1. **Protocol FWR-2002-0046-H: Perceptual and Thermal Effects of Millimeter Waves**

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6. **Protocol Objective:** To quantify the effects of millimeter waves (MMW) on humans. Specifically, we will measure variations in tolerance of dorsal exposures as a function of peak power density on target, as a function of orientation of the subject to the MMW beam, and as a function of the area of skin exposed. We will also examine the effect of interference patterns due to multipath transmission of the MMW beam. Data on skin cooling following exposures that nearly reach tolerance limits will be collected for use in thermal modeling of the effects. Pain threshold will be measured as a function of exposure area, and whether the skin is exposed directly to the MMWs, or clothing is present.

7. **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 waves 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. We (AFRL/HEDR) have conducted extensive research on the bioeffects of MMWs, both in animals and humans. We have demonstrated that the desired behavioral effect (prompt and highly motivated 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 and Henriques, 1947) assure us that there is a substantial safety margin between effective levels and damaging ones. 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. A new device that allows exposure of up to half of the body surface was recently tested on 72 subjects. Our previous research had shown that the pain threshold varies little with area of exposure (see Fig. 1, page 13), and that the tolerance of suprathreshold pain varies much more among individuals than the

pain threshold. We expected and found that exposure of large skin areas reduced the median effective dose (ED50). We thought that it might also reduce the variability among individuals, making the tolerance function steeper, but this hypothesis was not confirmed. However, there were sources of variation in the experiment that might have spuriously increased the observed variation; these will be better controlled in the current experiments. In any case, the shift in ED50 does indicate that the range of the weapon will be greater than old estimates based on the data from smaller exposure areas. This shift also makes the safety factor between maximal effectiveness and damage threshold larger than earlier estimates, potentially increasing the policy acceptability of this weapon system. Figure 2 (page 14) compares the likelihood of effect (repel) as a function of peak skin temperature for small (laboratory) and large (field) areas of exposure.

Although our previous tests with the prototype weapon produced highly useful data, they were limited in 2 respects. First, it was an unavoidable fact that many subjects were well aware of a limitation of the system that precluded exposures (at least initially) of durations greater than 3 seconds. These subjects thus knew that the system would not stay on after 3 sec., even if they were not forced to move out of the beam by then. Thus, a few subjects were able to tolerate the maximum available exposure, and it is probable that more than a few made a great effort to tolerate it, thus staying longer that they otherwise might have, which would add an unknown contribution to the variability of the data. Second, there was substantial day-to-day variation in the measurements of peak power density on target, some of it attributable to variations in the setup of the measuring instrumentation and some caused by limitations in the transmitter. Our final data analysis showed that the correlation between measured peak power density and skin-heating rates was not as large as would be expected if the power density measurements had been completely reliable. The transmitter we will use in these experiments is greatly improved over the one used previously; it contains a new MMW generating tube that can be operated for longer durations and with less time (seconds rather than minutes) between operations. We are devising methods that will provide move reliable estimates of peak power on target. The fact that the newer system can produce shots of longer duration, with minimal separation between shots (the previous prototype required several minutes of cool-down between shots), will allow us to specify the location and power density of the peak immediately before and after each subject exposure. We are in the process of calibrating a carbon-impregnated Teflon plate that shows surface-heating characteristics similar to skin. These laboratory calibrations will be completed and verified in the field before any subjects are exposed. IR thermographic analysis of test-shots on this plate prior to and/or after subject exposures will show the location and power density of the peak output from the transmitter. The new transmitter is expected to deliver power densities at range that vary less shot-to-shot and day-to-day, as it is not subject to variations due to overheating of tube components.

Interactions between MMWs and skin are quasi-optical, so the amounts absorbed and reflected depend on the angle of incidence of the beam at the skin surface. If a subject is oriented obliquely to the beam, the effect might be to reduce the area of

skin maximally stimulated. This is because full dorsal (or ventral) exposure places the most skin perpendicular to the beam, where maximal absorption occurs. To determine whether this effect is significant, we will compare the tolerance of a single power level for exposure of the back perpendicular to the beam path to two oblique (45°) orientations of the subjects' back to the beam.

We also need to determine the relationship between exposure area and pain threshold. This will allow us to extrapolate from smaller exposures under various controlled conditions in the laboratory to potential operational situations and scenarios.

Rationale. After measuring the power density required to evoke repel in animals, and determining that this effective level was well below power densities at which thermal damage occurs, we measured the pain threshold in humans for several different durations of exposure and several different areas of exposure. These results provided estimates of the power required at the effective range of the weapon to produce pain within 2 to 4 seconds. From classical studies of pain evoked by heating the skin with infrared radiation (e.g., Hardy et al., 1952), we knew that heating the skin beyond the pain threshold would soon exceed the tolerance limit. **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 between 55 and 60°C, at which point maximal pain is attained; 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 we 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 would be effective against essentially all individuals, while producing damage in few or no cases, it was necessary to determine both the average limit of pain tolerance, and the extent of variation among individuals. We have done this by testing 60 subjects at several power densities, using relatively small exposure areas (~10 cm^2 at the 90% contour, i.e., the area within which power density is within 10% of its peak value). As the spatial distribution of the small beam is roughly Gaussian, power density falls off rapidly beyond this contour, so most of the sensory effects arise from this central area. Even using this small area, we found that power densities that produce pain within 2 to 3 seconds were effective in reaching the limit of pain tolerance within 2.5 to 5 seconds. None of the subjects was able tolerate any exposure which produced damage to the skin, beyond a reddening produced by a transient increase in skin blood flow, and a lingering sensation of tenderness, both of which dissipated within a few minutes. As we stated above, we expected to find that a large increase in the area stimulated would change both the median effective dose (ED50) and the slope of the dose-effect function for pain tolerance as a function of skin temperature. As Fig. 2 (page 14) shows, the results from the field did show a reduction in the ED50, but no reduction in variability for the repel effect. However, several potential sources of variability were not as well controlled as they should have been in the field experiments, so we wish to repeat these observations

with better control and more reliable measurement of stimulus intensity (power density on target). We also wish to vary the areal extent of exposure, in order to do a within-subjects comparison of the effect of area on the tolerability of supra-threshold thermal pain. Only one such comparison was found in the literature (Price et al., 1989); they explored areas ranging only from 1 to 3 cm^2, and found that both the intensity and unpleasantness of pain increased with stimulus area. Except for our results (Fig. 2), there are no data comparing such effects for larger areas. Unfortunately, our data were collected from different groups of subjects, at different times, and under quite different experimental conditions (laboratory vs. field). We propose here to measure both pain threshold and pain tolerance limits for several values of stimulus area, using within subjects designs in the same experimental conditions. It is important to measure the pain threshold for these exposure areas, so that we can use the known relationships between threshold and tolerance to make extrapolations from controlled laboratory experiments (measuring, for example, the effects on pain threshold of potential countermeasures or variations in environmental conditions) to operational situations.

DoD relevance. Advanced Concept Technology Demonstration (ACTD) #11, "Active Denial System," was recently approved and funded by the DoD. The research proposed here, in support of the ACTD, will provide inputs to Military Utility Assessments and to the development of Concepts of Operation (CONOPS) by the potential users of the system.

The answers to these experimental questions are critical to both the operational effectiveness and the 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. An ACTD (see above) was recently approved. The planned experiments support the accomplishment of this ACTD.

9. **Experimental Plan:**

A) Equipment and Facilities: Microwave technicians assigned to AFRL/DEH will provide transmitter control, calibration/characterization, and maintenance. Microwave exposures will use a new transmitter located at Kirtland AFB, NM.

B) Subjects: Adult volunteer subjects will be recruited from among the military personnel, DoD civilians, and Contractor personnel working in AFRL/HEDR and AFRL/DEH. No gender or age restrictions are required, so volunteers of either gender can range in age from 18 to 80 years. 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.

Experiment 1. Pain tolerance as a function of power density (dorsal exposure only). Up to 96 subjects.

Experiment 2. Pain tolerance, normal vs. oblique. 18 subjects, a subset of the subjects in Experiment 1.

Experiment 3. Pain tolerance as a function of exposure area. 18 subjects, a subset of the subjects in Experiment 1.

Experiment 4. Pain tolerance, multipath vs. main beam. 18 subjects, a subset of the subjects in Experiment 1.

Experiment 5. Cool-down IR thermography. 12 subjects, a subset of the subjects in Experiment 1.

Experiment 6. Pain threshold as a function of exposure area. 12 subjects, a subset of the subjects in Experiment 3.

Experiment 7. Pain threshold, bare skin vs. clothing. 6 subjects, a subset of the subjects in Experiment 6.

Depending on their availability and willingness, subjects may volunteer to participate in from 1 (Expt.1 only) to 7 experiments. It is likely that many will participate in 3 or 4 experiments (e.g., 1, 3 plus 6 and/or 7, or 1 plus several from 2-5).

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) *General* –The subjects will stand in the beam of a microwave transmitter for all exposures. They will face away from the transmitter so that their backs are exposed to the beam of microwaves. They will be instructed to keep their hands in front of their bodies, so that the hands will not be exposed, as the thin skin on the palmar surfaces of the knuckles may be especially vulnerable to thermal damage. At the range from the transmitter where subjects will stand, the beam will irradiate the entire half of the body surface that is oriented toward the transmitter. The beam will be characterized by standard radiometric techniques (Durney, Massoudi, & Iskander. 1986). To verify the location and peak power of the beam pattern, a carbon impregnated Teflon plate, the surface of which heats at rates similar to the skin, will be exposed immediately before and/or after each subject exposure, and the heating distribution will be measured by IR thermography. As in previous experiments, the test area for the unobstructed beam will be defined as the central part of the approximately circular field in which the power density is at least 90% of the peak value at the center. Exposure areas smaller than the unobstructed beam will be

achieved by exposing the subject through a hole (6" or 12" diameter) cut in a thin reflector placed as close as possible to the skin, in order to minimize interference fringing effects. Subjects will remove all metallic objects from their clothing and person before exposure. Although the superficial absorption characteristics of microwaves at this frequency should cause no problem with implanted metallic objects, no person with an artificial joint or other large, metallic implant will be used as a subject. Subjects will wear only a swimsuit or briefs during exposure, except when the effect of clothing on pain threshold is being measured. Subjects in the threshold experiment will be instructed as to the nature of the sensory endpoint that should be the determinant of their yes-or-no response after each exposure (See attached "Instructions to Subjects"). All subjects will also be instructed in the use of the shielded area adjacent to the exposure area, where they can quickly move to reduce exposure to zero when their tolerance limit is reached. The exposed area will thus extend from the back of the head, over the entire backside of the body to the shoe tops, except when the exposure area is limited by the use of an aperture. Transmitter operators will be able to see and hear the subjects during exposure via video and 2-way radio. The operators will immediately turn off the transmitter at any sign of distress from any subject, with the exception of movements of subjects as they escape from the beam. For security reasons, all exposures will take place within a tent, so that no one without appropriate clearance and need-to-know will be able to see the subjects.

b) *Pain Tolerance:* (Experiment 1, n = 96). After an initial "orientation" exposure, which can be done with the subjects in street clothes (minus metallic objects), subjects will be asked to don briefs or swimsuits and stand in the microwave beam for 3-5 s exposures at each of 3 power levels that are expected to evoke the repel effect within an average of 2 to 4 sec, based on previous work. Maximum duration at each power level will be 5, 4, and 3 s, from lowest to highest level, respectively. If an exposure produces pain that reaches the subject's tolerance limit, he/she can escape from the field by moving laterally behind a shield that is impervious to millimeter waves. IR thermography will be used to determine the time at which escape responses are initiated, and the peak skin temperatures tolerated. The informed consent document and instructions to subjects (attached) make it clear that subjects are not expected to endure all exposures. The 3 power levels will be presented in random orders for different subjects. Randomization will be restricted, so that each power density occurs equally often in each serial position within each group of 6 subjects (i.e., the 6 possible orders will randomly assigned to subjects in groups of 6). No attempt is made to collect data from the "orientation" exposures, as we have found that vigorous startle responses and shorter-than-normal times to escape are common on first exposure. Despite extensive instruction, subjects are generally unable to anticipate the actual sensory effect, until they have experienced it once.

In all tolerance tests, the dependent variables will be peak skin temperature at effect (initiation of escape response) and time to effect.

c) *Tolerance for Oblique Exposures:* (Experiment 2). A subgroup (n=18) of the tolerance subjects will be asked to volunteer for exposures on 2 different days, with the exposures separated by no less than 1 nor more (hopefully) than 14 days. The additional day will be used to test whether exposures at oblique angles to the subjects' backs significantly affect tolerance, with each subject tested with the beam normal to the back and at the two 45° obliques to normal. All exposures in this test will be at the middle of the 3 power densities used in the tolerance testing. The within-subjects comparison used here will provide enough statistical power to answer the question with a relatively small number (18) of subjects.

d) *Pain Tolerance as a Function of Exposure Area.* (Experiment 3). A subgroup (n = 18) will be asked to return for testing on an additional day. In Experiment 3, exposures will be through each of 2 circular apertures, one 6" in diameter and one 12" in diameter. Two exposures for each aperture will be done, such that each of the 4 exposures will be on different areas of the back (e.g., 6" on upper right and lower left, 12" on upper left and lower right) so that aftereffects in the skin should not produce carryover effects. Exposure orders and positions will be counterbalanced between subjects. Only the middle of the 3 power densities from Experiment 1 will be used

e) *Pain Tolerance – Multipath vs. Main Beam.* (Experiment 4). A subgroup (n=18) of the tolerance subjects will be asked to volunteer for exposures on 2 different days. On the second day, they will be exposed only at an average power density equivalent to the middle of the 3 power densities used in experiment 1. They will be exposed 4 times, twice under condition A (multipath effects present) and twice under condition B (multipath effects absent). Half of the subjects will be exposed in condition order ABBA; half in order BAAB. Great care will be taken to center the beam on the middle of the subjects' backs. The dependent variable (temperature-at-effect) will be examined both as the peak temperature and the average temperature of the skin of the back. If the constructive interference associated with multipath effects confers an advantage in terms of output power required, it will be observed as a reduction in time-to-effect at the same average power, or the same average temperature.

f) *Cool-Down.* (Experiment 5). A subgroup (n=12) of the tolerance subjects will be asked to volunteer for one additional exposure at the middle power density level from Experiment 1. Subjects who tolerate higher than average peak skin temperatures will be invited to participate, so that we can observe cooling from temperatures that approximate the ED50 for the repel response. The additional exposure will occur 15 to 30 minutes after the last exposure of Experiment 1. The duration of the exposure will be reduced by 10% from the time-to-effect observed for the same subject at

the same power density in Experiment 1. Subjects will be instructed that, because of the reduction in duration, they might find this exposure sufficiently tolerable that they will be able to remain in position through the exposure and for 10 seconds afterward, while we are recording the cool-down of the exposed skin. As always, they will be encouraged to escape behind the adjacent barrier if the exposure reaches their tolerance limit. Subjects who choose to escape will be replaced.

g) *Pain Threshold as a Function of Exposure Area.* (Experiment 6). A subgroup (n = 12) of the subjects in Experiment 3 will be tested on 4 separate days, with 30 exposures each day. Three different areas will be tested: A – 6" diameter aperture; B – 12" diameter aperture; and C – unobstructed full beam exposure. The conditions will be presented in the order CABBAC, five times per experimental session. The ABBA portion of the sequence will stimulate 4 separate areas (upper and lower back, left and right sides) so that trials can proceed as quickly as the subject and apertures can be positioned. After each full beam trial, subjects will wait in a temperature-controlled booth until their skin temperature returns to baseline temperatures (33-35°C). We expect that skin temperature will return to baseline within 2 to 4 minutes after a full beam pain threshold trial. Thus, a 30-trial session could take 60 to 90 minutes. The pain threshold for each size stimulus 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 he/she felt a distinct sensation of pain. 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 2-3 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 5 s thereafter. The exposure value for each trial is controlled as follows: the investigator sets the power density to be used during the series to a value that will reach the pain threshold within 2 to 3 seconds in nearly all subjects. For each trial, the duration of the exposure (and thus the energy density (fluence) at the subject's skin) is determined by the staircase procedure, i.e., an initial duration is selected by the investigator (targeted for slightly below the sensory threshold), and subsequent values vary up and down by steps of a predetermined size (estimated to allow about 20 steps to cover the range of thresholds from most to 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 typically covers a range from nearly 0% "yes" to nearly 100% "yes" responses in each individual subject in 4-6 steps. Larger steps reduce the sensitivity of the procedure, while smaller steps make it more difficult for the subject to maintain a consistent decision criterion. The value for a given trial at each stimulus size steps up or down from the previous trial at the same size depending on the subject's response: If the subject said "yes", the duration is stepped down; if 2 "no" responses occur, the duration is stepped up on the staircase for the given area. Two staircases are operating simultaneously for each area, 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 thermography data are collected at a sampling rate of 60 Hz, so that 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.

h) *Pain Threshold* – Bare Skin vs. Clothed. A subgroup (n = 6) of the subjects in experiment 6 will be asked to provide data on pain threshold with clothes on (pants, shirt, and BDU jacket), in order to assess the effects of such clothing on the weapon's effectiveness. Preliminary experiments at Brooks AFB, using a much smaller beam size, indicated that the addition of a T-shirt and BDU shirt had no operationally significant effect. No IR thermographic data will be gathered in this phase of the study. Data will be collected using the 12" aperture, and the same power density as in experiment 6, so that a within-subjects comparison can be done with the 12", bare skin data from that experiment. Exposures at 4 positions (upper and lower, right and left back) will be repeated 8 times in a single session, with 3-minute rest/cool-down periods after each set of 4 exposures. Threshold duration (and fluence) will be determined by the double-random staircase method described above.

2) Data Analysis: Some of these experiments are exploratory in nature; inferential (hypothesis testing) statistics will not generally be used for them.

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 for each experimental condition. Since duration (and fluence) 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 30), "yes" response rate increases

monotonically with energy 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 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/she 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. Figure 1 (page 13) shows that one variable (area stimulated) doesn't have much effect on threshold. However, threshold (a constant perceptual effect in each subject) does allow us to see the effects of other variables (e.g., initial skin temperature, skin wetness, duration of stimulus, etc.). These experiments only propose to compare thresholds under 2 sets of conditions (3 different areas; bare skin vs. clothed). However, if we find (as expected) that the stimulus areas tested here produce little change in threshold, we will be able to use thresholds measured under a variety of conditions with smaller areas for extrapolation to operational exposure situations that are difficult to simulate in the laboratory. IR thermographic data will be analyzed to determine the peak skin temperature, mean skin temperature, and typical location (if any) of the peak skin temperature associated with the pain threshold. Testing pain tolerance at the set of areas in the same set of subjects strengthens the ability to extrapolate from pain threshold data gathered in the lab to a variety of operational scenarios.

Pain Tolerance. We will measure the duration of exposure (at several fixed power densities) 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 dose-effect functions like those shown in figure 2 (page 14). This is done by finding percentage effectiveness at several points between 10 and 90%, then finding the best-fit straight line (on a normal probability plot) to generate the best-fit cumulative ogive (on a linear scale). Shifts in the dose-effect function produced by varying stimulus area are of particular interest. If the resulting ogives vary in steepness, indicating changes in variability with size, the variances of the distributions will be compared by the use of appropriate F-tests. Time-to-effect and temperature-at-effect for the various stimulus sizes will be compared by repeated-measures analyses of variance.

3) Safety Precautions: The maximum power and duration of the transmitter output will be set at levels that cannot produce skin heating greater than 55°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 at range will cause an escape response well before damaging levels of skin temperature are reached. Maximum power density settings will be only slightly above those required to produce the criterion perceptual effect (pain threshold or pain tolerance limit). 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 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 rest is carried away by the blood that circulates in the skin. 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 joints 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.

4) On-site monitoring. Dr. Greer (the Medical Monitor) or his designated representative will monitor all exposures used for the testing of pain tolerance limits. The Kirtland AFB Clinic will be notified when threshold exposures are scheduled, and will be on call in the event of a mishap. The Medical Monitor or his designated alternate medical provider will examine the skin of each potential subject prior to any exposure. Potential subjects who have any abnormal skin condition that might suffer detrimental effects from surface heating will not be allowed to participate.

10. **Medical Risk Analysis**: 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 protocols # F-BR-1998-0026-H and # F-WR-2001-0006-H, that the sensory endpoints (pain threshold and tolerance limits) 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 waves. 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 MMWs 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 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 only produce superficial heating of the skin that is self-limiting at non-injurious levels.

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

A) Risk Assessment:

Potential Benefits: The subjects (DoD military and civilian personnel and contractors) will receive no direct benefit or compensation for participation. 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.

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

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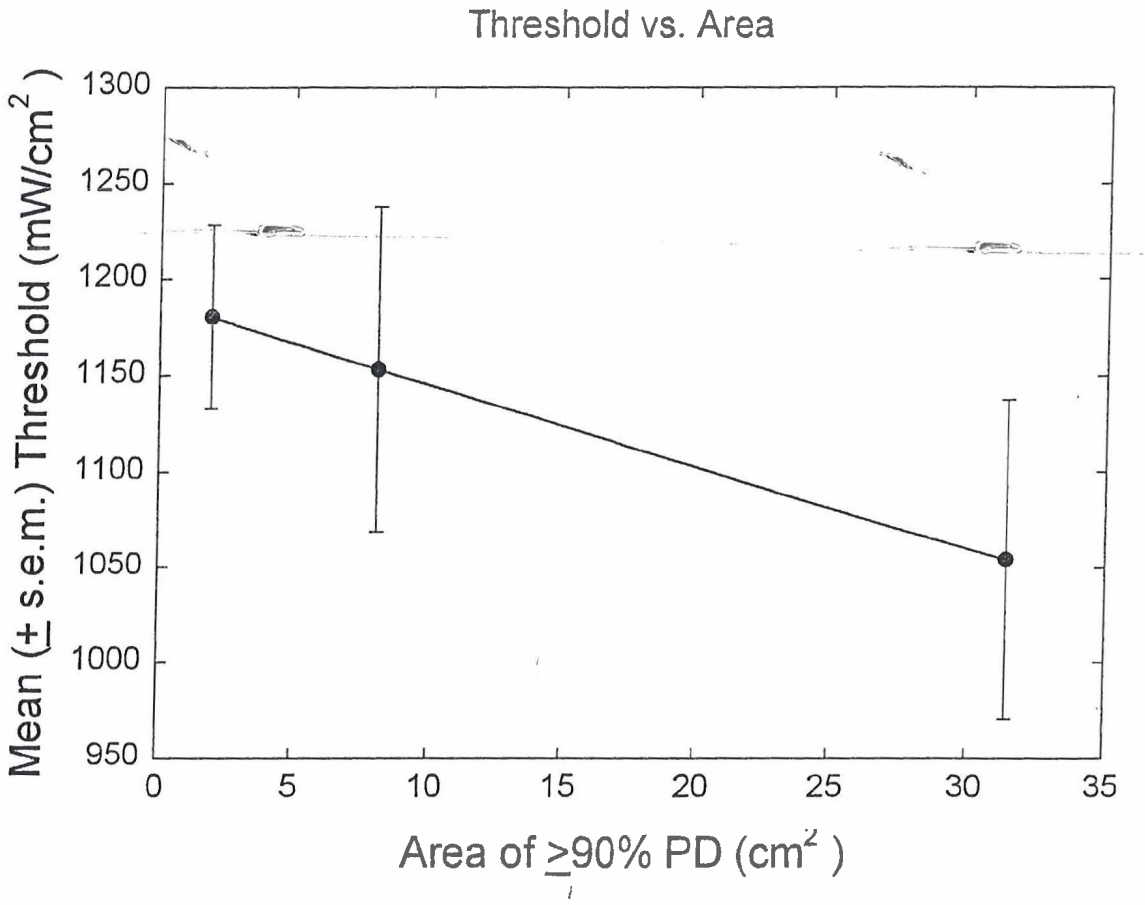

Figure 1. Effect of Area on Pain Threshold. For a small number of subjects who were tested at all three areas, the effect is quite small, i.e., less than 10% change in threshold over more than an order of magnitude change in area. We interpret this as probability summation, i.e., the greater the area stimulated, the more likely that one small patch of skin will reach its pain threshold.

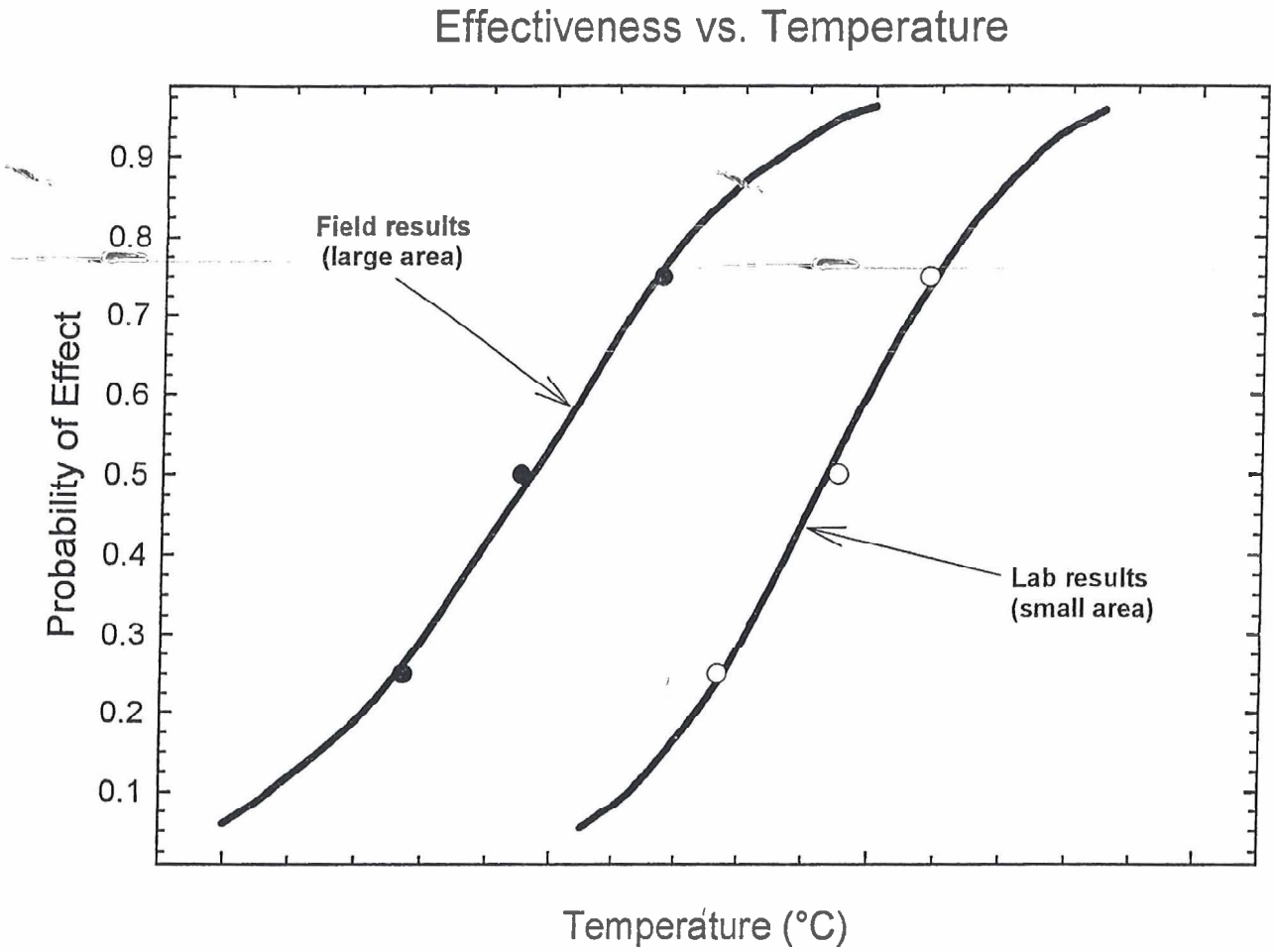

Figure 2. Probability of repel effect vs. temperature for different areas of exposure.

12. **Attachments:**

A. Informed Consent Documents (5).

B. Instructions for Subjects (2).

INFORMED CONSENT DOCUMENT (Pain Threshold)

High Energy Research and Testing Facility

Building 66071
Kirtland AFB, NM 87117

Institutional Review Board Approval Dates: 18 JAN 01 – 17 JAN 02

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. Your signature below indicates that you have read the Privacy Act Statement contained in DD Form 2005. You understand that the sponsoring agency and/or its designee may inspect records of this study.

TITLE OF STUDY

Perceptual and Thermal Effects of Millimeter Waves

INVESTIGATORS' NAMES, DEPARTMENTS, PHONE NUMBERS

Dennis W. Blick, Ph.D., AFRL/HEDR (Veridian), (210) 536-5126 (DSN 240-5126)
Thomas E. Dayton, AFRL/HEDR (Veridian), (210) 536-4702 (DSN 240-4702)
Lt.Col. Dennis M. Scholl, Ph.D., AFRL/HEDR, (210) 536-4041 (DSN 240-4041)
James H. Merritt, M.S., AFRL/HEDR, (210) 536-4703 (DSN 240-4703)

PURPOSE OF STUDY

You have been invited to participate in a research study at Kirtland AFB, sponsored by the Air Force Research Laboratory, Human Effectiveness Directorate, Radiofrequency Radiation Branch, entitled "Perceptual and Thermal Effects of Millimeter Waves." The objective of this experiment is to measure how people react to millimeter waves that heat their skin.

This study will enroll 12 subjects between the ages of 18 and 80, over a period of six to nine months. You may be tested in several visits to the testing site, lasting up to 90 minutes per session.

PROCEDURES

If you volunteer to participate in this study, you will be exposed to millimeter waves at intensities that will exceed the applicable safety standards by as much as 20-fold. This exposure will cause your skin temperature to rise to (or slightly above) your pain threshold, about 44 to 45 °C. The exposures will take place in a tent, with the millimeter waves entering through a wall of the tent. In the main experiment, the back of your body will be exposed while you are wearing a swimsuit. If you decide to participate in the second experiment, your back will be exposed while you are wearing BDUs.

PAIN THRESHOLD EXPERIMENT. This part of the study involves tests to determine the threshold for pain induced by skin heating. Exposures of varying duration (generally 2-3 seconds) 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 30 exposures on each of 4 separate days, separated by 2-3 minutes to let the skin cool back down to normal temperatures. 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. A second part of the study measures the effect of clothing on pain threshold. If you participate in this part of the study, you will be exposed 32 times, 8 each at 4 locations on your back, to intensities above the maximum allowed by applicable safety standards. All exposures will take place at Kirtland Air Force Base. If you have large metallic implants (e.g., an artificial joint) you cannot participate, as the presence of metal immediately under the skin

might change the way the skin responds to the energy. The millimeter waves involved in these experiments DO NOT affect cardiac pacemakers. If you have any unusual skin conditions that might be aggravated by surface heating, you should decline participation in this experiment.

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 waves. 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 understand that you may not participate in this study if you are pregnant or become pregnant during the course of the study. Although there is no evidence that exposure to millimeter waves of this type could affect a fetus, it remains a very remote possibility that there are potential risks of harm to an unborn child. 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

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 should contact the medical monitor, Michelle Bryce, Maj, USAF, MC, SFS, DSN 240-4007, 210-536-4007, or the investigator, Dennis W. Blick, Ph.D. (210-379-3779).

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 should contact the medical monitor, Michelle Bryce, Maj, USAF, MC, SFS, DSN 240-4007, 210-536-4007 Michelle.Bryce@brooks.af.mil), or the investigator, Dennis W. Blick, Ph.D. at 210-379-3779 (cell 'phone) (Dennis.Blick@brooks.af.mil). 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.

DECISION TO PARTICIPATE

The decision to participate in this research is completely voluntary on your part. 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 (210-379-3779), Thomas E. Dayton (210-536-4703), or James H. Merritt (210-536-4703)) 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 or she feels this to be in your best interest.

SUBJECT STATEMENT:

I have read the document "Instructions for Subjects—Pain Threshold."

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 Date

_____ _____
Witness (not involved) Date

Instructions for Subjects -- Pain Tolerance

These experiments involve exposure to stimuli that will heat the skin on the back of your body to painful levels. During exposure, you should keep your hands in front of your body, so that they will not be exposed. If you are willing, we will expose you 4 times. The first exposure is an "orientation" exposure, to familiarize you with the test situation, and the sensations that the exposures will evoke. This exposure (at the lowest power level that we use) will take place with you in street clothes, but you should remove any metal objects that would be exposed (necklaces, etc.). Testing in our laboratory has shown that clothing has little or no effect on the sensations evoked by millimeter waves. Most subjects are startled the first time they are exposed, and tend to flinch well before they need to move when the pain reaches their tolerance limit. If you choose to continue after the first exposure, we hope that you will be able to suppress this flinch, and stand still until you are forced to move by the pain. We will measure your skin temperature before and during the exposure, so we would like for you to stand as still as possible during the exposure, until you feel that you need to move to limit the pain.

In order to measure skin temperature on the remaining 3 trials, the skin must be bare, so you will be asked to change into a pair of briefs or a swim suit (women will wear a sports bra or bikini-type top, with no metal on the back). Appropriate apparel will be provided to volunteers who wish to be tested, but don't have such apparel with them. A bathrobe will be provided for your comfort between exposures. Footwear (slippers or sandals) is also provided, but you can wear your own shoes if you wish. The last 3 exposures will be at 3 different power levels, one the same as the first exposure, and 2 a little higher. The order of the 3 power levels varies from subject to subject, and you will not know in advance which will occur in any given trial.

We'll tell you about 5 seconds before exposure begins. We expect that the pain will become so intense that you will be unable to stand still. Most subjects will move out of the way before the stimulus ends, either because of involuntary reflex withdrawal, or because the pain reaches their tolerance limit and they want to move to end it. If you cannot 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 millimeter waves 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 you will return to normal within an hour at most. If the skin is still red and/or tender after 1 hour, you should notify the Investigator, who will arrange for the medical staff 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 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 waves 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?

Instructions for Subjects – Pain Threshold

These experiments involve exposure to stimuli that will heat the skin on the back side of your body. We will measure skin temperature before, during, and after each exposure, so you need to stand as still as possible during and for a few seconds after each exposure. We'll tell you 2-3 seconds before each trial starts, and we'll tell you when it's OK to move afterward. However, you are free to move at any time you feel discomfort that is unacceptable to you. At the end of some exposures, your back 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 trial, 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 shouldn't say "yes" if it almost got there, or if it just feels really hot. You should say "yes" only if you definitely felt the pain. On trials when you say yes, we want you to tell us as accurately as you can, where you felt the pain. 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.

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 (on average, only once every 3-10 minutes). However, we need to be sure that when you say you felt the pain, you really did, NOT that you though 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. After each exposure, we will wait until your skin cools back down to normal, before the next trial. We expect this to take 2 to 3 minutes.

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's too intense – so you can tell that it's going to get to threshold well before it ends, then you can shut it off using your kill-switch, or avoid pain by moving out of the way, whichever is easiest for you.

Any questions?

INFORMED CONSENT DOCUMENT (Pain Tolerance with Oblique Exposure)

High Energy Research and Testing Facility

Building 66071
Kirtland AFB, NM 87117

Institutional Review Board Approval Dates: 17 OCT 02 – 16 OCT 03

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. Your signature below indicates that you have read the Privacy Act Statement contained in DD Form 2005. You understand that the sponsoring agency and/or its designee may inspect records of this study.

TITLE OF STUDY

Perceptual and Thermal Effects of Millimeter Waves

INVESTIGATORS' NAMES, DEPARTMENTS, PHONE NUMBERS

Dennis W. Blick, Ph.D., AFRL/HEDR (Veridian), (210) 536-5126 (DSN 240-5126)
Thomas E. Dayton, AFRL/HEDR (Veridian), (210) 536-4702 (DSN 240-4702)
Lt.Col. Dennis M. Scholl, Ph.D., AFRL/HEDR, (210) 536-4041 (DSN 240-4041)
James H. Merritt, M.S., AFRL/HEDR, (210) 536-4703 (DSN 240-4703)

PURPOSE OF STUDY

You have been invited to participate in a research study at Kirtland AFB, sponsored by the Air Force Research Laboratory, Human Effectiveness Directorate, Radiofrequency Radiation Branch, entitled "Perceptual and Thermal Effects of Millimeter Waves." The objective of this experiment is to measure how people react to millimeter waves that heat their skin.

This study will enroll 18 subjects between the ages of 18 and 80, over a period of up to 12 months. You will be tested in a second single visit to the testing site, lasting up to 2 hours.

PROCEDURES

If you volunteer to participate in this study, you will be exposed to millimeter waves at intensities that will exceed the applicable safety standards by as much as 20-fold. This exposure could cause your skin temperature to rise to 55 °C, unless you take action to escape the beam by moving to the side behind a barrier that blocks the beam. The exposures will take place in a tent, with the millimeter waves entering through the end of the tent. For the 3 exposures in this part of the study, the back of your body will be exposed at 3 different angles while you are wearing a swimsuit or briefs, so that we can record your skin temperature with an infrared image system. You will be asked to remove all metal objects (jewelry, belt buckles, watches) to eliminate potential interaction of these objects with millimeter waves. You will stand with your feet together and hands in front of your body, to assure that only skin on the back surface of your body is exposed. The exposures will be limited in duration to prevent skin damage, but are likely to last beyond your tolerance for skin heating and pain. However, 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 that will begin after 1 to 3 seconds of exposure 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, and you want to move to end it. You will be exposed a maximum of 3 times, at 3 different orientations to the beam. After each exposure, it may take 5 to 15 minutes for the skin to

return to its normal temperature. Thus, the duration of your one-time participation in the experiment may be as long as 1 to 2 hours, given that some exposures may be delayed for a few minutes by conditions beyond our control (e.g., aircraft in the area). If an exposure produces skin reddening and/or tenderness that last for more than 15 minutes, exposures will be terminated. The operator of the millimeter wave device will be watching you via video and listening via two-way radio. He or she will terminate the exposure if you give any indication of distress, other than moving out of the beam. If you have large metallic implants (e.g., an artificial joint) you cannot participate, as the presence of metal immediately under the skin might change the way the skin responds to the beam. The millimeter waves involved in these experiments DO NOT affect cardiac pacemakers. If you have any unusual skin conditions that might be aggravated by surface heating, 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. 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. 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 waves. 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 understand that you may not participate in this study if you are pregnant. Although there is no evidence that exposure to millimeter waves of this type could affect a fetus, it remains a very remote possibility that there are potential risks of harm to an unborn child. 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

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 should contact the medical monitor, Michelle Bryce, Maj, USAF, MC, SFS, DSN 240-4007, 210-536-4007, or the investigator, Dennis W. Blick, Ph.D. (210-379-3779 [cell phone]).

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 should contact the medical monitor, Michelle Bryce, Maj, USAF, MC, SFS, DSN 240-4007, 210-536-4007 Michelle.Bryce@brooks.af.mil), the Principle Investigator, Dennis W. Blick, Ph.D. at 210-379-3779 (Dennis.Blick@brooks.af.mil), or the medical observer, Cathy Moreno,

R.N., at 210-241-5244 [cell phone] (Cathy.Moreno@brooks.af.mil). 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 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.

DECISION TO PARTICIPATE

The decision to participate in this research is completely voluntary on your part. 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 (210-536-5126), Thomas E. Dayton (210-536-4703), Dennis M. Scholl (210-536-4041), or James H. Merritt (210-536-4703)) 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 or she feels 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 Date

_____ _____
Witness (not involved) Date

INFORMED CONSENT DOCUMENT (Pain Tolerance by Area Exposed)

High Energy Research and Testing Facility

Building 66071
Kirtland AFB, NM 87117

Institutional Review Board Approval Dates: 17 OCT 02 – 16 OCT 03

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. Your signature below indicates that you have read the Privacy Act Statement contained in DD Form 2005. You understand that the sponsoring agency and/or its designee may inspect records of this study.

TITLE OF STUDY

Perceptual and Thermal Effects of Millimeter Waves

INVESTIGATORS' NAMES, DEPARTMENTS, PHONE NUMBERS

Dennis W. Blick, Ph.D., AFRL/HEDR (Veridian), (210) 536-5126 (DSN 240-5126)
Thomas E. Dayton, AFRL/HEDR (Veridian), (210) 536-4702 (DSN 240-4702)
Lt.Col. Dennis M. Scholl, Ph.D., AFRL/HEDR, (210) 536-4041 (DSN 240-4041)
James H. Merritt, M.S., AFRL/HEDR, (210) 536-4703 (DSN 240-4703)

PURPOSE OF STUDY

You have been invited to participate in a research study at Kirtland AFB, sponsored by the Air Force Research Laboratory, Human Effectiveness Directorate, Radiofrequency Radiation Branch, entitled "Perceptual and Thermal Effects of Millimeter Waves." The objective of this experiment is to measure how people react to millimeter waves that heat their skin.

This study will enroll 18 subjects between the ages of 18 and 80, over a period of up to 12 months. You will be tested in an additional single visit to the testing site, lasting up to 2 hours.

PROCEDURES

If you volunteer to participate in this study, you will be exposed to millimeter waves at intensities that will exceed the applicable safety standards by as much as 20-fold. This exposure could cause your skin temperature to rise to 55 °C, unless you take action to escape the beam by moving to the side behind a barrier that blocks the beam. The exposures will take place in a tent, with the millimeter waves entering through the end of the tent. For the 4 exposures in this part of the study, 4 different areas on your back of your body will be exposed to 2 different sizes of spots of millimeter waves while you have your shirt off (women should wear a bikini top, and be prepared to move straps out of the exposure areas), so that we can record your skin temperature with an infrared image system. You will be asked to remove all metal objects (jewelry, belt buckles, watches) to eliminate potential interaction of these objects with millimeter waves. You will stand with your feet together and hands in front of your body, in a way comparable to the full back exposure. The exposures will be limited in duration to prevent skin damage, but are likely to last beyond your tolerance for skin heating and pain. However, since the purpose of these experiments is to determine variations in tolerance as a function of size of exposure, 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 that will begin after 1 to 3 seconds of exposure 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, and you want to move to end it. You will be exposed a

Amendment to:

Protocol F-WR-2002-0023-H: Facial Sensitivity and Eye Aversion Response to Millimeter Waves.

Principal Investigator: Dennis W. Blick, Ph.D., AFRL/HEDR(VERIDIAN)/DSN 240-5126/Dennis.Blick@brooks.af.mil

Requested Changes:

We want to test the 10 subjects already tested in one additional session, exposing them to a single level of energy density (1.0 J/cm^2 , well below the 1.6 J/cm^2 maximum authorized by a previous amendment) with their heads in 10 different orientations to the beam: facing straight at the transmitter horn (as previously) plus 15, 30 and 45° above and below the horn, and 15, 30, and 45° to one side. In our initial eye aversion study, we found that reflections of the beam from the nose created patterns of constructive and destructive interference, typically resulting in a "hot spot" in the region of the inner canthus. This raises a concern that damage to the tear duct in this region might occur in cases of exposures of longer duration in planned frontal exposure experiments in the field. However, if the location of "hot spots" change with changes in head orientation, the expected rapid aversion responses would moderate this concern. The extent to which this occurs needs to be examined prior to preparation of a protocol for frontal exposures in the field. The patterns of heating in response to the low-level exposures proposed here should be the same as would be observed at higher levels in the field. However, the maximum temperatures in the patterns (at 1.0 J/cm^2) are too low to cause pain or damage. They can, however be used to predict the exposure levels at which damage might occur. In the previous exposures to 1.0 J/cm^2, none of the 10 subjects reported pain, and no damage to the eyes or the structures around the eyes was observed.

These changes are reflected in the revised Informed Consent Document. Inasmuch as the proposed changes do not increase the risk to volunteers, expedited consideration of this amendment is requested.