Protocol # F-BR-2006-0018-H (#NHRC.2005.0016): Effects of Exposure to 400-W, 95-GHz Millimeter Wave Energy on Non-Stationary Humans

Abstract

Objective: The Department of Defense is developing non-lethal, millimeter wave (MMW), directed energy weapons that heat the skin surface to painful levels, causing targeted individuals or groups to retreat or take cover before their skin temperature is raised to damaging levels. This study will quantify the effects of small-beam-diameter, 400-W, 95-GHz exposures on non-stationary (moving) humans in a laboratory maze-like setting.

2. **Intent:** Adult volunteers (n = 30) will be asked to traverse a course as quickly as possible. At the end of this course they must then unlock a door (a subtask requiring some degree of fine motor skills) in order to exit the course (complete the task). During commission of this task, subjects will be targeted by the small-beam-diameter, 400-W, 95-GHz device. Subjects will be examined before the experiments for any pre-existing, but not necessarily disqualifying, conditions and after exposures for any experimentally-related injuries or side-effects. Subjects will be free to terminate their participation in the study at any point in time.
3. **Relevance:** The Office of Force Transformation is developing a system of systems, dubbed Project Sheriff, to provide non-lethal and lethal options for urban operations. A 400-W, 95-GHz MMW system is among the non-lethal systems under consideration. The research proposed here will provide inputs to the decision process and to the development of Concepts of Operation and Techniques, Tactics, and Procedures. The answers to these experimental questions are critical to the assessment of military utility, operational effectiveness, and deployment of the system.
4. **Expected Outcome:** In contrast to comparable larger-spot systems, the present small-beam-diameter system may require higher power densities in order to effectively control/repel subjects.

1. **Protocol #F-BR-2006-0018-H (#NHRC.2005.0016): Effects of Exposure to 400-W, 95-GHz Millimeter Wave Energy on Non-Stationary Humans**

   Date of Submission: 17 August 2005.

   Approximate Dates of Research: 050915 to 060915.

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4. **Medical Monitor and Observer**:

   Medical Monitor: Bryce, Michelle L., DO, MTM&H, USAF, LtCol, MC, SFS, AFRL/HED, 8315 Hawks Road, Building 1184, Brooks City-Base, TX 78235, DSN 240-4007, Michelle.Bryce@brooks.af.mil

   Medical Observer: Chalfin, Steven, MD, FACS, FAAO, University of Texas Health Science Center at San Antonio, 7703 Floyd Curl Drive, San Antonio, TX 78284. (210) 567-8411, Chalfin@uthscsa.edu

5. **Contractor Support**: Conceptual MindWorks, Inc., San Antonio, TX

Facilities: Maginot Open Air Test System (MOATS) Facility, Naval Surface Warfare Center, Dahlgren, VA

Primary Performing Institution: Air Force Research Laboratory/Radio Frequency Radiation Branch (AFRL/HEDR)

Collaborating Institution: Naval Health Research Center (NHRC)

JRA/CRDA/MOU initiated? No

6. **Protocol Objective:** To quantify the effects of small-diameter, 95-GHz millimeter wave (MMW) exposure on non-stationary (moving) humans. Specifically, we propose to test the effectiveness of a 400-W system in a laboratory setting. Subjects will traverse a course at the end of which they will be required to perform a task involving fine motor skills in order to exit the course, all while being targeted by the 95-GHz system.

   Background and Relevance:

   A) The Department of Defense (DoD) is developing non-lethal, MMW weapons with various effective ranges from greater than that of small arms to the approximate distance of thrown rocks. The Active Denial System (ADS) uses MMWs to produce heating of the skin surface to painful levels that quickly reach the limits of pain tolerance, causing targeted individuals or groups to retreat or take cover. Over a decade of research performed by AFRL supports the safety and effectiveness of ADS as a non-lethal weapon. Project Sheriff, a 400-W Active Denial Technology (ADT) subsystem, delivers a power density similar to that of the ADS with a smaller spot size (approximately 10-20%). It should be noted that the 400-W designation specifies the MMW power output of the device's klystron and not at the skin surface, where power density is considerably lower. Exposure levels at the skin will be no greater than those which occurred over the course of 35 AFRL studies examining the human bioeffects of the ADS; these studies have involved over 9000 exposures with an injury rate of 0.04. These injuries have included an instance of physical urticaria in a subject who was wearing a sweater during a field exposure; the occurrence in one subject during a field exposure of small blisters; and a second degree burn incurred during a laboratory mishap. (The consequence of this laboratory mishap was the implementation of additional hardware, software, and administrative safety controls.) AFRL/HEDR has conducted extensive research on the bioeffects of MMWs, both in animals and humans. We have demonstrated that the desired behavioral effect (prompt escape behavior) is readily produced at exposure levels well below those that produce burns in animals. Studies with conventional heating of human skin (e.g., Moritz & Henriques, 1947) assure us that there is a substantial safety margin between effective levels and injury. Studies in our laboratories of rat and pig skin damage produced by MMWs are even more reassuring in this regard. Research by AFRL/HEDR and NHRC-Det scientists suggests that the system poses no undue risk of injury for the face and eye exposures, and also indicates the absence of risk for skin cancer or infertility.

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

The study herein proposed is one of a series designed to assess the effectiveness of a 400-W, 95-GHz small-spot-size system on both static and non-static human targets. Protocol #F-BR-2005-0057-H, "Thermal Effects of Exposure to 400 W, 95 GHz, Millimeter Wave Energy" (final approval pending) describes two studies which will assess the effectiveness of such a system on static (nonmoving) subjects. The research proposed in the present protocol seeks to extend those results by assessing effectiveness with non-static (moving) subjects.

B) Data Required. In order to ascertain whether the weapon will be effective against essentially all individuals, while producing injury in few or no cases, it is necessary to determine both the average limit of pain tolerance, and the extent of variation among individuals. Pain threshold (as opposed to tolerance) occurs at a skin temperature of 43 to 45 °C. The pain sensation continues to grow in intensity up to a skin temperature of between 55 and 60 °C, at which point maximal pain is attained (Hardy, Wolff, & Goodell, 1952). Further heating may produce skin injury, but no further increase in the perceived intensity of the pain. The limit of pain tolerance is a complex function of pain intensity, exposure duration, exposed area, and motivational and experiential characteristics of the individual. Data collected under Protocol #F-BR-2005-0057-H, "Thermal Effects of Exposure to 400 W, 95 GHz, Millimeter Wave Energy" will determine pain tolerance for static (stationary) subjects under a variety of exposure conditions.

The data collected during these experiments will help determine the operating parameters (MMW power density and maximum exposure duration) used in the assessment of system effectiveness in the present study. The present study is designed to explore the extent to which pain produced by MMWs impacts the performance of subjects when engaged in a task which consists of both rapid movement through a maze-like course and more fine motor skills (viz., unlocking a door which exits the course). For the present study, the primary dependent measures of interest will be the percentage of subjects successfully traversing the course and the latency to complete the course.

C) DoD Relevance. The Office of Force Transformation is developing a system of systems, dubbed Project Sheriff, to provide non-lethal and lethal options for urban operations. A 400-W, 95-GHz MMW system is among the non-lethal systems under consideration. The research proposed here will provide inputs to the decision process and to the development of Concepts of Operation and

Techniques, Tactics, and Procedures. The answers to these experimental questions are critical to the operational effectiveness of the system.

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

9. **Experimental Plan**

A) Equipment and facilities. Exposures for the experiment will employ a 95-GHz MMW transmitter (Sheriff 400-W ADT subsystem), mounted on a Stryker vehicle. The experiment will be conducted at the Maginot Open Air Test System (MOATS) Facility located at the Naval Surface Warfare Center (NSWC), Dahlgren, VA. NSWC is the site of testing, the assemblage point for the transmitter, and NSWC scientists, engineers, and others who will observe this study to assess the field utility of the system. Protocol investigators (AFRL/HEDR and/or their contractors) with appropriate training and authorization will direct operation of the non-lethal transmitters within the Stryker vehicle. Training, estimated to take 1-2 weeks, will be provided by the appropriate engineering and technical staff. Experienced research support technicians from AFRL/HEDR and their contractors will operate bioeffects data collection equipment during the trials.

B) Subjects. Thirty adult subjects will be recruited from among active duty Naval or Marine personnel. Volunteers may be of either gender, and must be at least 18 years of age; there is no maximum age limit. If volunteers of both genders are available, efforts will be made to have each gender represented by no less than 3 members. With the exception of medical exclusions, no specific groups will be excluded.

Sample size determination. A power analysis was conducted which assumed the following: the probability of making a Type I error (α) was .05; desired power (1 – the probability of a Type II error [β]) was 0.80; the least operationally meaningful difference between the two treatment conditions was 0.7 min; and the estimate of uncertainty (S^2) was 1.0 min (the latter being a very rough estimate based on unpublished data collected under Protocol FWR-2003-0031-H, "Limited Military Utility Assessment of the Active Denial System [ADS]"). Such assumptions yielded a sample size of n = 19. Eleven additional subjects are requested to account for possible subject attrition, equipment failure, etcetera.

Subject recruitment. Subjects will be recruited from active duty Naval or Marine personnel stationed near Dahlgren or Quantico VA, or from the Washington, DC metro-area. These recruitment sites were chosen due to their proximity to the

critical experimental equipment (viz., the Stryker-mounted 400-W Sheriff subsystem). Recruitment will be conducted by the principal investigator and/or one (or more) of the associate investigators for this protocol. Additionally, the medical monitor will be present at all recruitment sessions, and will serve as an ombudsman per AFI 40-402. Potential participants will be made aware of the study via IRB-approved fliers or through a general announcement such as an IRB-approved e-mail sent by non-line personnel. Solicitation will primarily occur in a group setting; unit commanders, officers, and noncommissioned officers will not be present during the recruitment of enlisted personnel per DoD Directive 3216.2. However, signed letters from Commanding Officers of any participating units acknowledging that their personnel will be asked to participate in the study will be required before recruitment begins. Recruitment meeting dates will be provided to the NHRC and Brooks City-Base Institutional Review Boards (IRBs) before initiation. During each group recruitment session, the principal investigator or an associate investigator will read verbatim a script, provided as Attachment E, describing the experiment details. A video recording of the recruitment presentation will also be made available. To protect privacy and guard against the potential influence of group coercion during group recruitment sessions, potential subjects will be provided with an envelope containing their informed consent document (ICD; see Attachment A). Interested subjects will be instructed to print their name on the appropriate line in the ICD and place it in the envelope, with their witnessed signature to be obtained after the potential participant is contacted by the investigator, met with individually, and any questions they have are answered. Those not interested will be instructed to place their blank ICD in the envelope as well. Envelopes will be deposited in a box at the back of the room.

If the group recruitment approach does not yield the requisite number of volunteers, recruitment efforts may be extended to include the posting of flyers, which direct interested parties to review the video presentation at a specified location, after which any interested individuals are to seek out the investigator to answer questions and read/sign the informed consent document. Recruitment flyers will be submitted to the NHRC and Brooks City-Base IRBs for review upon approval of the protocol. All potential research participants will be given the opportunity to ask questions about the research before signing the ICD. Copies of the ICD will be provided to all subjects. A copy will also be mailed or delivered to each subject's Tricare Service Center or primary medical facility, so that it can be placed in his or her medical record. Subjects in the present study will not be compensated for their participation. The ICD and the study protocol will be approved by both Navy and Air Force IRBs; however the Air Force will retain primary responsibility for this study.

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

C) Procedures

1) Experimental Procedures

i) Medical screening and exclusions. Medical and vision examinations (limited physical examination, medical history, limited vision examination) will be given to all subjects prior to and following experimental participation.

a. Pre-exposure examinations. Pre-exposure examinations, to be performed by the medical monitor (Dr. Michelle Bryce), will be given to all subjects in order to document any pre-existing (but not necessarily disqualifying) conditions (see Attachment C, *Medical Documentation Form*). Pre-exposure examinations will include (a) medical and (b) vision examinations. The medical examination will include a limited physical examination (examination of the skin for color, presence of lesions, photographs of the skin [at the discretion of the medical monitor or observer]; etc.) and medical history. These initial medical examinations will be performed within 10 days prior to the subject's test date.

Medical exclusions will include the following: Individuals with mobility limitations will be excluded. Individuals with implanted metallic objects (e.g., joints) will be excluded. (There is no known risk of significant heating of any subcutaneous structures with the exposures contemplated in this experiment. Since this is the case, the presence of implanted metallic objects poses no known health risk. They are excluded 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.) Individuals with diabetes will be excluded. Pregnant women may not participate in this study in the interests of utmost safety. (There is no evidence that exposure to MMWs could affect a fetus; research is ongoing.) All female recruits will undergo a urine pregnancy test before each exposure trial. Individuals with other chronic conditions/medical histories may be excluded at the discretion of the medical monitor or observer.

Subjects will be instructed not to apply creams or lotions prior to participation, as this could confound any results.

The medical monitor will sign a document authorizing participation in the experiment by each subject to be stamped by the NHRC IRB. A blank authorization form is provided as Attachment D.

Pre-exposure vision examinations, to be administered by Dr. Steven Chalfin (medical observer and a licensed ophthalmologist) will include a slit lamp examination. The slit lamp examination will be limited to include the superficial structures of the eye: eyelids, conjunctiva, and the cornea. The cornea examination requires

fluorescein stain to be placed on the cornea. Contact lenses must be removed at least 24 hours prior to the slit lamp examination (since contact removal may result in minor corneal scratching which would make interpretation of the examination problematic). Additional eye testing will be at the discretion of the ophthalmologist. These initial vision examinations will be performed within 10 days prior to the subject's test date.

Medical exclusions related to the eye include: history of cataract extraction or other intra-ocular surgery, glaucoma, uveitis, herpes simplex, herpes zoster, and pathologic dry eyes. Further, as the effects of refractive eye surgery on eye exposure to MMWs have not yet been determined, subjects who have had photorefractive keratectomy (PRK) or laser-assisted in situ keratomileusis (LASIK) will not be allowed to participate.

b. Post-exposure (experiment) examinations. The same limited medical and vision examinations will be repeated after the completion of all exposures for a subject, specifically no later than 10 days after exposures are concluded. Subjects may not use contact lens until after the post-exposure slit lamp eye examination is conducted.

c. Inter-trial examinations. Additionally, during the course of the experiment, brief examinations (i.e., brief physical check of the skin and eyes for redness, blisters, and sweating) will be performed within a 15-min window following each of the four individual trials.

All medical examinations, including the brief inter-trial exams, will be performed by the medical monitor, Dr. Michelle Bryce, or the medical observer, Dr. Steven Chalfin. The vision examinations will be performed by Dr. Chalfin, who is a licensed ophthalmologist.

ii) Dosimetry. The MMW beam will be characterized each day prior to testing and then again after testing is concluded by standard radiometric techniques (Durney, Massoudi, & Iskander, 1986). Specifically, AFRL/HEDR personnel will verify the peak power of the beam patterns by exposing a carbon-impregnated Teflon plate before and/or after each subject exposure. The heating distribution will be measured by infrared thermography (Ross, Allen, Beason, & Johnson, 2005). Personnel involved in the characterization will identify areas where irradiation will occur with high visibility tape and employ hand-held radios as needed to facilitate communication about pending and current MMW transmissions, in order to minimize exposures.

Calibration of the transmitter will be examined at the beginning and end of each day. A calibration log will be maintained.

iii) Subject exposures. Experimental testing dates will be provided to the NHRC IRB and Brooks City-Base IRB before initiation. The exposure parameters will be set at those found to produce intolerable pain in prior experiments with stationary subjects under Protocol #F-BR-2005-0057-H, as noted above. No eyewear or clothing restrictions are imposed on the subjects. (However, subjects should not wear contact lenses for at least 24 hours prior to the pre-exposure slit-lamp examination, during the exposures, or until after the final slit-lamp examination; this is because contact insertion/removal can cause irritation to the cornea which makes interpretation of the slit-lamp examination results problematic.

All subjects will traverse the course (see Figure 1) under one of two conditions. In the "exposure" condition, subjects will start at the end of the alleyway farthest from the transmitter (see Figure 1). The goal is to traverse the course, unlock the door (running a short distance), and exit the course. The escape door will consist either of a free-standing hanging door-like structure or a door within the facility. The lock will be a three-digit combination-style lock, with a hinged latch.

The system operator will be continually targeting the subject with the MMW device as they move through the course. Subjects will be targeted at different body locations to ensure that no exposure at a single location exceeds 12 J/cm^2. Exposure of different body locations is specified by changing the beam center position in any direction by a distance corresponding to 50% of the beam diameter, which is defined as the spot producing the full width, half maximum, power density, or identically, the 3-dB spot size. Any exposures to the same body location will be separated by at least 10 seconds. Exposures will be temporarily halted any time subjects fall or are otherwise off their feet. After subjects regain mobility, exposures will resume. Subject exposures occurring within four feet of the escape door will involve only shoulder-level or lower areas, reflecting the subject's approximate stationary target status in this area. Subjects can retreat behind MMW-impervious barriers (positioned roughly every 5 to 10 meters throughout the course, as well as directly next to the escape door; see Figure 1) should they want to escape the beam. Barriers will be constructed of a MMW-impervious material with a height of at least 7 feet. The trial will terminate when the subject successfully exits the course via the door, remains behind a barrier for more than 30 s, fails to exit the course within 3 min, or "surrenders" (either by raising both hands over their head or shouting "stop"). Stopwatches will be used to measure the time a subject remains behind a barrier.

Each subject will be given two opportunities (trials) to run the course under the exposure treatment condition. The second condition under which subjects will attempt to traverse the course is the "no-exposure" condition. Trials in this condition will be identical in procedure to the exposure trials except that subjects will not be targeted by the MMWs.

Each subject will be given two opportunities to run the course under the no-exposure treatment condition. The sequence of trial types (exposure vs. no exposure) will be counterbalanced across subjects, and subjects will not be informed about the selected exposure/no-exposure condition prior to performing the experiment. There will be a minimum interval of 5 min between trials. Subjects will be given verbal instructions and allowed to ask questions before each trial; all verbal or written communication with subjects will be reviewed and approved by the IRB, prior to the start of the experiment. Subject performance during all of the trials will be videotaped. After each trial, subjects will be asked for a self-report of "hits" and the perceived effectiveness of those hits utilizing a pain scale (0-10 with 0 being no pain and 10 being the worst pain ever experienced in their life). (The form used in summarizing these subject responses is provided as Attachment F.)

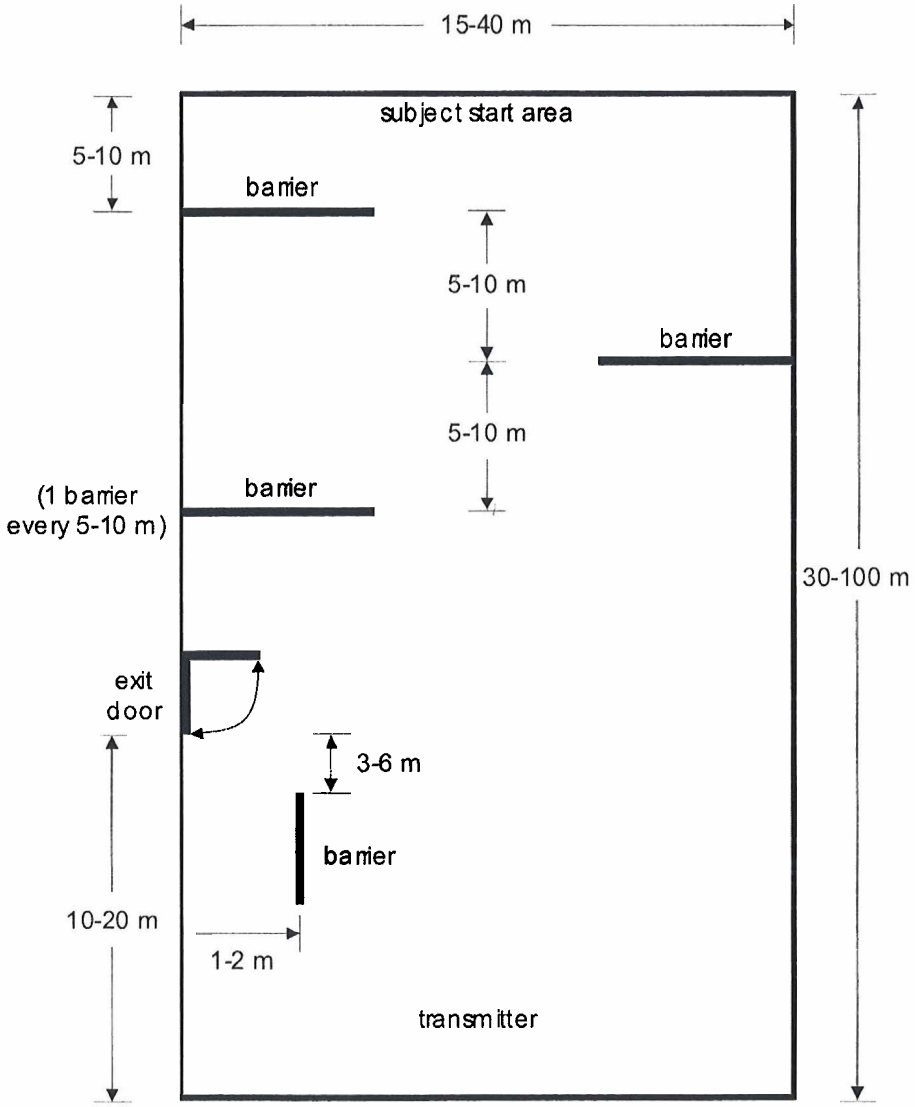

Figure 1. Schematic of course to be traversed by subjects (not drawn to scale).

2) Data analysis. Data analysis will consist primarily of contrasting dependent measures (percentage of subjects successfully traversing the course and the latency to complete the course) calculated for the exposure versus the no-exposure treatment conditions.

3) Safety precautions. All subjects will be instructed in the use of the shielded areas that are available throughout the test course, where they can quickly move to reduce exposure level to zero when their tolerance limit is reached (see *Subject Instructions*, Attachment B). If, for any reason, a subject cannot move to a shielded area, they may alternatively shout "stop", at which time the operator will immediately turn off the beam. Transmitter operators will be able to view the subject at all times during the trial/exposure (except when subject remains behind a barrier). During instances when subjects remain behind barriers, the stopwatch operator will provide verbal feedback to the transmitter operator, for safety purposes.

   The maximum power and duration of the transmitter output will be set at levels that cannot produce skin heating greater than 60 °C (140 °F). For short durations, this temperature exceeds the pain threshold, but does not exceed the threshold for tissue damage. Even in the event of operator error (setting the output to a higher level) the maximum available power density that the system can produce will cause an escape response well before damaging levels of skin temperature are reached. Power density will be verified at the beginning and end of each day, as described in Section 9.C.1.ii, *Dosimetry*.

   MMWs at 95 GHz 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 s. The blood that circulates in the skin redistributes the remaining heat. The fraction that is conducted to structures deeper than the skin is negligible. Thus, there is no known risk of significant heating of any subcutaneous structures or organs with the exposures contemplated in this experiment. There are no known aftereffects of heating the skin to painful but non-damaging levels. As stated in Section 9.C.1.i (*Medical screening and exclusions*), each subject will be cleared in writing by the medical monitor prior to participation.

   Per the Armed Forces Epidemiological Board memorandum of March 2005 and the Under Secretary of Defense (AT&L) memorandum of 18 July 2005, research subject participation needs to be documented within an official registry. At this time, the Air Force subject participation registry is not operational; nor is it anticipated that such a registry will be available during the timeframe of this experiment. In lieu of the official registry, a record of each subject's participation will be documented in a study-specific database; each entry will include subject name, date of birth, gender, social security number, date of exposures, and the cumulative dosage and number of exposures (determined in part from videotapes) will be captured. Only

personnel who have signed an assurance statement will have access to this database. All database information will be transferred to the official registry once it becomes available. Once the official Air Force Radio Frequency Radiation Exposure Registry is operational, all data from the study-specific database will be entered into the registry per procedures specified at the AFIOH/SDRD Web site.

Subjects will not be scheduled for follow-up appointments, nor will they be contacted for medical updates, unless new, pertinent information is discovered (as a result of this research) that directly impacts the health and/or safety of the participant. Subjects will be informed in the consent document on how to contact the investigators if they wish to report any symptoms or health concerns following their participation. Any health concerns by subjects will be reported to the NHRC IRB and AFRL IRB in a timely fashion.

Transmitter operator safety is ensured, as they will be fully contained within the Stryker vehicle during all exposures. Other experiment personnel (data collection, stopwatch operator, monitors, etc.) will remain fully outside of the beam path; areas of beam path will be demarcated with security tape. All experiment personnel will have the use of hand-held radios for communication.

4) On-site monitoring.

The Principle Investigator and/or one or more of the Associate Investigators will be present during all phases of the experiment.

Dr. Michelle Bryce will serve as the medical monitor for the proposed study. In this capacity, Dr. Bryce will serve as ombudsman at recruitment sessions, act as subject advocate, answer questions of subjects or investigators, monitor the actual trials, and report all adverse events to the NHRC and Brooks-City Base IRBs within 24 hours. (See also Attachment C, *Medical Documentation Form.*)

Dr. Bryce's medical degrees include DO (1992, College of Osteopathic Medicine of the Pacific) and MTM&H (1999, Uniformed Services University of Health Sciences); she completed her residency in 2001 (USAFSAM, Aerospace & Preventive Medicine, Board Eligible Occupational) and has over two years of experience serving as medical monitor in studies related to directed energy exposures. Dr. Bryce is board certified in ABPM (Aerospace Medicine, Preventive Medicine) and AOBPM (Aerospace Medicine).

Dr. Steven Chalfin will serve as medical observer in the proposed study. In this capacity, Dr. Chalfin will act as subject advocate, answer questions of potential subjects, actual subjects, or investigators, monitor the actual trials, and report all medical events immediately to the medical monitor. The pre- and post-experiment limited eye examinations (to include slit-lamp examinations) will also be performed by Dr. Chalfin, who is a certified

ophthalmologist. Dr. Chalfin will provide guidance on eye health issues during the course of the experiment.

Dr. Chalfin received his medical degree (MD) in 1980 from Hahnemann Medical College, Philadelphia, PA and is a Fellow of the American College of Surgeons. He completed residencies in ophthalmology (National Naval Medical Center, Bethesda, MD, 1988) and general surgery (Graduate Hospital, University of Pennsylvania, Philadelphia, PA, 1982), and has over six years of experience in research on the ocular effects of non-ionizing radiation.

Resumes for Drs. Bryce and Chalfin can be found in Attachment G.

Dr. Bryce and Dr. Chalfin will be present to monitor all exposures. They will conduct limited medical examinations prior to and following experimental participation for each subject (see 9.C.1.i, *Medical screening and exclusions*, for details of the examinations).

If an eye injury is suspected, evaluation may require standard ophthalmic staining drops to be applied to the subject's eyes. Suspected injury would necessitate referral to an ophthalmologist/optometrist for further evaluation. It will be at the discretion of the ophthalmologist whether any further eye testing is warranted.

The medical staff will activate the emergency response system in the unlikely event of an accident or significant medical incident. Non-MMW related injuries (e.g., ankle sprain) will be evaluated and treated by on-site local Navy medical personnel. If necessary, subjects will be referred to local medical facilities for further evaluation and treatment. The use of local medics for non-MMW related injuries is to allow the medical monitor and observer to focus on the research being conducted and not be distracted by having to provide medical evaluation and treatment to other types of incidents. The medical monitor and medical observer will be informed of standard emergency medical response procedures used at the testing facility and implement these in the unlikely event of an accident or significant medical incident. The use of standard Navy medical procedures has been deemed sufficient to deal with any untoward events and/or injuries.

All injuries other than minor temporary skin reddening or tenderness (lasting 24 hours or less), small heat blisters (that resolve within 72 hours), and eye discomfort (that resolves within 15 minutes after the trial's end) will be reported as adverse events as soon as practicable and in line with the gravity of the injury. Any injury requiring outpatient care at a treatment facility will be reported to NHRC IRB and Brooks City-Base IRB within 72 hours. Any injury requiring inpatient treatment, an overnight stay at a treatment facility, or that involves eye discomfort or injury that does not resolve within 12 hours will be reported to NHRC IRB and Brooks City-Base IRB within 24 hours. Adverse event reporting will be done by the medical monitor, will fully describe the injury, the treatment, and prognosis, and may

initially be done via e-mail to the IRB Chairs. Follow-up reports indicating final status of any injuries are required.

The NHRC IRB members will be granted access to the trials at Dahlgren upon request to view the research.

5) Organization of research effort

i) Duties and responsibilities

Bryce, Michelle: medical monitor, recruitment ombudsman, responsible for reporting adverse events to NHRC and Brooks City-Base IRBs, conducts medical examinations, serves as medical observer during the exposures, acts as subject advocate, answers questions of potential subjects, actual subjects, or investigators, supervises the medical observer.

Chalfin, Steven: medical observer, acts as subject advocate, answers questions of potential subjects, actual subjects, or investigators, and reports all medical events immediately to the medical monitor, serves as the on-site ophthalmologist and conducts the eye evaluations.

Cook, Michael C.: experimental oversight, scientific oversight, statistical analysis, subject recruitment.

Handler, Erin L.: data collection, data analysis, system operator.

Johnson, Leland R.: technical lead (equipment engineering, maintenance, calibration, dosimetry, etc.), system operator.

Mason, Patrick A.: scientific oversight, experimental design.

McMurray, Tom: data collection, data analysis, software engineering, system operator.

McQuade, Jill: scientific oversight, experimental design, system operator.

Miller, Stephanie A.: experimental oversight, scientific oversight, experimental design, liaison with Navy personnel, subject recruitment.

Pointer, Kristie L.: experimental assistance.

Suniga, Valerie A.: experimental assistance.

Ziriax, John M.: scientific oversight, liaison with Navy personnel, subject recruitment.

ii) Chain of command

All of the co-investigators will report directly to the principal investigator, Michael Cook. The medical observer will report directly to the medical monitor, Dr. Michelle Bryce.

6) Maintenance of records

i) Experimental data. Data will include electronic databases detailing subject responses over the course of the study, dosimetric data in the

form of infrared camera files, videotape of the subject performance during each of the trials, etcetera. Each subject will be assigned a unique identification number; the aforementioned electronic databases will reference subjects by this identification number rather than by their name. A separate, password-protected file will indicate the correspondence between subject name and identification number.

Original paper documents including medical histories, examination results, etc. will be maintained by the Air Force Research Laboratory's Radio Frequency Radiation Branch in locked files at 8262 Hawks Road, Building 1162, Room C-26, Brooks City-Base, TX 78235. Videotapes of the trials will be made available upon request for viewing by NHRC and Brooks City-Base IRB members as part of their oversight role. The subject database containing name, social security number, age, sex, race, exposures, and dates of exposures will be maintained at AFRL and provided to NHRC IRB as well as Air Force IRB.

ii) ICDs. ICDs will be maintained by the Air Force Research Laboratory's Radio Frequency Radiation Branch in locked files at 8262 Hawks Road, Building 1162, Room C-26, Brooks City-Base, TX 78235. Signed copies of Informed Consent Documents will be sent via express mail to the NHRC IRB Chairperson on a weekly basis.

iii) Medical records. Individual medical records will be returned to the subjects after review.

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

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

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

B) 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.

C) Repeated overexposure to MMWs has not been demonstrated to initiate or promote cancer (Mason et al., 2001).

D) In the event of an overexposure to a power density sufficient to produce thermal injury, there is an extremely low probability that scars derived from such injury

might later become cancerous. Proper wound management further decreases this probability, as well as the probability of hypertrophic scarring or keloid formation.

Walters, Blick, Johnson, Adair, and Foster (2000) demonstrated that the 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. The conclusions of both Walters et al. (2000) and Ryan et al. (2000) provide confidence that the proposed exposures will produce only superficial heating of the skin that will be self-limiting at non-injurious levels.

No damage to the eyes is expected. Chalfin, D'Andrea, Comeau, Belt, and Hatcher (2002) showed that energy densities of 5 to 6 J/cm^2 produce a threshold damage to the cornea that resolves within 24 hours. D'Andrea, Ziriax, Cox, Henry, and Kosub (2005) have shown that monkeys and humans produce blink reflexes with latencies less than 250 ms that serve to protect the cornea at energy densities of about 1 J/cm^2. Ziriax et al. (2005) have observed "hot spots" in the region of the inner canthus with direct frontal exposure of the human face. However, both modeling studies and testing have shown that these "hot spots" shift and disappear with changes in orientation of the head to the MMW beam. Such changes in orientation are expected to occur rapidly as exposed individuals perform eye and head aversion responses while attempting to escape the MMW beam.

Some skin (e.g., eyelids) may be more vulnerable to thermal damage than other skin, so there may be a small risk of mild thermal damage (small blisters) in subjects with a high pain tolerance. As such, pain similar to touching a lit light bulb is a known risk associated with exposure. Such damage should resolve within a few days without sequelae. Of note, blistering has been observed in six individuals from overexposure to MMWs in the approximately 9000 exposures performed by AFRL/HEDR personnel to date. These blisters were considered minor as they resolved without residual effects and did not require medical treatment.

Risks associated with running the course include muscle injuries, sprains, strains, collisions with barriers, or other trauma associated with any physical activity.

There are no known risks specific to experiment personnel. All efforts will be made to keep personnel free from beam exposure (see Section 9.C.3, *Safety precautions*, para 6). Additionally, there is no known risk prevalence for any specific ethnic, age, or gender groups.

Risk Assessment:

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

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

11. **References:**

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12. **Attachments:**

A) Informed Consent Document

B) Instructions for Subjects

C) Medical Documentation Form

D) Medical Authorization Form

E) Recruitment Briefing Script

F) Volunteer Evaluation Form

G) Resumes: Dr. Michelle Bryce, Dr. Steven Chalfin

Informed Consent Document

Naval Surface Warfare Center, Dahlgren, VA 22448/Brooks City-Base, TX 78235

Institutional Review Board Approval Dates: 1 February 2006 – 31 January 2007

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

TITLE OF STUDY

Effects of Exposure to 400-W, 95-GHz Millimeter Wave Energy on Non-Stationary Humans

INVESTIGATORS' NAMES, DEPARTMENTS, PHONE NUMBERS

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BACKGROUND INFORMATION

Investigators at the Air Force Research Laboratory in Brooks City-Base, Texas, and the Naval Health Research Center Detachment, also in Texas, are conducting a research study of a new technology that uses millimeter waves to heat up skin. This technology is called non-lethal weaponry and may soon be deployed to operational theaters. The military is occasionally faced with situations where large crowds of people wish our troops harm. An example of this is the "Black Hawk Down" incident in Somalia. A number of soldiers were trapped in an urban setting by large mobs of people. U.S. soldiers died, and the use of lethal force to extract the trapped soldiers resulted in the deaths of a number of the large group of people surrounding those

troops. Scientists have now developed a device that should allow the military to disperse a group of people from a distance without using lethal force. This device could also potentially be used to keep small piloted boats from getting near a Navy ship, thereby avoiding attacks like the one that occurred with the USS Cole.

The new device emits millimeter waves, which is electromagnetic radiation, at a frequency that causes a painful level of heating when it makes contact with human skin. Volunteers are needed so that the military can assess the effectiveness of this device at various distances and strengths. The beam levels to be used in this research will cause pain, but all preliminary studies indicate that the exposures are likely to be safe. Although exposures may exceed permissible exposure limits specified by the relevant safety standard, AFOSH 48-9 (U.S. Air Force, 1997), by as much as 20-fold, we have shown in previous work that the pain tolerance limits occur well below exposure levels that produce any but minor effects (e.g., small burns, temporary skin reddening, and sensation of tenderness). The study attempts to quantify at what energy levels you can bear the heat when the beam is targeted at you and how long it takes you to run through a maze-like course and perform a manual dexterity task — opening a door with a combination lock. At any time, you may run behind a protective barrier or yell "STOP." The beam cannot penetrate the barrier, and the beam will immediately be turned off if you say "STOP." Participation is completely voluntary, and you may quit the experiment at any time.

The system uses a 95-GHz beam, and the energy on your body will vary up to 12 joules per square centimeter. This is a limit that has been recognized by the Pentagon as within acceptable parameters for demonstrations of this technology. The beam works by heating the water in your skin. The beam's effect has been compared to the burning sensation you would experience if you touched a light bulb that had been on for a while. Exposure to the beam for an extended period of time would burn your skin, but because of the pain it causes, it is expected that you will reflexively take evasive action or yell "STOP" before any lasting damage can be done to the skin. The beam can raise the temperature of your skin to 140 degrees Fahrenheit. The beam penetrates to less than 1/64 of an inch, so it should not impact any organs beneath the skin. The pain from the heat should end within a few seconds after you go behind a protective barrier or after the beam is shut off because you yelled "STOP" or raised your arms in surrender.

PROCEDURES

If you volunteer, it is desired that you run the course four times. On two of the trials you would be exposed to the beam, and on two of the trials you would just be timed to see how long it takes you to run through the course and unlock the door under normal conditions. This might require that you be at the test site twice, for approximately two hours each time. You will be fully clothed for all trials. You should not apply creams or lotions prior to participation, as this could confound any results. You will start at the end of an alleyway furthest from the millimeter wave device and run the course in the direction of the device. When you arrive at the near end, you will attempt to unlock the door and exit the course. Figure 1 is a drawing of the course. On the two exposure trials, the device operator will be targeting you continually as you travel the course. The goal during all trials is to move as quickly as possible through the course. You may retreat behind the barriers at any time to protect yourself from the beam. A trial will end if any of the following circumstances occur:

- you reach the door and successfully exit within three minutes

- you remain behind a barrier for more than 30 seconds
- you are not able to exit the range within the three-minute period
- you yell "STOP" or raise your arms above your head signifying surrender

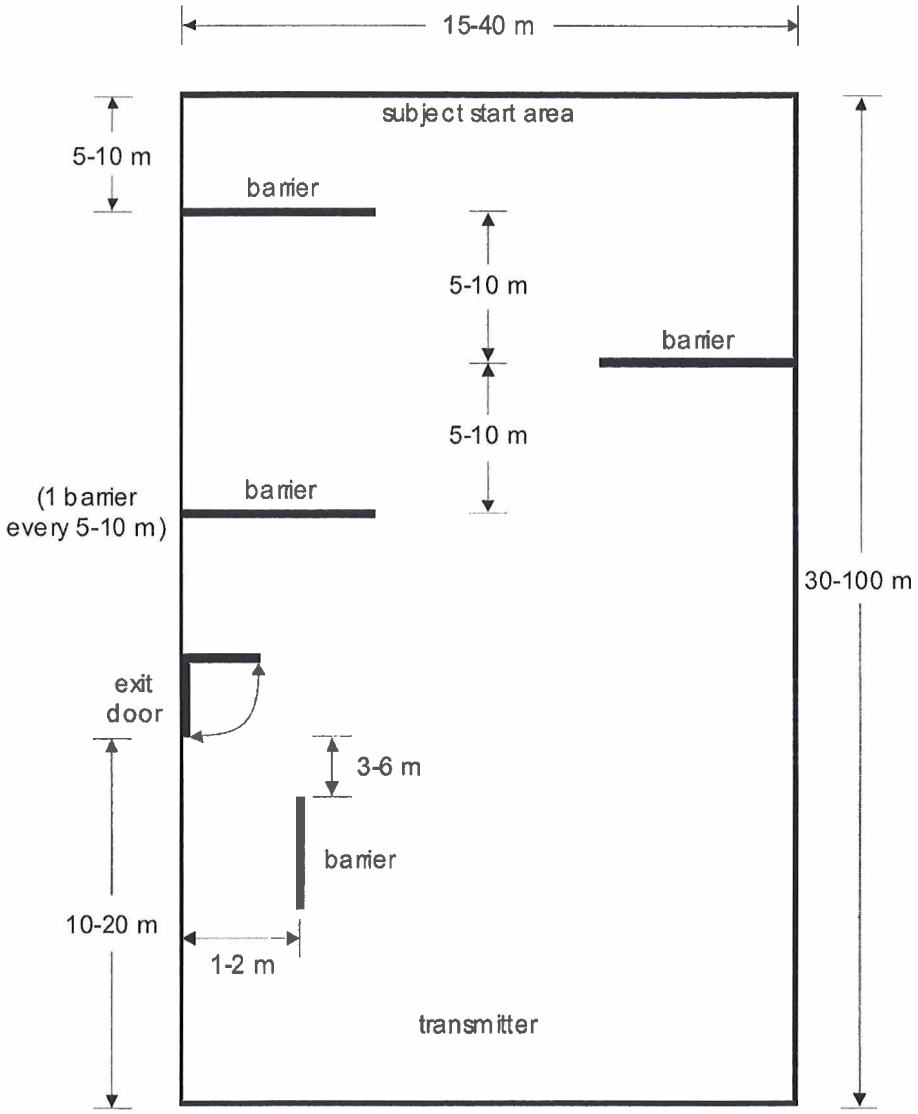


Figure 1. Schematic of course to be traversed by subjects (not drawn to scale).

If you choose to volunteer you may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled. Data from all four trials are needed from 30 subjects, but voluntary means voluntary, and you may discontinue your participation at any time.

RISKS/INCONVENIENCES

You will feel a burning sensation like touching a lit light bulb when targeted by the beam. The targeted area may turn red and feel tender for a few minutes. This tenderness should not last

more than 1 or 2 hours at the most. However, some volunteers who tolerate the heat may experience prolonged redness or even small blisters. This is rare, however. Any small blisters should clear up within 72 hours with no aftereffects. Any prolonged redness or tenderness should last no longer than one day. If small blisters last longer than 72 hours or redness or tenderness lasts more than one day, you should contact the investigator or medical staff and be re-examined. Any eye irritation that lasts longer than few minutes should also be reported. Some scarring is a remote possibility. Like scarring from tattoos, vaccinations, and gunshot wounds, scars from burns have some low but increased risk of resulting in skin cancer. The same exposure levels to be used in this study have been used in a number of studies in the past without serious incident or any known long-term effects. To establish safety margins, monkeys were previously exposed to the beam when they were under the influence of an anesthetic and had their eyes held open with a physical device. When the beam was tested on these monkeys' eyes at a lower energy density level than in this study, and for brief periods of time, the monkeys developed lesions on their corneas that typically cleared up within one day. Negative effects to your eyes in this study are unlikely because turning your head and/or the natural blink reflex will limit the exposure to your eyes. If you feel discomfort in your eyes or in the skin surrounding your eyes for more than a few minutes after the trial, you should be examined by a medical doctor. A slit-lamp eye examination (basically a microscope) will be conducted on you both before your participation and after your final participation, but this examination will cause no discomfort other than a slight burning when staining drops are placed in your eye. If you normally wear contact lenses you may not wear these until after the final post-trial eye examination is performed. We will try to perform these examinations soon after your participation, but you could be restricted from wearing contact lenses for up to 10 days while waiting for the examination. Let the investigator know immediately after reading this document if this delay may be a problem for you. No other eye examinations are planned, but it is at least slightly possible that the ophthalmologist will indicate that further examination is warranted. The beam technology has been studied in various forms for more than a decade. No long-term negative effects are known to exist with the exposures planned for this study, but it is possible that there are unforeseeable effects. Energy wave exposures at substantially greater energy densities than planned in this study or for longer durations than planned in this study would likely result in damage to the skin.

DISQUALIFYING CONDITIONS

There are no known harmful effects of the beam to a fetus or to pregnant women. However, in the interest of utmost safety, if you are female without documentation indicating sterility, we are requiring a negative urine pregnancy test before each week's trials. All men and women that participate will receive limited medical screening both before and after the trials. If you have any of the following conditions you cannot participate: metal implants, physical conditions that may limit mobility, an eye or skin condition that exposure might aggravate, herpes simplex or herpes zoster, uveitis, pathologic dry eyes, glaucoma, cataract extraction, diabetes, or refractive eye surgery like LASIK or PRK. If you have any of these conditions, or any other that you think might be a factor, bring them to the investigator's attention during the pre-screening process.

PRECAUTIONS

The following precautions are being taken to minimize the likelihood of any injury other than the temporary pain that the beam will cause:

- you will be physically examined, and your medical history will be reviewed before being allowed to participate
- the exposure levels of this study have been used previously without serious incident
- there are protective barriers in the trial that you can hide behind
- your movements should keep any one area of your body from being continuously targeted
- if the exposure causes skin redness or tenderness that lasts more than 15 minutes, or eye irritation that lasts more than a few minutes, you will not be further exposed to the beam on that day
- calibration of the device will be examined at the beginning and end of each day

  we are using beam frequencies that will likely cause you to retreat or yell "STOP" before any negative effects other than redness or tenderness could occur
- if any information relevant to your participation becomes known during the study, the investigators will inform you of that information
- you will be physically examined after each day's trials

In the event of injury you are entitled to medical care as a member of the active duty forces. It is not Department of Defense policy to pay monetary compensation for any injury sustained, but this statement is not a waiver or release of any your rights. Medical care is limited to that normally provided to Department of Defense health care beneficiaries. If you have any questions about your entitlement to medical care or believe you have incurred a research-related injury, you should contact the medical monitor, Dr. Michelle Bryce at (210) 536-4007 or Michelle.Bryce@brooks.af.mil. She functions as an independent physician and will be present during all testing. She will have the authority to end the experimentation if she believes the likelihood of injury is significant.

BENEFITS

There are no expected direct benefits to you from your participation. The information gathered from this study however may benefit your fellow service members if the device is deployed and can effectively deter attacks.

ALTERNATIVES

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

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. The trials will be videotaped, but no names or other identifying information will be associated with the images when shown to others. The tapes will only be shown at DoD briefings and by request to regulatory bodies charged with keeping research participants safe. Medical and performance documentation will be identified in research records by subject number to maintain confidentiality. However, your name, contact information, and exposure parameters will be entered into a subject database that we are required to maintain indefinitely. The data entered into the subject database will be also be kept in the Air Force Radio Frequency Radiation Registry. Once you have participated in the study, you will not be able to withdraw your information from the Air Force Radio Frequency Radiation Registry.

The Principal Investigator, Michael Cook, is responsible for maintaining your consent forms and research records related to your participation in the study. These records will be maintained by the Air Force Research Laboratory's Radio Frequency Radiation Branch in locked files at 8262 Hawks Road, Building 1162, Brooks City-Base, TX. A copy of the consent form and the database of exposure parameters will also be securely maintained at the Naval Health Research Center in San Diego. Complete confidentiality can not be guaranteed because information regarding your health may be required to be reported to appropriate medical or command authorities. Also, any DoD regulatory body with oversight responsibility for human subjects research could inspect the records.

Information on any medical symptoms arising during or after the trial will be collected by the researchers, as will information about chronic conditions that might disqualify you, any medications currently being taken, and relevant information about eye or skin conditions that you may have before participation. You are entitled to inspect the medical information being collected by contacting the principal investigator in writing at Michael.Cook@brooks.af.mil. You can also revoke in writing your authorization for us to collect any new medical data as part of this research, but there can be no guarantee that already-collected data from which your name and social security number have been stripped will be removed from any existing database. The research data will be maintained until all research questions on this technology are answered. A copy of your consent form will also become a permanent part of your military medical record.

Thirty research participants are being sought. Again, you are free to participate or not to participate. And you are free to discontinue your participation at any time. The investigators or medical monitor may also discontinue your participation if they feel it is in your best interest. If you are removed from the study, there is no penalty or loss of benefit. The Department of Defense, Air Force, and the Navy strongly respect the rights of study participants, so you should ask any questions of the investigators that you may have about your participation. If you have questions later about the study procedures, you should contact Michael Cook at (210) 536-3059 or Michael.Cook@brooks.af.mil. If you have any questions about ethical aspects of the study or rights as a volunteer you may contact Christopher Blood, the Subject Protection Chairperson at the Naval Health Research Center in San Diego at (619) 553-8386 or Blood@nhrc.navy.mil or Col Rocky D. Calcote, USAFSAM/ATTU, Brooks City-Base IRB Chair, at (210) 536-1797. You may be contacted by a representative of the NHRC IRB following the trials to hear any comments you may have about your research participation. If you wish to

report any health concerns after your participation has ended, feel free to contact Dr. Bryce at Michelle.Bryce@brooks.af.mil or Dr. Cook at Michael.Cook@brooks.af.mil.

Your signature on this consent form represents that you have read the form, that you understand the research, that you have had any questions you have answered, and that you wish to be considered for participation. After you sign the consent form you are to be given a copy of that form for your own personal records.

Printed Name of Research Volunteer	Social Security Number	Telephone Number

Signature of Research Volunteer	Date

Printed Name of Witness	Affilated Organization

Signature of Witness	Date

Printed Name of Investigator	Name of Employer

Signature of Investigator	Date

Privacy Act Statement

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

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

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

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

Effects of Exposure to 400-W, 95-GHz Millimeter Wave Energy on Non-Stationary Humans

Instructions for Subjects

These experiments involve exposure to millimeter wave energy that will heat your skin to painful levels. You will be fully clothed during the exposures since testing in our laboratory has shown that clothing has little or no effect on the sensations evoked by millimeter waves. You should not apply creams or lotions prior to participation, as this could affect the results. Furthermore, contact lenses should not be worn for at least 24 hours prior to your pre-exposure eye examination, and should not be used again until after the final eye examination. This is because insertion and removal of contact lens may cause some irritation to the surface of the eye, affecting the interpretation of the examination. You should use your glasses during the exposures.

During this study you will be asked to navigate through a maze-like course and at the end of this course perform a task involving fine motor skills, all while being targeted by a millimeter wave device. You will start at the end of the alleyway farthest from the device. The goal is to move through the course, unlock the door, and exit as quickly as possible. The device operator will be targeting you continually as you move through the course. You can at any time retreat behind any of a number of barriers that block millimeter waves should you want to escape the effects of the beam. (If, for any reason, you feel that you cannot adequately move to the shielded area, you may shout "stop", and the device operator will immediately turn off the beam and the trial will be terminated.) A given trial will end when you either (a) reach the door, successfully unlock it, and exit the course, all within a 3-minute period; (b) remain behind a given barrier for more than 30 seconds; (c) fail to exit the course within the required 3 minutes; or (d) raise both your hands over your head or shout "stop", signifying surrender. You will be run individually and will have four opportunities (trials) to run the course. During two of those trials, you will be targeted by the millimeter wave device as described above. During the other two trials you will not be targeted by the millimeter wave device. We will measure the time required for you to complete the course and videotape your performance.

While attempting to accomplish the objective of successfully exiting the course through the door you may be exposed to the millimeter wave beam a number of times. During these exposures, if the pain experienced becomes too intense, you may move behind a barrier or you may surrender (by raising both your hands over your head or by shouting "stop"). During any of the exposures that target your face, you should feel free to close your eyes, avert your face, or shield your face with your arms and/or hands.

Most subjects will move away from the millimeter wave beam, either because the pain causes an involuntary reflex or because the pain reaches the subject's tolerance limit.

When you move out of the beam, or when the beam is turned off, the sensation of pain may linger for a few seconds. The exposed area may also be reddened and feel tender for a few minutes. We expect that these conditions will disappear within an hour or two.

If the skin is still red and/or tender after a day, you should notify the investigator, who will arrange for the medical staff to examine you and apply any appropriate treatment. Any eye discomfort or concerns that last longer than a few minutes should also be reported. There is no reason to expect any aftereffects more serious than a mild sunburn. In contrast to a sunburn, which entails some long-term risk from the aftereffects of ultraviolet exposure, millimeter waves have no known long-term effects.

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

Effects of Exposure to 400-W, 95-GHz Millimeter Wave Energy on Non-Stationary Humans

Medical Documentation Form

Naval Surface Warfare Center, Dahlgren, VA 22448/Brooks City-Base, TX 78235

Note: All medical documentation forms must be completed, signed, and dated by the medical monitor or medical observer. Eye and vision examinations must be completed by the licensed ophthalmologist where indicated.

Date/Time: _____/_____ Subject # _____

Subject's Medical Facility/Tricare Service Center: _____

Pre-Exposure History

Comments must be provided for affirmative responses.

1. Indicate the status of below items. Affirmative response to any of the following will result in absolute DQ.

• Pregnancy:	☐ Yes	☐ No
• Date of pregnancy test: _____		
• Mobility limitations:	☐ Yes	☐ No
• Large metal implants:	☐ Yes	☐ No
• Diabetes:	☐ Yes	☐ No
• Eye exclusions (affirmative response requires comment from ophthalmologist):		
o PRK/LASIK:	☐ Yes	☐ No
o Cataract extraction:	☐ Yes	☐ No
o Other intra-ocular surgery: _____	☐ Yes	☐ No
o Glaucoma:	☐ Yes	☐ No
o Uveitis:	☐ Yes	☐ No
o Pathologic Dry Eyes:	☐ Yes	☐ No
o Herpes Simplex:	☐ Yes	☐ No
o Herpes Zoster:	☐ Yes	☐ No

Comments: _____

_____

2. Indicate the status of below items. For affirmative response, indicate if entity requires DQ. Provide rationale in "Comments" section below.

• Skin condition:		
o Ongoing disease:	☐ Yes	☐ No
o History of skin cancer:	☐ Yes	☐ No
o Grafts, thick scars (keloids):	☐ Yes	☐ No
o Photosensitivity:	☐ Yes	☐ No
• Other chronic medical problems:		
o Cancer:	☐ Yes	☐ No
o Neuropathy:	☐ Yes	☐ No
o High blood pressure:	☐ Yes	☐ No

- Stroke: ☐ Yes ☐ No
- Heart problems: ☐ Yes ☐ No
- Heart medications: ☐ Yes ☐ No
- Other physical injury, ailments that might impede performance on timed trials ☐ Yes ☐ No

Comments: _____

_____

_____

3. List current medications (Rx/OTC): _____

_____

_____

_____

4. Indicate presence of eye-specific entities. (Affirmative response for other than prescription lenses requires comment from ophthalmologist.)

- Contact lenses (must remove 24 hr before initial slit-lamp examination and leave out until after final examination) ☐ Yes ☐ No
- Prescription glasses ☐ Yes ☐ No
- Current eye complaints ☐ Yes ☐ No
- Foreign body sensation ☐ Yes ☐ No
- Eye burning, dryness, discharge ☐ Yes ☐ No
- Current eye medications ☐ Yes ☐ No
- Impaired blink reflex ☐ Yes ☐ No
- Eye surgery ☐ Yes ☐ No

Comments: _____

_____

_____

5. Please check one of the following:

☐ History is contributory (subject NOT cleared to participate).
☐ History is NON-contributory (subject cleared to participate); proceed to "Medical Authorization Form".

_____

Medical Monitor/Medical Observer (circle appropriate title) Date/Time

_____

Ophthalmologist Date/Time

Pre-Exposure Examination

Date/Time _____/_____

1. Skin: circle conditions that apply.
   - Color: redness, sunburned
   - Moisture: dry, sweating, oily
   - Texture: rough, smooth, crusty areas, other: _____
   - Lesions: macules, papules, vesicles, other: _____
   - Scars: _____

   Comments: _____

   _____

2. Face: indicate the presence of the following entities.
   - Significant facial scars ☐ Yes ☐ No
   - Pre-malignant lesions ☐ Yes ☐ No
   - Sunburn ☐ Yes ☐ No
   - Other abnormalities on face? ☐ Yes ☐ No

   Comments: _____

   _____

3. Eye exam: circle conditions that apply (to be completed by ophthalmologist).
   - Eye lids: redness, normal, other: _____
   - Conjunctiva: injected, normal, other: _____
   - Cornea: _____
   - Visual acuity: _____
   - Other eye abnormalities? ☐ Yes ☐ No

     Describe: _____

     _____

   Comments: _____

   _____

_____

Medical Monitor/Medical Observer (circle appropriate title) Date/Time

_____

Ophthalmologist Date/Time

Inter-Trial Brief Examinations

Circle conditions that apply. (Affirmative response to eye conditions requires signature of ophthalmologist).

Trial #1

Date/Time _____/_____

Trial condition (circle): exposure, sham

Examination: skin/eye: redness, blisters, sweating, normal, other:

_____

_____

_____

Trial #2

Date/Time _____/_____

Trial condition (circle): exposure, sham

Examination: skin/eye: redness, blisters, sweating, normal, other:

_____

_____

_____

Trial #3

Date/Time _____/_____

Trial condition (circle): exposure, sham

Examination: skin/eye: redness, blisters, sweating, normal, other:

_____

_____

_____

Trial #4

Date/Time _____/_____

Trial condition (circle): exposure, sham

Examination: skin/eye: redness, blisters, sweating, normal, other:

_____

_____

_____

Medical Monitor/Medical Observer (circle appropriate title)	Date/Time
Ophthalmologist	Date/Time

Final Post-Exposure Examination

Circle conditions that apply.

Date/Time _____/_____

1. Skin: circle conditions that apply.
   - Color: redness, sunburned
   - Moisture: dry, sweating, oily
   - Texture: rough, smooth, crusty areas, other: _____
   - Lesions: macules, papules, vesicles, other: _____
   - Scars: _____

   Comments: _____

   _____

2. Other worth noting: _____

   _____

3. Eye exam: circle conditions that apply (to be completed by ophthalmologist).
   - Subject eye complaints: _____
   - Foreign body sensation ☐ Yes ☐ No
   - Burning, dryness, discharge? ☐ Yes ☐ No
   - Eye lids: redness, blisters, normal, other: _____
   - Conjunctiva: injected, normal, other: _____
   - Cornea: _____
   - Visual acuity: _____
   - Other eye abnormalities? ☐ Yes ☐ No

     Describe: _____

     _____

   Comments: _____

   _____

   Need for referral? ☐ Yes ☐ No
   If "Yes", to: local clinic: _____
   Normal examination? ☐ Yes ☐ No

_____

Medical Monitor/Medical Observer (circle appropriate title) Date/Time

_____

Ophthalmologist Date/Time

Effects of Exposure to 400-W, 95-GHz Millimeter Wave Energy on Non-Stationary Humans

Medical Authorization Form

Naval Surface Warfare Center, Dahlgren, VA 22448/Brooks City-Base, TX 78235

This participant, _____, has been examined and cleared for participation in the study entitled "Effects of Exposure to 400-W, 95-GHz Millimeter Wave Energy on Non-Stationary Humans".

_____

Medical Monitor/Medical Observer (circle appropriate title) Date/Time

Effects of Exposure to 400-W, 95-GHz Millimeter Wave Energy on Non-Stationary Humans

Recruitment Briefing Script

Hi. My name is Michael Cook, and I would like to tell you about a research study that the Air Force Research Laboratory and the Naval Health Research Center in Texas would like to conduct.

The military and all scientists in this country are required by federal law to explain any study thoroughly to potential research participants and to make sure that people participate of their own free will. The Department of Defense, Air Force, and the Navy all strongly believe in this concept of "voluntary consent" and have their own regulations that require it.

To ensure compliance with these "human subject" protection requirements, I must read this script verbatim, and I need you to listen carefully. On each desk is an envelope with a consent form inside. When I am done reading this script, you will be given time to read over the consent form and ask any questions. The consent form has the same information in it that I am going to read you from this script, and you may follow along if you'd like. If after this brief, you decide you do not want to participate, you will just look over the consent form and place it back in the envelope without writing anything on it. If you do want to participate, then please print your name and social security number very clearly on the last page of the consent document and place the document back in the envelope. Do not sign the document at this time because regulations require us to witness your signature and for a witness to sign at the same time that you do. When we review the envelopes later, we will contact anybody that printed their name on the form to see if they have any questions, to get their signature on the document, and then to start the pre-screening process. So, whether you print your name on the document or not, you will put the form back in the envelope and place the envelope in the box by the door on your way out.

Now let me tell you about the study. The military is occasionally faced with situations where large crowds of people wish our troops harm. An example of this is the "Black Hawk Down" incident in Somalia. A number of soldiers were trapped in an urban setting by large mobs of people. U.S. soldiers died, and the use of lethal force to extract the trapped soldiers resulted in the deaths of a number of the large group of people surrounding those troops. Scientists have now developed a device that should allow the military to disperse a group of people from a distance without using lethal force. This device could also potentially be used to keep small piloted boats from getting near a Navy ship, thereby avoiding attacks like the one that occurred with the USS Cole.

The new device emits millimeter waves, which is electromagnetic radiation, at a frequency that causes a painful level of heating when it makes contact with human skin. Volunteers are needed so that the military can assess the effectiveness of this device at various distances and strengths. The beam levels to be used in this research will cause

pain, but all preliminary studies indicate that the exposures are likely to be safe. Although exposures may exceed permissible exposure limits specified by the relevant safety standard, AFOSH 48-9 (U.S. Air Force, 1997), by as much as 20-fold, we have shown in previous work that the pain tolerance limits occur well below exposure levels that produce any but minor effects (e.g., small burns, temporary skin reddening, and sensation of tenderness). The study attempts to quantify at what energy levels you can bear the heat when the beam is targeted at you and how long it takes you to run through a maze-like course and perform a simple manual dexterity task — opening a door with a combination lock. At any time, the volunteer may run behind a protective barrier or yell "STOP". The beam cannot penetrate the barrier, and the beam will immediately be turned off if you say "STOP". Participation is completely voluntary, and you may quit the experiment at any time.

The system uses a 95-GHz beam, and the energy density will vary up to 12 joules per square centimeter. This is a limit that has been recognized by the Pentagon as within acceptable parameters for demonstrations of this technology. The beam works by heating the water in your skin. The beam's effect has been compared to the burning sensation you would experience if you touched a light bulb that had been on for a while. Exposure to the beam for an extended period of time would burn your skin, but because of the pain it causes, it is expected that participants will reflexively take evasive action or yell "STOP" before any lasting damage can be done to the skin. The beam can raise the temperature of your skin to 140 degrees Fahrenheit. The beam penetrates to less than 1/64 of an inch, so it should not impact any organs beneath the skin. The pain from the heat should end within a few seconds after you go behind a protective barrier or after the beam is shut off because you yelled "STOP" or raised your arms in surrender.

It is desired that volunteers run the course four times. On two of the trials you would be exposed to the beam, and on two of the trials you would just be timed to see how long it takes you to run through the course and unlock the door under normal conditions. This might require that you be at the test site twice, for approximately two hours each time. You will be fully clothed for all trials. You should not apply creams or lotions prior to participation, as this could confound any results. You will start at the end of an alleyway furthest from the millimeter wave device and run the course in the direction of the device. When you arrive at the near end, you will attempt to unlock the door and exit the course. Figure 1 is a drawing of the course. On the two exposure trials, the device operator will be targeting you continually as you travel the course. The goal during all trials is to move as quickly as possible through the course. You may retreat behind the barriers at any time to protect yourself from the beam. A trial will end if any of the following circumstances occur:

- you reach the door and successfully exit within three minutes
- you remain behind a barrier for more than 30 seconds
- you are not able to exit the range within the three-minute period
- you yell "STOP" or raise your arms above your head signifying surrender

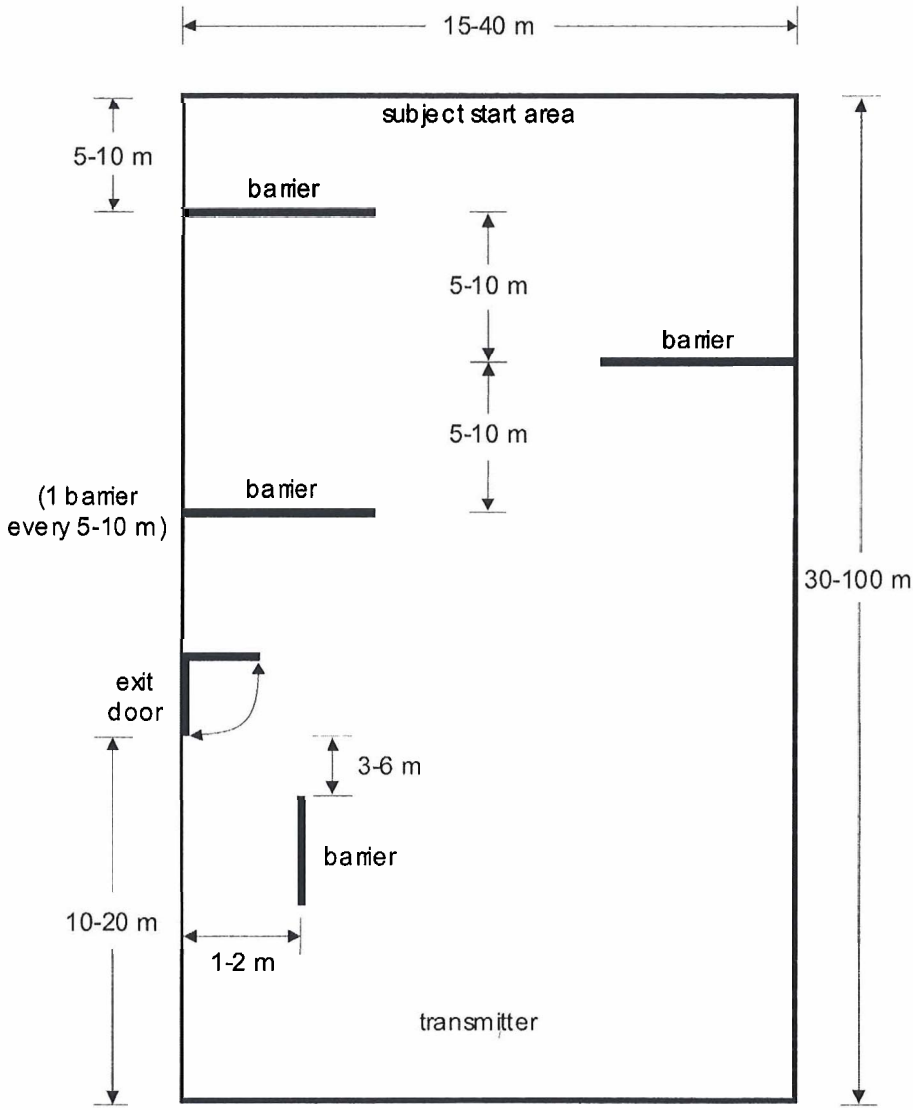


Figure 1. Schematic of course to be traversed by subjects (not drawn to scale).

If you choose to volunteer you may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled. Data from all four trials are needed from 30 subjects, but voluntary means voluntary, and you may discontinue your participation at any time.

You will feel a burning sensation like touching a lit light bulb when targeted by the beam. The targeted area may turn red and feel tender for a few minutes. This tenderness should not last more than 1 or 2 hours at the most. However, some volunteers who tolerate the heat may experience prolonged redness or even small blisters. This is rare, however. Any small blisters should clear up within 72 hours with no aftereffects. Any prolonged redness or tenderness should last no longer than one day. If small blisters last longer than 72 hours or redness or tenderness lasts more than one day, you should contact the investigator or medical staff and be re-examined. Any eye irritation that lasts longer than few minutes should also be reported. Some

scarring is a remote possibility. Like scarring from tattoos, vaccinations, and gunshot wounds, scars from burns have some low but increased risk of resulting in skin cancer. The same exposure levels to be used in this study have been used in a number of studies in the past without serious incident or any known long-term effects. To establish safety margins, monkeys were previously exposed to the beam when they were under the influence of an anesthetic and had their eyes held open with a physical device. When the beam was tested on these monkeys' eyes at a lower energy density level than in this study, and for brief periods of time, the monkeys developed lesions on their corneas that typically cleared up within one day. Negative effects to your eyes in this study are unlikely because turning your head and/or the natural blink reflex will limit the exposure to your eyes. If you feel discomfort in your eyes or in the skin surrounding your eyes for more than a few minutes after the trial, you should be examined by a medical doctor. A slit-lamp eye examination (basically a microscope) will be conducted on you both before your participation and after your final participation, but this examination will cause no discomfort other than a slight burning sensation when the staining drops are placed in your eye. If you normally wear contact lenses you may not wear these until after the final post-trial eye examination is performed. We will try to perform these examinations soon after your participation, but you could be restricted from wearing contact lenses for up to 10 days while waiting for the examination. Let the investigator know immediately after reading this document if this delay may be a problem for you. No other eye examinations are planned, but it is at least slightly possible that the ophthalmologist will indicate that further examination is warranted. The beam technology has been studied in various forms for more than a decade. No long-term negative effects are known to exist with the exposures planned for this study, but it is possible that there are unforeseeable effects. Energy wave exposures at substantially greater energy densities than planned in this study or for longer durations than planned in this study would likely result in damage to the skin.

There are no known harmful effects of the beam to a fetus or to pregnant women. However, in the interest of utmost safety, if you are female without documentation indicating sterility, we are requiring a negative urine pregnancy test before each week's trials. All men and women that participate will receive limited medical screening both before and after the trials. If you have any of the following conditions you cannot participate: metal implants, physical conditions that may limit mobility, an eye or skin condition that exposure might aggravate, herpes simplex or herpes zoster, uveitis, pathologic dry eyes, glaucoma, cataract extraction, diabetes, or refractive eye surgery like LASIK or PRK. If you have any of these conditions, or any other that you think might be a factor, bring them to the investigator's attention during the pre-screening process.

The following precautions are being taken to minimize the likelihood of any injury other than the temporary pain that the beam will cause:

- you will be physically examined and your medical history will be reviewed before being allowed to participate

the exposure levels of this study have been used previously without serious incident

- there are protective barriers you can hide behind
- your movements should keep any one area of your body from being continuously targeted
- if the exposure causes skin redness or tenderness that lasts more than 15 minutes, or eye irritation that lasts more than a few minutes, you will not be further exposed to the beam on that day.
- calibration of the device will be examined at the beginning and end of each day
- we are using beam frequencies that will likely cause you to retreat or yell "STOP" before any negative effects other than redness or tenderness could occur
- if any information relevant to your participation becomes known during the study, the investigators will inform you of that information
- you will be physically examined after each day's trials

In the event of injury you are entitled to medical care as a member of the active duty forces. It is not Department of Defense policy to pay monetary compensation for any injury sustained, but this statement is not a waiver or release of any your rights. Medical care is limited to that normally provided to Department of Defense health care beneficiaries. If you have any questions about your entitlement to medical care or believe you have incurred a research-related injury, you should contact the medical monitor, Dr. Michelle Bryce at (210) 536-4007 or Michelle.Bryce@brooks.af.mil. She functions as an independent physician and will be present during all testing. She will have the authority to end the experimentation if she believes the likelihood of injury is significant.

There are no expected direct benefits to you from your participation. The information gathered from this study, however, may benefit your fellow service members if the device is deployed and can effectively deter attacks.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. The trials will be videotaped, but no names or other identifying information will be associated with the images when shown to others. The tapes will only be shown at DoD briefings and by request to regulatory bodies charged with keeping research participants safe. Medical and performance documentation will be identified in research records by subject number to maintain confidentiality. However, your name, contact information, and exposure parameters will be entered into a subject database (registry) that we are required to maintain indefinitely.

The principal investigator, Michael Cook, is responsible for maintaining your consent forms and research records related to your participation in the study. These records will be maintained by the Air Force Research Laboratory's Radio Frequency Radiation Branch in locked files at 8262 Hawks Road, Building 1162, Brooks City-Base, TX. A copy of the consent form and the database of exposure parameters will also be securely maintained at the Naval Health Research Center in San Diego. Complete confidentiality cannot be guaranteed because information regarding your health may be

required to be reported to appropriate medical or command authorities. Also, any DoD regulatory body with oversight responsibility for human subjects research could inspect the records.

Information on any medical symptoms arising during or after the trial will be collected by the researchers, as will information about chronic conditions that might disqualify you, any medications currently being taken, and relevant information about eye or skin conditions that you may have before participation. You are entitled to inspect the medical information being collected by contacting the principal investigator in writing at Michael.Cook@brooks.af.mil. You can also revoke in writing your authorization for us to collect any new medical data as part of this research, but there can be no guarantee that already collected data from which your name and social security number have been stripped will be removed from any existing database. The research data will be maintained until all research questions on this technology are answered. A copy of your consent form will also become a permanent part of your military medical record.

Thirty research participants are being sought. Again, you are free to participate or not to participate. And you are free to discontinue your participation at any time. The investigators or medical monitor may also discontinue your participation if they feel it is in your best interest. If you are removed from the study, there is no penalty or loss of benefit. The Department of Defense, Air Force, and the Navy strongly respect the rights of study participants, so you should ask any questions of the investigators that you may have about your participation. If you have questions later about the study procedures, you should contact Michael Cook at (210) 536-3059 or Michael.Cook@brooks.af.mil. If you have any questions about ethical aspects of the study or rights as a volunteer, you may contact Christopher Blood, the Subject Protection Chairperson at the Naval Health Research Center in San Diego at (619) 553-8386 or Blood@nhrc.navy.mil. or Col Rocky D. Calcote, USAFSAM/ATTU, Brooks City-Base IRB Chair, at (210) 536-1797. You may be contacted by a representative of the NHRC IRB following the trials to hear any comments you may have about your research participation. If you wish to report any health concerns after your participation has ended, feel free to contact Dr. Bryce at Michelle.Bryce@brooks.af.mil or Dr. Cook at Michael.Cook@brooks.af.mil.

I thank you for listening and for providing your consideration about participation in this important study. If you have questions, I or the medical monitor will answer them now. After you have made your decision, please place the consent document with your name printed or without any writing at all on it back into the provided envelope and drop it in the box on your way out.

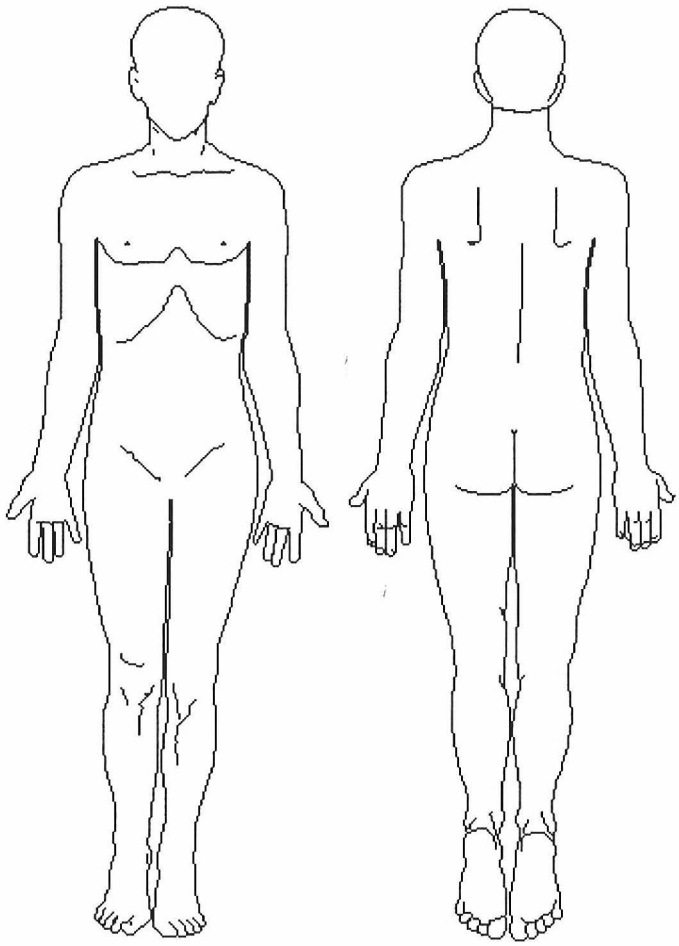
Effects of Exposure to 400-W, 95-GHz Millimeter Wave Energy on Non-Stationary Humans

Volunteer Evaluation Form: Perceived Hits and Effectiveness

Subject #: _____

Trial # _____

1. On the diagram below, please mark or shade the areas where you believe you were "hit" by the beam during the trial you just completed. If you were hit multiple times in one location, please indicate the number of hits (e.g., "x2"). If you cannot recall these details, please describe as much as you can remember.



2. On a scale of 1-10, with 0 being no pain and 10 being the worst pain you have ever experienced in your life, please rate the pain received during the trial.

Pain rating (1-10) _____

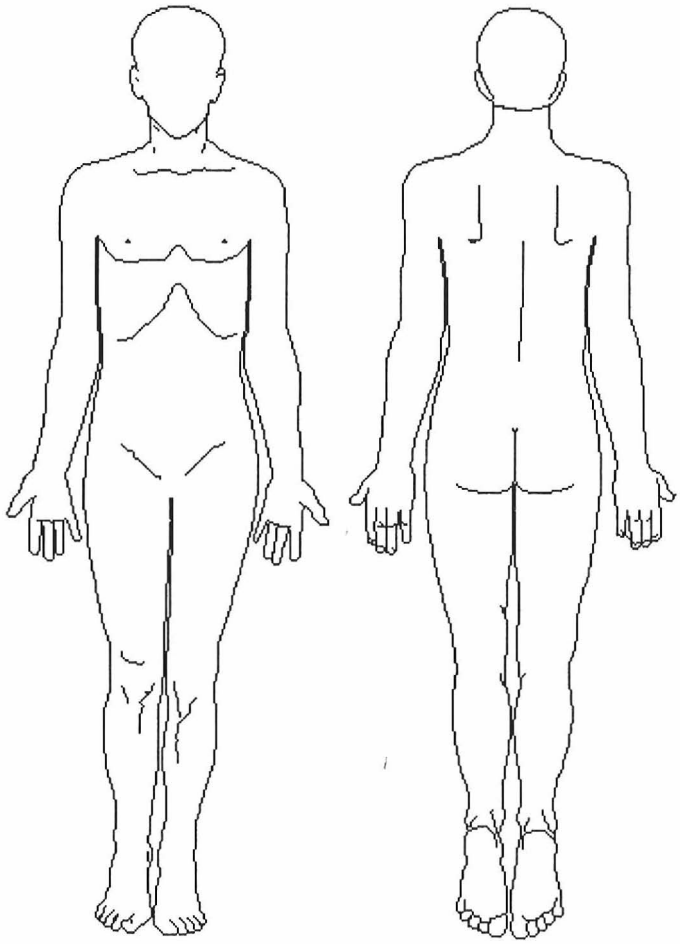
3. Please indicate if there were particular parts of the body, where you felt the beam to be more effective (i.e., produced more pain, or was more effective in preventing you from proceeding).

4. Additional comments:

Subject #:

Trial # _____

1. On the diagram below, please mark or shade the areas where you believe you were "hit" by the beam during the trial you just completed. If you were hit multiple times in one location, please indicate the number of hits (e.g., "x2"). If you cannot recall these details, please describe as much as you can remember.



2. On a scale of 0-10, with 0 being no pain and 10 being the worst pain you have ever experienced in your life, please rate the pain received during the trial.

Pain rating (1-10) _____

3. Please indicate if there were particular parts of the body, where you felt the beam to be more effective (i.e., produced more pain, or was more effective in preventing you from proceeding).

_____

_____

_____

_____

4. Additional comments:

_____

_____

_____

_____

Effects of Exposure to 400-W, 95-GHz Millimeter Wave Energy on Non-Stationary Humans

Medical Authorization Form

Naval Surface Warfare Center, Dahlgren, VA 22448/Brooks City-Base, TX 78235

This participant, _____, has been examined and cleared for participation in the study entitled "Effects of Exposure to 400-W, 95-GHz Millimeter Wave Energy on Non-Stationary Humans".

_____

Medical Monitor/Medical Observer (circle appropriate title) Date/Time