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1. **Protocol #F-BR-2005-0057-H: Thermal Effects of Exposure to 400 W, 95 GHz, Millimeter Wave Energy**
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4. **Medical Monitor:** Lt. Col. Michelle Bryce, DO, MTM&H, USAF, MC, SFS, AFRL/HED, 8315 Hawks Road, Building 1184, Brooks City-Base, TX 78235, (210) 536-4007 (DSN 240-4007), Michelle.Bryce@brooks.af.mil
5. **Contractor Support:** Conceptual MindWorks, Inc., San Antonio, TX

   Facilities: Building 1161, Brooks City-Base, TX 78235
6. **Protocol Objective:** To quantify the effects of small diameter, 95-GHz, millimeter wave (MMW) exposure on humans. Specifically, we will measure variations in tolerability of exposures as a function of peak power density on target, number of beams, and skin temperature.

7. **Background and Relevance:**

A) The Department of Defense (DoD) is developing non-lethal, MMW weapons with various effective ranges from greater than that of small arms to the approximate distance of thrown rocks. The Active Denial System (ADS) uses MMWs to produce heating of the skin surface to painful levels that quickly reach the limits of pain tolerance, causing targeted individuals or groups to retreat or take cover. A decade of research from AFRL supports the safety and effectiveness of ADS as a non-lethal weapon. The Project Sheriff, 400-W, Active Denial Technology (ADT) subsystem delivers similar power density with approximately 10–20 % of the spot size of the ADS. (It should be noted that the 400-W designation specifies the MMW power at the device aperture and not at the skin surface, where power density is considerably lower. Exposure levels at the skin will be no greater than those which occurred over the course of 35 AFRL studies examining the human bioeffects of the ADS; these studies have involved over 6000 exposures with an injury rate of 0.05%.) AFRL/HEDR has conducted extensive research on the bioeffects of MMWs, both in animals and humans. We have demonstrated that the desired behavioral effect (prompt escape behavior) is readily produced at exposure levels well below those that produce burns in animals. Studies with conventional heating of human skin (e.g., Moritz & Henriques, 1947) assure us that there is a substantial safety margin between effective levels and injury. Studies in our laboratories of rat and pig skin damage produced by MMWs are even more reassuring in this regard. Research by AFRL/HEDR and Naval Health Research Center-Detachment (NHRC-Det) scientists suggests that the system poses no undue risk of injury for the face and eye exposures, and also indicates the absence of risk for skin cancer or infertility.

Some of our early work testing the repel effect in humans (60 subjects) was done with relatively small areas of exposed skin, due to output limitations of the available transmitters. Another device that allowed exposure of a large portion of the body surface was tested on 72 subjects, using dorsal exposure. Data from these two experiments showed that exposure of large skin areas reduced the median effective dose (ED50) and the peak skin temperature at which escape responses occur. While there is a considerable safety margin in either case, the data highlight a possible reduction in effectiveness when small-diameter beams are used. It is the purpose of these experiments to assess the effectiveness of a 400-W, 95-GHz system.

B) Data Required. Pain threshold occurs at a skin temperature of 43 to 45 °C. The pain sensation continues to grow in intensity up to a skin temperature of between 55 and 60 °C, at which point maximal pain is attained (Hardy et al., 1952). Further heating may produce skin damage, but no further increase in the perceived intensity of the pain. The limit of pain tolerance is a complex function of pain intensity, duration, area, and characteristics of the individual, such as motivation, stoicism, and prior experience with pain. Thus, it is expected that pain tolerance would vary more from individual to individual than pain threshold, which (in terms of skin temperature) shows very little variation among all

mammals. In order to ascertain whether the weapon will be effective against essentially all individuals, while producing damage in few or no cases, it is necessary to determine both the average limit of pain tolerance, and the extent of variation among individuals. Similar tolerance and variability data will be obtained using two simultaneous exposures.

Frontal exposures may be more effective, as being "hit in the face" with a blast of heat can be quite impressive and intimidating. Similarly, multiple beam exposures may be more effective. We wish to investigate this possibility, starting at exposure levels below those used for dorsal exposure, and working up to levels that are equally effective. If these effective levels (of power density or peak temperature) are substantially lower than those found for dorsal exposure, the safety margin of the system would be even greater, inasmuch as most operational scenarios envision frontal exposures. Data collected during these experiments will help determine, in part, operating parameters used in further assessment of system effectiveness in scenarios where the participants are performing various maneuvers.

C) DoD Relevance. The Office of Force Transformation is developing a system of systems, dubbed Project Sheriff, to provide non-lethal and lethal options for urban operations. A 400-W, 95-GHz MMW system is among the non-lethal systems under consideration. The research proposed here will provide inputs to the decision process and to the development of Concepts of Operation (CONOPS) and Techniques, Tactics, and Procedures. The answers to these experimental questions are critical to operational effectiveness of the system.

8. **Impact Statement:** The technology to be tested in these experiments was developed in response to several Mission Needs Statements (MNS, AFSOC 003-95, Nonlethal/Limited Effects Weapon Capability, dated 22 July 1996; MNS LOG 1.85, dated 20 February 1996, which stated requirements for improved capabilities in Military Operations Other Than War; Marine Corps Development Center MNS #MCCDC-9602029, NAVMC HQ-355). The Joint Non-Lethal Weapons Directorate (http://www.usmc.mil/nlw) has responded to these needs statements by drafting an Operational Requirement Document for Non-Lethal Active Denial Technology Capability dated 25 October 1999.

9. **Experimental Plan**

A) Equipment and Facilities. Exposures for the two experiments, detailed subsequently, will use 95-GHz, MMW transmitters (viz., a 400-W, Department of Energy [DoE] ADT system and a 100-W, laboratory transmitter). Experiments will be performed at Brooks City-Base, TX. Experienced research support technicians from AFRL/HEDR and their contractors will operate bioeffects data collection equipment and control research trials for health and safety of the volunteers.

B) Subjects. Twenty-five adult volunteer subjects (n = 15 for Experiment 1 and n = 10 for Experiment 2) will be recruited from among active-duty and retired military personnel.. No gender or age restrictions are required, so volunteers of either gender, 18 years of age or older may participate. If volunteers of both genders

are available, efforts will be made to have each gender represented by no less than 3 members in each experiment. Since no evidence exists demonstrating any adverse effects from cumulative, noninjurious, exposures to MMW energy, subjects may participate in more than one experiment.

Duration of the Study. It is anticipated that data collection can be completed within 1 year after final approval of this protocol.

C) Procedures

1) Experimental Procedures

i) General. Medical examinations will be given to all subjects prior to experiment participation to document any pre-existing (but not necessarily disqualifying) conditions. Additionally, visual screening exams will be given to subjects participating in Experiment 1, prior to any facial exposures. The same screening examinations will be repeated after all exposures are completed. Additionally, brief exams will be performed after each exposure. As the effects of refractive eye surgery on eye exposure have not yet been determined, subjects who have had photorefractive keratectomy (PRK) or laser-assisted in situ keratomileusis (LASIK) will not be allowed to participate.

In Experiment 1, subjects will stand either facing toward or away from the MMW beam, providing frontal or dorsal exposures, targeting the face and center of the back, respectively. Initially, single beam, dorsal exposures will be performed. Next, single beam, frontal exposures will be accomplished. In Experiment 2, dual beams will be employed for dorsal exposures exclusively. The beams will irradiate a portion of the body surface that is oriented toward the transmitter. All subjects will be instructed in the use of the shielded areas, where they can quickly move to reduce exposure to zero when their tolerance limit is reached. If for any reason, the subject cannot move to the shielded area, they may alternatively shout "stop", at which time the operator will immediately turn off the beam. Transmitter operators will be able to view the subjects during the exposure and will also be able to monitor skin temperature increases via an infrared (IR) camera.

The beams will be characterized each day before testing begins and then again after testing is concluded by standard radiometric techniques (Durney, Massoudi, & Iskander, 1986). To verify the peak power of the beam patterns, a carbon-impregnated Teflon plate will be exposed before and/or after each subject exposure. The heating distribution will be measured by IR thermography.

ii) Experiment 1: Determination of Effective Power Density. The purpose of Experiment 1 is to determine an ADT subsystem power density that is effective in achieving pain intolerance (and hence escape behavior) during exposures. Exposures will occur as described above under General Experimental Procedures. Each subject can be exposed up to a

maximum of 5 times in the front and back (10 total exposures) per day. Although subjects will be limited to 5 front and back exposures per day, they may be exposed over multiple days.

Initial exposures using a single beam will be at power densities substantially lower than that required to produce rapid behavioral withdrawal (as determined by prior studies of dorsally and ventrally exposed subjects). Successive exposures will involve adjusting the ADT subsystem power density in upward steps not to exceed 10 % until the time-to-repel for the exposed subjects is within 3 sec. If an exposure produces pain that reaches the subject's tolerance limit, they can escape from the MMW beams by moving laterally behind a shield that is impervious to MMW energy, or by shouting "stop". The operational definition of intolerable pain level is the level at which at least 90 % of all subjects are repelled. Power density is increased if <90 % of subjects are repelled by the exposure. Dependent measures will include latency of the repel effect (assuming it occurs) and IR thermography (used to determine the time at which behavioral responses are initiated and the peak skin temperatures tolerated). If <90 % of subjects are repelled by 100 % power for 3 sec, subjects will be asked to return. During the return session, power density will remain constant at 100 %, and exposure duration will increase in 1-sec increments up to a maximum of 7 sec. Previous research indicates that skin temperature returns to baseline in approximately 60 sec; therefore during Experiment 1, there will be at least 60 sec between exposures. Parameters necessary to produce intolerable pain for dorsal exposures will be determined before proceeding to facial exposures. The same procedures will be followed for dorsal and facial exposures except that in the case of the facial exposures, the dependent measures will include the latency to avert (turn head, raise hand, move out of beam) and IR thermography (used to determine the time at which behavioral responses are initiated and the peak skin temperatures tolerated).

iii) Experiment 2: Exposure of Subjects to Dual Beams. The purpose of Experiment 2 is to determine the dual beam power densities that are effective in achieving pain intolerance (and hence escape behavior) during exposures. Only dorsal exposures with dual beams are performed. Each subject can be exposed up to a maximum of 5 times in the back per day. Although subjects will be limited to 5 back exposures per day, they may be exposed over multiple days, as described for Experiment 1. Dual beam exposures will use the effective power density derived from the single beam exposures previously performed. Subsequent power density adjustments are performed as described for the single beam experiments. In addition to performing exposures with spatially separate beams, the 2 beams will also be overlapped. Laser pointers will be used to position the 2 beam centers on the subject. Complete and fractional spatial coincidence of the beams will be performed. The enhanced heating effect

of superimposed beams on the skin, if observed, is expected to produce a more rapid escape response that prohibits tissue damage.

2) Data Analysis. Because these experiments are exploratory in nature, inferential (hypothesis-testing) statistics will not generally be employed. We will measure the duration of exposure and the skin temperature at which the limit of tolerance is reached (i.e., pain forces action to escape exposure). The data will be transformed by straightforward procedures to a dose-effect function. This is done by finding percentage effectiveness at several points between 10 and 90 %, and then finding the best-fit straight line (on a normal probability plot) to generate the best-fit cumulative ogive (i.e., a polygon [line plot] graph of the cumulative frequency or the relative cumulative frequency). The variances of the distributions will be compared by the use of appropriate *F*-tests.

3) Safety Precautions. The maximum power and duration of the transmitter output will be set at levels that cannot produce skin heating greater than 60 °C. For short durations, this temperature exceeds the pain threshold, but does not exceed the threshold for tissue damage. Even in the event of operator error (setting the output to a higher level) the maximum available power density that the system can produce will cause an escape response well before damaging levels of skin temperature are reached.

   MMWs at this frequency are completely absorbed in the skin. The incident power density at the skin surface falls to $1/e^2$ (13.5 %) at a depth of 0.4 mm. For the brief exposures contemplated, much of the heat deposited in the most superficial layers of the skin is re-radiated to the environment over the next 10-20 seconds. The blood that circulates in the skin redistributes the remaining heat. The fraction that is conducted to structures deeper than the skin is negligible. Thus, there is no risk of significant heating of any subcutaneous structures or organs with the exposures contemplated for these experiments. Since this is the case, implanted metallic joints or objects are probably irrelevant. We exclude them only because some subjects might have a concern about being exposed if they had them. This would be a distraction, and an unnecessary worry, in such subjects. There are no known aftereffects of heating the skin to painful but non-damaging levels.

   A site safety survey will be conducted prior to commencing the study.

4) On-Site Monitoring. (See attached Medical Documentation Form.) Dr. Bryce (the Medical Monitor) and/or her designated representative will monitor all exposures used for the testing of pain tolerance limits. The Medical Monitor or her designated medical observer will examine the skin and eyes of each potential subject prior to any exposure. Individuals who have any abnormal skin or eye condition that might suffer detrimental effects from surface heating will not be allowed to participate. In addition, certain chronic medical conditions may be disqualifying, at the discretion of the Medical Monitor. A brief examination of the skin will be conducted following

each exposure and brief medical and visual examinations will be given following the subject's final exposure. If eye injury is suspected, evaluation may require standard ophthalmic staining drops to be applied to the subject's eyes. Suspected injury would necessitate referral to an ophthalmologist/optometrist for further evaluation. The medical staff will activate the emergency response system in the unlikely event of an accident or significant medical incident.

10. **Medical Risk Analysis:** Although exposures may exceed permissible exposure limits specified by the relevant safety standard (AFOSH 48-9, 1997) by as much as 20-fold, we have shown in previous work, under protocols # F-BR-1998-0026-H, # F-WR-2001-0006-H, # F-BR-2002-0046, # FWR-2003-0028-H, and # FWR-2003-03-31-H, that the pain tolerance limits occur well below exposure levels that produce any but the most minor effects (e.g., transient reddening and sensation of tenderness). Separating exposures in time by adequate intervals ensures that there is little or no carryover effect from exposure to exposure. Incident MMW energy is absorbed superficially in the skin. Since the affected sensory receptors are also quite superficial, the MMWs are quite efficient in producing sensations at non-damaging levels of incident power.

    Ryan et al. (2000) reviewed the health and safety issues related to exposure to MMWs. They concluded that:

    1) Such exposures result only in superficial heating of the skin.
    2) Such heating is very unlikely to cause damage in conscious, mobile humans, as it is readily sensed and becomes sufficiently painful to motivate escape responses long before the skin is heated enough to cause burns.
    3) Repeated overexposure to MMWs has not been demonstrated to initiate or promote cancer (Mason et al., 2001).
    4) In the event of an overexposure to a power density sufficient to produce thermal injury, there is an extremely low probability that scars derived from such injury might later become cancerous. Proper wound management further decreases this probability, as well as the probability of hypertrophic scarring or keloid formation.

    Walters et al. (2000) showed that skin heating associated with painful exposure to MMWs is consistent with a simple thermal model that takes into account the shallow penetration depth at these wavelengths. These results (Walters et al., 2000) and conclusions (Ryan et al., 2000) give us confidence that the proposed exposures will produce superficial heating of the skin that is self-limiting at non-injurious levels. No damage to the eyes is expected. Chalfin et al. (2002) showed that energy densities of 5 to 6 J/cm^2 produce a threshold damage to the cornea that resolves within 24 hours. D'Andrea et al. (2005) have shown that monkeys and humans produce blink reflexes that protect the cornea at energy densities of about 1 J/cm^2, with response latencies less than 250 ms. Due to security concerns, we cannot state precisely what safety margin this provides, but it is sufficient to discount eye damage under any planned exposure scenario. Ziriax et al. (2005)

have observed "hot spots" in the region of the inner canthus with direct frontal exposure of the face. Both modeling studies and human testing have shown that these "hot spots" move away and disappear with changes in orientation of the head to the beam. Such changes in orientation are expected to occur rapidly as exposed individuals perform eye aversion responses and attempt to escape the exposure.

Some skin (e.g., eyelids) may be more vulnerable to thermal damage than other skin, so there may be a small risk of mild thermal damage (small blisters) in subjects with a high pain tolerance. Such damage should resolve within a few days, without sequelae.

Information for Briefing Subjects: See attached Informed Consent Documents (ICDs) and Instructions for Subjects.

Risk Assessment:

Potential Benefits: The subjects will receive no direct benefit or compensation for their participation in this study.

The benefit to the DoD is the acquisition of data that will be used to optimize a non-lethal weapon system. Human bioeffects data are essential, not only for optimizing weapon design parameters, but also for answering questions related to Policy Acceptability of such a weapon. The controlled exposures proposed here are a necessary prerequisite to the assessment of the military utility and deployment of the 400 W ADT subsystem.

Risk-Benefit Ratio: The benefits listed above are large relative to the risks to subjects, producing an acceptable risk-benefit ratio.

11. **References:**

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12. **Attachments:**

A) Informed Consent Documents (2) (Experiment 1 and Experiment 2)

B) Instructions for Subjects (2) (attached to ICDs)

C) Medical Documentation Forms (2) (Experiment 1 and Experiment)

INFORMED CONSENT DOCUMENT

(Pain Tolerance)

Building 1161
Brooks City-Base, TX 78235

Institutional Review Board Approval Dates: 5 July 05 – 4 July 06

PRIVACY ISSUES: Records of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C. 552a, and its implementing regulations. You understand that the sponsoring agency and/or its designee may inspect records of this study.

TITLE OF STUDY

Thermal Effects of Exposure to 400 W, 95 GHz, Millimeter Wave Energy
(Experiment 1)
INVESTIGATORS' NAMES, DEPARTMENTS, PHONE NUMBERS

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PURPOSE OF STUDY

You have been invited to participate in a research study at Brooks City-Base, TX sponsored by the Air Force Research Laboratory, Human Effectiveness Directorate, Radiofrequency Radiation Branch, entitled "Thermal Effects of Exposure to 400 W, 95 GHz, Millimeter Wave Energy." The objective of this experiment is to measure how people react to millimeter waves that heat their skin. Specifically, we are trying to find out how much exposure people can tolerate before they are forced to take action to escape the beam. Therefore, you will be asked to stand still in the beam until you are forced to escape by the pain that the beam evokes.

(Please note that the 400 watts referred to in the title of the study specifies the power output at the source of the device and not at the skin surface, where power levels are considerably lower. In fact, exposure levels at the skin will be no greater than those which occurred over the course of 35 previous studies which examined the effects of millimeter waves on humans; these studies have involved over 6000 exposures with an injury rate of 0.05%.)

This study will enroll 15 subjects who are at least 18 years of age. You may be tested over several visits to the testing site, each lasting up to 3 hours.

PROCEDURES

If you volunteer to participate in this study, you will be exposed to millimeter wave energy at intensities that will exceed the applicable safety standard by as much as 20-fold. This exposure could cause your skin temperature to rise to 60 °C (140 °F), unless you take action to escape the beam by moving to the side behind a barrier that blocks the beam. (If, for some reason, you find yourself unable to move behind a barrier, you may shout "stop", and the operator will immediately turn off the beam.) For back exposures, you will be asked to remove your shirt, so we can record your skin temperature with an infrared camera. Women can wear a swimming suit top. Testing in our laboratory has shown that clothing has little or no effect on the sensations evoked by millimeter waves. Individuals who have had refractive eye surgery will not be allowed to participate.

You will stand with your feet together and hands at your side, to assure that only skin on the front and/or back surface of your body is exposed. Your face and the center of your back will be exposed to millimeter wave energy. The exposures will be limited in duration to prevent skin damage, but are likely to last beyond your pain, tolerance for skin heating and pain. Since the purpose of these experiments is to determine variations in tolerance among people, you should try to extend your exposure to the limit of your tolerance, and you should attempt to remain in the same position as long as you can. However, the pain is likely to become so intense that you will be forced to move to the side, behind a barrier that blocks the beam, to escape the pain, either by involuntary reflex, or because you feel that the pain is reaching your tolerance limit. During the facial exposures you should feel free to close and/or shield your eyes, turn your head, or escape behind the barrier as needed. You will be exposed a maximum of 5 times on the front and 5 times on the back (10 total exposures) in one day. After each exposure, it may take a minute or two for the skin to return to its normal temperature. Exposures may be performed on multiple days. If less than 90 % of subjects tested move out of the beam produced at 100 % power, you will be asked to return another day for additional exposures. On each exposure day, the duration of your one-time participation in the experiment may be as long as 1 to 3 hours.

If an exposure produces skin reddening and/or tenderness that last for more than 15 minutes, your exposures for that day may be terminated. Although not anticipated, if an eye injury is suspected, you may be referred for further evaluation. If you have large metallic implants (e.g., an artificial joint) you cannot participate, as your concern about the presence of such implants may affect your behavior. Cardiac pacemakers are not affected by millimeter wave energy used in these experiments. If you have any unusual skin or eye conditions that surface heating might aggravate, you should decline participation in this experiment. **You are free to discontinue participation at any time.**

RISKS/INCONVENIENCES

Participation involves a risk of skin reddening. The affected area might remain slightly tender and red for several minutes after exposure. It has been our experience in rare cases (less than 1%) that mild redness or even very small blisters may persist for 24-48 hours, but these resolve

completely without requiring any medical treatment. If the skin remains tender or reddened more than 72 hours after exposure, this should be reported to the investigator or medical staff, and the medical staff will then examine you. If you feel discomfort in the eyes or the skin around the eyes for more that a few minutes, you should have the area examined by a medical observer. If eye injury is suspected, evaluation may require that ophthalmic staining drops be applied to your eyes. You are completely free to decline participation or to terminate your voluntary participation at any time. Many scientific studies have looked for possible detrimental effects (for example: skin cancer, damage to the cornea, and male infertility) of exposure to microwave energy (which includes millimeter wave exposures). Except for the heating effects, there are no known effects (detrimental or beneficial) of exposure to millimeter wave energy. It is extremely unlikely that brief heating of the skin to painful but non-damaging temperatures will have any short- or long-term deleterious effects. Normal reflexes (closing the eyes, turning the head, protecting the eyes with a hand) will protect the eyes from heating.

PRECAUTIONS FOR FEMALE SUBJECTS

You may not participate in this study if you are pregnant. There is some concern that you could stumble and fall as you are rapidly moving away from the beams. Although there is no evidence that exposure to millimeter waves of this type could affect a fetus, research is ongoing. Therefore, if you are a female of childbearing potential, and are not certain whether or not you are pregnant, you should consult with the Medical Monitor, who may ask you to take a pregnancy test.

BENEFITS

Subjects will receive no direct benefit or compensation for participation. These data will help in the understanding of the responses of humans to millimeter waves.

ALTERNATIVES

Choosing not to participate is an alternative to volunteering for this study.

EVENT OF INJURY

Federal laws and regulations govern your entitlement to medical care and/or compensation in the event of injury. If you have questions about your rights or if you believe you have received a research-related injury, you should contact the Medical Monitor, Michelle Bryce, Lt. Col., USAF, MC, SFS, (office 210-536-4007 [DSN 240-4007]), or medical observer, or one of the investigators listed at the top of this document.

Should you be injured as a direct result of being in this study, you will be provided medical care for that injury at no cost. You will not receive any compensation (payment) for injury. This is not a waiver or release of your rights. Medical care is limited to the care normally allowed for Department of Defense health care beneficiaries (patients eligible for care at military hospitals and clinics). For civilian employees and contract civilian personnel, medical care is limited to treatment within Air Force medical treatment facilities. Necessary medical care does not include in-home care or nursing home care. In case of any medical incident, you will be treated on site, unless personnel on site judge it to be an emergency, in which case they will call for ambulance service.

OCCURRENCE OF UNANTICIPATED ADVERSE EVENT

If an unanticipated event occurs during your participation in this study, you will be informed immediately. If you are not competent at the time to understand the nature of the event, such information will be brought to the attention of your next of kin.

Next of kin if needed: Name_____ Phone # _____

CONFIDENTIALITY

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. While medical documentation will be identified only by subject number to maintain your anonymity, your name, contact information, and exposure parameters will be entered into a subject database. Access to this database will be limited to those with a need to know. Names will not be associated with subjects captured on video images. Complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities.

DECISION TO PARTICIPATE

The decision to participate in this research is completely voluntary on your part. Refusal to participate will involve no penalty or loss of benefits to which you are entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. The investigators will answer questions you have about this study, your participation, and the procedures involved. The investigators will be available to answer any questions concerning procedures throughout this study. If significant new findings develop during the course of this research that may relate to your decision to continue participating, you will be informed. You may withdraw this consent at any time and discontinue further participation in this study without prejudice to your entitlements. The investigators may terminate your participation at any time, and the Medical Monitor or Medical Observer may terminate your participation if they feel this to be in your best interest.

SUBJECT STATEMENT

I have read the document "Instructions for Subjects—Pain Tolerance." I have read all of the above. My questions have been answered concerning areas I did not understand. I am willing to take part in this study. After I sign this form, I will receive a copy.

Full Name: _____ _____ _____

(please print) SSN (optional) Telephone Number

_____ _____

Volunteer Signature Date and Time

_____

Investigator (please print)

_____ _____

Investigator Signature Date

Witness (not involved, please print)

Witness Signature Date

Privacy Act Statement

Authority: We are requesting disclosure of personal information, to include your Social Security Number (SSN). Researchers are authorized to collect personal information (including social security numbers) on research subjects under The Privacy Act-5 USC 552a, 10 USC 55, 10 USC 8013, 32 CFR 219, 45 CFR Part 46, and EO 9397, November 1943 (SSN).

Purpose: It is possible that latent risks or injuries inherent in this experiment will not be discovered until some time in the future. The purpose of collecting this information is to aid researchers in locating you at a future date if further disclosures are appropriate.

Routine Uses: Information (including name and SSN) may be furnished to Federal, State, and local agencies for any uses published by the Air Force in the Federal Register, 52 FR 16431, to include furtherance of the research involved with this study and to provide medical care.

Disclosure: Disclosure of the requested information is voluntary. No adverse action whatsoever will be taken against you, and no privilege will be denied you based on the fact you do not disclose this information. However, your participation in this study may be impacted by a refusal to provide this information.

Instructions for Subjects — Pain Tolerance
Experiment 1

These experiments involve millimeter wave energy that will heat the skin on the front and/or back of your body to painful levels. If you are willing, we will expose you up to 5 times on the front and 5 times on the back (10 total exposures) per day on up to 2 different days. Your face and the center of your back will be exposed to millimeter wave energy. If less than 90 % of subjects tested move out of the beam produced at 100 % power, you will be asked to return on another day for additional exposures. During the facial exposures, you will be in street clothes. Testing in our laboratory has shown that clothing has little or no effect on the sensations evoked by millimeter waves. In order to measure skin temperature for the back exposures, the skin must be uncovered, so during these exposures you will need to remove your shirt. Women may wear a swimsuit top. A bathrobe will be provided for your comfort between exposures.

During exposure, we hope that you will stand still until you feel that you need to move to limit the pain. Most subjects will move away from the millimeter wave beams before the end of the maximal exposure duration, either because of involuntary reflex withdrawal or because the pain reaches the subject's tolerance limit. If you cannot tolerate the full exposure duration, you should move to the side behind a barrier that blocks the beam. (If for any reason, you feel that you cannot adequately move to the shielded area, you may shout "stop", and the operator will immediately turn off the beam.) We will measure how long you are able to remain still and how warm your skin becomes before you move. After you move, or the beams are turned off, you may experience "burning" pain that lingers for a few seconds. The exposed area may also be reddened and feel tender for up to a few minutes. We expect that these conditions will disappear within an hour or two at most. If the skin is still red and/or tender after 72 hours, you should notify the investigator, who will arrange for the medical staff to examine it and apply any appropriate treatment. Any eye discomfort or concerns that last longer than a few minutes should also be reported. There is no reason to expect any aftereffects more serious than a mild sunburn. In contrast to a sunburn, which entails some long-term risk from the aftereffects of ultraviolet exposure, millimeter waves have no known long-term effects.

You should NOT be afraid of the exposure. The most that might happen is that you could be forced to escape the millimeter wave energy because the pain becomes too intense. The minimal skin damage that may occur (reddening, tenderness) should not last more than a few minutes to a few hours. Some subjects who tolerate the most heating may experience minor damage to the skin (for example, redness and small blisters). This occurs rarely. If it should occur, it will clear up within a few days, leaving no aftereffects.

Please feel free to ask any questions or express any concerns regarding this experiment.

INFORMED CONSENT DOCUMENT

(Multi-Beam Pain Tolerance)

Building 1161
Brooks City-Base, TX 78235

Institutional Review Board Approval Dates: 5 July 05 – 4 July 06

PRIVACY ISSUES: Records of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C. 552a, and its implementing regulations. You understand that the sponsoring agency and/or its designee may inspect records of this study.

TITLE OF STUDY

Thermal Effects of Exposure to 400 W, 95 GHz, Millimeter Wave Energy (Experiment 2)

INVESTIGATORS' NAMES, DEPARTMENTS, PHONE NUMBERS

Principal Investigator:
Cook, Michael C., Ph.D., AFRL/HEDR, 8262 Hawks Road, Building 1162, Brooks City-Base, TX 78235, (210) 536-3059 (DSN 240-3059), Michael.Cook@brooks.af.mil

Associate Investigators:
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Mason, Patrick A., Ph.D. AFRL/HEDR, 8262 Hawks Road, Building 1162, Brooks City-Base, TX 78235, (210) 536-2362 (DSN 240-2362), Patrick.Mason@brooks.af.mil
Jill McQuade, Ph.D., AFRL/HEDR, 8262 Hawks Road, Building 1162, Brooks City-Base, TX 78235, (210) 536-4046 (DSN 240-4046), Jill.McQuade@brooks.af.mil
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Miller, Stephanie A., AFRL/HEDR, 8262 Hawks Road, Building 1162, Brooks City-Base, TX 78235, (210) 536-3881 (DSN 240-3881), Stephanie.Miller@brooks.af.mil
Pointer, Kristie L., AFRL/HEDR, 8262 Hawks Road, Building 1162, Brooks City-Base, TX 78235, (210) 536-4082 (DSN 240-4082), Kristie.Pointer@brooks.af.mil
Suniga, Valerie, AFRL/HEDR (Conceptual MindWorks), 8262 Hawks Road, Building 1162, Brooks City-Base, TX 78235, (210) 536-5604 (DSN 240-5604), Valerie.Suniga.ctr@brooks.af.mil

PURPOSE OF STUDY

You have been invited to participate in a research study at Brooks City-Base, TX sponsored by the Air Force Research Laboratory, Human Effectiveness Directorate, Radiofrequency Radiation Branch, entitled "Thermal Effects of Exposure to 400 W, 95 GHz, Millimeter Wave Energy." The objective of this experiment is to measure how people react to millimeter waves from two transmitters that heat their skin. Specifically, we are trying to find out how much exposure people can tolerate before they are forced to take action to escape the beams. Therefore, you will be asked to stand still in the beams until you are forced to escape by the

pain that the beams evoke. (Please note that the 400 watts referred to in the title of the study specifies the power output at the source of the device and not at the skin surface, where power levels are considerably lower. In fact, exposure levels at the skin will be no greater than those which occurred over the course of 35 previous studies which examined the effects of millimeter waves on humans; these studies have involved over 6000 exposures with an injury rate of 0.05%.)

This study will enroll 10 subjects who are least 18 years of age. You may be tested over several visits to the testing site, each lasting up to 3 hours.

PROCEDURES

If you volunteer to participate in this study, you will be exposed to millimeter wave energy from two transmitters at intensities that will exceed the applicable safety standard by as much as 20-fold. This exposure could cause your skin temperature to rise to 60 °C (140 °F), unless you take action to escape the beams by moving to the side behind a barrier that blocks the beams (If, for some reason, you find yourself unable to move behind a barrier, you may shout "stop", and the operator will immediately turn off the beams.) You will be asked to remove your shirt, so we can record your skin temperature with an infrared camera. Women can wear a swimming suit top. Testing in our laboratory has shown that clothing has little or no effect on the sensations evoked by millimeter waves.

You will stand with your feet together and hands at your side, to assure that only skin on your back is exposed. Specifically, the center of your back will be exposed to millimeter wave energy. The exposures will be limited in duration to prevent skin damage, but are likely to last beyond your pain tolerance for skin heating and pain. Since the purpose of these experiments is to determine variations in tolerance among people, you should try to extend your exposure to the limit of your tolerance, and you should attempt to remain in the same position as long as you can. However, the pain is likely to become so intense that you will be forced to move to the side, behind a barrier that blocks the beams, to escape the pain, either by involuntary reflex, or because you feel that the pain is reaching your tolerance limit. You will be exposed a maximum of 5 times on the back in one day. After each exposure, it may take a minute or two for the skin to return to its normal temperature. Exposures may be performed on multiple days. If less than 90 % of subjects tested move out of the beams produced at 100 % power, you will be asked to return another day for additional exposures. On each exposure day, the duration of your one-time participation in the experiment may be as long as 1 to 3 hours.

If an exposure produces skin reddening and/or tenderness that last for more than 15 minutes, your exposures for that day may be terminated. If you have large metallic implants (e.g., an artificial joint), you cannot participate, as your concern about the presence of such implants may affect your behavior. Cardiac pacemakers are not affected by millimeter wave energy used in these experiments. If you have any unusual skin conditions that surface heating might aggravate, you should decline participation in this experiment. **You are free to discontinue participation at any time.**

RISKS/INCONVENIENCES

Participation involves a risk of skin reddening. The affected area might remain slightly tender and red for several minutes after exposure. It has been our experience in rare cases (less than 1%) that mild redness or even very small blisters may persist for 24-48 hours, but these resolve completely without requiring any medical treatment. If the skin remains tender or reddened more than 72 hours after exposure, this should be reported to the investigator or medical staff, and the medical staff will then examine you. You are completely free to decline participation or

to terminate your voluntary participation at any time. Many scientific studies have looked for possible detrimental effects (for example: skin cancer, damage to the cornea, and male infertility) of exposure to microwave energy (which includes millimeter wave exposures). Except for the heating effects, there are no known effects (detrimental or beneficial) of exposure to millimeter wave energy. It is extremely unlikely that brief heating of the skin to painful but non-damaging temperatures will have any short- or long-term deleterious effects.

PRECAUTIONS FOR FEMALE SUBJECTS

You may not participate in this study if you are pregnant. There is some concern that you could stumble and fall as you are rapidly moving away from the beams. Although there is no evidence that exposure to millimeter waves of this type could affect a fetus, research is ongoing. Therefore, if you are a female of childbearing potential, and are not certain whether or not you are pregnant, you should consult with the Medical Monitor, who may ask you to take a pregnancy test.

BENEFITS

Subjects will receive no direct benefit or compensation for participation. These data will help in the understanding of the responses of humans to millimeter waves.

ALTERNATIVES

Choosing not to participate is an alternative to volunteering for this study.

EVENT OF INJURY

Federal laws and regulations govern your entitlement to medical care and/or compensation in the event of injury. If you have questions about your rights or if you believe you have received a research-related injury, you should contact the Medical Monitor, Michelle Bryce, Lt. Col., USAF, MC, SFS, (office 210-536-4007 [DSN 240-4007]), or medical observer, or one of the investigators listed at the top of this document.

Should you be injured as a direct result of being in this study, you will be provided medical care for that injury at no cost. You will not receive any compensation (payment) for injury. This is not a waiver or release of your rights. Medical care is limited to the care normally allowed for Department of Defense health care beneficiaries (patients eligible for care at military hospitals and clinics). For civilian employees and contract civilian personnel, medical care is limited to treatment within Air Force medical treatment facilities. Necessary medical care does not include in-home care or nursing home care. In case of any medical incident, you will be treated on site, unless personnel on site judge it to be an emergency, in which case they will call for ambulance service.

OCCURRENCE OF UNANTICIPATED ADVERSE EVENT

If an unanticipated event occurs during your participation in this study, you will be informed immediately. If you are not competent at the time to understand the nature of the event, such information will be brought to the attention of your next of kin.

Next of kin if needed: Name_____ Phone #_____

CONFIDENTIALITY

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. While medical documentation will be identified only

by subject number to maintain your anonymity, your name, contact information, and exposure parameters will be entered into a subject database. Access to this database will be limited to those with a need to know. Names will not be associated with subjects captured on video images. Complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities.

DECISION TO PARTICIPATE

The decision to participate in this research is completely voluntary on your part. Refusal to participate will involve no penalty or loss of benefits to which you are entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. The investigators will answer questions you have about this study, your participation, and the procedures involved. The investigators will be available to answer any questions concerning procedures throughout this study. If significant new findings develop during the course of this research that may relate to your decision to continue participating, you will be informed. You may withdraw this consent at any time and discontinue further participation in this study without prejudice to your entitlements. The investigators may terminate your participation at any time, and the Medical Monitor or Medical Observer may terminate your participation if they feel this to be in your best interest.

SUBJECT STATEMENT

I have read the document "Instructions for Subjects—Multi-Beam Pain Tolerance." I have read all of the above. My questions have been answered concerning areas I did not understand. I am willing to take part in this study. After I sign this form, I will receive a copy.

Full Name: _____ _____ _____

(please print) SSN (optional) Telephone Number

_____ _____ _____

Volunteer Signature Date and Time

_____

Investigator (please print)

_____ _____

Investigator Signature Date

_____

Witness (not involved, please print)

_____ _____

Witness Signature Date

Privacy Act Statement

Authority: We are requesting disclosure of personal information, to include your Social Security Number (SSN). Researchers are authorized to collect personal information (including social security numbers) on research subjects under The Privacy Act-5 USC 552a, 10 USC 55, 10 USC 8013, 32 CFR 219, 45 CFR Part 46, and EO 9397, November 1943 (SSN).

Purpose: It is possible that latent risks or injuries inherent in this experiment will not be discovered until some time in the future. The purpose of collecting this information is to aid researchers in locating you at a future date if further disclosures are appropriate.

Routine Uses: Information (including name and SSN) may be furnished to Federal, State, and local agencies for any uses published by the Air Force in the Federal Register, 52 FR 16431, to include furtherance of the research involved with this study and to provide medical care.

Disclosure: Disclosure of the requested information is voluntary. No adverse action whatsoever will be taken against you, and no privilege will be denied you based on the fact you do not disclose this information. However, your participation in this study may be impacted by a refusal to provide this information.

Instructions for Subjects — Multi-Beam Pain Tolerance
Experiment 2

These experiments involve millimeter wave energy from two transmitters that will heat the skin on your back to painful levels. If you are willing, we will expose you up to 5 times on the back per day on up to 2 different days. The center of your back will be exposed to millimeter wave energy. If less than 90 % of subjects tested move out of the beams produced at 100 % power, you will be asked to return another day for additional exposures. In order to measure skin temperature for the back exposures, the skin must be uncovered, so during these exposures you will need to remove your shirt. Women may wear a swimsuit top. A bathrobe will be provided for your comfort between exposures.

During exposure, we hope that you will stand still until you feel that you need to move to limit the pain. Most subjects will move away from the millimeter wave beams before the end of the maximal exposure duration, either because of involuntary reflex withdrawal or because the pain reaches the subject's tolerance limit. If you cannot tolerate the full exposure duration, you should move to the side behind a barrier that blocks the beams. (If for any reason, you feel that you cannot adequately move to the shielded area, you may shout "stop", and the operator will immediately turn off the beams.) We will measure how long you are able to remain still and how warm your skin becomes before you move. After you move, or the beams are turned off, you may experience "burning" pain that lingers for a few seconds. The exposed area may also be reddened and feel tender for up to a few minutes. We expect that these conditions will disappear within an hour or two at most. If the skin is still red and/or tender after 72 hours, you should notify the investigator, who will arrange for the medical staff to examine it and apply any appropriate treatment. There is no reason to expect any aftereffects more serious than a mild sunburn. In contrast to a sunburn, which entails some long-term risk from the aftereffects of ultraviolet exposure, millimeter waves have no known long-term effects.

You should NOT be afraid of the exposure. The most that might happen is that you could be forced to escape the millimeter wave energy because the pain becomes too intense. The minimal skin damage that may occur (reddening, tenderness) should not last more than a few minutes to a few hours. Some subjects who tolerate the most heating may experience minor damage to the skin (for example, redness and small blisters). This occurs rarely. If it should occur, it will clear up within a few days, leaving no aftereffects.

Please feel free to ask any questions or express any concerns regarding this experiment.

ADT SUBSYSTEM MEDICAL DOCUMENTATION FORM

FRONTAL/DORSAL EXPOSURES

BROOKS CITY-BASE

DATE/TIME: _____ SUBJECT # _____

VITAL SIGNS: R _____ BP _____ P _____

PRE-EXPOSURE HISTORY: circle if any apply. Otherwise circle history non-contributory.

1. Absolute DQ if: pregnant, large metal implants, PRK/LASIK.

2. May require DQ, must check with medical monitor (or alternate) if:
   - Skin condition: ongoing disease, history of skin cancer, grafts, thick scars (Keloids), photosensitivity.
   - Other chronic medical problems: cancer, neuropathy, uncontrolled high blood pressure, stroke, heart problems, on heart medications.

3. Current medications:

4. Eye specific:
   - Do you currently have any eye complaints? No___ Yes___
   - Any foreign body sensation (like something is in your eye)? No___ Yes___
   - Any eye burning, dryness, discharge? No___ Yes___
   - Any condition requiring eye medication? No___ Yes____
   - Diabetes? No___ Yes___
   - Impaired blink reflex? No___ Yes___
   - Eye surgery? No___ Yes___

PRE-EXPOSURE EXAM:

1. Skin: circle if they apply.
   - color: redness, sunburned
   - moisture: dry, sweating, oily
   - texture: rough, smooth, crusty areas, other:
   - lesions: macules, papules, vesicles, other:
   - scars:

2. Heart:
   - RRR, other:

3. Face:
   - Any significant facial scars? No___ Yes___
     Any pre-malignant looking lesions? No___ Yes___
     Sunburn? No___ Yes___
   - Other abnormalities on face? No___ Yes___ describe:

4. Eye exam
   - Eye lids: redness, normal, other:
   - Conjunctiva: injected, normal, other:
   - Other eye abnormalities? No___ Yes___ describe:

Note: The next 5 are quick external looks only!

TIME _____ EXPOSURE #1 Skin/Eye: redness, blisters, sweating, normal, other:

TIME _____ EXPOSURE #2 Skin/Eye: redness, blisters, sweating, normal, other:

TIME _____ EXPOSURE #3 Skin/Eye: redness, blisters, sweating, normal, other:

TIME _____ EXPOSURE #4 Skin/Eye: redness, blisters, sweating, normal, other:

TIME _____ EXPOSURE #5 Skin/Eye: redness, blisters, sweating, normal, other:

FINAL POST EXPOSURE HISTORY: TIME _____

1. Concerns or complaints: none, other:

2. Eye specific:
   - Do you currently have any eye complaints? No____ Yes____
   - Any foreign body sensation (feel like something is in your eye)? No____ Yes____
   - Any eye burning, dryness, discharge? No____ Yes_____
   - Any complaints? No____ Yes____

FINAL POST EXPOSURE EXAM: circle if any apply. Otherwise circle normal exam.

1. Skin: redness, blisters, rash, sweating, other:

2. Heart: RRR, other:

3. Other worth noting:

4. Eye exam
   - Eye lids: redness, blisters, normal, other:
   - Conjunctiva: injected, normal, other:
   - Other eye abnormalities? No___ Yes___ describe:

Need for referral (eye symptoms > 15 min): no____ yes____ to: local Air Force clinic (Brooks City-Base, Lackland AFB)

ADT SUBSYSTEM MEDICAL DOCUMENTATION FORM

MULTI-BEAM EXPOSURES

BROOKS CITY-BASE

DATE/TIME: _____ **SUBJECT #** _____

VITAL SIGNS: R _____ **BP** _____ **P** _____

PRE-EXPOSURE HISTORY: circle if any apply. Otherwise circle history non-contributory.

1. Absolute DQ if: pregnant, large metal implants.

2. May require DQ, must check with medical monitor (or alternate) if:
   - Skin condition: ongoing disease, history of skin cancer, grafts, thick scars (Keloids), photosensitivity.
   - Other chronic medical problems: cancer, neuropathy, uncontrolled high blood pressure, stroke, heart problems, on heart medications.

3. Current medications:

PRE-EXPOSURE EXAM:

1. Skin: circle if they apply.
   - color: redness, sunburned
   - moisture: dry, sweating, oily
   - texture: rough, smooth, crusty areas, other:
   - lesions: macules, papules, vesicles, other:
   - scars:

2. Heart:
   - RRR, other:

Note: The next 5 are quick external looks only!

TIME _____ EXPOSURE #1 Skin/Eye: redness, blisters, sweating, normal, other:

TIME _____ EXPOSURE #2 Skin/Eye: redness, blisters, sweating, normal, other:

TIME _____ EXPOSURE #3 Skin/Eye: redness, blisters, sweating, normal, other:

TIME _____ EXPOSURE #4 Skin/Eye: redness, blisters, sweating, normal, other:

TIME _____ EXPOSURE #5 Skin/Eye: redness, blisters, sweating, normal, other:

FINAL POST EXPOSURE HISTORY: TIME _____

1. Concerns or complaints: none, other:

FINAL POST EXPOSURE EXAM: circle if any apply. Otherwise circle normal exam.

1. Skin: redness, blisters, rash, sweating, other:

2. Heart: RRR, other:

3. Other worth noting:

Protocol # F-BR-2004-0074-H: Effects of Ethanol on Millimeter-Wave-Induced Pain

Abstract

Objective and Intent

A developmental directed energy non-lethal weapon uses painful levels of skin heating to repel personnel from protected areas. In some cases, the weapon will be used to repel mobs, members of which may have consumed substantial amounts of alcohol. Alcohol intoxication may impact thresholds for (a) eye aversion (eyelid closure and/or head turn); (b) skin pain detection; and (c) whole body repel/escape behavior. If alcohol affects any of these thresholds, then both the effectiveness and the safety margin of the weapon could be affected. To ascertain the likelihood of such effects, we propose to measure ethanol-induced changes in the pain threshold, the threshold for repel/escape from suprathreshold pain, and the threshold level of facial exposure required to produce eye aversion.

Relevance

Experimental results will be critical to both the operational effectiveness and policy acceptability of the non-lethal weapon system. That is, they will be instrumental in determining whether this system will produce the desired escape response in inebriated targets without unacceptably reducing the safety margin between effectiveness and thermal damage to the targets.

Expected Outcomes

Based on previous research conducted with this system, as well as on studies examining the effects of ethanol consumption on pain perception, it is expected that alcohol intoxication will increase pain threshold estimates and may also increase latencies for whole body escape and eye/facial aversion. The degree of any such increase is, at this juncture, unclear.

1. **Protocol # F-BR-2004-0074-H**: Effects of Ethanol on Millimeter-Wave-Induced Pain
2. **Principal Investigator:** Michael C. Cook, Ph.D., AFRL/HEDR/DSN 240-3059/Michael.Cook@brooks.af.mil
3. **Associate Investigators:**

   Leland Johnson, AFRL/HEDR/DSN 240-2243/Leland.Johnson@brooks.af.mil

   Stephanie A. Miller, AFRL/HEDR/DSN 240-3881/Stephanie.Miller@brooks.af.mil

   Kristie L. Pointer, AFRL/HEDR/DSN 240-4082/Kristie.Pointer@brooks.af.mil

   John M. Ziriax, Ph.D., NHRC/DET/DSN 240-6530/John.Ziriax@brooks.af.mill
4. **Medical Monitor:** LtCol Michelle Bryce, DO, MTM&H, USAF, MC, SFS, AFRL/HED/ DSN 240-4007/Michelle.Bryce@brooks.af.mil

   The medical monitor will appoint a medical observer to be available by telephone throughout the experiment. All technicians involved with the study will receive written instructions on the mechanism for responding to urgent and emergent medical conditions. These instructions will include information on the appropriate urgent medical disposition of subjects who are injured or become ill while participating in the research protocol while waiting for telephone response from the medical monitor. The medical monitor overseeing the protocol must be notified of any serious adverse event resulting from the research exposure within 12 hours. All illnesses or injuries occurring in subjects while participating in an experiment, but not causally related to the experiment must be brought to the attention of the medical monitor within 48 hours. The medical monitor will ensure that serious and unexpected events will be reported IAW AFI 40-402, 3.8.1, HEP OI 40-403, 4.2. (This description of the role and scope of the medical monitor conforms to AFI 40-402, 2.8.)
5. **Contractor and Facility:** Advanced Information Engineering Services, Inc.
6. **Protocol Objective:** A developmental directed energy non-lethal weapon uses painful levels of skin heating to repel personnel from protected areas. It is expected that, in some cases, the weapon will be used to repel mobs, members of which may have consumed substantial amounts of alcohol prior to exposure. Alcohol intoxication may impact thresholds for (a) eye aversion (eyelid closure and/or head turn); (b) skin pain detection; and (c) whole body repel/escape behavior. If alcohol affects any of these thresholds, then both the effectiveness and the safety margin of the weapon could be affected. To ascertain the likelihood of such effects, we propose to measure ethanol-induced changes in the pain threshold, the threshold for repel/escape from suprathreshold pain, and the threshold level of facial exposure required to produce eye aversion.
7. **Background and Relevance:**

   A. Data Required. The U.S. Air Force is developing a non-lethal microwave weapon, the Active Denial System (ADS), with an effective range greater than that of small arms. The device uses millimeter wavelength microwaves to produce heating of the skin surface to painful levels that quickly become

intolerable, causing targeted individuals to retreat. We (U.S. Air Force Research Laboratories, Human Effectiveness Directorate, Radio Frequency Radiation Branch [AFRL/HEDR]) have conducted extensive research on the bioeffects of millimeter waves (MMWs), both in animals and humans. We have demonstrated that the desired behavioral effect (prompt and highly-motivated escape behavior) is readily produced at levels well below those that produce burns in animals. Studies with conventional heating of human skin (e.g., Moritz & Henriques, 1947) assure us that there is a substantial safety margin between effective levels and damaging ones. These conclusions have been reinforced by more recent work measuring facial sensitivity, threshold for eye aversion, and threshold for corneal damage in rhesus macaques (*Macaca mulatta*) performing a visually-cued task (Chalfin, D'Andrea, Comeau, Belt, & Hatcher, 2002).

The rapidity with which the pain response is recruited by exposure to the ADS frequency and the attendant rapidity of the resulting behavioral and psychological reactions suggest that the psychophysical response is unique and that the associated repel response is, at least in part, reflexive in nature. Safe operation of the ADS is critically dependent upon this reflexive reaction to the stimulus. It is therefore important to investigate the impact that a substance like alcohol might have on the psychophysical function and hence the latency of the repel response.

Our previous research has shown that the pain threshold (i.e., do subjects find a given stimulus level painful?) varies relatively little from subject to subject. Studies of the pain threshold for infrared-induced heating (Wolff, Hardy, & Goodell, 1942) suggest that the pain threshold is elevated by 40 to 45% by ethanol; this result, however, has not been verified for MMWs (which penetrate the skin more deeply than does infrared radiation).

In contrast to pain *threshold*, intersubject variability for *tolerability* of suprathreshold pain (i.e., how long can subjects remain exposed to a painful stimulus level?) is much greater. The point of intolerability is a complex function of pain intensity, duration, exposure area, and characteristics of the individual (such as motivation, stoicism, expectation, and prior experience with pain). Thus, it can be expected that pain tolerance will vary more from individual to individual than pain threshold, which (in terms of skin temperature) shows very little variation among all mammals. In order to ascertain whether the ADS would be effective against essentially all individuals, while at the same time producing substantial damage in few or no cases, it is necessary to determine the extent to which mild ethanol intoxication impacts the average point of pain intolerability and its variation among individuals.

B. DoD relevance. The results of these experiments will help us to answer two important questions:

1) Will this non-lethal weapon produce the desired escape response in inebriated targets without unacceptably reducing the safety margin between effectiveness and thermal damage to the targets?

2) Does the state of the subject (inebriated or non-inebriated) have to be taken into account in generating operational scenarios?

The answers to these questions are critical to both the operational effectiveness and policy acceptability of the system.

8. **Impact Statement:** The technology to be tested in these experiments was developed in response to several Mission Needs Statements (MNS) (AFSOC MNS 003-95, Nonlethal/Limited Effects Weapon Capability, dated 22 July 1996; MNS LOG 1.85, dated 20 February 1996, which stated requirements for improved capabilities in Military Operations Other Than War; Marine Corps Development Center MNS #MCCDC-9602029, NAVMC HQ-355). The Joint Non-Lethal Weapons Directorate (http://www.usmc.mil/nlw) has responded to these needs statements by drafting an Operational Requirement Document (ORD) for Non-Lethal Active Denial Technology Capability dated 25 October 1999. The planned experiments will assist in specifying the design characteristics and operational applications of acquisitions planned to meet this ORD.

9. **Experimental Plan:**

A. Equipment and Facilities: A transmitter located in our laboratories at Brooks City-Base, Texas, will be used for all MMW exposures. Microwave technicians assigned to Brooks City-Base will provide transmitter control, calibration, characterization, and maintenance.

After undergoing the experimental procedures, subjects will be allowed to rest, recover, and receive their meals in a room collocated in the building complex which houses the transmitter. The room will include a couch, table, television monitor and CD/DVD player. (See also Section 9. D., *Alcohol administration and measurement*.)

B. Subjects: Thirty-two adult volunteer subjects, all at least 21 years old, will be recruited from among military personnel, Department of Defense (DoD) civilians, and contractor personnel. If volunteers of both genders are available, efforts will be made to have each gender represented by no less than 3 individuals. (For a "medium" effect size and $k = 3$ treatment groups, a sample size of $n = 14$ yields a power of $1 - \beta = 0.80$. Thus, the total sample size for the two studies combined — both with three treatment groups — is: 14 + 14 = 28. Four additional subjects are specified in anticipation of subject attrition.)

All volunteers will be asked if they are recovering alcoholics. Recovering alcoholics will be excluded from participating. Volunteers will be screened for potential alcohol abuse problems using the Alcohol Use Disorders Identification Test (AUDIT) (Babor, Higgens-Biddle, Saunders, & Monteiro, 1992). A score lower than 2 typically indicates a non-drinker who should be discouraged from participating. Those with low total scores (2-7) will be automatically accepted as subjects. Volunteers with scores of 8 or more (indicative of hazardous alcohol use and possible alcohol dependence) will be rejected and further evaluated by the medical monitor, medical observer, or a medical provider from the 311th Medical Squadron, who will urge any volunteers identified as possible alcoholics

to contact their primary care provider (who may recommend an appropriate treatment program).

Other exclusionary criteria will include: (a) No pregnant females will be permitted to participate due to the known adverse impact of ethanol consumption on the developing fetus (Maier & West, 2001; Mattson, Schoenfeld, & Riley, 2001; Warren & Foudin, 2001). In the event that there exists any question concerning the status of pregnancy in female volunteers, a pregnancy test will be offered. (b) Individuals who, for various reasons, are chronic users of prescribed or over-the-counter (OTC) pain relievers and fever reducers may be excluded from participation in the study at the discretion of the medical monitor due to the possible negative interaction of such drugs with ethanol (U.S. Food and Drug Administration, 1998; Aalykke & Lauritsen, 2001). A non-exhaustive list of analgesics and antipyretics of concern includes: acetominophne, aspirin, carbaspirin calcium, choline salicylate, ibuprofen, ketoprofen, magnesium salicylate, naproxen sodium, and sodium salicylate. (c) Individuals with diabetes will be excluded from participation (Van De Wiel, 2004). (d) Individuals using any of various physician-prescribed medications including but not limited to narcotic analgesics (codeine, propoxyphene [Darvon], meperidine [Demerol], etc.), benzodizepines (diazepam [Valium], chlordiazepoxide [Librium], flurazepam [Dalmane], etc.), barbiturates (secobarbital [Seconal], pentobarbital [Nembutal], etc.), antibiotics (cefamandole [Mandol], isoniazid [Nydrazid], etc.), high-blood pressure medications, anxiolytics or tricyclic anti-depressants (amitriptyline [Endep], clomipramine [Anafranil], etc.), and anticoagulants (warfarin [Coumadin], etc.) may be excluded from participation in the study at the discretion of the medical monitor because of the known negative synergistic effects of such drugs when used in combination with alcohol (Weathermon & Crabb, 1999). (See Attachment D for medical documentation form to be employed during course of study.)

C. Duration of the Study: It is anticipated that data collection can be completed within 1 year after final approval of this protocol.

D. Procedures:

Experimental design overview. Subjects will be assigned to one of two studies, each study consisting of 3 sessions, and each session occurring on a separate day. For each session, subjects will be assigned to one of three alcohol dosage conditions: (a) 0.00%, (b) 0.08%, or (c) 0.12%. Subjects in the 0.08% and 0.12% conditions will consume enough alcohol to attain an approximate blood alcohol level (BAL) of either 0.08% or 0.12%; respectively; alternatively, subjects in the 0.00% (control) condition will drink no alcohol. Dosage order will be counterbalanced across subjects. Once subjects attain their approximate target BAL (see *Alcohol administration and measurement*, below, for details), they will undergo one or more experimental tests/procedures. These tests are enumerated in Table 1 and explained in additional detail below (see *Pain threshold*, *Pain intolerability*, and *Eye aversion*).

Table 1. Experimental procedures and alcohol dose for Studies 1 and 2.

	Alcohol dosage		
	0.00%	0.08%	0.12%
Study 1	pain threshold, eye aversion	pain threshold, eye aversion	pain threshold, eye aversion
Study 2	pain intolerability	pain intolerability	pain intolerability

Alcohol dosage procedures and counterbalancing for Sessions 4-6 will be identical to those in Sessions 1-3; the experimental procedure assigned to the subjects will, however, differ. (This is summarized in Table 1; see *Pain intolerability* below for details of the procedure.)

Alcohol administration and measurement. Subjects in all three dosage conditions will be asked to refrain from consuming alcohol during the 24 hours prior to testing. All subjects will be asked to refrain from using OTC analgesics, anipyretics, and various CNS-active agents (sleep aids: diphenhydramine [Sominex, Sleep-Eze], cold/flu remedies (dextromethorphan/ doxylamine/pseudoephedrine hydrochloride [Nyquil]) during the 24 hr prior to testing. All subjects will also be asked to report to the laboratory in the morning (approximately 0730-0830) without having eaten breakfast. (A meal will be provided immediately after testing.)

Alcohol administration will consist of presenting each subject with 24 oz. (0.71 l) of liquid. For subjects in the 0.08% and 0.12% conditions, total ethanol (80 Proof Vodka) in the vehicle (orange juice) will be determined from a nomogram

(e.g., http://www.nd.edu/~aldrug/BACestimates.html, or http://www.insure.com/auto/baccalc.html),

that will take in account the assigned target BAL (0.08% or 0.12%), gender, and weight of the subject. Subjects assigned to the control condition will be given 24 oz. of vehicle (orange juice with no added ethanol) to consume. The subjects will be coached to sip the drink as evenly as possible, consuming the entire dose over a 15-min consumption period. Post-consumption timing will begin upon completion of ingestion. This procedure has been employed successfully in previous experimentation performed at the AFRL/HEDR laboratories under Protocol FWR-1996-0026-H, "Animal-to-human extrapolation: Effects of ethanol on human performance" (see also Blick, Weathersby, Miller, Cosgrove, & Murphy, 2000).

BAL will first be assessed 15 min post-consumption, and at 1- to 10-minute intervals thereafter until peak BAL is attained. The assessment device will be an Intoxilyzer (M/N 5000, CMI, Owenboro, KY). (Use of this device involves obtaining a breath sample from the subject; the device then employs an infrared energy absorption methodology to detect alcohol molecules and hence measure the alcohol content of the breath sample. Since amount of alcohol in the breath is proportional to that in the bloodstream, the unit can thus calculate the BAL in

accordance with the Uniform Vehicle Code. The unit will be calibrated by CMI technicians prior to its use in this study.) Total time to obtain a subject breath sample and calculate the BAL based on that sample is approximately 1 min.

Previous work in the AFRL/HEDR laboratories using this procedure (Protocol FWR-1996-0026-H, "Animal-to-human extrapolation: Effects of ethanol on human performance") has shown that in a small number of cases, subjects are not provided sufficient alcohol to attain their target BAL of either 0.08% or 0.12%. This becomes apparent during the series of BAL measurements prior to testing on the experimental tasks. If it is determined that a given subject's BAL will not reach his or her target, that subject will be provided a small supplemental dose of alcohol (in a vehicle consisting of orange juice); such supplemental doses are a small proportion of original alcohol dose [approximately 10 to 20%]). Once the target level is attained, testing for the experimental tasks (see Table 1 and below) will commence. Subject BAL will be measured at the completion of each task. Following completion of the last experimental task, the subject will be given a meal, and asked to remain in the laboratory until the BAL reaches 0.04% and the experimenters determine that the subject's observable behavior has attained sufficient normalcy. While waiting for BAL to fall to safe and legal levels, subjects will be offered refreshments (coffee, soda, snacks) and entertainment (magazines, radio, CDs, videos) to help alleviate boredom. Once the subject's BAL reaches 0.04%, subjects will be transported home by taxi cab. Further, subjects will be cautioned not to operate automobiles or other heavy equipment for at least 2 hours.

Pain threshold. For this series of up to 32 exposures (trials), a dielectric lens will be used to focus the transmitter output on a small area of the back. The area of exposure will be no greater than 5 cm^2 (where the boundary of the area exposed is defined as that point where the increase in skin temperature is 90% of the maximum skin temperature increase). Between trials, the beam will be redirected so that a previously unexposed area will be exposed on the next trial. The pain threshold will be determined by a modified up-and-down procedure (Dixon, 1991; Dixon & Massey, 1983) called the double random staircase procedure (Cornsweet, 1962; Simpson, 1989). This procedure produces a very efficient measurement of sensory thresholds by concentrating the observations close to the value of interest, while preventing the subject from being able to predict the stimulus intensity that will be presented on any given trial. After each stimulus presentation, the subject is required to indicate by a yes-or-no response whether the sensation for that trial met the criterion for the threshold.

Two "staircases" are operating simultaneously, and the staircase that determines the power for a given trial is selected randomly (thus "double random staircase"). The power density setting for the first trial (per staircase) employs an initial value selected by the investigator that is estimated to be near the pain threshold. Power density values for subsequent trials are a function of the staircase algorithm, which calculates values that vary up or down (based on subject responses) by steps of a predetermined size. This step size (50 mW/cm^2 has worked well for 3-s pain thresholds) is estimated to allow about 20 steps to cover

the range from below threshold for the most sensitive subject to above threshold for the least sensitive. Previous experience in measuring a variety of thresholds has shown that allowing for approximately this number of steps is quite efficient, since intra-individual variability in response at threshold tends to be approximately proportional to the range of inter-individual variation in threshold. In more concrete terms, such a step size typically traverses a range from nearly 0% "yes" to nearly 100% "yes" responses in 4-6 steps for each subject. Larger steps reduce the sensitivity of the procedure, while smaller steps make it more difficult for the subject to maintain a consistent decision criterion because a larger proportion of the trials are in his range of uncertainty. As noted, for each staircase, the power for a given trial steps up or down depending on the subject's response to the previous trials on that staircase. Prior to a subject's first "yes" response, if the subject says "no" on a trial, then power on the subsequent trial is stepped up by a 50 to 200 mW/cm² increment. Once a subject's first "yes" response is recorded, then: (a) if the subject says "yes" on a given trial, power is stepped down by 50 mW/cm² on the next trial; (b) if two consecutive "no" responses occur, then the power is stepped up by 50 mW/cm².on the subsequent trial.

Subjects will be in continuous contact with experimenters via intercom, and will be observed from the front by a video camera, and from the back with a calibrated infrared camera (FLIR Systems, Inc., Model SC 3000, Boston, MA) that allows precise determination of skin surface temperature (IR thermography). Subjects will be warned via intercom 1-2 s before the onset of each exposure. They will be asked to hold a stationary sitting position as steadily as possible for the duration of the exposure (3 s), and for 3 s thereafter. For testing on the back, intertrial intervals will be about 15-20 s (required to reposition the beam and record the IR data).

For each trial, the power density value is entered into a computer program that controls the output of the MMW transmitter. Transmitter operators can instantly abort transmitter output if anything unexpected occurs. IR thermographic data will be collected before the onset of stimulation, during stimulation, and for several seconds thereafter (to assess cooling rates).

Pain intolerability. In order to measure the effects of ethanol on pain tolerability directly, 4 pain tolerability trials will be conducted. Two trials will be conducted with a small exposure area (the same size as used for pain threshold testing), and two trials will use a larger exposure area. The larger exposure area will be no greater than 14 cm^2 (where the boundary of the area exposed is defined as that point where the increase in skin temperature is 90% of the maximum skin temperature increase). Four different areas (high, low, left, and right) on the back will be tested.

Subjects will be warned approximately 2-3 s before the onset of each trial/exposure. Subjects will be seated at the outset of the exposures. For each of the 4 trials, they will be instructed to remain in the MMW beam for as long as they can endure the pain; subjects will be further instructed that when and if the pain reaches the point of intolerability, they should terminate the exposure by

either (a) moving quickly to the left or right (i.e., moving out of the beam), or (b) using the kill switch to terminate the beam. The maximum possible duration of any exposure (assuming the subject does not move) will be limited to 5 s, an amount of time that will not result in skin damage.

During and between trials, subjects will be in continuous contact with experimenters via intercom, and will be observed with both video camera and a calibrated infrared camera. For each trial, the power density value will be entered into a computer program that controls the output of the MMW transmitter. Transmitter operators can instantly abort transmitter output if anything unexpected occurs. The maximum possible duration of each exposure will be automatically limited to prevent skin damage.

IR thermographic data of the subjects' backs will be collected before the onset of stimulation, during stimulation, and for several seconds thereafter (to assess cooling rates).

Eye/facial aversion. Subjects will sit facing the transmitter horn with the height of the seat adjusted so as to place the center of the MMW beam midway between the pupils. The distance from the transmitter horn will be selected to provide reasonably uniform heating ($\geq$ 90% of maximum) over the entire face. At pseudo-random intervals (mean = approximately 50 s, range = approximately 30-90 s) the transmitter will be turned on at a randomly-selected energy density (0.0 [i.e., sham], 0.6, 1.0, or 1.4 joules/cm^2). These energy densities will be achieved by varying the duration of a 2-W/cm^2 pulse of MMWs from 300 to 700 ms (in 200-ms steps). These energy densities are approximately an order of magnitude lower than the threshold for minimal corneal damage (Chalfin et al., 2002). Subjects will be exposed five times at each of the four energy densities (for a **total of 20 trials). This should provide a reliable estimate of the aversion** threshold (energy density at which aversion occurs 50% of the time) in each subject. The rate of spurious aversion responses will be established during the sham (0 joules/cm^2) trials. A close variation of this procedure has been previously successfully employed in the AFRL/HEDR laboratories with both rhesus monkeys and humans under Protocols NBR-2002-0010-A, "Eye aversion to 94 GHz radiation by non-human primates (*Macaca mulatta*)" and FWR-2002-0023-H, "Facial sensitivity and eye aversion response to millimeter waves", respectively.

Both video and IR images of the subjects' faces will be recorded before, during, and after each exposure. The IR images will show how much skin heating is required to evoke the aversion response.

10. **Data Analysis**:

A. Pain Threshold. As implemented here, the up-and-down (staircase) procedure (Cornsweet, 1962; Dixon, 1991; Simpson, 1989) produces two sequences of presentations that converge toward a power density at which the subject indicates that the sensation evoked met the criterion for pain 33% of the time. Since power density is varied in a stepwise fashion, the threshold is defined by linear interpolation between the two step values (one per staircase) that bracket

the "yes" response rate of 33%. Previous work (Blick et al., 1997; Dixon et al., 1983) has shown that over a series of trials as long as 32, the "yes" response rate increases monotonically with power density (except occasionally at the extremes of the distribution, where only one or a few presentations occurred). In most psychophysical experiments, threshold is typically defined as the indifference point; that is, the point at which the subject says "yes" and "no" equally often. While the present procedure yields a slightly lower threshold, this does not bias the comparison of thresholds between conditions, as subjects use the same criteria in all conditions. The present procedure does, however, substantially reduce both the total MMW exposure per subject and the number of times the subject is exposed to stimuli that cause pain, without a significant reduction in the reliability of the results. Our operational definition of the threshold in these experiments is an unbiased estimate of the power density at which a "yes" response (it was painful) is elicited from a given subject 33% of the time. Variation in this threshold among subjects under constant conditions is one of the questions of interest. The threshold (a constant perceptual effect in each subject) allows us to examine the effects of other variables (e.g., initial skin temperature, skin wetness, duration of stimulus, etc.). This experiment proposes to compare thresholds under several conditions (no alcohol vs. two levels of nonzero BAL). Pain thresholds for the subjects under each of the three conditions will be analyzed by a repeated-measures analysis of variance (ANOVA). IR thermographic data (collected before, during, and for several seconds after the exposures) will be analyzed to determine the skin temperature associated with the pain threshold. These data will also be analyzed by ANOVAs.

B. Pain Intolerability. IR thermographic data of the subjects' backs collected before, during, and for several seconds after the exposures will be used to assess to time at which pain intolerance was reached for each exposure as well as the skin temperature associated with that time point. ANOVAs will be used to determine if these measures differ across the three alcohol treatment conditions (no alcohol vs. two levels of nonzero BAL).

C. Eye Aversion Threshold. Video images obtained for each of a subject's trials will contain a time marker, allowing the latency of the aversion response to be determined. Aversion response latencies for each trial will be scored (using the scoring chart in Attachment C) by at least 5 individuals unaware of the subject exposure conditions. The probabilities of each response will be analyzed to produce a probit curve for each subject at each ethanol dose. The probit curve will show the probability of each type of aversion response (e.g., blinking, or head turning) as a function of power density. IR images will be analyzed to determine how much skin heating is required to evoke aversion responses.

11. **Safety Precautions:** For the back exposures (pain aversion and pain intolerability tests), the maximum power and duration of the transmitter output will be set at levels that cannot produce skin heating greater than 60 °C. For the short durations used in the present studies, this temperature exceeds the pain threshold, but does not exceed the threshold for tissue damage. In the case of facial exposures, the

maximum power and duration of the transmitter output will be set at levels that cannot produce skin temperatures greater than 40 °C. This level of skin heating will not reach the pain threshold, nor will it reach the threshold for skin or eye damage. Power density settings will be limited to maximum values only slightly above those required to produce the criterion perceptual effects (eye aversion, pain threshold, and slightly suprathreshold pain). Previous studies (e.g., Kenshalo, Anton, & Dubner, 1989; and work done in our laboratory) have shown that there is a substantial difference (either in power density or in duration of exposure) between such levels and the levels that cause damage to the skin. These provisions assure that no subject will be exposed to damaging levels of microwave irradiation. Microwaves at this frequency are completely absorbed in the skin or the most superficial portion of the cornea. The incident power density at the surface falls to $1/e^2$ (13.5%) at a depth of 0.4 mm. For the brief exposures contemplated, much of the heat deposited in the most superficial layers of the skin is re-radiated to the environment over the next 60 s. The blood that circulates in the skin carries the rest away. The fraction that is conducted to structures deeper than the skin or cornea is negligible. Thus, there is no risk of significant heating of any subcutaneous structures or organs with the exposures contemplated for these experiments. The total thermal load produced by the stimuli in a test session is readily dissipated by normal thermoregulatory mechanisms, so no increase in core temperature is to be expected. In the event of an unexpectedly intense exposure, subjects will be instructed that they can terminate the exposure by pushing a conveniently located safety switch, or by simply moving out of the beam.

12. **On-Site Monitoring**: The present studies do not require on-site monitoring. On-call medical personnel will be identified and available in the event of any untoward event occurring during the study or thereafter.

13. **Medical Risk Analysis**:

    A. General. Although exposures may exceed levels specified by the relevant safety standard (IEEE C95.1-1999; Institute of Electrical and Electronics Engineers, 1999), we have shown in previous work (under Protocol F-BR-1998-0026-H) that the sensory endpoints (pain threshold and slightly suprathreshold pain) occur well below exposure levels that produce any damaging effects. Separating exposures in time by adequate intervals insures that there is no carryover effect from exposure to exposure. Depth of penetration of non-ionizing radiation in this frequency range is very shallow; incident power densities fall to $1/e^2$ (13.5%) within 0.4 mm of the surface exposed. Since the effects on affected sensory receptors are also quite superficial, the microwaves are quite efficient in producing sensations at non-damaging levels of incident power.

    Ryan, D'Andrea, Jauchem, and Mason (2000) have recently reviewed the health and safety issues related to exposure to MMW radiation. They concluded that:

    1) Such exposures result in only superficial heating of the skin.

    2) Such heating is very unlikely to cause damage in conscious, mobile humans, as it is readily sensed and becomes sufficiently painful to motivate escape responses long before the skin is heated enough to cause burns.

3) Even repeated overexposure to MMWs cannot initiate or promote cancer. In the event of an overexposure to a power density sufficient to produce thermal injury, there is an extremely low probability that scars derived might later become cancerous. Proper wound management decreases this probability even further, as well as the probability of hypertrophic scarring or keloid formation.

4) Walters, Blick, Johnson, Adair, and Foster (2000) showed that skin heating associated with painful exposure to millimeter waves is consistent with a simple thermal model that takes into account the shallow penetration depth at these wavelengths.

These conclusions provide confidence that the proposed exposures will produce only superficial heating of the skin that is self-limiting at non-injurious levels. Thus, there is no danger to the subject, unless control systems on the equipment should fail. If such a failure were to happen, subjects and experimenters have ready access to separate kill-switches that will instantly terminate exposure. Further, subjects can also avoid damage from inadvertent overexposures simply by moving out of the beam.

Alcohol is a drug that can have toxic effects. It impairs perceptual, cognitive, and motor functioning (e.g., in the context of the proposed experimental procedures, alcohol consumption may increase the risk of loss of balance, falling, etc.). It is also a reinforcing agent that may cause changes in behavior, including repetitive or excessive consumption. Therefore, the consumption of alcohol in this study presents some risk to all volunteers.

B. Category of Study. This research study proposed is greater than minimal risk, both because subjects will be exposed to a central nervous system depressant (ethanol) and because they will be exposed to MMWs at levels that exceed the permissible exposure level (PEL).

C. Information for Briefing Subjects. See the attached Informed Consent Document (ICD) (Attachment A) and Instructions for Subjects (Attachments B-1, B-2, and B-3).

D. Risk Assessment.

1) Risks: The subjects will be exposed to MMWs at levels that exceed the PEL. These levels will produce pain, but will not damage the skin or cornea. They will also consume alcohol in quantities sufficient to produce intoxication — BALs that exceed the legal limit for vehicle operators by up to 50%. The subjects will be characterized as "moderate drinkers;" non-drinkers and heavy drinkers will be asked not to participate. Thus, it is expected that the alcohol exposures involved will fall within the previous, voluntary experiences of the subjects.

2) Benefits: The subjects (DoD military and civilian personnel, and contractors) will receive no direct benefit or compensation for participation. The benefit of the study to the DoD is that it allows determination of the extent to which applications of a non-lethal weapon might be modified in safety or efficacy,

given that targeted individuals are inebriated. Such information is critical to consideration involving both policy acceptability and concept of operations.

The benefit:risk ratio is judged to be appropriate.

14. **References:**

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15. **Attachments:**

A. Informed Consent Document.

B. Instructions for Subjects

1) Pain Threshold.

2) Pain Tolerance.

3) Facial Aversion.

C. Facial Aversion Scoring Sheet.

Attachment A

INFORMED CONSENT DOCUMENT
Building 1185
Brooks City-Base, TX 78235
Institutional Review Board Approval Dates: 19 January, 2005 - 18 January, 2006

PRIVACY ISSUES: Records of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C. 552a, and its implementing regulations. You have read the Privacy Act Statement contained in DD Form 2005. You understand that records of this study may be inspected by the U.S. Food and Drug Administration (FDA), the sponsoring agency, and/or their designee, if applicable

TITLE OF STUDY

Effects of Ethanol on Millimeter-Wave-Induced Pain

NAMES, DEPARTMENTS, PHONE NUMBERS FOR INVESTIGATORS

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MEDICAL MONITOR DUTIES

The medical monitor will appoint a medical observer to be available by telephone throughout the experiment. All technicians involved with the study will receive written instructions on the mechanism for responding to urgent and emergent medical conditions. These instructions will include information on the appropriate urgent medical disposition of subjects who are injured or become ill while participating in the research protocol while waiting for telephone response from the medical monitor. The medical monitor overseeing the protocol must be notified of any serious adverse event resulting from the research exposure within 12 hours. All illnesses or injuries occurring in subjects while participating in an experiment, but not causally related to the experiment must be brought to the attention of the medical monitor within 48 hours. The medical monitor will ensure that serious and unexpected events will be reported IAW AFI 40-402, 3.8.1, HEP OI 40-403, 4.2. (This description of the role and scope of the medical monitor conforms to AFI 40-402, 2.8.)

PURPOSE OF STUDY

You have been invited to participate in a research study at Brooks City-Base, sponsored by the Air Force Research Laboratory, Human Effects Directorate, Radio Frequency Radiation Branch, entitled "Effects of Ethanol on Millimeter-Wave-Induced Pain." The objective of this experiment is to measure how people react to millimeter waves that heat their skin to painful levels, and how alcohol intoxication affects the pain sensation. This study will enroll up to 32 subjects at least 21 years of age over a period of one year. You will be tested during a minimum of three visits to the testing site.

PROCEDURES

Prior to enrollment in the study, you will be asked to fill out a series of questionnaires covering your medical history and alcohol use. Volunteers who drink rarely or not at all, or who show a substantial potential for alcohol abuse, or who are recovering alcoholics, will not be allowed to participate. Volunteers who are identified as possible alcoholics will be urged to contact their primary care provider (who may recommend an appropriate treatment program). Volunteers using various over-the-counter or prescribed medications or who have certain medical conditions may be excluded from participation. Female volunteers who are pregnant will not be allowed to participate.

If you volunteer to participate in this study, you will be exposed to millimeter waves at intensities that may exceed the applicable safety standards set by the U.S. Government. The exposures will take place in a shielded room.

Volunteers will be assigned to one of two studies. Testing for each of the two studies will be done during three separate sessions, one session without alcohol and two with different levels of alcohol consumption.

STUDY 1: PAIN THRESHOLD AND FACIAL AVERSION EXPERIMENTS

The pain threshold procedure involves exposure of your back to millimeter waves in order to determine the threshold for pain induced by skin heating. Brief exposures (3 seconds in duration) will rapidly heat the skin on your back to near the point where sensations of intense warmth change to a brief pinprick of pain that disappears as soon as the millimeter wave heating stops. The area of the back being maximally heated during each exposure will be no greater than 4 cm^2. These exposures will be separated from one another by 15 to 20 seconds during which the location and intensity of the beam are changed. Some of these exposures will produce brief, painful sensations; the rest will only produce sensations of warmth or heat. To determine the pain threshold, you will be exposed to intensities that exceed the current safety standards. Video images (which may include your face) will be recorded before, during, and after each exposure.

Immediately following pain threshold testing, you will participate in the facial/eye aversion procedure. During this portion of the study your face will be exposed to millimeter waves over a series of brief exposures (each less than one second). Each exposure will result in reasonably uniform heating over the entire face. These exposures will be separated from one another by from 30 to 90 seconds. Some of these exposures will produce a brief, painful sensation which may cause you to blink/close your eyes and/or avert your face and eyes from the millimeter waves; the rest of the exposures will only produce sensations of warmth or heat. Video images of your face will be recorded before, during, and after each exposure.

STUDY 2: PAIN TOLERANCE EXPERIMENT

During this study you will be asked to participate in 4 pain tolerance trials. On each of the 4 trials, a different area on your back will be stimulated with millimeter waves that are intense enough to reach the pain threshold within a few seconds. We will ask you to remain in the beam for as long as you can stand the pain. The maximum possible duration of any exposure will be limited to an amount of time that will not cause skin damage. The area of the back being maximally heated during each exposure will be no greater than 14 cm^2. When you feel that you can no longer stand the pain, you can end the exposure by moving out of the beam — to the left or right. We expect that the intensity of the pain will force you to move before your skin gets hot enough to be damaged. We will limit the duration of the exposure to prevent damage to your

skin, even if you have an exceptionally high pain tolerance. Video images (which may include your face) will be recorded before, during, and after each exposure.

ALCOHOL CONSUMPTION AND BLOOD ALCOHOL LEVEL

For testing sessions involving alcohol, you will be asked to come to the laboratory in the morning (approximately 0730 to 0830). Because you will be transported home at the conclusion of testing via taxi cab (which we will pay for), you should try and arrange for an alternate method of transportation to the laboratory (e.g., riding with a co-worker or spouse). If an alternate means of transportation to the laboratory is not available to you, we will arrange for you to be transported by taxi cab (which we will pay for). Refrain from consuming alcohol for 24 hours prior to testing. Refrain from eating breakfast on the day of testing. This is necessary because variations in stomach contents can greatly affect the rate of alcohol absorption, and thus the final blood alcohol level reached. We will be trying to reach two specific blood alcohol levels (0.08% and 0.12%), which in most people correspond to (a) "tipsy" or "high," and (b) "drunk," respectively. A blood alcohol level of 0.08% is the "legal limit" for operating a motor vehicle in the state of Texas — driving a motor vehicle at this level or higher is legally defined as driving while intoxicated. The alcohol you consume (Vodka) will be mixed with orange juice, and presented to you in one or more 12-ounce cups. You will be asked to consume the contents over a 15-minute period, as steadily and evenly as possible. After you finish drinking, we will measure your blood alcohol periodically using a breathalyzer. When your blood alcohol level reaches the target level (0.08% or 0.12%), we will begin testing, which should take approximately 25-40 minutes.

After testing is completed, you will take another breathalyzer test and you will be allowed rest, recover, and receive meals (which we can provide) in a room located in the building complex in which the study takes place. The room will include a couch, table, television monitor and CD/DVD player. We will continue periodic breathalyzer testing until your blood alcohol level is low enough (i.e., 0.04% or less) to permit normal activities (**NOT** to include driving motor vehicles or operating heavy/dangerous equipment), and the experimenters see that your observable behavior appears sufficiently normal, at which time you will be provided a cab ride to your home residence. Even though you will be under the legal intoxication limit, after you leave the laboratory, you should wait at least 2 hours before driving a vehicle or operating heavy/dangerous equipment. By that time your blood alcohol level will be well below 0.05%, but you should exercise appropriate caution until you feel that you have returned to a completely normal, sober condition. While waiting in the laboratory for your alcohol level to reach 0.04%, you will be able to read, listen to music, watch videos, eat, or take a nap. Depending on your metabolism of alcohol, you might have to remain in the laboratory for up to 2.5 hours after your BAL reaches the lower alcohol dose (0.08%), and up to 4.5 hours after it reaches the higher dose (0.12%). Once your BAL reaches 0.04% or lower, you will be transported home by taxi cab (which we will pay for). You should not to operate automobiles or other heavy equipment for at least 2 hours following your departure from the laboratory.

You are free to discontinue participation at any time. However, if you do so after consuming alcohol, you will be asked to remain in the laboratory until your blood alcohol level declines to a safe level.

RISKS/INCONVENIENCES

Participation involves a risk of skin reddening. The affected area might remain slightly tender and red for several minutes after exposure. If the skin remains tender or reddened more than two hours after exposure, this should be reported to the experimenter, and examined by the medical staff. In rare instances skin reddening may last for as long as 24 hr. If the skin is red

and/or tender after 24 hrs, this should be reported to the investigator, who will arrange for the medical monitor to examine the area and apply any appropriate treatment. Many scientific studies have looked for possible detrimental effects (for example, cancer, damage to the cornea or lens of the eye, birth defects) of exposure to non-ionizing radiation (which includes millimeter waves). Except for their heating effects, there are no known effects (detrimental or beneficial) of exposure to millimeter wave radiation. It is extremely unlikely that brief heating of the skin to painful but non-damaging temperatures will have any short- or long-term deleterious effects.

Alcohol is a drug that can have toxic effects. In the short term it can impair perceptual, cognitive, and motor functions (e.g., in the context of the proposed experimental procedures, alcohol consumption may increase the risk of loss of balance, falling, etc.). It is also a reinforcing agent that may cause changes in behavior, including repetitive or excessive consumption. Therefore, the consumption of alcohol in this study presents some risk to all volunteers. You are completely free to decline participation, or to terminate your voluntary participation at any time.

The millimeter waves involved in these experiments **DO NOT** affect cardiac pacemakers.

BENEFITS

You will receive no direct benefit or payment for your participation in this study. These data may help in the understanding of the responses of humans to millimeter waves.

ALTERNATIVES

Choosing not to participate is an alternative to volunteering for this study.

EVENT OF INJURY

Federal laws and regulations govern your entitlement to medical care and/or compensation in the event of injury. If you have questions about your rights or if you believe you have received a research-related injury, you may contact Mr. Frank Herrera (311 MDS/SGST) at the Brooks Medical Clinic (Building 615, Brooks City-Base, 210-536-3849), the medical monitor, LtCol Michelle Bryce, DO (Building 1162, Brooks City-Base, 210-536-4007), or the investigator, Michael Cook (Building 1162, Brooks City-Base, 210-536-3059).

Should you be injured as a direct result of participating in this study, you will be provided medical care for that injury at no cost. You will not receive any compensation (payment) for injury. This is not a waiver or release of your rights. Medical care is limited to the care normally allowed for Department of Defense health care beneficiaries (patients eligible for care at military hospitals and clinics). For civilian employees and contract civilian personnel, medical care is limited to treatment within Air Force medical treatment facilities. Necessary medical care does not include in-home care or nursing home care. If you have any questions, you may contact Mr. Frank Herrera (311 MDS/SGST) at the Brooks Medical Clinic (Building 615, Brooks City-Base, 210-536-2087), the medical monitor, LtCol Michelle Bryce, DO (Building 1162, Brooks City-Base, 210-536-4007, Michelle.Bryce@brooks.af.mil), or the investigator, Michael Cook (Building 1162, Brooks City-Base, 210-536-3059, Michael.Cook@brooks.af.mil). In case of any medical incident, you will be transported to the Brooks City-Base Clinic for care, unless personnel on site judge it to be an emergency, in which case they will call an ambulance service.

OCCURRENCE OF UNANTICIPATED ADVERSE EVENT

If an unanticipated event occurs during your participation in this study, you will be informed immediately. If you are not competent at the time to understand the nature of the event, such information will be brought to the attention of your next of kin.

CONFIDENTIALITY

To maintain your anonymity, when the results of the research are published or discussed in conferences, only subject numbers will used to identify medical, psychological, or other documentation. Video images (which may include your face) may also be published or presented during conferences, but your name will not be associated with these images. Complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities. The alcohol use questionnaire will be used only for screening; records of the results will not be kept.

DECISION TO PARTICIPATE

The decision to participate in this research is completely voluntary on your part. No one has coerced or intimidated you into participating in this program. You are participating because you want to. You know that refusal to participate will involve no penalty or loss of benefits to which you are entitled, and that you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. One of the investigators (Stephanie Miller, 210-536-3881; Michael Cook, Ph.D., 210-536-3059; John M. Ziriax, Ph.D., 210-536-6530; Kristie Pointer, 210-536-4082; or Leland Johnson, 210-536-2243) has adequately answered any and all questions you have about this study, your participation, and the procedures involved. You understand that one or more of these investigators will be available to answer any questions concerning procedures throughout this study. If significant new findings develop during the course of this research that may relate to your decision to continue participating, you will be informed. You may withdraw this consent at any time and discontinue further participation in this study without prejudice to your entitlements. The investigators may terminate your participation at any time, and the medical monitor for the study (or designated medical observer) may terminate your participation if she feels this to be in your best interest.

An experimenter will go over written instructions with you prior to the beginning of each type of testing.

I have read all of the above. My questions have been answered concerning areas I did not understand. I am willing to take part in this study. After I sign this form, I will receive a copy.

Volunteer Full Name (Print)	SSN (optional)	Telephone Number

Volunteer Signature	Date

Investigator Signature	Date
Witness Signature (not involved)	Date
Next of Kin (Print)	Telephone Number

Attachment B-1

Instructions for Subjects – Pain Threshold

This experiment involves exposure to stimuli that will heat your skin. We will measure skin temperature before, during, and after each exposure, so we would like you to sit as still as possible during and for a few seconds after each one. Of course, if the pain gets too intense, you are free to move out of the beam at any time. We'll tell you 1 to 2 seconds before each one comes on, and we'll tell you when we stop collecting data, so you can relax and move around. At the end of some exposures, your skin will get hot enough that you will feel a brief pain that feels like a pin-prick. The pain will go away as soon as the stimulus is turned off. We want you to pay very close attention to the sensations in your skin as these stimuli are presented. After each one, we want you to tell us whether or not you felt the sharp, pin-prick sensation of pain. Sometimes this judgment is difficult, but if you are not certain that you felt it, you should say "no." You should say "yes" only if you definitely felt the pain. We have set it up so that you should only feel pain about 1 trial out of 3, so you won't have to deal with a lot of pain. However, we need to be sure that when you say you felt the pain, you really did, **NOT** that you thought you might have (or would have if the stimulus lasted even a little bit longer). The order of stimuli is random, so there can be long strings of exposures (perhaps 4 to 8) that don't cause pain, and sometimes there might be 2 or 3 in a row that do. So, you shouldn't base judgments on what happened in the last few trials, but only on what this particular exposure feels like. It should be noted that pain anywhere in the body will influence the pain threshold on your skin, so you should not participate if you are in any pain (e.g., sunburn, sore muscles, etc.) except for that produced by the experimental exposures.

You should **NOT** be afraid of the exposures. The most that might happen is that you could reach threshold a little bit before the end of the stimulus, so it might feel just a little more intense than the threshold pin-prick. Even if this happens, there is no chance that your skin will be damaged. In the extremely unlikely event that the equipment should malfunction and present you with a stimulus that feels wrong to you (for example, too hot, too fast), then you can shut the stimulus off by using your kill-switch, or avoid the pain it causes by moving out of the way — whichever method is easiest for you.

Any questions?

Attachment B-2

Instructions for Subjects – Pain Tolerance

This experiment involves exposure to stimuli that will heat the skin on your back to painful levels. We'll tell you 2 to 3 seconds before each exposure begins. We will measure skin temperature before and during the exposure, so we would like for you to sit as still as possible until the pain forces you to terminate the exposure. You may terminate the exposure either by moving to your left or right out of the beam or by using the kill switch. Many subjects, in fact, terminate the stimulus, either because of involuntary reflex withdrawal, or because they find the pain so intolerable that they want to reduce it. If you do not tolerate the full exposure, we will measure how long you are able to remain still, and how hot your skin becomes before you move. After you move, or when the microwaves are turned off, you may experience burning pain that lingers for a few seconds or minutes. The exposed area may also be reddened and feel tender for up to two hours. If the skin remains tender or reddened more than two hours after exposure, this should be reported to the experimenter, and examined by the medical staff. In rare instances skin reddening may last for as long as 24 hr. If the skin is red and/or tender after 24 hrs, this should be reported to the investigator, who will arrange for the medical monitor to examine the area and apply any appropriate treatment. In any case, there is no reason to expect any aftereffects more serious than a mild sunburn. In contrast to a sunburn, which entails some long-term risk from the aftereffects of ultraviolet radiation, microwaves have no known long-term effects.

You should **NOT** be afraid of the exposure. The most that might happen is that you could be forced to escape the microwaves because the pain becomes too intense. The minimal skin damage that may occur (reddening, tenderness) should not last more than a few minutes to a few hours.

Any questions?

Attachment B-3

Instructions for Subjects – Facial Aversion

In this experiment, we are going to expose your face and eyes to short bursts of millimeter waves that will cause superficial heating. In these tests, the intensity will only be enough to cause sensations of warmth. As the intensity increases, a reflex that protects your eyes from damage will occur. This reflex, eye aversion, involves closing the eyes, turning the head, and possibly shielding the eyes with your hand. The purpose of these tests is to determine the threshold intensity that evokes this reflex and how long it takes for the reflex to occur. During some (but not all) of the eye aversion trials, your face will be exposed to millimeter waves, which may or may not be intense enough to cause an aversion response.

You should **NOT** be afraid of the exposures. Essentially all of the energy is absorbed in the first 64th of an inch of tissue, so there is no danger of damage to structures deeper than the surface of the skin or eye, even if the intensity or duration of the exposures were much greater than the ones that you will be exposed to. Although your cornea (i.e., the front surface of your eye) might get a little warmer than normal, the aversion reflex will occur long before the temperature gets to levels that could possibly cause damage. This has been verified in rhesus monkeys, which have a visual system that is (except for size) identical to the human visual system.

Any questions?

Attachment C

Facial Aversion Scoring Sheet

A. Face/Head Movements

0 = no change
1 = change in normal expression
2 = head movement

B. Eye Blink

0 = no blink
1 = one eye blink
2 = multiple eye blinks
3 = closed eyes/squint

Attachment D

Protocol # F-BR-2004-0074-H: Effects of Ethanol on Millimeter-Wave-Induced Pain
Medical Documentation Form

Subject #: _____ Date/time: _____

Pre-Exposure History

Circle if any apply. Otherwise circle history non-contributory.

1. Absolute DQ if: pregnant or diabetic.
2. May require DQ, must check with medical monitor (or alternate) if:

   Skin condition: ongoing disease, history of skin cancer, grafts, thick scars (Keloids), photosensitivity.

   Eye condition: Current eye complaints, medications, eye surgery, contact lens use.

   Other chronic medical problems: cancer, neuropathy, uncontrolled high blood pressure, stroke, heart problems, on heart medications.
3. Current medications: Use of analgesics, antipyretics, narcotics, high blood pressure medications, anxiolytics or tricyclic anti-depressants and anticoagulants may cause a subject to be excluded.
4. Are you a recovering alcoholic? Yes No (Recovering alcoholics must be excluded.)
5. See AUDIT form for potential alcohol abuse problems.

   Score: _____ (Participation requires a score of 2-7.)
6. Have you used alcohol, OTC analgesics, antipyretics, sleep aids, during the last 24 hours?

   Yes No

Pre-Exposure Exam

1. Skin condition: circle if they apply.

   color: redness, sunburned

   moisture: dry, sweating, oily

   texture: rough, smooth, crusty areas, other:

   lesions: macules, papules, vessicles, other:

   scars:
2. Eye: circle if they apply.

   lids: wnl, redness, lesions

   conjunctiva: wnl, injected
3. Weight (kg): _____

4. Alcohol dosage: _____ End time of consumption: _____

5. BAL: _____ Time (15 min after above): _____

Peak BAL: _____ Time: _____

Exposures

Pain Threshold

Exposure 1: Any complaints/concerns? Y/N If none, no exam required.
Exposure 2: Any complaints/concerns? Y/N If none, no exam required.
Exposure 3: Any complaints/concerns? Y/N If none, no exam required.
Exposure 4: Any complaints/concerns? Y/N If none, no exam required.
Exposure 5: Any complaints/concerns? Y/N If none, no exam required.
Exposure 6: Any complaints/concerns? Y/N If none, no exam required.
Exposure 7: Any complaints/concerns? Y/N If none, no exam required.
Exposure 8: Any complaints/concerns? Y/N If none, no exam required.
Exposure 9: Any complaints/concerns? Y/N If none, no exam required.
Exposure 10: Any complaints/concerns? Y/N If none, no exam required.
Exposure 11: Any complaints/concerns? Y/N If none, no exam required.
Exposure 12: Any complaints/concerns? Y/N If none, no exam required.
Exposure 13: Any complaints/concerns? Y/N If none, no exam required.
Exposure 14: Any complaints/concerns? Y/N If none, no exam required.
Exposure 15: Any complaints/concerns? Y/N If none, no exam required.
Exposure 16: Any complaints/concerns? Y/N If none, no exam required.
Exposure 17: Any complaints/concerns? Y/N If none, no exam required.
Exposure 18: Any complaints/concerns? Y/N If none, no exam required.
Exposure 19: Any complaints/concerns? Y/N If none, no exam required.
Exposure 20: Any complaints/concerns? Y/N If none, no exam required.
Exposure 21: Any complaints/concerns? Y/N If none, no exam required.
Exposure 22: Any complaints/concerns? Y/N If none, no exam required.
Exposure 23: Any complaints/concerns? Y/N If none, no exam required.
Exposure 24: Any complaints/concerns? Y/N If none, no exam required.
Exposure 25: Any complaints/concerns? Y/N If none, no exam required.
Exposure 26: Any complaints/concerns? Y/N If none, no exam required.
Exposure 27: Any complaints/concerns? Y/N If none, no exam required.
Exposure 28: Any complaints/concerns? Y/N If none, no exam required.
Exposure 29: Any complaints/concerns? Y/N If none, no exam required.
Exposure 30: Any complaints/concerns? Y/N If none, no exam required.
Exposure 31: Any complaints/concerns? Y/N If none, no exam required.
Exposure 32: Any complaints/concerns? Y/N If none, no exam required.

Pain Intolerability

Exposure 1: Any complaints/concerns? Y/N If none, no exam required.
Exposure 2: Any complaints/concerns? Y/N If none, no exam required.
Exposure 3: Any complaints/concerns? Y/N If none, no exam required.
Exposure 4: Any complaints/concerns? Y/N If none, no exam required.

Eye/Facial Aversion

Exposure 1: Any complaints/concerns? Y/N If none, no exam required.
Exposure 2: Any complaints/concerns? Y/N If none, no exam required.
Exposure 3: Any complaints/concerns? Y/N If none, no exam required.

Exposure 4: Any complaints/concerns? Y/N If none, no exam required.
Exposure 5: Any complaints/concerns? Y/N If none, no exam required.
Exposure 6: Any complaints/concerns? Y/N If none, no exam required.
Exposure 7: Any complaints/concerns? Y/N If none, no exam required.
Exposure 8: Any complaints/concerns? Y/N If none, no exam required.
Exposure 9: Any complaints/concerns? Y/N If none, no exam required.
Exposure 10: Any complaints/concerns? Y/N If none, no exam required.
Exposure 11: Any complaints/concerns? Y/N If none, no exam required.
Exposure 12: Any complaints/concerns? Y/N If none, no exam required.
Exposure 13: Any complaints/concerns? Y/N If none, no exam required.
Exposure 14: Any complaints/concerns? Y/N If none, no exam required.
Exposure 15: Any complaints/concerns? Y/N If none, no exam required.
Exposure 16: Any complaints/concerns? Y/N If none, no exam required.
Exposure 17: Any complaints/concerns? Y/N If none, no exam required.
Exposure 18: Any complaints/concerns? Y/N If none, no exam required.
Exposure 19: Any complaints/concerns? Y/N If none, no exam required.
Exposure 20: Any complaints/concerns? Y/N If none, no exam required.

Final Post-Exposure History

Date/time: _____

1. Concerns or complaints: none, other:

Final Post-Exposure Exam

Circle if any apply. Otherwise circle normal exam.

1. Skin: redness, blisters, rash, sweating, other:
2. Eye lids (for eye aversion study): normal, redness, other:
3. Conjunctiva (for eye aversion study): normal, injected, other:
4. BAL (must be 0.04% or less): _____ Time: _____

SUBJECT REQUIRED TO REPORT TO MEDICAL MONITOR AND PRINCIPAL INVESTIGATOR PER PROTOCOL SPECIFIC: "Skin tender or reddened for more than 24 hours."

Mbryce/mb/AFRL/HED/22 September 2004