1. Protocol # F-WR-2002-0024-H: **Effects of Ethanol on Millimeter-Wave-Induced Pain**
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Contractor and Facility: Veridian Engineering, an Operation of Veridian.

5. **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 among which many of the participants will have consumed substantial alcohol prior to exposure. If alcohol affects the pain threshold or the aversion (intolerability) threshold, both the effectiveness and the safety margin of the weapon could be affected. We propose to measure ethanol-induced changes in both the pain threshold and the aversiveness of suprathreshold pain to ascertain whether such effects are likely.
6. **Background and Relevance:**

   a) Data Required. The Air Force is developing a non-lethal microwave weapon 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 or groups to retreat. We (AFRL/HEDR) have conducted extensive research on the bioeffects of millimeter waves, both in animals and humans. We have demonstrated that the desired behavioral effect (prompt and highly motivated escape behavior, the GOODBYE effect) is readily produced at levels well below those that produce burns in animals. Studies with conventional heating of human skin (e.g., Moritz and Henriques, 1947) assure us that there is a substantial safety margin between effective levels and damaging ones.

   Our previous research has shown that the pain threshold varies relatively little from subject to subject, and that the tolerability of suprathreshoid pain varies much more among individuals than the pain threshold. The point of intolerability is a complex function of pain intensity, duration, 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 weapon would be effective against essentially all individuals, while producing substantial damage in few or no cases, it is necessary to determine the average point of pain intolerability, the extent of variation among individuals, and the extent to which a mild ethanol intoxication might change pain tolerance. Studies of the pain threshold for IR-induced heating (Wolff, Hardy & Goodell, 1942) suggest that the pain threshold is elevated by 40 to 45% by ethanol; this needs to be verified for MMW. Wolff et al. also showed that ethanol elevated the threshold for an "alarm reaction," a sudden change in skin resistance, by as much as 80%. To the extent that this change reflects a change in the perceived intensity or unpleasantness of the skin heating, it might indicate a substantial reduction in the effectiveness of the ADS in intoxicated subjects.

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

1) Will this non-lethal weapon produce the desired GOODBYE effect in inebriated targets without the safety margin between effectiveness and thermal damage to the targets being unacceptably reduced? and
2) Does the state of the subject (drugged or non-drugged) have to be taken into account in generating operational scenarios?

The answers to these questions are critical to both 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 003-95, Nonlethal/Limited Effects Weapon Capability, dated 22 July 96; MNS LOG 1.85, dated 20 FEB 96, which stated requirements for improved capabilities in Military Operations Other Than War (MOOTW); 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 (ADT) Capability dated 25 OCT 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: Microwave technicians assigned to AFRL/HEDR will provide transmitter control, calibration/characterization, and maintenance. A new transmitter that is located in our laboratories at Brooks AFB, TX will be used for millimeter wave exposures.

B) Subjects: Ten adult male volunteer subjects at least 21 years old will be recruited from among the military personnel, DoD civilians, and contractor personnel working in AFRL/HEDR who are familiar with microwave bioeffects research. Subjects will be screened for potential alcohol abuse problems, using the Alcohol

Use Disorders Identification Test (AUDIT). Volunteers with low total scores (2-7) will be accepted automatically. A score lower than 2 probably indicates a non-drinker who should be discouraged from participating. Volunteers with scores greater than 18 will be rejected because of likely alcohol dependence. Volunteers with intermediate scores (8-18) will be evaluated by a medical provider from the 311th Medical Squadron, who will decide whether they will be allowed to participate. The medical provider or the Medical Monitor will attempt to get any potential subjects who are identified as probable alcoholics into an appropriate treatment program. All potential subjects will be asked if they are recovering alcoholics. Recovering alcoholics will be excluded from participating, as will privileged medical providers and security personnel.

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:

1) *Experimental Procedures:*

a) **Alcohol administration and measurement**. In order to minimize variation associated with stomach contents, subjects will be asked to report to the laboratory in the morning (0800 or 0900) without having breakfast. A meal will be provided immediately after testing. Each subject will be presented with 24 oz. of liquid on each alcohol-testing occasion. The subjects will be coached to sip the drink as evenly as possible over a timed, 15-minute consumption period. Total ethanol in the vehicle (water or non-caffeine or decaffeinated diet soda, depending on subjects' preferences) will be determined from a nomogram (e.g., http://www.insure.com/auto/baccalc.html or http://www.nd.edu/~aldrug/BACestimates.html), based on target blood alcohol level (BAL -- 0.08% or 0.12%) and gender and weight of the subject. Subjects will be asked to consume the entire dose within 15 minutes of its presentation; post-consumption timing will begin on completion of ingestion. Intoxilyzer tests will be administered 15 minutes post-exposure, and at 5-min intervals thereafter until peak BAL is attained. Once the target level is attained, threshold or pain scaling trials will begin immediately. Testing should be completed within 15-20 minutes, at which time an Intoxilyzer test will be administered to determine whether the BAL is still within tolerance (± 0.01%) of the target level. If not, the test will be repeated on another day. The subject will be given a meal, and asked to remain in the laboratory until his BAL falls below 0.04% and the experimenters determine that his observable behavior has attained sufficient normalcy, at which time he may return to his work station. While waiting for BAL to fall to safe and legal levels, subjects will be offered refreshments (coffee or sodas, snacks) and a choice of magazines, radio, CDs, or videos to help alleviate boredom. When leaving the laboratory, subjects will be cautioned not to operate automobiles or other heavy equipment for at least 2 hours. If a subject needs to leave the immediate

area around the laboratory (to go home or to a distant workplace), an experimenter will transport him to the destination.

b) **Pain Threshold.** For these experiments, a dielectric lens will be used to focus the transmitter output on a small area of the back. Between exposures, the beam will be redirected so that a previously unexposed area will be exposed on the next trial. A 32-position matrix on the subject's back (4 left-to-right by 8 top-to-bottom) will allow determination of threshold during a single 32-trial session in which no skin area is tested more than once. 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). 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 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 his sensation for that trial met the criterion for the threshold. Subjects will be in contact with experimenters continuously via intercom, and will be observed from the front by a video camera, and from the back with a calibrated infrared camera that allows precise determination of skin surface temperature (IR thermography) before, during, and after the exposure. Subjects will be warned via intercom 1-2 s before the onset of each exposure. They will be asked to hold their position as steadily as possible for the duration of the exposure, and for 3 s thereafter. For testing on the back, intertrial intervals will be about 15 s (required to reposition the beam and record the IR data). Power density for each trial is controlled as follows: the investigator determines the maximum power density to be used during the series, and selects a transmitter power output setting that will achieve this. For each trial, the target power density is determined by the staircase procedure, i.e., the investigator selects an initial value (targeted for slightly below the pain threshold), and subsequent values vary up and down by steps of a predetermined size (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 subject). Previous experience measuring a variety of thresholds has shown that such a step size 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. Such a step size (50 mW/cm^2 works well for 3-sec pain thresholds) typically traverses a range from nearly 0% "yes" to nearly 100% "yes" responses in 4-6 steps for each individual 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. The value for a given trial steps up or down from the previous trial depending on the subject's response: on a given staircase, if the subject says "yes" the power is stepped down; if 2 consecutive "no" responses occur, the power is stepped up. Two

staircases are operating simultaneously, and the staircase that determines the value for a given trial is selected randomly (thus "double random staircase"). The target value is entered into a computer program that controls the output of the transmitter. The transmitter operators can instantly abort transmitter output if anything unexpected occurs. IR thermographic data are collected at a sampling rate of 60 frames/sec; samples will be taken before the onset of stimulation, at and during stimulation, at the offset, and for several seconds thereafter, to assess cooling rates after varying exposures.

c) **Pain Intolerability.** In order to measure the effects of ethanol on pain tolerability directly, 4 tolerability trials will be conducted at the end of each pain threshold test session. Two trials will be conducted with the small exposure area used for threshold testing, and two trials will use the larger area to be used in the scaling experiment. Four different areas (high, low, left, and right) on the back will be tested.

d) **Scaling Of Pain Intensity and Unpleasantness.** This experiment will use standard sensory scaling techniques (magnitude estimation) to determine whether stimulus area affects the qualities (intensity and unpleasantness) of suprathreshold pain, and whether the ingestion of ethanol influences the perception of suprathreshold pain. Painful stimuli (2 areas X 5 intensities) will be delivered by the millimeter wave transmitter, using a dielectric lens to produce the small area, and direct exposure to produce the larger area. The 3 levels of ethanol (0, 0.08, and 0.12% BAL) will be tested in 3 separate sessions for each subject. Each of the 6 possible orders of the 3 levels will be tested in one subject, with orders assigned randomly to subjects. The 2 levels of exposure area will be combined factorially with the 5 levels of intensity (0.3 to 1.5 dB above pain threshold, in 0.3 dB steps) to yield 10 distinct conditions, which will be tested twice (in random order) in 3 20-trial sessions (one for each alcohol level). After each exposure, the subject will be asked to provide 2 numbers; the first will represent the unpleasantness of the pain, the second will represent the intensity of the pain sensation. Subjects are allowed to use any range of numbers they choose. They are instructed that the numbers should relate to the stimuli and each other as follows: if a given stimulus feels twice as unpleasant (or intense) as another, the number given should be twice as great; if it was half as unpleasant (or intense), the number should be half as large, and so forth. With a little practice, subjects give very regular magnitude estimates for a variety of intensitive sensory continua (e.g., loudness, brightness, heaviness, warmth, cold, and pain). Each test session will begin with 2 practice trials. The practice stimuli will consist of a small area millimeter wave stimulus at or near the bottom of the intensity range, and a stimulus with the larger area at or near the top of the intensity range.

2) *Data Analysis*:

Pain Threshold. As it is used here, the up-and-down (staircase) procedure

(Dixon, 1991; Cornsweet, 1962) produces 2 sequences of presentations that converge toward a power density at which the subject indicates that the sensation evoked met the criterion for pain 1/3 of the time. Since power density increases in stepwise fashion, the threshold is defined by linear interpolation between the two step values (from the combined staircases) that bracket the "yes" response rate of 33%. Previous work (Blick et al., 1997; Dixon & Massey, 1983) has shown that (over trial series as long as 32), "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, i.e., the point at which the subject says "yes" and "no" equally often. While our procedure yields a slightly lower threshold, this does not bias the comparison of thresholds between conditions, as the same subjects use the same criteria in all conditions. Our procedure does, however, substantially reduce both the total microwave 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, for each subject, is an unbiased estimate of the power density at which he says "yes" (it was painful) 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) does allow 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. 2 levels of BAL). Pain thresholds for the 10 subjects under each of the 3 conditions will be entered into a repeated-measure analysis of variance (ANOVA). IR thermographic data will be analyzed to determine the peak skin temperature and mean skin temperature associated with the pain threshold. These data will also be entered into ANOVAs.

Scaling Data. For each of the 10 stimulus conditions, a geometric mean of the magnitude estimations of intensity and unpleasantness of the pain will be calculated at each BAL for each subject. These geometric means will be plotted in log-log coordinates against power density. Linear regression will be used to estimate the slopes of the 6 functions for each subject (i.e., the exponent of the power function relating the magnitude of the sensation to the magnitude of the stimulus). Examination of these data will indicate the extent to which the ingestion of ethanol influences the intensity and/or unpleasantness of suprathreshold thermal pain. The derived measures of slope for perceived intensity and perceived unpleasantness will be entered into repeated-measures analyses of variance (ANOVA), with BAL, stimulus area, and stimulus intensity as within-subjects variables.

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 within the trial duration. For short durations, this temperature exceeds the pain threshold, but does not exceed the threshold for tissue damage. Subjects will also be instructed that they should move out of the beam if the stimulus has

unexpectedly high intensity. Power density settings will be limited to maximum values only slightly above those required to produce the criterion perceptual effects (pain threshold and slightly suprathreshold pain). Previous studies (e.g., Kenshalo et al., 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 levels that can damage 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. 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 carries the rest away. 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. 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 can terminate the exposure by pushing a conveniently located safety switch, or by simple moving out of the beam.

4) On-site monitoring. These pain threshold and scaling experiments do not require on-site monitoring. However, on-call medical personnel will be identified and available in the event of any untoward event.

10. **Medical Risk Analysis:**

A) General: Although exposures may exceed levels specified by the relevant safety standard (IEEE C95.1, 1999) by as much as 20-fold, 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 affected sensory receptors are also quite superficial, the microwaves are quite efficient in producing sensations at non-damaging levels of incident power. Ryan et al. (2000) have recently reviewed the health and safety issues related to exposure to millimeter wavelength radiofrequency radiation. 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) Even repeated overexposure to millimeter waves cannot initiate or promote cancer.

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 decreases this probability even further, as well as the probability of hypertrophic scarring or keloid formation.

Walters et al. (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 results (Walters et al., 2000) and conclusions (Ryan et al., 2000) give us confidence that the proposed exposures will only produce 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, experimenters have ready access to a kill-switch that will instantly terminate exposure. Subjects can avoid damage from inadvertent overexposures simply by moving out of the beam. They will also have ready access to a safety switch that they can push to terminate exposure. Alcohol is a drug that can have toxic effects. 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 is Greater than Minimal Risk, both because subjects will be exposed to a CNS depressant (ethanol) and because they will be exposed to millimeter-waves (MMW) at levels that exceed the PEL.

C) Information for briefing subjects: See attached Informed Consent Documents (ICDs) and Instructions for Subjects.

D) Risk Assessment:

Risks: The subjects will be exposed to MMW at levels that exceed the PEL. These levels will produce pain, but will not damage the skin. They will also consume alcohol in quantities sufficient to produce intoxication – blood alcohol levels that exceed the legal limit for vehicle operators by 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, experience of the subjects.

Benefits: The subjects (DoD military and civilian personnel and contractors) will receive no direct benefit or compensation for participation. The benefit to the DoD of the study is to determine 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 both CONOPS and policy acceptability considerations.

The benefit:risk ratio is judged to be appropriate.

11. **References:**

Blick, D.W., Adair, E.R., Hurt, W.D., Sherry, C.J., Walters, T.J., & Merritt, J.H. (1997). Thresholds of microwave-evoked warmth sensations in human skin. *Bioelectromagnetics, 18,* 403-409.

Cornsweet, T.N. (1962). The staircase-method in psychophysics. *American Journal of Psychology, 75,* 485-491.

Dixon, W.J. (1991). Staircase bioassay: The up-and-down method. *Neuroscience and Biobehavioral Reviews, 15,* 47-50.

Dixon, W.J., & Massey, F.J., Jr. (1983). Sensitivity Experiments. In W.J. Dixon & F.J. Massey, Jr. (Eds.), *Introduction to Statistical Analysis.* (pp. 426-441). New York: McGraw-Hill.

Kenshalo, D.R., Anton, F., & Dubner, R. (1989). The detection and perceived intensity of noxious thermal stimuli in monkey and in human. *Journal of Neurophysiology, 62,* 429-436.

Moritz, A. R., & Henriques, F. C., Jr. Studies of thermal injury. II. The relative importance of time and surface temperature in the causation of cutaneous burns. Am. J. Path. 23:695-720; 1947.

Ryan, K. L., J. A. D'Andrea, J. R. Jauchem, & P. A. Mason (2000). Radio frequency radiation of millimeter wavelength: Potential occupational safety issues relating to surface heating. *Health Physics 78(2)*, 170-181.

Walters, T. J., D. W. Blick, L. R. Johnson, E. R. Adair, & K. R. Foster (2000). Heating and pain sensation produced in human skin by millimeter waves: Comparison to a simple thermal model. *Health Physics 78(3)*, 259-267.

Wolff, H. G., J. D. Hardy, & H. Goodell (1942). Studies on pain: Measurement of the effect of ethyl alcohol on the pain threshold and on the "alarm" reaction. *J. Pharmacol. Exper. Ther.* **75:** 38-49

12. **Attachments:**

A. Informed Consent Document.

B. Instructions for Subjects (3).

INFORMED CONSENT DOCUMENT

Effects of Ethanol on Millimeter-Wave-Induced Pain

Building 1185
Brooks AFB, TX 78235

Institutional Review Board Approval Dates: 19 June 2003 – 18 June 2004

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. I have read the Privacy Act Statement contained in DD Form 2005. I understand that the sponsoring agency and/or their designee may inspect records of this study.

TITLE OF STUDY

Effects of Ethanol on Millimeter-Wave-Induced Pain

INVESTIGATORS' NAMES, DEPARTMENTS, PHONE NUMBERS

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PURPOSE OF STUDY

You have been invited to participate in a research study at Brooks AFB, sponsored by the Air Force Research Laboratory, Human Effects Directorate, Radiofrequency 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 10 male subjects between the ages of 21 and 80, over a period of six to nine months. You will be tested in 6 visits to the testing site, some lasting up to 90 minutes.

PROCEDURES

Prior to enrollment in the study, you will be asked if you are a recovering alcoholic, and you will be asked to fill out a questionnaire related to your alcohol use. Volunteers who do not drink at all, or who show a substantial potential for alcohol abuse, or who are recovering alcoholics, 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. Small areas of bare skin of your back will be exposed for a few seconds at a time.

PAIN THRESHOLD AND PAIN TOLERANCE EXPERIMENT. The first part of the study involves tests to determine the threshold for pain induced by skin heating. Exposures of 3-sec duration will rapidly heat the skin 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. This part of the study will require 32 exposures at 32 different locations on your back. These exposures will be separated by 15 to 20 seconds during which the location and intensity of the beam are changed. Less than ½ 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. Pain threshold testing will be done in 3 sessions, one without alcohol and 2 with different levels of alcohol consumption. At the end of each pain threshold session, you will be asked to perform 4 pain tolerance trials. Four different areas on your back will be stimulated with millimeter waves intense enough to reach the pain threshold within about 2 seconds. We wish to measure the effect of ethanol on your pain tolerance, so we will ask you to remain in the beam for as long as you

can stand the pain. 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. As soon as we see you moving, we will turn off the beam. 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 exceptionally high pain tolerance.

Pain Scaling Experiment: In each of 3 sessions (lasting up to 90 minutes), 2 with and 1 without alcohol consumption, areas of the bare skin on your back will be stimulated with millimeter waves that heat the skin to the point that you feel pain. After each stimulus, you will be asked to give 2 numerical ratings. The first number should reflect how UNPLEASANT the pain felt to you. You can use any numbers you want, but they should relate to the unpleasantness in the following way: If this stimulus feels twice as unpleasant as the previous one, the number should be twice as great. If it feels half as unpleasant, the number should be half as great, and so forth. The second number on each trial should reflect how INTENSE the stimulus felt to you. As you probably know, the unpleasantness of a painful stimulus is not necessarily related to how intense it is. For example, a pain sensation that is not very intense can become extremely unpleasant if it lasts a long time and you are unable to control it. Also, some drugs may reduce the unpleasantness associated with pain, without having much effect on the intensity of the pain. Therefore, you should concentrate on each aspect (unpleasantness and intensity) in turn, and respond with numbers that relate to each aspect of your sensations.

For testing sessions involving alcohol, you will be asked to come to the laboratory in the morning (0800 or 0900) without eating breakfast. 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 2 specific blood alcohol levels (.08% and .12%), which in most people correspond to a) "tipsy" or "high," and b) "drunk." A blood alcohol level of .08% is the "legal limit" in Texas – driving a motor vehicle at this level or higher is legally defined as driving while intoxicated. You will be provided with a meal immediately after testing is completed. The alcohol (Vodka) will be mixed with water or a non-caffeine or decaffeinated diet soft drink of your choice, and presented to you in two 12-ounce cups. You will be asked to consume the contents of the cups over a 15-minute period, as steadily and evenly as possible. After you finish drinking, we will measure your blood alcohol every 15 minutes, using a breathalyzer. When your blood alcohol level reaches the target level, we will begin threshold testing, which should take less than 15 minutes. After testing is completed, you will do another breathalyzer test, and then have a meal. We will continue periodic breathalyzer tests until your blood alcohol level is low enough (i.e., less than 0.04%) to permit normal activities (NOT to include driving vehicles or operating heavy/dangerous equipment), and the experimenters see that your observable behavior appears sufficiently normal, at which time you can return to your workplace. If you need to leave the area immediately surrounding the laboratory (to go home, or to a remote workplace), one of the experimenters will drive you there. 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 0.04%, but you should exercise appropriate caution until you feel that you have returned to a completely normal, sober condition. While waiting for your alcohol level to go low enough to leave the laboratory, you will be able to read, listen to music, watch videos, 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 the lower alcohol dose, and up to 4 hours after the higher dose.

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

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 an hour after exposure, this should be reported to the experimenter, and examined by the medical staff. 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: 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. 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.

BENEFITS

You will receive no direct benefit or payment for my 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 the 311th Medical Clinic (210-536-2087), or the medical monitor, Harry Greer, M.D., at (210) 536-4825, or the investigator, Dennis W. Blick, Ph.D., at 210-536-5126.

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. If you have any questions, you may contact the 311th Medical Clinic (210-536-2087), or the medical monitor, Harry Greer, M.D. at (210) 536-4825 (Harry.Greer@brooks.af.mil), or the investigator, Dennis W. Blick, Ph.D. at 210-536-5126 (Dennis.Blick@brooks.af.mil). In case of any medical incident, you will be transported to the Base Clinic for care, 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.

CONFIDENTIALITY

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. 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 (Dennis W. Blick, Ph.D. (210-536-5126), Thomas E. Dayton (210-536-4703), Dennis M. Scholl, Ph.D., Stephanie Miller (210-536-3881), or Philip E. Tobin (210-536-1398)) 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 of the study may terminate your participation if he feels this to be in your best interest.

An experimenter will go over written instructions with me 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.

Full Name: _____ _____ _____

(Please Print) SSN (optional) Telephone Number

_____ _____

Volunteer Signature Date

_____ _____

Investigator Date

_____ _____

Witness (not involved) Date

_____ _____

Next of Kin Phone

Instructions for Subjects – Pain Threshold

These experiments involve 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 1-2 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 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 (4-8) 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 trial 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 it off by using your kill-switch, or avoid pain by moving out of the way, whichever is easiest for you.

Any questions?

Instructions for Subjects – Rating of Above-Threshold Pain

In this experiment, we are going to stimulate your back with a variety of radiant stimuli, ranging from ones that you can barely feel pain from, to ones that are hot enough to approach (but not get to) intolerable levels. 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 1-2 seconds before each one comes on, and we'll tell you when we stop collecting data, so you can relax and move around. After each trial, we want you to give us 2 numbers corresponding to how the painful stimulus felt to you. The first number will tell us how INTENSE the pain felt to you. Think of a scale that ranges from "not painful" to " the most intense pain I've ever felt." You can use any numbers you want, but if a stimulus feels twice as painful as another, you should make the number twice as big. If another feels 5 times more intense then you should give us a number 5 times as big. Different stimuli will be presented in random order; sometimes successive ones will differ by a lot, sometimes by little or nothing. Try to concentrate on each one as it comes along, and give us a number that corresponds to how intensely painful it feels. After you give us a number indicating the intensity of the pain sensation, we want you to give us another number indicating how UNPLEASANT it felt. Obviously, pain is generally unpleasant, but the unpleasantness doesn't only depend on its intensity. Brief, predictable, intense pain may not be very unpleasant, while long-lasting pain which seems like it's never going to end can be very unpleasant, even though the pain is not very intense. Think of a scale ranging from "slightly unpleasant" to "the most unpleasant thing I've ever experiences." Again, you can use any numbers you like, as long as you try to rate an exposure that feels half as unpleasant as another with a number that's half as large. There are no right or wrong answers. Even though you might feel like you're picking some numbers out of thin air, it will turn out that when we put the numbers from all of the subjects together, there will be a very systematic relationship between the properties of the stimuli and the numbers assigned. We are going to present a couple of practice trials so you can get an idea of the range you'll be dealing with, and see how it works. For half of the trials, a large area of skin surrounding the painful area will also be heated up. Heating of this area should not cause pain outside of the central area. If it does, please tell us, so we can adjust it to a non-painful level. The ratings of intensity and unpleasantness you give us should refer to the pain in the central area, and not to any pain that might occur in the surrounding area.

You should NOT be afraid of the exposures. Although the stimuli will be painful on nearly every trial, we have set the range of intensities so that none of them should become intolerable, and certainly none of them should produce any thermal damage to your skin. In the extremely unlikely event that the equipment should malfunction and present you with a stimulus that feels too strong to you, then you can shut it off by using your kill-switch, or avoid pain by moving out of the way, whichever is easiest for you.

Do you have any questions before we start the practice trials?

Instructions for Subjects – Pain Tolerance

This experiment involve exposure to stimuli that will heat the skin on your back to painful levels. 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 move. We'll tell you 2-3 seconds before each exposure begins. The pain may become so intense that you may be unable to sit still. Many subjects, in fact, move out of the way before the stimulus ends, either because of involuntary reflex withdrawal, or because they find the pain so intolerable that they want to move 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 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 several hours. We expect that you will return to normal within 24 hours at most. If the skin is still red and/or tender after 24 hours, you should notify the Investigator, who will arrange for the Medical Monitor to examine it 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?