of the activities involved in the training fire study. The subjects will be asked to agree or decline being in photos.

### **Specific Sampling Protocols for Stage 1 and Stage 2 training fires:**

#### **Urine sampling: before and after the fire:**

For each urine sample collected, the total amount of each voided sample will be collected in a 200ml sample collection container and stored in an ice chest until picked up by the UA study team. The subjects will collect all their urine after the fire training for a period of up to 12 hours in the same manner as they collected their urine prior to the fire training.

#### **Core body/heart rate monitoring before and after the fire:**

The monitor that records their core temperature and heart rate is a small instrument, approximately the size of a double deck of playing cards ( $3/4'' \times 1 \frac{3}{4}'' \times 4 \frac{3}{4}''$ ) in a fabric protective pouch that can be worn on a belt or placed into a jacket pocket. The monitor will be turned on before the firefighter enters the training room fire and not turned off until up to 8 hours after the fire.

The heart rate belt is a 3/4" strap (T31 Polar Transmitter) that is worn around the body in the chest height area. It will be donned by the firefighter before the monitor is turned on and not removed until the monitor is turned off.

Monitoring of the core body temperature and the heart rate by the UA study team begins before the fire and continues for up to 8 hours after the fire so that a comparison between the standard post-fire and the sauna post-fire methods can be compared for core body temperature return to normal and heart rate return to normal.

#### **Dermal wipes: before and after the fire:**

Dermal wipes are 2x4" alcohol wipes. They will be collected by the UA study team from the right calf, right arm, and right neck before the firefighter dons turnout gear (before entering the training room fire.) To collect the samples, the UA study team member will gently wipe the area of the right calf (midway between the back of the knee and the heel) in a 2x4" rectangle gently but firmly in 2 up and down wiping directions. This process will be repeated on the opposite calf, arm, and neck after the fire when the firefighter removes the turnout gear and before the firefighter wipes his skin off with the standard rehab baby wipes, and again right after exit from the sauna (if in the sauna treatment group) or at the same time post-fire (if in the standard treatment group—the no-sauna group.)

## **9) Cost to subjects**

There will be no monetary cost to the subjects. The fire department has given their support for the time required to recruit and consent firefighters individually. The department has also given support for allowing the firefighters the time to participate in the research portions of the training exercise.

## 10) Risks to subjects

- Biological and Air Sampling: There is no risk to the firefighter to self-collect urine samples or skin wipes, or to wearing a personal air monitor.
- Survey: There are no known risks with filling out survey questions; the firefighters will be informed that any section can be left unanswered if unknown or stressful. Individual participant's answers to the questions will not be made available to the fire department.
- Flashover or Burn Room Training: The fire training itself is a part of the job and is a continuing education event required by fire department for active firefighters. According to NFPA (National Fire Protection Agency) 1001, fire departments must develop recurring proficiency cycles for fighting structure fires with the goal of preventing skill degradation and potential for injury and death of members and an annual skill check to verify minimum professional qualifications of its members. The firefighter may be required by the fire department to have training in the burn room and/or flashover training. If the firefighter is not scheduled for a specific training, the fire department will not schedule them. As documented in the supporting letter from the fire department, there is no risk to the firefighter's job for not participating in the study.
- Infrared Sauna: No adverse effects have been reported with infrared saunas
- Core Body Temperature/Heart Rate monitoring: In accordance with the CorTemp User Manual, page 6, use of the CorTemp ingestible temperature sensor is contraindicated for the following conditions:
  - In any subject whose body weight is less than eighty (80) pounds.
  - In the presence of any known or suspected obstructive disease of the gastrointestinal tract, including but not limited to diverticulitis and inflammatory bowel disease.
  - In any subject exhibiting or having a history of disorders or impairment of the gag reflex.
  - In any subject with previous gastrointestinal surgery.
  - In any subject having felinization\* of the esophagus.
  - In any subject who might undergo Nuclear Magnetic Resonance (NMR)/Magnetic Resonance Imaging (MRI) scanning during the period that the CorTemp Core Body Temperature Sensor is within the body.
  - In any subject with hypomotility disorders of the gastrointestinal tract, including but not limited to ileus.
  - In any subject having a cardiac pacemaker or other implanted electromedical device.

\*Felinization=Transient transverse folds of the esophageal mucosa as seen by barium esophagography and on endoscopic examination have been termed "felinization." This finding has been considered a normal variant or has been associated with reflux esophagitis. No symptoms have been associated with its presence.

Additionally, the CorTemp Core Body Temperature Sensor may not be appropriate in individuals who have experienced swallowing disorders. If an individual experiences difficulty swallowing the sensor, they may not be a candidate for the study.

The minimal risk will be mitigated by having all participants complete a contraindications form at the time of consenting and then reviewing their form prior to swallowing the pill. Any firefighter who indicates they suffer from one or more of the contraindications will be excluded from the study. The contraindications form has been clinically verified by Dr. Jeff Burgess and found to be an adequate screening tool to ensure the safety of study participants. Additionally, if any participants experience difficulty swallowing the sensor, they will be excluded from the study.

### **11) Potential benefits to subjects and/or society**

There is no direct benefit to the participants in this study. However, there are very few studies to actually monitor a firefighters core body temperature in a post-fire sauna detoxification period. This study is expected to aid in a better understanding if infrared sauna treatment reduces absorbed toxicants from the fire and if it results in an increased core body temperature.

### **12) Provisions to protect the privacy of subjects and the confidentiality of data**

**a. Protection of subject privacy:** Subjects will be consented individually, under private conditions. Fire department officers responsible for scheduling training fires will have access to a list of firefighters who consented to participate in the study so that they may be efficiently scheduled for the training fires.

In order to protect the privacy of participants, the consent forms, and contraindication forms will be accessible only to the UA study team. When not in use, they will be kept in a locked drawer in the Medical Research Building, Lab 130. Urine samples and skin wipes will be identified only by a subject ID number and whether baseline or post-fire collections. Survey answers, personal air monitors, and the core body temperature/heart rate data downloaded will be identified by subject ID number only.

**b. Protection of data confidentiality:** As described above, all personally identifiable information will either be kept in a locked cabinet or on a password protected computer. The final report to fire department and any manuscripts or publications will contain aggregate and statistical representation of the study population. If pertinent to discuss individual results in the report, random anonymous numbers (subjected ID numbers) will be assigned to each study participant and any results discussing individuals will be referenced by such an anonymous identifier.

### **13) Subject compensation**

Subjects will not be compensated.

### **14) Medical care and compensation for injury**

There are no funds set aside for injury to the subjects. If the subject suffers an injury from participating in this study, they are advised in the consent form to seek treatment and that the University of Arizona has no funds set aside for the payment of treatment expenses for this study.

### **15) Monitoring for subject safety**

The fire department's training fire is a required training exercise, but the research concerns the comparison of the post-fire sauna treatment versus the standard (no-sauna) treatment post-fire. The data from the core body temperature/heart rate monitor data recorder will be downloaded within 48 hours and examined for excessive core body temperature rise (above 102 Deg F) by the PI, Dr. Jeff Burgess. The firefighter, after exiting the sauna, will have blood pressure pulse readings taken and documented as part of the fire department's post-fire treatment protocols. Firefighters who do not participate in the sauna treatment will be monitored and the data downloaded in a likewise time period, but the data will not be examined by Dr. Burgess until the data are analyzed by statistical methods as the standard treatment is not being changed by the study from what the fire department normally performs on its firefighters during their normal annual fire training exercises.

#### **16) Withdrawal of subjects**

It will be made clear to the firefighters that their participation is voluntary and that they may withdraw on their own volition at any time. It is not anticipated that the PI or other UA study team members will have to withdraw a subject after the consent and verification of the contraindication form. However, there is potential that the firefighter may become not medically fit for duty for an unrelated reason between the consenting and sampling period. This situation would result in the subject being withdrawn from the study.

In addition, in order to adequately achieve the end total of up to 24 firefighter participating in the Stage 2 exercise, it may become imperative to consent more than 24 firefighters. When the time is reached that 24 firefighters have been evaluated for the Stage 2 training fire testing, additional testing of firefighters who consented but haven't been tested will be stopped and the untested firefighters will be withdrawn from the study.

#### **17) Sharing of results with subjects**

Firefighters will not be given individual results to the urine analysis for PAHs, their dermal wipe analyses, nor their core body/heart rate data analysis, nor any comparison of their individual survey results to the other firefighters in the study. However, aggregate results will be shared with the fire department, a report will be prepared for distribution via the fire department newsletter, and potential manuscripts, publications or PowerPoints may be prepared for presentation at meetings and conferences.

#### **18) Future use and long-term storage of data or specimens**

Urine samples will be stored by subject ID number and baseline or post-fire sampling methods until the end of the study or longer, if space is available for storage. Subjects will be asked if their samples can be used for other testing during the consenting process. We have no immediate plans for future research for the stored urine or dermal samples, but if there are samples remaining after the pilot study urine or dermal analysis is complete, we will store the samples in accordance with the selection chosen by the subject in the consent form. Data from the core body temperature analysis will be kept indefinitely for future firefighter related occupational toxic chemical, heat, or infrared exposure research