Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz
Millimeter Wave Energy Spots
FWR20120147H

1. Principal Investigator
   
2. Associate Investigators
   a. 
   b. 
   c. 
   d. 

3. Medical Consultants or Research Monitors
   a. 
   b. 

A Research Monitor may appoint a Medical Observer who may assist with medical monitoring functions. The Research Monitor responsibilities include: participant ombudsman and overseeing participant safety. To be qualified as Research Monitor a person must have experience as a principal investigator, thoroughly understand the scientific method and its application, and understand the properties of skin with respect to heating. The Medical Observer will have the same responsibilities and qualification requirements as the Research Monitor. The Medical Observers duties include ascertaining any condition that requires medical treatment following an RF exposure and coordinating with a Research Monitor. Furthermore, a Research monitor will train the Medical Observer; this training will include, at a minimum, reviewing with the Observer the Active Dental System for Medical Personnel training package. All technicians involved with the study will receive written instructions on the mechanism for responding to urgent and emergent medical conditions. These instructions will include information on the appropriate urgent medical disposition of participants who are injured or become ill while participating in the research protocol. A Research monitor overseeing the protocol must be notified of any serious adverse event resulting from the research within 12 hours. All illnesses or injuries occurring in participants while participating in an
experiment, but not causally related to the experiment must be brought to the attention of a Research monitor within 48 hours. A Research monitor will ensure that adverse events will be reported in accordance with AFI 40-402, 3.8.1 and AFRL 40-402, 1.6.2.

4. Facility/Contractor

Facilities: The experiments performed under this protocol will take place at the Tri-Service Research Laboratory (TSRL) on JBSA Fort Sam Houston, Texas.

On-site contractor support will be provided by General Dynamics Information Technology (GDIT) under Contract Number FA8650-07-D-6800 with managerial direction from GDIT Program Manager, and Contracting Officer Representative, The Department of Defense (DoD) Single Project Assurance number for this contractor is F50415. Contractor personnel may receive and handle personally identifiable data. Contractor personnel will assist with participant scheduling (not recruiting), administration of informed consent documents, collection of experimental data, experiment administration, and/or data analysis of non-identifiable data. The contractor personnel have all completed CITI training. The contractor personnel have also been trained in safeguarding data subject to the Privacy Act of 1974. Contractor personnel who will be involved with this study include:

5. Objective

The proposed research focuses on two areas: acquiring data for the empirical skin heating model RASTER-HEATER and identifying effective suprathreshold pain response levels for small moving and stationary 95-GHz millimeter wave (MMW) spots on the human upper posterior skin surface.

Acquiring data for the empirical skin heating model RASTER-HEATER will enable the model to more accurately model skin heating for moving spots and dynamic engagements. Accurately modeling skin heating for moving spots will reduce the need for human experimentation in support of future Active Denial System (ADS) system design. Accurately modeling skin heating for dynamic engagements increases the precision of exposure parameter recommendations for system demonstrations and Military Utility Assessments.
The research will enhance basic scientific understanding and will quantify the effects of moving spots of 95-GHz MMW exposures on humans as compared to stationary spots. Specifically, we will measure variations in tolerability of exposures as a function of spot motion, along with acquiring data necessary for modeling skin heating from small moving 95-GHz MMW spots. Identifying effective suprathreshold pain response levels for small moving and stationary 95-GHz MMW spots will enable system design trade studies that examine the benefits of using a small rapidly moving spot to heat an area of skin versus a system that heats up a larger area of skin, but has a relatively stationary spot.

6. Background

The DoD is developing non-lethal, MMW weapons with various effective ranges from rock throwing distance to greater than that of small arms. One such system, the 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 fifteen years of research at Air Force Research Laboratory (AFRL) supports the safety and effectiveness of ADS as a non-lethal weapon. The proposed research will provide critical data for attempts to develop systems that are smaller, cheaper, and lighter, while maintaining the effectiveness and safety of the current versions of the ADS.

711 HPW/RHDR has conducted extensive research on the bioeffects of MMWs, both in animals and humans. We have shown 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) provide data that demonstrate a substantial safety margin between levels that cause behavioral effect and physical injury. Studies in our laboratories of rat and pig skin damage produced by MMWs further support this conclusion. Research by 711HPW/RHDR and Naval Medical Research Unit scientists indicates that the system poses no undue risk of injury to the face and eyes, and also indicates the absence of risk for skin cancer or infertility.

Some prior work testing the repel effect in humans was done with relatively small areas of exposed skin. Another study employing a device that allowed exposure of a large portion of the body surface was tested on 72 participants, using dorsal exposures. Data from these two experiments showed that exposure of large skin areas reduced the median effective dose (ED50) and the peak skin temperature at which escape responses occur compared to smaller spots. This was further validated by two studies that examined spots less than 0.1% (Protocol F-WR-2007-0061-H, “Pain Intolerability from Short Small Spot 95-GHz Exposures at Various Heat Rates”) and greater than 30% (Protocol F-WR-2006-0070-H, “Thermal and Behavioral Effects of Exposure to Small-Diameter, 95-GHz Millimeter Wave Energy”) of the typical ADS spot size. Thus, for very small and large spot sizes, the existing human effects data provides adequate trends in expected human response over the ranges measured, but highlight the differences between the two spot

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz Millimeter Wave Energy Spots
FWR20120147. Version 3.00
AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015
size regimes. Two protocols investigated repel effects in this middle region: one used a spot of 5% of the ADS beam in Protocol F-WR-2005-0057-H, “Thermal Effects of Exposure to 400 W, 95-GHz, Millimeter Wave Energy” and the other a spot that is 17% of the ADS beam in Protocol F-WR-2006-0055-H, “Thermal and Behavioral Effects of Exposure to 30-kW, 95-GHz Millimeter Wave Energy”. Under a protocol currently under review “Thermal and Behavioral Effects of Exposure to Small-Diameter, 95-GHz Millimeter Wave Energy, Part 2” RHDR will be investigating the region of intermediate spot sizes. All of this work was performed with spots that were stationary on the skin.

The skin heating/cooling model RASTER-HEATER will be used as a guide, to the extent possible, in determining the exposure parameter space for this experiment. RASTER-HEATER is an in-house developed model that uses an in-house developed empirical skin heating algorithm (Beason & Parker, 2009; Beason, Johnson & Kuhnel, 2011) and a cooling algorithm (Beason & Parker, 2007; Beason, Johnson & Kahnel, 2011). The model has been shown to accurately predict skin temperatures for skin that has been heated by MMWs, and then allowed to cool. The model accurately predicts Carbon Loaded Teflon (CLT) temperatures for CLT that has been heated by MMWs with multiple pulses, and then allowed to cool.

One of the objectives of this experiment is to compare the multiple heating/cooling algorithms that were developed using CLT for skin to moving spot data. This will be done by comparing the predicted skin temperature time history with that obtained in the experiment. If the model does not produce a similar result, then the model will be adjusted to more closely align with the experimental data. If successful, much of the data previously obtained from the stationary spot work may be used to estimate the human response to moving spots instead of conducting additional experiments. In addition, the data being obtained for the skin heating model will allow us to predict how skin is heated by moving spots, again reducing the amount of future human experimentation required for the ADS program. The model will then be useful for accurately predicting other exposure conditions.

The RASTER-HEATER model makes no behavioral response predictions, but the behavioral response we are seeking is related to the skin temperature.

The proposed experiment compares stationary spots similar in area to those performed under Protocol F-WR-2007-0061-H, “Pain Intolerability from Short Small Spot 95-GHz Exposures at Various Heat Rates” with comparable heated areas produced by a moving spot. The objective is to determine the response relationships produced from equivalent areas resulting from moving and stationary spots.

7. Impact to Air Force Mission
The Joint Non-Lethal Weapons Directorate is actively engaged in defining the next generation of directed energy non-lethal weapons. This effort will provide valuable trade

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz Millimeter Wave Energy Spots
FWR20120147, Version 3.00
AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015

4
space information that will optimize weapons design choices resulting in shorter delivery times and increased operational effectiveness for the warfighter. In addition, moving spots offer an alternative method of ADS supplication that may result in novel future systems.

8. Experimental Plan

a. Equipment:

This experiment will use RHDR’s 1 kW 95 GHz Coupled Cavity Traveling Wave Tube (CCTWT) system at Tri-Service Research Laboratory (TSRL), JBSA Fort Sam Houston, Texas to provide the MMW exposures.

b. Participants:

Thirty-three adult volunteer participants (n = 33) (n = 18 for Experiment #1 and n = 15 for Experiment #2) will be recruited from among Tri-Care beneficiaries (active duty military, dependents of active duty military, or retirees) to participate in the exposures. Participants will be recruited initially using emails and fliers to gain interest. Interested parties who reply to the email and/or call the numbers in the email or on the flier will be contacted via phone call to further assess eligibility. Prior to any experimentation, a pre-study meeting will be held to explain all details to potential participants and allow for any questions. Volunteers of either gender, 18 years of age or older may participate. Participants in an active military duty status will need to request permission from their supervisor and will continue to receive their normal pay when participating during duty hours. No other compensation will be offered to participants. Participant recruitment will be performed by the principal investigator and/or one of the associate investigators and will be accomplished through the use of e-mail and/or fliers (see Attachment D). For Experiment #1A, each session is expected to be no more than two and half hours, and will need to be repeated until a sufficient spot size is determined from the skin heating data. We expect that the Experiment #1A sessions will not need to be repeated more than three times, which would make the total time requirement to be ten hours (= 4 trials x 2.5 hrs/session) total per participant. For Experiment #1B and #2, the total time for participation is expected to be no more than four visits for ten hours total per participant. Since no evidence exists demonstrating any adverse effects from cumulative, non-injurious, exposures to MMW energy, participants may participate in multiple experiments.

c. Duration:

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

d. Description of experiment, data collection, and analysis:

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz Millimeter Wave Energy Spots
FWR20120147, Version 3.00
AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015
Experiment #1A will initially consist of a series of static exposures using 6 participants who will be exposed to 4 different power densities for 5 s at each of 2 different spot sizes on the torso. The skin temperature increase will be measured using IR thermography. After each exposure, the participants will need to remain motionless for 10s for IR cooling data acquisition. For the first (smaller) spot, a 1.0 cm full width at half maximum (FWHM) spot (or smallest spot the system can produce that is equal to or greater than 1 cm FWHM) will be used. For the second spot, the FWHM will be increased by 0.5 cm. The four power levels to be used are 50, 100, 200, and 400 mW/cm². Previous experiments have shown exposures for these power levels and this time period do not produce pain. For each pair of exposures at a given power level, the temperature increase at the center of the spot relative to the pre-exposure baseline will be assessed to see if a “sufficient” spot size has been reached. A “sufficient” spot size is reached when the average temperature increase for the two different spot sizes are within 0.6 standard deviations of each other. If a sufficient spot size has not been reached, an additional set of 8 exposures with the FWHM at the previous largest spot size and a spot FWHM increased by an additional 0.5 cm will be conducted, and the data compared. This will be repeated until a “sufficient” spot size has been reached. The end result of this experiment is an empirical determination of the smallest spot size that is still large when compared to the radial heat conduction rate times the exposure time, which is a key assumption in the RASTER-HEATER model.

Experiment #1B will consist of a series of static exposures using 10 participants who will be exposed to the smallest “sufficient” spot determined from #1A to determine heating and cooling rates for a stationary beam for multiple pulses. Each trial will consist of a series of 5 total pulses with the power, pulse length, and the time between pulses held constant. The exposures will be conducted for 3 powers (100, 200, and 400 mW/cm²) with 4 pulse lengths (0.5, 1.0, 2.0, and 5.0 s) and 4 different times between pulses (0.5, 1.0, 2.0, 4.0 s), for a total of 48 trials (240 exposures) per participant. The participants will remain motionless for 5 s after last pulse for IR cooling data acquisition.

Experiment #2 will consist of a series of static and dynamic MMW exposures using 12 participants. In the dynamic exposures, participants will be exposed to a MMW beam size equal to the smallest “sufficient” spot determined from #1A. The spot will move in a circle, with two different circle radii of 0.5, and 1.0 times the spot Full Width Half Maximum (FWHM). Three (3) different rotation speeds between 0.25 and 10 Hz will be used. The exposure will continue until the participant “self limits” the exposure. Four powers will be used, spread so that pain intolerability occurs between 1 s and 10 s. A total of 24 exposures will be required for each participant. Each power versus radii versus rotation speed combination will be used once per participant. The powers used will be determined by running the RASTER-HEATER model to estimate the range of powers that should be used.

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz Millimeter Wave Energy Spots
FWR20120147, Version 3.00
AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015
For the static exposures, the same 12 participants will be exposed to the smallest "sufficient" spot determined from #1A and three larger spot sizes. The FWHM of the three larger spot sizes will be determined from the skin surface area that achieves half the peak temperature increase reached in the dynamic exposures. Four powers will be used, and will be the same as in the dynamic exposures. A total of 16 static exposures will be required for each participant. The total number of exposures per participant in Experiment 2 is 36+16=40.

Prior to data collection, subjects will experience a single exposure to determine if they are hypersensitive to thermal stimuli. If any unusual response is noted, the Research Monitor will consult the subject to determine if they wish to continue. At the beginning of each session in Experiment 1 and 2, the participant will be given verbal directions on where to stand, will be handed a "dead-man switch", and will be told how to safely withdraw from the MMW beam if desired. They will be instructed to remain stationary in the beam until the sensation becomes intolerable, at which time they should release the "dead-man switch" and/or move as they desire.

Data Collection and Analysis. Participant behavior during each exposure will be recorded using infrared (IR) imagery techniques. The IR imagery will be used to define the exposure start time, time to retreat, and the real-time changes in skin temperature. Mean and variance of the measured epicondylar time will be calculated. For experiment #2 a short, three question, post-trial questionnaire (Attachment C) will be administered verbally after each shot to ascertain the participant's qualitative assessment of the epicondylar effect for that exposure condition.

Experiment #1A. The data from experiment #1A will be used to establish a sufficient spot size for use in experiment #2. For each iteration of this experiment, the temperature rises from the smaller spot size will be compared with the temperature rises from the larger spot size at 5 seconds. The sample size required for this comparison was found using the following assumptions: (1) the type I error rate (α) was limited to 0.05, (2) with power at least 0.80, (3) the least meaningful difference in temperature rise was set to 0.3 degrees, and (4) the expected common standard deviation is 0.5 degrees. Using these assumptions, 6 participants will be required for a total of 24 exposures at the smaller spot size and 24 exposures at the larger spot size.

Experiment #1B. The data from experiment #1B will be used to refine the RASTER-HEATER code. The sample size required to compare the final temperature rise at any two factor levels was found using the following assumptions: (1) the type I error rate (α) was limited to 0.05, (2) with power at least 0.80, (3) the least meaningful difference in temperature rise was set to 0.5 degrees, and (4) the expected common standard deviation is 0.5 degrees. Using these assumptions for data, 10 participants will be required.
Two additional participants are requested for Experiment 1 (either #1A or #1B, as required) to account for possible participant attrition, equipment failure or other logistical challenges for a total of 18 maximum recruited participants (6-10+2).

Experiment #2. For experiment #2, an ANOVA will be used to assess differences in repel time. The independent variable of interest is whether the spot is static (Experiment #2B) or dynamic (Experiment #2A). The sample size required to compare the dynamic to static treatment was assessed using the following assumptions: (1) the type I error rate (α) was limited to 0.05, (2) with power at least 0.80, (3) the least meaningful difference in repel time was set to 0.5 seconds, and (4) the standard deviation for the highest power setting is estimated to be 2.0 seconds. These assumptions for paired data suggest 128 matched pairs are necessary. Since 4 levels of power and 3 effective spot sizes are being directly compared (4x3=12 factor levels), at least 11 participants are required (12x11=132 matched pairs). Twelve participants will be used to facilitate counterbalancing and three additional participants are requested to account for possible participant attrition, equipment failure or other logistical challenges for a total of 15 participants.

e. Safety monitoring:

The maximum power and duration of the transmitter output will be set at levels that are unlikely to produce skin heating greater than 60 °C. For short durations, this temperature exceeds the pain threshold, but does not exceed the threshold for tissue damage. A combination of operator and software monitoring will be used to prevent skin temperatures above 60 °C. Additionally, skin temperatures near 60 °C will be limited to 3s or less. An erroneous input (setting the output to a higher level) will be rejected by the software as the maximum power density that the system can produce will be constrained such that an escape response can occur well before damaging levels of skin temperature are reached.

MMWs at this frequency are completely absorbed in the skin. The incident power density at the skin surface falls to 1/e² (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. The blood that circulates in the skin redistributes the remaining heat. The fraction that is conducted to structures deeper than the skin is negligible. Thus, there is no risk of significant heating of any subcutaneous structures or organs with the exposures contemplated for these experiments. There are no known aftereffects of heating the skin to painful but non-damaging levels.

A site safety survey will be conducted prior to commencing the study. A copy of the safety survey will be submitted to the Wright-Patterson Institutional Review Board (IRB), and IRB approval of the site safety survey is required prior to commencing the study.

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz Millimeter Wave Energy Spots
FWR20120147, Version 3.00
AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015
The Research Monitor and/or Medical Observer will evaluate the risks for potential participants prior to their participation in the experiment based on their responses to the medical questionnaire (see Attachment C). Additionally, an orientation exposure will be given to subjects to determine if they have increased sensitivity to thermal stimuli. Should any increased sensitivity be observed the Research Monitor will consult the participant to determine their willingness to continue.

Exclusions from participation in this study are as follows: there are no known harmful effects of the beam to a fetus or to pregnant women; however, as an extra caution, pregnant women are excluded from participation due the possibility of tripping during the course of the study. No special participants (45 CFR 46 subparts B-D) will be involved in these studies. Acute sunburn, depending on location and the extent, may also be disqualifying. Individuals with skin conditions such as eczema, psoriasis, or hyperhidrosis (excessive sweating) will not be able to participate in the experiment. In addition, certain chronic medical conditions may be disqualifying at the discretion of the Research Monitor or Medical Observer. Such conditions include diabetes and other sensory neuropathies, uncontrolled high blood pressure, chronic heart conditions, etcetera. Depending upon the participant responses to the medical questionnaire (e.g., a “yes” answer, a comment concerning a medical condition, the use of medications, etcetera) the Research Monitor or Medical Observer may require a more in-depth history and examination (e.g., additional questions regarding any issue on the form or a visual exam of any skin condition that may be of concern). Photographs to document pre-existing conditions may also be required.

The Research Monitor or Medical Observer will examine any participant who reports an injury or concern. Each trial will require on-site medical observation. A quick exam of the exposed sites will be done each day prior to a participant’s first trial. Post-trial examinations of the exposed sites will occur after each trial. Skin erythema must resolve before subsequent exposures can resume on a given day. Participants returning the following day will be examined before they resume participation. After completion of their participation, all participants will answer a post-exposure medical questionnaire. Based on their answers, they may have to be further examined by the Medical Observer. Women of child bearing age will perform a pregnancy test within the 72 hours prior to participation. This requirement can be waived based upon the judgment of the Research Monitor if the participant has a medical condition/procedure that precludes pregnancy. If any participant needs to be referred to local medical providers for evaluation and treatment of exposure-related effects and/or injuries, the 711 HPW/RHD medical personnel will be available for consultation. In the event of a medical emergency, on-site medical personnel will provide aid until emergency medical system responders arrive. The medical team will be available to examine/treat any participant reporting an exposure-related injury. The medical staff will activate the base emergency response system by either directly calling 911 or directing other personnel to call 911 in the unlikely event of an accident or significant medical incident. The principal investigator and/or one or more of the associate investigators will be present during all phases of the experiment.

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz Millimeter Wave Energy Spots
FWR20120147, Version 3.00
AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015
and B mishaps will be reported to the safety office and the Wright-Patterson IRB within 8 hours.

f. Confidentiality Protection:

Records of participation in this study will only be disclosed according to federal law, including the Federal Privacy Act, 5 U.S.C. 552a, and its implementing regulations. Participant personal information will be stored in a secure (locked) cabinet or office. All data files will use participant numbers such that information cannot be linked to specific individuals. The only people who will have access to personally identifiable information will be the researchers named above, the Research Monitors, the AFRL Wright Site IRB, any other IRB involved in the review and approval of this protocol, and any individuals with access to the Radio Frequency Radiation Exposure Registry (RFRER). Backup records will be scanned and stored in a secure electronic database. When they are no longer needed for research purposes, all personally identifiable information will then be destroyed in a secure manner. Complete confidentiality for military personnel cannot be promised because information bearing on the member’s health may be required to be reported to appropriate medical or command authorities.

Participation in this study may be photographed, filmed or audio/vediotaped. Complete confidentiality cannot be promised. Participant consent to the use of these media for DoD review, training and data collection purposes will be acquired prior to conducting the study. Any release of records of participation in this study may only be disclosed according to federal law, including the Federal Privacy Act, 55 U.S.C. 552a, and its implementing regulations. In the event of such a potential release, participants will be contacted for appropriate consent prior to release. This means personal information will not be released to unauthorized source without the participant’s permission. Images will not be intentionally blurred. They will be protected (password protected if digital or locked if physical) such that only personnel concerned with this study will have access to these records. They will be maintained for up to 10 years.

Radio Frequency Radiation Exposure Registry (RFRER)
A registry recording personnel exposed to RF energy beyond the Permissible Exposure Limit was established to comply with the Armed Forces Epidemiological Board memorandum of March 2005 and the Under Secretary of Defense Acquisition, Technology, & Logistics (AT&L) memorandum of 18 July 2005. One of the past Surgeon General’s Human and Animal Research Protections Committee chairs requested that research participants be added to the database as well, thus volunteer research participation is documented within the registry. Disclosure of the social security number is required for participation in the study. At this time, a version of the Air Force Radio Frequency Radiation Exposure Registry is available through the USAFSAM web portal. A record of each participant’s involvement will be documented in this database; each entry will include the participant’s name, date of birth, gender, social security number, date of exposures, the cumulative dosage and number of exposures. Only personnel who

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz Millimeter Wave Energy Spots
FWR20120147. Version 3.00
AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015
10
have been authorized by Air Force Institute of Occupational Health will have access to
this database. The RFRER was constructed to document radio frequency exposures for
epidemiological purposes. Data will be maintained within the RFRER for an indefinite
period.

9. Risk Analysis

Although exposures may exceed permissible exposure limits specified by the relevant
as much as 88-fold, we have shown in previous work, under protocols # F-BR-1998-
the pain tolerance limits occur well below exposure levels that produce any but the most
minor effects (e.g., transient reddening and sensation of tenderness). Our thermal model
RASTER-HEATER will be used to ensure that the repeated exposures conducted in this
experiment remain safe. Separating trials in time by adequate intervals ensures that there
is little or no carryover effect from trial to trial. This time interval depends upon
individual response but generally takes from 1 to 10 min. 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.

Skin exposure levels during the proposed study will be within the safety limits (12J/cm²
maximum) established over the course of 20 previous 711 HPWRHD studies
conducted over a 15-year period examining the human bioeffects of 95-GHz energy.

Approximately 11,000 exposures have occurred throughout the history of ADS research.
The formation of small blisters has occurred in approximately 0.1% of participant
exposures. In addition, effects have included two instances of heat-induced urticaria
resulting in wheals that spontaneously resolved within 24 h; 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.) An
additional, non-research related, over-exposure occurred during a warfighter exercise
using ADS System 1. (711 HPWR personnel were not operating the system when the
mishap occurred.) The incident resulted in a second-degree burn to the target’s thighs
that were treated with a porcine skin dressing. (Photographs of these injuries will be
made available to any potential participants who wish to view them.) The cause of the
mishap was determined to be operator error. During the experiments described in this
protocol, only highly-trained operators (either themselves 711 HPWRHD personnel or
closely monitored by RHDR personnel) will be operating the exposure system.

It is generally accepted that radio frequency radiation (RFR) exposure is not mutagenic
because of the lack of energy necessary to break chemical bonds (Brusic et al., 1998;
Repacholi, 1997; Verschaeve & Maes, 1998). Many studies investigating the
carcinogenic potential of RFR have focused on whether it promotes or co-promotes

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz
Millimeter Wave Energy Spots
FWR20120147, Version 3.00
AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015

11
cancer. Several studies have looked for and failed to find carcinogenic effects employing frequencies ranging from 435 MHz to 94 GHz on mammary cancer, liver cancer, lymphoma, brain cancer, colon cancer, sarcoma, and skin cancer (e.g., Adey et al., 2000; Katsumi et al., 1998; Mason et al., 2001; Szudzinski et al., 1982; Toler, Shelton, Frei, Merritt, & Stedham, 1997). The Mason et al. (2001) study looked specifically at possible promotion and co-promotion of cancer following repeated 94-GHz exposures and found no effect.

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

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

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

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

4) In the event of an overexposure to a power density sufficient to produce thermal injury, there is an extremely low probability that scars derived from such injury might later become cancerous. Proper wound management further decreases this probability, as well as the probability of hypertrophic scarring or keloid formation.

Walters et al. (2000) showed that skin heating associated with painful exposure to MMWs is consistent with a simple thermal model that takes into account the shallow penetration depth at these wavelengths. These results (Walters et al., 2000) and conclusions (Ryan et al., 2000) give us confidence that the proposed exposures will produce superficial heating of the skin that is self-limiting at non-injurious levels.

There is a small risk of mild thermal damage (small blisters) in participants with a high pain tolerance. Such damage should resolve without treatment or sequelae.

10. References


Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz
Millimeter Wave Energy Spots
FWR20120147, Version 3.00
AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015


11. Attachments

*Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz Millimeter Wave Energy Spots*

FWR20120147, Version 3.00

AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015
a. Informed Consent Document
b. Curriculum Vitae of Investigators
c. Medical Questionnaires
d. Participant Questionnaire
e. Participant Recruiting Materials
f. Supplemental Information Forms
Attachment A: Informed Consent Document

INFORMATION PROTECTED BY THE PRIVACY ACT OF 1974

Informed Consent Document

For

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz Millimeter Wave Energy Spots

711 HPW/RHDR, JBSA Fort Sam Houston, Texas

Principal Investigator:

Associate Investigators:

1. Nature and purpose: You have been offered the opportunity to participate in either or both Experiment #1 or Experiment #2 of the “Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz Millimeter Wave Energy Spots” research study. Your participation will occur at JBSA Fort Sam Houston, Texas.

Prior to participating in an experiment you will complete a medical history questionnaire and participate in a review of the document with the research monitor or medical observer to ensure no medical conditions exist that preclude your participation. For Experiment #1, the purpose of this research is to acquire data for the empirical skin heating model RASTER-HEATER. This will enable the model to more accurately model skin heating for moving spots and dynamic engagements which enables future directed energy system designs.

For Experiment #2, the purpose of this research is to acquire data for identifying effective suprathreshold pain response levels for small moving and stationary 95-GHz millimeter wave (MMW) spots and will enable system design trade studies to be performed that can examine

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz Millimeter Wave Energy Spots

FWR20120147, Version 3.00

AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015

15
the benefits of using a small rapidly moving spot to heat an area of skin versus a system that heats up a larger area of skin, but has a relatively stationary spot.

You may decide to participate in one or both studies. The time requirement for each volunteer in Experiment #1 is expected to be no more than four 2.5 hour visits for ten hours total. A maximum of 18 volunteers will be enrolled. The time requirement for each volunteer in Experiment #2 is expected to be no more than four 2.5 hour visits for ten hours total. A maximum of 15 volunteers will be enrolled. Volunteers must be Tri-Care beneficiaries (active duty military, dependents of active duty military, or retirees). You will need to disclose your social security number so that your information may be included in a USAF Radio Frequency database, in order to participate in this research.

2. **Experimental procedures:** If you decide to participate, you will first experience a single exposure to determine if you are hypersensitive to thermal stimuli. If any unusual response is noted, the Research Monitor will consult you to determine if you wish to continue. During the course of the study, you will be exposed to MMW energy at intensities that will exceed the applicable safety standard by as many as 88 times. In Experiment #1, the low level exposures you will experience are not expected to cause pain, but they could cause your skin temperature to rise up to 44 °C (111 °F). You will have the option to stop the exposures with a "dead-man switch" or by moving out of the path of the beam. For Experiment #2, MMW exposures are expected to exceed your pain tolerance limit and could cause your skin temperature to rise up to 60 °C (140 °F), unless you take action to stop the exposure with a "dead-man switch" or by moving out of the path of the beam. Individuals who have certain skin conditions or are pregnant will not be allowed to participate.

For the exposures in each trial, you will be asked to remove your shirt, so that we can record your skin temperature with an infrared (IR) camera. Women may wear a swimming suit top, sports bra, or similar attire that will allow measurement of their skin temperature. Testing in our laboratory has shown that clothing has little or no effect on the sensations evoked by millimeter waves; however, IR cameras cannot read skin temperature through clothing.

Before each exposure, you will stand with your feet together and hands at your side to assure that only the skin on your torso is exposed, with your front or back pressed up against a frame to help keep you stationary. Each exposure will be limited in duration to prevent skin damage, but in Experiment #2 it is likely to last beyond your pain tolerance.

In Experiment #1, since the purpose of these experiments is to acquire skin heating and cooling data, you should attempt to remain in the same position for as long as you can even after the series of exposures is complete. We will inform you when you may move. After each exposure, it may take a minute or two for the skin to return to its normal temperature.

Experiment #1 will involve two separate phases, and you may choose to participate in either or both phases. For the first phase of Experiment #1, the exposures will involve two different spot sizes and four different intensity levels for a total of eight exposures to determine an
appropriate spot size for the remainder of Experiment 1 and Experiment 2. Additional trials at increasing spot sizes, each trial consisting of 8 exposures, will be conducted until the spot size is determined. We do not expect that more than 4 trials (4x8=32 total exposures) will be necessary to achieve the end goal. For the first portion of Experiment #1, each exposure will consist of a single RF pulse. For the second phase of Experiment #1, each trial will consist of five pulses of four durations, separated by four different times at three different powers, for a total of 48 trials (240 =5x4x4x3 exposures).

In Experiment #2, since the purpose of these experiments is to determine differences in tolerance among people, you should try to extend your time in the beam to the limit of your tolerance, and you should attempt to remain in the same position for as long as you can. However, the pain is likely to become so intense that you will be forced to move to the side in order to escape the pain, either by involuntary reflex, or because you feel that the pain has reached your tolerance limit. After each trial, it may take a minute or two for the skin to return to its normal temperature.

In Experiment #2 you will receive a total of 40 exposures. The exposures will involve four different beam sizes and four different intensity levels, with the beam either moving in a circle or remaining stationary. The exposures will all be on your torso. Because of the number of exposures, the exposures are planned to be performed over several days (up to four).

For experiment #2 a short, three-question, post-trial questionnaire will be administered verbally after each shot to ascertain your qualitative assessment of the repel effect for that exposure condition.

Each trial will require on-site medical observation. A quick exam of the exposed sites will be done each day prior to your first trial. Post-trial examinations of the exposed sites will occur after each trial. Skin erythema (reddening) must resolve before subsequent exposures can resume on a given day. If an exposure produces skin reddening and/or tenderness that lasts for more than 15 minutes, your exposures for that day may be terminated. After completion of your participation, you will be asked to answer a post-exposure medical questionnaire. Based on your answers, you may have to be further examined by the Medical Observer.

If you have any unusual skin conditions that surface heating might aggravate such as eczema, psoriasis, or hyperhidrosis (excessive sweating), you will not be permitted to participate. You are free to discontinue participation at any time.

3. Discomfort and risks: You will feel a sensation like touching a lit light bulb when targeted by the beam. The targeted skin 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. Some volunteers who tolerate the heat may experience prolonged redness or rarely, blisters. Additionally, it is possible that wheals may be formed in rare cases (two people in the history of 94-GHz research). Any

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz
Millimeter Wave Energy Spots
FWR20120147, Version 3.00
AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015
blisters or wheals should clear up with no aftereffects. If the redness or tenderness lasts more than 72 hours, you should contact the investigator or medical staff and be re-examined. 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. 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. 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. An over-exposure occurred during a warfighter exercise with a similar system operated by non-Air Force Research Laboratory (AFRL) personnel. This over-exposure resulted in extensive blistering on the target individual’s thighs. Pictures are available, if you would like to view these prior to participation in the experiment. The cause of the mishap was determined to be operator error. During this research, only highly-trained operators (either themselves AFRL personnel or closely monitored by AFRL personnel) will be operating the exposure system.

4. Precautions for female participants: There are no known harmful effects of the beam to a fetus or to pregnant women; however, as an extra caution, pregnant women are excluded from participation due the possibility of tripping during the course of the study. Women of child bearing age will need to perform a pregnancy test within the 72 hours prior to participation. This requirement can be waived based upon the judgment of the Research Monitor if the participant has a medical condition/procedure that precludes pregnancy.

5. Benefits: You are not expected to benefit directly from participation in this research study.

6. Compensation: You will not receive any payment specifically for participation in this research. If you arrange this research to fall during your normal work day you will receive your normal pay.

7. Alternatives: Your alternative is to choose not to participate in this study. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. Notify one of the investigators of this study to discontinue.

8. Entitlements and confidentiality:

a. Records of your participation in this study may only be disclosed according to federal law, including the Federal Privacy Act, 5 U.S.C. 552a, and its implementing regulations and the Health Insurance Portability and Accountability Act (HIPAA), and its implementing regulations, when applicable, and the Freedom of Information Act, 5 U.S.C. Sec 552, and its implementing regulations when applicable. Your personal information will be stored in a locked cabinet in an office that is locked when not occupied. Electronic files containing your personal information will be password

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz
Millimeter Wave Energy Spots
FWR20120147, Version 3.00
AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015
18
Attachment A: Informed Consent Document

protected and stored only on a secure server. It is intended that the only people having access to your information will be the researchers named above and this study’s Research Monitor or Consultant, the Wright-Patterson Institutional Review Board (IRB), the Air Force Surgeon General’s Research Compliance office, the Director of Defense Research and Engineering office and those individuals authorized access to the Radio Frequency Radiation Exposure Registry (RFRER described below in paragraph b). When no longer needed for research purposes your information will be destroyed in a secure manner (shredding). Complete confidentiality cannot be promised, in particular for military personnel, whose health or fitness for duty information may be required to be reported to appropriate medical or command authorities. Video footage may be used in government approved briefings.

b. An office of the USAF Surgeon General has mandated that a volunteer’s participation needs to be documented within an official registry. At this time, a version of the Air Force Radio Frequency Radiation Exposure Registry is available through the Occupational and Environmental Health Department Dosimetry Section (711HPW/OEHHD). A record of your participation will be documented in this database; each entry is required to include name, date of birth, gender, social security number, date of exposures, and the cumulative dosage and number of exposures will be captured. Only personnel who have been authorized by 711HPW/OEHHD will have access to this database. All database information will be input to the official registry and will remain therein for an indefinite period. Your data may possibly be used to make comparisons between individuals exposed to radio frequency radiation and those that haven’t (i.e., epidemiological assessments).

Your entitlements to medical and dental care and/or compensation in the event of injury are governed by federal laws and regulations. If you desire further information you may contact the base legal office (ASC/IA, (937) 257-6142, DSN 787-6142 for Wright-Patterson AFB). In the event of a research related injury, you may contact one or all of the Research Monitors.

c. If an unanticipated event (medical misadventure) occurs during your participation in this study, you will be informed. 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 or emergency contact information:

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz Millimeter Wave Energy Spots
FWR20120147, Version 3.00
AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015

19
Attachment A: Informed Consent Document

Name __________________________________________ Phone# __________________________

d. The decision to participate in this research is completely voluntary on your part. No one may coerce or intimidate you into participating in this program. You are participating because you want to participate. or an associate, has adequately answered any and all questions you have about this study, your participation, and the procedures involved. or an associate, will be available to answer any questions concerning procedures throughout this study. If significant new findings develop during the course of this research, which may relate to your decision to continue participation, you will be informed. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. Notify one of the investigators of this study to discontinue. The investigator or Research Monitor of this study may terminate your participation in this study if he feels this to be in your best interest. If you have any questions or concerns about your participation in this study or your rights as a research participant, please contact

e. You understand that your participation in this study may be photographed, filmed, or audio/ videotaped. Complete confidentiality cannot be promised. You consent to the use of these media for DoD review, training and data collection purposes and understand that any release of records of your participation in this study may only be disclosed according to federal law, including the Federal Privacy Act, 55 U.S.C. 552a, and its implementing regulations. In the event of such a potential release, you will be contacted for appropriate consent prior to release. This means personal information will not be released to an unauthorized source without your permission. Images will not be intentionally blurred. They will be stored in a locked cabinet in a room that is locked when not occupied. Only the investigators of this study will have access to these records. They will be maintained for 10 years.

YOU FULLY UNDERSTAND THAT YOU ARE MAKING A DECISION WHETHER OR NOT TO PARTICIPATE. YOUR SIGNATURE INDICATES THAT YOU HAVE DECIDED TO PARTICIPATE HAVING READ THE INFORMATION PROVIDED ABOVE.

Volunteer Signature ___________________________ Date ________________

Volunteer Name (printed) ________________________________

Advising Investigator Signature ___________________________ Date ________________

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz Millimeter Wave Energy Spots
FWR20120147, Version 3.00
AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015
20
Attachment A: Informed Consent Document

Investigator Name (printed) ____________________________________________

Witness Signature ___________________________ Date ____________________

Witness Name (printed) ____________________________________________

We may wish to present some of the video/audio recordings from this study at scientific
conventions or use photographs in journal publications. If you consent to the use of your image
for publication or presentation in a scientific or academic setting, please sign below.

Volunteer Signature ___________________________ Date ____________________

Privacy Act Statement

Authority: We are requesting disclosure of personal information. Researchers are authorized to collect personal
information 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.

Purpose: It is possible that latent risks or injuries inherent in this experiment will not be discovered until sometime
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 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, furnishing 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.

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz
Millimeter Wave Energy Spots
FWR20120147, Version 3.00
AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015

21
Attachment B: Curriculum Vitae of Investigators

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz Millimeter Wave Energy Spots
FWR20120147, Version 3.00
AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015

24
Attachment B: Curriculum Vitae of Investigators

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz Millimeter Wave Energy Spots
FWR20120147, Version 3.00
AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015

25
Attachment B: Curriculum Vitae of Investigators

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz Millimeter Wave Energy Spots
FWR20120147, Version 3.00
AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015
Attachment C: Medical Questionnaires

Participant Number __________

ADS PRE-EXPOSURE MEDICAL SURVEY FORM

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz Millimeter Wave Energy Spots

1. Age: ________
   (Circle Yes or No only)

2. Does your medical history include any of the following:    Yes       No
   - Chest pain or angina
   - Heart attack
   - Heart failure
   - Stroke
   - High blood pressure or hypertension
   - Rapid or irregular heartbeat
   - General heart concerns
   - Eczema
   - Atopic dermatitis
   - Psoriasis
   - Hyperhidrosis (excessive sweating)
   - Skin numbness (paresthesia)
   - Sensory neuropathy
   - Third degree burn
   - Dermatographism
   - Xeroderma pigmentosum
   - Porphyria cutanea tarda
   - Erythropoietic protoporphyria
   - Pellagra
   - Lupus erythematosus
   - Dermatomyositis
   - Albinism
   - Vitiligo
   - Piebaldism
   - Keratosis follicularis
   - Rothmund-Thompson syndrome
   - Bloom's syndrome
   - Cockayne's disease
   - Hartnup disease
   - Pityriasis rubra pilaris
   - Diabetic neuropathy
   - Causalgia
   - Reflex sympathetic dystrophy
   - Meralgia paresthetica
   - Tic douloureux
   - Trigeminal neuralgia
   - Familial dysautonomia
   - Riley-Day syndrome
   - Sciatica with leg numbness
   - Pinched nerve
   - Peripheral neuropathy
   - Hyperalgesia
   - Analgesia
   - Dyesthesia
   - Hypoesthesia or hypoesthesia
   - Hyperpathia
   - Chronic pain
   - Pacemaker
   - Automatic Implantable Cardioverter-Defibrillator

4. Are you currently or have you taken within the last 90 days any of the following medications?    Yes       No
   - Tetracycline (Sumycin)
   - Doxycycline (Vibramycin)
   - Minocycline (Minocin)
   - Chlorpromazine (Thorazine)
   - Promethazine (Phenergan)
   - Sulfamethamide (Sultrim cream)
   - Sulfadiazine (Silvadene)
Attachment C: Medical Questionnaires

- Sulfathiazole
- Diuretic (water pill)
- Chlorothiazide (Diuril)
- Chlorthalidone (Thalitone)
- Hydrochlorothiazide (Hydrodiuril)
- Quinidine (Quinaglute)
- Sulfamethoxazole (Bactrim, Septra)
- Glimepiride (Duetact, Avandaryl, Amaryl)
- Glyburide (Diabeta, Micronase, Glynase)
- Cisplatin (Platinol)
- Suramin (Germainin)
- Docetaxel (Taxotere)
- Paclitaxel (Taxol)
- Vincristine (Oncovin)
- Chloroquine (Aralen)
- Hydroxychloroquine (Plaquenil)
- Isoniazid (INH, Nydrazid)
- Metronidazole (Flagyl)
- Nitrofurantoin (Macrodantin, Macrobid)
- Didanosine (Videx)
- Lamivudine (3TC, Epivir)
- Stavudine (d4T, Zerit)
- Zalcitabine (Hivid)
- Amiodarone (Cordarone)
- Hydralazine (Apresoline)
- Colchicine (Colcrys)
- Disulfiram (Antabuse)
- Gold (Aurolate)
- Statin (many, including atorvastatin (Lipitor), simvastatin (Zocor)
- Phenytoin (Dilantin)
- Pyridoxine (Vitamin B6)
- Bortezomib (Velcade)
- Chloramphenicol (Chloromycetin)
- Disopyramide (Norpace)
- Ethanibutol (Myambutol)
- Etoposide (Eposin)
- Leflunomide (Arava)
- Linezolid (Zyvox)

5. Are you currently taking or have you taken within the last 90 days any nutritional or herbal supplements?  
   Yes ☐ No ☐

   1. ________________________________________________________________

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz Millimeter Wave Energy Spots
FWR20120147, Version 3.00
AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015
40
ADS POST-EXPOSURE MEDICAL SURVEY FORM

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz Millimeter Wave Energy Spots

DATE: _______________ Name: __________________________________

NOTE: If you have a yes response to any of these questions, please report to one of the medics

Do you have any skin complaints (burning, blisters, redness, etc.)  No  Yes

Do you have any concerns from your experience with ADS?  No  Yes

Do you have any medical questions or concerns from the ADS?  No  Yes
Following each trial, request from participant:
Rate pain level of last shot (1-10). 1 = mild, 10 = unbearable
Rate your readiness for the next shot (1-10). 1 = now, 10 = in 30 minutes
Describe how the shot felt (1-10). 1 = Slight warmth, like a sunny day, 10 = fell into a pool of lava or burn from something hot.

<table>
<thead>
<tr>
<th>Time</th>
<th>Trial</th>
<th>Spot Size</th>
<th>Location</th>
<th>Skin Complaint</th>
<th>Skin Exam</th>
<th>Continue Exposure</th>
<th>Follow Up?</th>
<th>Pain</th>
<th>Readiness</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y / N</td>
<td>N / R / B</td>
<td>Y / N</td>
<td>Y / N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y / N</td>
<td>N / R / B</td>
<td>Y / N</td>
<td>Y / N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y / N</td>
<td>N / R / B</td>
<td>Y / N</td>
<td>Y / N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y / N</td>
<td>N / R / B</td>
<td>Y / N</td>
<td>Y / N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y / N</td>
<td>N / R / B</td>
<td>Y / N</td>
<td>Y / N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y / N</td>
<td>N / R / B</td>
<td>Y / N</td>
<td>Y / N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y / N</td>
<td>N / R / B</td>
<td>Y / N</td>
<td>Y / N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y / N</td>
<td>N / R / B</td>
<td>Y / N</td>
<td>Y / N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y / N</td>
<td>N / R / B</td>
<td>Y / N</td>
<td>Y / N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Y / N</td>
<td>N / R / B</td>
<td>Y / N</td>
<td>Y / N</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 Skin Exam: N-normal, R-redness, B-bliister (circle if present)
Attachment D: Participant Recruitment Materials

Recruitment Email

The Air Force Research Laboratory, 711 HPW/RHDR is conducting an experiment to identify effective 95-GHz millimeter wave (MMW) exposures using small moving and stationary spots. Participants will be exposed to MMW energy and we will measure the time to tolerance levels and skin temperature. We are looking for 33 military health care beneficiaries aged 18 or older to participate. In the interest of safety, pregnant females will not be allowed to participate. Individuals with certain skin disorders will not be allowed to participate. The tests will be conducted in Spring/Summer 2013. The system under investigation consists of a MMW energy beam that penetrates the skin very superficially (1/64th of an inch) and produces an intense heating sensation. Seventeen years of bioeffects research have led to the conclusion that MMWs present no acute or long term health effects beyond those associated with heating. It is expected that individuals will be exposed to levels that will induce the participants to quickly move out of the beam.

The experiment will be conducted at the Tri-Service Research Laboratory (TSRL) on JBSA Fort Sam Houston, Texas.

If you are interested in participating in this assessment, please contact [Phone Number]

This research project has been approved for the use of human subjects by the Air Force Research Laboratory’s Institutional Review Board in accordance with AFI 40-402 and AFRL.40-402, Protocol Number F-WR-2012-0147-H.
Attachment D: Participant Recruitment Materials

RECRUITMENT FLYER

ACTIVE DENIAL TOLERABILITY ASSESSMENT

Spring/Summer 2013

Volunteers needed—The Air Force Research Laboratory, 711 HPW/RHDR is conducting an experiment to identify effective 95-GHz millimeter wave (MMW) exposures using small moving and stationary spots. Participants will be exposed to MMW energy and we will measure the time to tolerance levels and skin temperature. We are looking for 33 military health care beneficiaries aged 18 or older to participate as test participants. In the utmost interest of safety, pregnant females will not be allowed to participate. Individuals with certain skin disorders will not be allowed to participate. The tests will be conducted in Spring/Summer 2013. The system under investigation consists of a MMW energy beam that penetrates the skin very superficially (1/64th of an inch) and produces an intense heating sensation. Seventeen years of bioeffects research have led to the conclusion that MMWs present no acute or long-term health effects beyond those associated with heating. It is expected that individuals will be exposed to levels that will induce the participants to quickly move out of the beam.

The experiment will be conducted at the Tri-Service Research Laboratory (TSRL) on JBSA Fort Sam Houston, Texas. If you are interested in participating in this assessment, please contact (b) 

(b) (b)

This research project has been approved for the use of human participants by the Air Force Research Laboratory’s Institutional Review Board in accordance with AFI 40-402 and AFRLI 40-402, Protocol Number FWR20120147H.
SUPPLEMENTAL INFORMATION FORM
Radio Frequency Radiation Exposure Registry (RFRER)

Participant name (First, Last, MI) ____________________________________________

Service (check one): □ Army  □ Air Force  □ Marines  □ Coast Guard
□ Navy  □ N/A  □ other ________________________________________________

Status (check one): □ active  □ retired  □ dependent
AFSC/MOS (if applicable): ________________________________________________

Gender (M/F): __________________________________________ Date of birth (mm/dd/yyyy): _______________

SSN: __________________________________________ Duty phone: _______________________

E-mail address: __________________________________________________________

Work or home mailing address: ______________________________________________

FOR OFFICIAL USE

Exposure Date: ___________________________ Exposure time: ______________________

Individual exposure limit: skin temperature will be limited to 60°C

Estimated number of exposures: ___________________________ Estimated dose: ______________________

Circle one: Full body exposures  Partial body exposures

Type of exposure: Normal  Unexpected Exposure  Adverse Health Outcome

Comments (includes environmental conditions, results from overexposure investigations, or assessment of adverse health event outcome)

______________________________________________________

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.

Per the Armed Forces Epidemiological Board Memorandum of March 2005 and the Undersecretary of Defense (AT&L) Memorandum of 18 July 2005, research subject participation involving non-ionizing radiation exposure will be documented within the Radio Frequency Radiation Exposure Registry (RFRER). The RFRER is a system.

Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz
Millimeter Wave Energy Spots
FWR20120147, Version 3.00
AFRL IRB Approval Valid from 24 September 2014 to 24 September 2015
Attachment E: Supplemental Information Form

designed to track medical and epidemiological data associated with radio frequency exposures. Data recorded from this form will be used to input relevant exposure data into this repository for future reporting and analysis. The below personal/demographic information, as well as information regarding the number of RF exposures and cumulative energy received will be recorded for each subject in this database. It is possible that latent risks or injuries incurred in this experiment will not be discovered until sometime in the future. The purpose of collecting this information is to aid researchers in locating subjects at a future date if further disclosures are appropriate. Only those responsible for monitoring the health and safety of DoD personnel will have access to this information.