1. **Protocol FWR-2004-0029-H:** Effects of Active Denial System Exposures on the Performance of Military Working Dog Teams

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6. **Protocol Objective:** The purpose of the present studies is to determine whether the Active Denial System (ADS) has adverse effects on the performance of the Military Working Dog (MWD) team. If performance is affected, how long does it take for full recovery? Although both the dog and handler will be exposed, this protocol is required because of the information

we seek to gain from human handler component of the MWD Team. A separate protocol was approved in June 2004 by the Brooks City-Base Institutional Animal Care and Use Committee (IACUC) and by AFMSA/SGRC, addresses effects on the MWD. The handler component of the MWD team will be evaluated based on a series of standardized tasks. A questionnaire directed to the handler regarding the dog's response to the ADS will provide additional detail as to how the dog has been affected. Additionally, in the future, the video may provide useful information as a training aid.

7. **Background and Relevance:**

A. The research and evaluation proposed in this protocol includes an innovative partnership between multiple cooperative Air Force and Army entities for the purposes of rapid fielding and acquisition of a highly desired new military capability. The ADS is a non-lethal weapon with an effective range greater than small arms fire. It uses millimeter waves (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. The ADS is the subject of an ongoing Advanced Concept Technology Demonstration (ACTD). 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), as well as recent laboratory and field studies involving the ADS (e.g., a Limited Military Utility Assessment [LMUA] conducted in September of 2003) assure us that there is a substantial safety margin between effective levels and injury. A Military Utility Assessment (MUA) of the system may be conducted as early as December of 2004. Because an MUA may involve the participation of MWDs, it would be useful to examine the possible effects of the ADS beam on their ongoing behavior.

B. Data Required. The performance of the handler component of the MWD team will be evaluated based on a series of standardized tasks. These team tasks will employ standard evaluation criteria that are currently utilized in DoD evaluations. This evaluation process records detrimental and acceptable human behavior and performance as part of the MWD team. This is important to acquire as inappropriate handler action could adversely affect the dogs performance. Hence evaluation of the handler will ensure their actions were normal and appropriate. This will allow us to eliminate handler behavior as a causal factor, should any change in their dog's performance occur. A questionnaire directed to the handler regarding the dogs response to the ADS will provide additional detail as to how the dog has been affected. The exposure and testing sessions will be video taped for potential future use as a training aid and as back up to the evaluation process.

C. Current R&D Status and Warfighter Demand. Prior to deploying the ADS for operational use, it would be useful to know if inadvertent exposures by the ADS onto the MDW team would have any effects on their ongoing performance. A team of experts (including members of the USAF Security Forces Center and the 341st Training Squadron [MWD School]) recently convened and concurred that that this was an issue

that needed to be evaluated. The information will prove invaluable in the development of the Concept of Operations (CONOPS) for the ADS. Furthermore, the results can also be used to train the forces that will be working in areas where ADS may be employed. Execution of the research outlined in this protocol will significantly add to our understanding of the effects that ADS exposures might have on the performance of MWD teams.

D. Rationale. AFRL/HEDR is supporting an ACTD of a non-lethal weapon, the ADS. Application of this system will be used predominantly by the security forces of the DoD. The Military Working Dog (MWD) plays a role that is vital to force protection. Prior to transition of the ADS to real world operations, it would be worthwhile to determine if it has effects that would compromise the performance of the MWD team (i.e., dog and/or handler) on either a short- or long-term basis. The utility of investigating such possible effects was endorsed by a panel of experts from the USAF Security Forces Center and the 341st TRS (MWD School. The study described in this protocol will assist in assessing whether the ADS adversely impacts the performance of the MWD team. Further, if performance is affected, the study will assess whether performance deficits are short term (minutes) and/or long term (hours). A separate animal use protocol has been approved by both the 311 Human System Wing IACUC and the AFMSA/SGRC. Both animal and human use protocol must be approved prior to commencement of the studies described herein.

E. DoD Relevance. The ADS will be deployed to the field and it is important to determine the effect that it will have on the behavior of MWDs and their handlers given the likelihood that they will be exposed, even if inadvertently.

8. **Impact Statement:** The technology to be tested in these experiments was developed in response to several Mission Needs (MNS, AFSOC 003-95, Nonlethal/Limited Effects Weapon Capability, dated 22 July 1996; MNS LOG 1.85, dated 20 February 1996, which stated requirements for improved capabilities in Military Operations Other Than War; Marine Corps Development Center MNS #MCCDC-9602029, NAVMC HQ-355). The Joint Non-Lethal Weapons Directorate (http://www.usmc.mil/nlw) has responded to these needs statements by drafting an Operational Requirement Document for Non-Lethal Active Denial Technology Capability dated 25 October 1999. An ACTD (see above) was approved in February 2002. The planned experiment supports the accomplishment of this ACTD, especially with regard to the safe execution of a MUA we plan on conducting in Dec 04, in cooperation with the Air Force Operational Test and Evaluation Center (AFOTEC) and the development of CONOPs and TTPs.

9. **Experimental Plan:**

A. Equipment and Facilities. Exposures will use a MMW transmitter (ADS System 0+ or System 1) located at Kirtland Air Force Base, NM. The high power microwave specialists at AFRL/DEHA and their contractors will direct operation of the ADS

System. Experienced research support technicians from AFRL/HED and their contractors will operate bioeffects data collection equipment and control research trials for the health and safety of the volunteers.

B. Subjects. Adult volunteer subjects (n = 3 for Experiment 1 and n = 10 for Experiment 2; see below for details) will be recruited from among military personnel, DoD civilians, and government contractor personnel from the 341st TRS, MWD School at Lackland Air Force Base, TX and 377th Military Working Dog Kennel Facility at Kirtland Air Force Base. Volunteers will be at least 18 years of age.

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

C. Procedures

i. General. Each subject will undergo medical and visual screening examinations to document any pre-existing (but not necessarily disqualifying) conditions. The same screening examinations will be repeated after exposures are completed. (See Attachment D, Medical Documentation Form). As the effects of eyewear (spectacles or contact lenses) on eye exposure have not yet been determined, subjects will not be allowed to wear eyewear during exposures. For similar reasons, potential subjects who are using eye medication or who have a history of eye surgery (e.g., PRK, LASIK) will not be allowed to participate.

Subjects will be exposed facing toward, away from, or perpendicular to the MMW beam during the exposures to be described. The beam will irradiate a large portion of the body surface that is oriented toward the transmitter. The beam will be characterized by standard radiometric techniques (Durney, Massoudi, & Iskander, 1986). To verify the location and peak power of the beam pattern, a carbon-impregnated Teflon plate, the surface of which heats at rates similar to the skin, will be exposed before and/or after each subject exposure, and the heating distribution will be measured by infrared (IR) thermography. All subjects will be instructed how to move out of the way of the beam in order to escape the pain produced. Transmitter operators will be able to view the subjects during the exposure via video and infrared cameras. Video cameras will also record subject facial expressions before, during, and immediately after exposure.

Each subject will be exposed while positioned in the scenario location shown in Figure 1. The subject will be exposed while performing random activity to include standing and walking.

Experiment 1: ADS effect on naïve dogs. Before the main study begins, it is important to verify the range of responses an ADS exposure is likely to elicit from the dog subjects. That is, it is presently unknown whether a dog will ignore the exposure, become aggressive, attack the handler, or pull away and try to escape from the handler. To address this shortcoming, the present study will expose 3 naïve (untrained) dogs along with their respective handlers to the

ADS. Immediately prior to, during, and immediately following the exposure, subject behavior will be observed and an ethogram (a comprehensive list of discrete, observable behaviors) will be developed. This ethogram will, in part, serve as the basis by which Experiment 2 subjects will be scored during similar ADS exposures.

Handlers and dogs will have had only minimal contact with one another prior to testing. The purpose for this relative lack of rapport between dog and handler is to increase the variety/range of responses likely to be elicited by ADS exposure and included in the ethogram. That is, a greater degree of familiarity (as in Experiment 2, where there will be 2-week period to develop rapport between dogs and their handlers) is likely to result in less reactive behavior and consequently a deficient ethogram.

Each of the 3 dog-handler teams will be exposed six times: For two of the exposures the team will face toward the path of the ADS beam; for another two they will be oriented perpendicular to the path of the beam; and for a final two they will be facing away from the beam. For half of the six exposures (to include one exposure per type of orientation to the beam: toward, away, and perpendicular) the ADS will be turned on and the team will be exposed to the ADS beam; in contrast, the remaining three exposures will be sham exposures (i.e., procedurally identical to the "real" exposures except that the system will not be turned on). Both dog and handler will be stationary during the six exposures. The order of the six exposures will be randomized. Handlers will not be apprised in advance of the order of the exposure conditions (real vs. sham), thus minimizing the effect of handler cues on the dogs. Each team will receive a maximum of three exposures (real or sham) per day with at least 15 minutes separating consecutive exposures.

Prior to any of the six team exposures, each of the handlers will receive a single "orientation" exposure during which they will experience ADS exposure *without* their dog. Individuals naïve to the effects of ADS often are highly aroused and nervous prior to their first exposure. The purpose of the orientation exposure is to familiarize the handler with the effects of the ADS beam, thereby diminishing the effect of handler cues (e.g., visible behaviors indicative of a nervous state) on the dog during subsequent exposures. For the orientation exposure, prior to the beam onset, handlers will be standing stationary and facing toward the ADS. Once beam onset occurs, the handler will be free to move out of the beam immediately, effectively terminating the exposure. Maximum ADS duration and power density settings will be those derived from the behavioral results collected during the recent AFRL research done at ADS field tests and during the recent LMUA of the ADS.

For the team exposures, experimenters will request that the subjects (handler and dog) remain stationary prior to the beam onset. Once beam onset occurs (in the case of the non-sham exposures), the subjects (both handler and dog) will be free to move out of the beam path, effectively terminating the exposure. Dogs will be on lead during exposures. The length and tautness of the lead will be such that they will be able to quickly move out of the beam path, but beyond this requirement lead length/tautness will be at the discretion of the handler based on the handler's assessment of the dog; that is, these parameters will be optimized for each dog so as to minimize the chance of handler-directed aggression. Note that in the case of the team exposures, the ADS operator will direct the beam at the dog rather than the handler. However, the handler will most likely not be outside the range of the beam and will therefore probably feel some

effect. The maximum ADS duration and power density settings will be the same as those used for the orientation exposure.

Immediately prior to and/or following each of the exposures (both non-sham team and handler-alone orientation) the ADS beam will be characterized by a dosimetry exposure. The dosimetry exposure will consist of exposing a carbon-impregnated Teflon® plate (alternately referred to as carbon-loaded Teflon, or CLT). CLT is a homogeneous suspension of carbon powder in Teflon (PolyTetraFluoroEthylene). Prior laboratory and field work performed by AFRL/HEDR researchers have demonstrated that the CLT surface heats at rates similar to skin; thus, measurement of the CLT surface temperature distribution using infrared (IR) thermography allows estimation of both the ADS beam location and its peak power (Ross, Allen, Beason, & Johnson, 2004; cf. Durney, Massoudi, & Iskander, 1986).

Data collection. Data collection during the team exposures will include: (a) videotape of each team's reactions before, during, and after each exposure; (b) IR thermography of the subjects (although this will be of limited value since clothing and fur invalidate the IR results); (c) enumeration of canine behavioral responses during the data collection period, to be used in the development of the aforementioned ethogram, and (d) questions directed to the handler after exposure will be completed by the 341st Evaluator (see attachment C). The data collection period will extend from 5 min prior to beam onset until 5 min following beam offset.

Experiment 2: Determination of performance effects of ADS on trained MWD team equivalents. Ten dogs have been procured by members of the 341st TRS from their usual sources (see Appendix 1 and Section V. 3 for further details) and will undergo approximately 3 months of training at the 341st TRS MWD School, Lackland Air Force Base. Trainers will include the same civilian contractors currently utilized by the 341st TRS for training. (Thus, the dogs will receive training that is comparable to actual MWDs.) The dogs will be trained to a level of competency to include standard patrol work, obedience, and odor detection. Once training is complete, dogs will be introduced to their handlers and allowed to develop rapport for a period of about 2 weeks. Teams will then be transported to Kirtland Air Force Base, where the ADS testing will occur. Handlers for the testing phase will be active duty handlers, DoD civilians, and/or contractors from the 341st TRS MWD School or 377th Security Forces Squadron.

Prior to any of the six-team exposures, each of the handlers will receive a single "orientation" exposure during which they will experience ADS exposure *without* their dog as described above. Individuals naïve to the effects of ADS often are highly aroused and nervous prior to their first exposure. The purpose of the orientation exposure is to familiarize the handler with the effects of the ADS beam, thereby diminishing the effect of handler cues (e.g., visible behaviors indicative of a nervous state) on the dog during subsequent exposures.

Each dog-handler team will experience four ADS exposures. Orientation of the team to the ADS beam will be identical for all four of the exposures. The orientation will be one of the following: (a) facing toward the beam, (b) facing away, or (c) facing perpendicular to the beam. Which of the three orientations is used for the four Experiment 2 exposures will depend upon the results of Experiment 1. Specifically, the orientation that was judged to result in the greatest perturbation of dog behavior in Experiment 1 will be employed for all four Experiment 2 exposures.

Teams will be engaged in one of two "activities" during the exposure interval. For two of the four exposures, both dog and handler will remain stationary prior to and up until the ADS beam onset. For the other two exposures, the dog-handler team will be moving between two points (Points A and B) prior to beam onset; as the team approaches Point B (and immediately prior to beam onset), the team will become stationary as the dog focuses on a suddenly-appearing "decoy". (The decoy will be a trained handler that the dog has been trained to react to as a threat. Use of the decoy allows evaluation of the dog's reaction to the ADS while focused on a task/decoy. The decoy is not intended to be in the path of the ADS beam.)

For half of the four exposures (to include one exposure per type of activity) the ADS will be turned on and the team will be exposed to the beam; in contrast, the remaining two exposures will be sham exposures (i.e., procedurally identical to the "real" exposures except that the system will not be turned on). The order of the four exposures will be randomized. Handlers will not be apprised in advance of the order of the exposure conditions (real vs. sham), thus minimizing the effect of handler cues on the dogs. Each team will receive a maximum of one exposure per day.

Once beam onset occurs (in the case of the non-sham exposures), the subjects (both handler and dog) will be free to move out of the beam path, effectively terminating the exposure. Dogs will be on lead during exposures. The length and tautness of the lead will be such that they will be able to quickly move out of the beam path, but beyond this requirement lead length/tautness will be at the discretion of the handler based on the handler's assessment of the dog; that is, these parameters will be optimized for each dog so as to minimize the chance of handler-directed aggression. The maximum ADS duration and power density settings will be those used in Experiment 1.

Teams will be evaluated in each of four "performance areas" at three time points:

1. Pre-test: within the hour preceding the ADS exposure.
2. Post-test: within 1 hr following the exposure.
3. Follow-up: approximately 3-6 hr following exposure.

The handler is required to be teamed with the dog during testing of four performance areas:

1. Aggression. This series of tests examines the dog's responses to decoys in various conditions. For example, the "attack" subtest examines the dog's response (off leash) to the decoy when the handler gives the command to "get 'em." Other subtests include: false run, out/guard, stand off/guard, search, and reattack. Duration of the test is approximately 5-10 min. (A brief description along with the scoring for each subtest can be found in Appendix 2.)

2. Obedience course. This series of tests examines the dog's ability to traverse on command a number of physical obstacles. Subtests include: barrel, tunnel, steps, hurdle, window, "A" frame, and dog walk. Duration of the test is approximately 5-10 min. (A brief description along with the scoring for each subtest can be found in Appendix 2.)

3. Obedience. This series of tests examines the dog's response to a number of simple commands. Subtests include: heel, down, sit, end of leash (EOL) down, EOL sit, and EOL heel. Duration of the test is approximately 5-10 min. (A brief description along with the scoring for each subtest can be found in Appendix 2.)

4. Odor detection. In this task 12 boxes, each with a "nose hole," are arranged within an enclosed area. One-third of the boxes will contain the target odor which the dog has been trained to detect (chlorate for the present experiment); one-third will contain nothing; and a final one-third will contain a distractor (eugenol and/or other aromatic oils). Position of the boxes within the enclosure is randomized so that neither handler nor dog knows the contents of the boxes (thus minimizing the possible effect of handler cues on dog responses). Further, the task is described as "random re-entry," meaning that the choice of which box to examine first is randomly determined. (E.g., if the third is randomly chosen to be the first one examined, then examination order is: Box 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 1, and 2.) Dependent measures derived from the task are: number of correct responses, number of misses, and number of false positives. Duration of the test is approximately 5-10 min.

The performance of the handler component of the MWD team will be evaluated during the performance of the above standardized tasks: aggression, obedience course, and obedience. This handler evaluation employ's the standard evaluation process used by the 341st TRS, MWD School. A score of satisfactory or unsatisfactory will be used for each set of criteria (attachment F). The detection work evaluation will not utilize handler evaluation criteria as none are currently used by the MWD School. This evaluation process records and determines adverse and acceptable human behavior and performance as part of the MWD team. This is important to acquire as inappropriate handler action could adversely affect the dogs performance. Hence evaluation of the handler will ensure their actions were normal and appropriate. This will allow us to eliminate handler behavior as a causal factor, should any change in the dogs' performance occur. A questionnaire directed to the handler regarding the dogs response to the ADS will provide additional detail as to how the dog has been affected. The exposure and testing sessions will be video taped for potential future use as a training aid.

Testing for the four performance areas will take place in one of two locations: (a) aggression and obedience course testing will be conducted near the Kirtland Air Force Base kennel where the dogs are housed, and (b) detection and obedience testing will occur at the ADS site. Transport between the two sites (via air-conditioned vehicles) requires about 15-20 min.

Immediately prior to and/or following each of the exposures (both non-sham team and handler-alone orientation) the ADS beam will be characterized by a dosimetry exposure. The procedures employed for these exposures are the same as those described for Experiment 1. Figure 1 details the sequence of events prior to and following a given team exposure during Experiment 2.

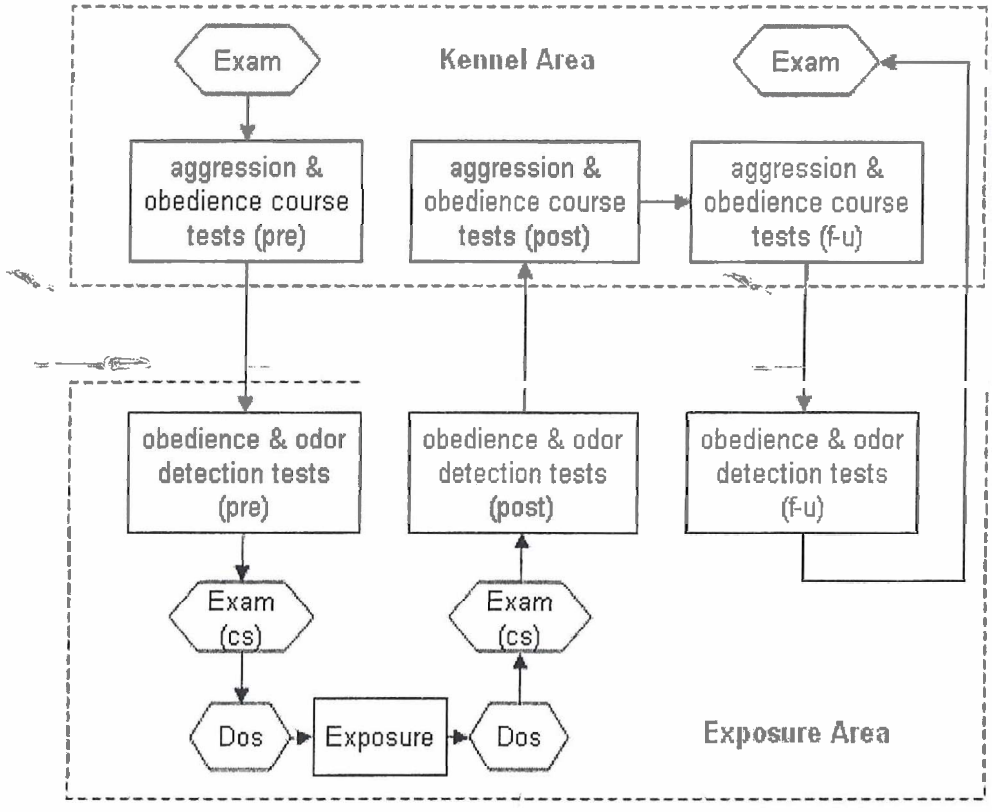

Figure 1. MWD-handler team sequence of events, at various sites, prior to and following a given Experiment 2 exposure. (Exam = temperature, respiration, etc. [see Paragraph V.4.4., *Animal Manipulations* for details]. Exam (cs) = MWD corneal staining. Dos = dosimetry exposure. pre = pre-exposure. post = post-exposure test. f-u = follow-up test.)

Data collection during the team exposures will include: (a) videotape of each team's reactions before, during, and after each exposure; (b) IR thermography of the subjects; (c) evaluation of the handlers appropriate or inappropriate actions and voice, in response to the dogs actions during exposure and performance tasks by the 341st Evaluator (see attachment F); (d) questions directed to the handler after the exposure and performance tasks are completed by the 341st Evaluator (see attachment C).

Data Analysis. The video tape may be used as a training aid in the future. No data will be extracted from it unless it is felt it is needed as a backup in the evaluation of the team. Data files derived from IR thermography will be examined to observe for any hot spots on the team. The questionnaire (Appendix C) will provide additional detail as to how the dog was affected. Nonparametric test statistics will be employed to contrast scores on the handler's performance at pre- versus post-exposure time points obtained during the aggression, obedience course, and obedience performance areas (see Appendix F). Additionally, interaction between dog and human performance will be tested using nonparametric test statistics. The odor detection task will not be included as part of the data analysis as currently no evaluation criteria exists.

Safety Precautions. The maximum power and duration of the transmitter output will be set at levels that cannot produce skin heating greater than 50°C. The maximum ADS duration and power density settings will not exceed those employed during the recent ADS field tests and Limited Military Utility Assessment (LMUA) of the ADS. For short durations, this temperature exceeds the pain threshold, but does not exceed the published threshold for tissue damage (Moritz and Henriques, 1947). Even in the event of operator error (setting the output to a higher level) the maximum available power density that the system can produce at range will normally cause an escape response or other protective responses (e.g., covering the eyes or averting the face) well before damaging levels of skin or eye temperature are reached. MMWs at this frequency are completely absorbed in the skin. The incident power density at the skin surface falls to $1/e^2$ (13.5%) at a depth of 0.3 mm. For the brief exposures contemplated, much of the heat deposited in the most superficial layers of the skin is re-radiated to the environment over the next 10-20 seconds. The blood that circulates in the skin carries the rest away. The fraction that is conducted to structures deeper than the skin is negligible. There are no known aftereffects of heating the skin to painful but non-damaging levels.

On-Site Monitoring. (See attached Medical Documentation Form) Dr. Allnutt (the Medical Monitor) and/or his designated representative will monitor all exposures. The Medical Monitor or his designated medical observer will perform a brief screening examination of the skin and eyes of each potential subject prior to any exposure. Individuals who have any abnormal skin or eye condition that might suffer detrimental effects from surface heating will not be allowed to participate. In addition, certain chronic medical conditions may be disqualifying, at the discretion of the Medical Monitor. A brief examination of the skin will be conducted following each exposure and brief medical and visual examinations will be given following the subject's final exposure (See Attachment D, medical documentation form). If eye injury is suspected, evaluation may require standard ophthalmic staining drops to be applied to the subject's eyes. Suspected injury would necessitate referral to an ophthalmologist/optometrist for further evaluation. The medical staff will activate the emergency response system in the unlikely event of an accident or significant medical incident.

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

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 have not been demonstrated to initiate or promote cancer (Mason et al., 2001).

4) In the event of an overexposure to a power density sufficient to produce thermal injury, there is an extremely low probability that scars derived from such injury might later become cancerous. Proper wound management further decreases this probability, as well as the probability of hypertrophic scarring or keloid formation. Walters *et al.* (2000) showed that skin heating associated with painful exposure to MMWs is consistent with a simple thermal model that takes into account the shallow penetration depth at these wavelengths. These results (Walters *et al.*, 2000) and conclusions (Ryan *et al.*, 2000) give us confidence that the proposed exposures will produce superficial heating of the skin that is self-limiting at non-injurious levels. No damage to the eyes or surrounding structures is expected. Chalfin *et al.* (2002) showed that the energy density required for a 50% probability of producing corneal erythema in anesthetized nonhuman primates is 5 to 6 J/cm^2. This degree of injury resolves within 24 hours. Recent AFRL work in conjunction with the Navy Research Laboratory (NHRC DET) have shown that monkeys and humans produce blink reflexes that protect the cornea at energy densities of about 1 J/cm^2, with response latencies less than 250 ms. Due to security concerns, we cannot state precisely what safety margin this provides, but it is sufficient to discount eye damage under any planned exposure scenario. Additionally, they have observed "hot spots" in the region of the inner canthus with direct frontal exposure of the face. Both modeling studies and human testing have shown that these "hot spots" move away and disappear with changes in orientation of the head to the beam. Such changes in orientation are expected to occur rapidly as exposed individuals perform eye aversion responses and attempt to escape the exposure. Subjects will normally make responses protective of the eyes and face while attempting to tolerate continued exposure. Some skin (e.g., eyelids) may be more vulnerable to thermal damage than other skin, so there may be a small risk of mild thermal damage (small blisters) in subjects with high pain tolerance. Also, in rare cases where MMW energy is concentrated by reflection and constructive interference, minor thermal damage to the skin (redness that lasts more than a few hours and/or small blisters) may occur. Such damage should resolve within a few days, without sequellae or requiring medical treatment.

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.

One of our recent protocols (Protocol FWR-2002-0046-H: Perceptual and Thermal Effects of Millimeter Waves) exposed 135 subjects to the ADS. Exposures were directed at subjects' back. A total of 494 exposures were executed. Per protocol, there was 1 event that required reporting. During frontal exposures (Protocol FWR-2003-0028-H: Perceptual and Thermal Effects of Frontal Exposure to Millimeter Wave Energy) of 34 subjects, 87 exposures, 1 injury occurred that required reporting. Recently at the Limited Military Utility Assessment (LMUA), the ADS was fired 636 times. Most subjects received multiple exposures on any single day. There were 5 reactions with symptoms lasting less than 48 hours. All reactions were considered to be very

minor, to include mild erythema and tingling. Two subjects experienced very small blisters (~1 mm in diameter) on their eyelids. All reactions resolved in less than 48 hr without sequelae. In over 1000 field exposures to the ADS conducted at Kirtland AFB, there have been few medical events and they involved inconsequential skin reactions that resolved within 48 hours, without treatment, and without sequelae. These results suggest consistent, well-defined operating parameters from the ADS. We have a high comfort zone that the ADS operating parameters will not injure subjects.

There is also risk of being bitten or scratched by the MWD. There is a potential for injury if the MWD performs inappropriate or unanticipated actions. These include trying to run away, becoming upset and uncontrollable, or perhaps showing aggression as they are trained to do.

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

Risk Assessment:

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

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

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

11. **References:**

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12. Attachments:

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

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

C) Questionnaires (2: naïve and trained dogs)

D) Medical Documentation Form.

E) IACUC Protocol

F) MWD Handler Evaluation Criteria

G) Memo from AETC ADO to 37TRG/341TRS to Support AFRL in this research project

INFORMED CONSENT DOCUMENT

EFFECTS OF ACTIVE DENIAL SYSTEM EXPOSURES ON THE PERFORMANCE OF MILITARY WORKING DOG TEAMS

Kirtland AFB, NM 87117

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 ACTIVE DENIAL SYSTEM (ADS) EXPOSURES ON THE PERFORMANCE OF MILITARY WORKING DOG TEAMS (EXPERIMENT 1: ADS Effect on Naïve Dogs) Kirtland AFB, NM 87117

INVESTIGATORS' NAMES, DEPARTMENTS, PHONE NUMBERS

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PURPOSE OF STUDY

The Active Denial System (ADS) is a system designed to protect the lives of our service members and reduce fatalities among adversaries and innocent persons. The ADS will provide non-lethal force to accomplish military objectives prior to, during, and following operations. This technology works by projecting a beam of millimeter wave energy toward adversaries. Millimeter waves are similar to microwaves but are shorter in wavelength. Millimeter waves cause heating of water molecules in the skin, causing an intolerable pain sensation leading the exposed individual them to leave the path of the beam in order to stop the pain. Millimeter wave penetration of the skin is very shallow; the energy is absorbed in the first 1/64 inch of the skin.

You have been invited to participate in a research study at Kirtland AFB, sponsored by the Air Force Research Laboratory, Human Effectiveness Directorate, Radiofrequency Radiation Branch, titled "Effects of Active Denial System (ADS) Exposures on the Performance of Military Working Dog teams." The objective of this experiment is to determine if the ADS has any adverse effects on the Military Working Dog (MWD) team's performance. You will be asked to stand in the beam until you are forced to escape by the pain that the beam evokes.

This study will enroll 3 dog-handler teams, with the handler being at least 18 years of age. Prior to any team exposures, you will receive an orientation exposure without the dog. Individual's naïve to the effects of ADS often are highly aroused and nervous prior to their first exposure. The purpose of the orientation exposure is for you to become familiar with the effects of the ADS beam. This will hopefully decrease handler cues to the dog in the team exposures.

You will be at the test site for 1-2 days, for up to 8 hours each day. Immediately after the exposure, you will be asked a few questions about the Active Denial System (ADS) and its potential effect on the MWD team.

PROCEDURES

If you volunteer to participate in this study, you will be exposed to millimeter wave energy at intensities that will exceed the applicable safety standard by as much as 20-fold. This exposure could cause your skin temperature to rise to 50 °C, unless you take action to escape the beam by moving out of the path of the beam.. For the orientation exposure, prior to the beam being turned on, you will be standing still, facing toward the ADS. You will not be warned when the beam will be turned on. Once the beam is on, you will be free to move out of the beam immediately, which will end the exposure. Research into possible risks of eyewear and eye medications is on going, therefore, eyeglasses or contact lenses cannot be worn during exposure. If your vision is dangerously weak without glasses or contact lenses, you should not participate in the study. If you are using eye medications or have a history of eye surgery, you will not be allowed to participate. Chronic medical conditions, to include skin abnormalities, may be disqualifying at the discretion of the Medical Monitor. You will have a very brief medical evaluation before you start and at the end of this experiment. If it is deemed necessary as part of an eye exam, you may be required to have drops placed in your eyes.

During your orientation shot without your dog, you will stand with your feet together and hands at your side. The exposures will be limited in duration to minimize the risk of skin damage, but are likely to last beyond your pain tolerance for skin heating and pain. The pain is likely to become so intense that you will be forced to shield your face with your hands and/or move out of

the beam to escape the pain, either by involuntary reflex or because you feel that the pain is reaching your tolerance limit. You will be exposed once without your dog. After the orientation exposure, it may take 15 minutes or up to 2 hours or longer for your skin to return to its normal temperature.

If you choose to continue, we will then start the experiment. We will refer to each exposure, real or not, as an exposure. Next, you will be asked to stand with your MWD in the beam six times. The beam will primarily target the dog, but you will probably feel some of it. Three of the exposures will be shams in that there will not be any energy from the ADS. Three other exposures will be real and you will experience the effect of the ADS. You will not know ahead of time whether the exposure is going to be real or not.

For 2 of the team exposures, you will face the beam, 2 you will face away, and 2 you will be sideways to the beam. Remember that half of these will be with the power on and half will be sham exposures. You and your dog will be stationary during the 6 exposures. The order of the 6 exposures will be mixed up and not in any particular order. You will receive a maximum of 3 real and 3 sham exposures.

The duration of your participation in the experiment on any day may be as long as 8 hours, given that some exposures may be delayed due to conditions beyond our control (e.g., aircraft in the area).

If an exposure produces skin reddening and/or tenderness that lasts for more than 2 hours, your exposures for that day may be terminated. In rare cases, a mild heat reaction similar to sunburn may occur. This may include redness that last more than a few hours and/or small blisters. This should resolve within a few days, without long-term effects, or requiring medical treatment. Although this has never been required from previous ADS exposures, if you experience eye complaints that suggest you may have a minor injury from either the ADS or the environment, it may require staining drops to be placed in your eye or for you to be referred for further evaluation. Cardiac pacemakers are not affected by millimeter wave energy used in these experiments. If you have any unusual skin conditions or eye surgery that might be aggravated by surface heating, you should decline participation in this experiment. **You are free to discontinue participation at any time.** Lastly, your dog will be required to have an exam at the beginning and end of the day. Additionally, the dog's eyes and skin will be briefly examined between exposures.

During the ADS exposures, a video camera will record the MWD team's reactions. This recording may be used as a training aid in the future. Signing this consent affirms your willingness to release the video footage. These recordings may also be qualitatively reviewed to assess the reaction of and score the team while you are actually experiencing the effects of the ADS and during the 5 minutes pre- and post-exposure. After each exposure, you will be asked a series of questions about the exposure (Attachment C). You will be given brief medical and vision screening examinations before the first exposure, examinations of the skin following each exposure, and brief medical and vision examinations after your last exposure.

RISKS/INCONVENIENCES

Participation involves a risk of being bitten or scratched by your dog. There is a potential for injury if the MWD performs inappropriate or unanticipated actions. These include trying to run away, becoming upset and uncontrollable, or perhaps showing aggression as they are trained to do. Additionally, as described above, there is risk of skin reddening. The affected area might remain slightly tender and red for several minutes after exposure. If the skin remains tender or reddened more than two hours after exposure, this should be reported to the experimenter, and examined by the medical staff. If you feel discomfort in the eyes or the skin around the eyes for more that a fifteen minutes, you should have the area examined by a medical observer. If eye injury is suspected, evaluation may require that ophthalmic staining drops be applied to your eyes. This will allow an injury to be seen by the medical provider. Subjects who tolerate the most extreme skin heating may develop skin reddening or a few millimeter sized skin blisters, which will heal within a few days, leaving no aftereffects. You are completely free to decline participation or to terminate your voluntary participation at any time. Many scientific studies have looked for possible detrimental effects (for example: skin cancer and damage to the cornea or lens of the eye) Except for the heating effects, there are no known effects (detrimental or beneficial) of exposure to millimeter wave energy. It is extremely unlikely that brief heating of the skin to painful but non-damaging temperatures will have any short- or long-term deleterious effects. Normal reflexes (closing the eyes, turning the head, protecting the eyes with a hand) will protect the eyes from heating that might cause damage.

PRECAUTIONS FOR FEMALE SUBJECTS

You may not participate in this study if you are pregnant. There is some concern that you could stumble and fall as you are rapidly moving away from the beam. Although there is no reason to believe that exposure to millimeter waves of this type will affect a fetus because the energy is absorbed in the skin, research on this specific question has not yet been completed. Therefore, if you are a female of childbearing potential, and are not certain whether or not you are pregnant, you should consult with the Medical Monitor, who may ask you to take a pregnancy test.

BENEFITS

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

ALTERNATIVES

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

EVENT OF INJURY

Federal laws and regulations govern your entitlement to medical care and/or compensation in the event of injury. If you have questions about your rights or if you believe you have received a research-related injury, you should contact the Medical Monitor, Ric Allnutt, Col, USAF, MC, CFS, (office 937-255-0311, ext 203 [DSN 787-0311], or a on site medical observer, or one of the investigators listed at the top of this document.

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

OCCURRENCE OF UNANTICIPATED ADVERSE EVENT

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

Next of kin if needed: Name_____ Phone # _____

CONFIDENTIALITY

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. Medical and psychological documentation will be identified only by subject number to maintain your anonymity. However, complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities.

DECISION TO PARTICIPATE

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

SUBJECT STATEMENT

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

Full Name: _____ _____ _____
(Please Print) SSN (optional) Telephone Number

_____ _____
Volunteer Signature Date and Time

_____ _____
Investigator Date

_____ _____
Witness (not involved) Date

Privacy Act Statement

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

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

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

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

Instructions for Subjects — ADS Effects on Naïve Dogs
Experiment 1

These experiments involve millimeter wave energy that will heat your skin to painful levels. If you are willing, we will expose you up to 7 times. These exposures will take place with you in your work attire.

During your orientation exposure, we hope that you will stand still until you feel that you need to move to limit the pain. Most subjects will move away from the millimeter wave beam before the end of the maximal exposure duration, either because of involuntary reflex withdrawal or because the pain reaches their tolerance limit. After you move, or the beam is turned off, you may experience "burning" pain that lingers for a few seconds. The exposed area may also be reddened and feel tender for up to a few minutes. We expect that these conditions will disappear within an hour or two at most. If the skin is still red and/or tender after two hours, you should notify the Investigator, who will arrange for the medical staff to examine it and apply any appropriate treatment. Any eye discomfort or concerns that last longer than fifteen minutes should also be reported. There is no reason to expect any aftereffects more serious than a mild sunburn. In contrast to sunburn, which entails some long-term risk from the aftereffects of ultraviolet exposure, millimeter waves have no known long-term effects.

The purpose of the first exposure (without your dog) is to familiarize you with the effects of the ADS beam. It is hoped this will prevent you from giving inadvertent cues to the dog during the real exposure. During the next six exposures, you will be exposed with your dog. Three of the exposures will be done with the system turned on and three will be sham exposures meaning no power is applied. You will not know ahead of time if the exposure will be a sham or real. During these exposures, we ask that you try and remain as neutral to the dog as possible. Try not to provide any input to the dog. Keep the leash loose; however, do not allow the dog to pull the leash out of your hands. Remember that these dogs have not been trained other than training they may have received before they were purchased by the Department of Defense. There will be an extra safety line on the dog as a safety measure in the event they become aggressive or upset as a result of the exposure. The purpose of this part of the experiment is to determine the variety of responses an ADS exposure is likely to produce from the dogs.

Two exposures will be done with you and your dog facing the beam. Two will be done sideways to the beam. Two will be done facing away from the beam. This information will be used to determine the orientation of the team in Experiment 2.

You should NOT be afraid of the exposure. The most that might happen is that you could be forced to escape the millimeter wave energy because the pain becomes too intense. Additionally, you are at risk of being scratched or bitten by your dog. The minimal skin damage that may occur as a result of your exposure to the ADS (reddening, tenderness) should not last more than a few minutes to two hours. Some subjects who tolerate the most heating may experience minor damage to the skin (for example, redness and a few small blisters). Although this is unlikely, if it should occur, it will clear up within a few days, leaving no aftereffects. We do not expect any injury to occur to the dog.

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

INFORMED CONSENT DOCUMENT

EFFECTS OF ACTIVE DENIAL SYSTEM (ADS) EXPOSURE ON THE PERFORMANCE OFMILITARY WORKING DOG TEAMS
Kirtland AFB, NM 87117

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

ADS PERFORMANCE EFFECTS ON MILITARY WORKING DOGS (EXPERIMENT 2: ADS Effect on Trained Dogs) Kirtland AFB, NM 87117

INVESTIGATORS' NAMES, DEPARTMENTS, PHONE NUMBERS

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Clayton, Oscar 37TRG/DORQ, Military Working Dog Evaluator, (210) 671-5959 (DSN 473-5959), Oscar.Clayton@lackland.af.mil

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PURPOSE OF STUDY

The Active Denial System (ADS) is a system designed to protect the lives of our service members and reduce fatalities among adversaries and innocent persons. The ADS will provide non-lethal force to accomplish military objectives prior to, during, and following operations. This technology works by projecting a beam of millimeter wave energy toward adversaries. Millimeter waves are similar to microwaves but are shorter in wavelength. Millimeter waves cause heating of water molecules in the skin, causing an intolerable pain sensation leading the exposed individual them to leave the path of the beam in order to stop the pain. Millimeter wave penetration of the skin is very shallow; the energy is absorbed in the first 1/64 inch of the skin.

You have been invited to participate in a research study at Kirtland AFB, sponsored by the Air Force Research Laboratory, Human Effectiveness Directorate, Radiofrequency Radiation Branch, titled "Effects of Active Denial System (ADS) Exposures on the Performance of Military Working Dog teams." The objective of this experiment is to determine if the ADS has any adverse effects on the Military Working Dog (MWD) team's performance. You will be asked to stand in the beam until you are forced to escape by the pain that the beam evokes.

This study will enroll 10 dog-handler teams, with the handler being at least 18 years of age. Prior to any team exposures, you will receive an orientation exposure without the dog. Individual's naïve to the effects of ADS often are highly aroused and nervous prior to their first exposure. The purpose of the orientation exposure is for you to become familiar with the effects of the ADS beam. This will hopefully decrease handler cues to the dog in the team exposures.

You will next be tested in 4 visits to the testing site, lasting up to 10+ hours each. Immediately after the exposure you will be asked a few questions about the Active Denial System (ADS) and its potential effect on the MWD team. As soon as possible after the exposure and questionnaire, you and your dog will proceed with the performance tasks.

PROCEDURES

If you volunteer to participate in this study, you will be exposed to millimeter wave energy at intensities that will exceed the applicable safety standard by as much as 20-fold. This exposure could cause your skin temperature to rise to 50 °C, unless you take action to escape the beam by moving to the side behind a barrier that blocks the beam. For the orientation exposure, prior to the beam being turned on, you will be standing still, facing toward the ADS. You will not be warned when the beam will be turned on. Once the beam is on, you will be free to move out of the beam immediately, which will end the exposure. Eyeglasses or contact lenses cannot be worn during exposure. If your vision is dangerously weak without glasses or contact lenses, you should not participate in the study. If you are using eye medications or have a history of any eye surgery, you will not be allowed to participate. Chronic medical conditions, to include skin abnormalities, may be disqualifying at the discretion of the Medical Monitor. You will have a very brief medical evaluation before you start and at the end of this experiment. If it is deemed necessary as part of an eye exam, you may be required to have drops placed in your eyes.

During your orientation shot, you will stand with your feet together and hands at your side, to assure that only skin on the front surface of your body is exposed. The exposures will be limited in duration to minimize the risk of skin damage, but are likely to last beyond your pain tolerance

for skin heating and pain. The pain is likely to become so intense that you will be forced to shield your face with your hands and/or move behind a barrier that blocks the beam to escape the pain, either by involuntary reflex or because you feel that the pain is reaching your tolerance limit. You will receive one such exposure. After the orientation exposure, it may take 15 minutes up to 2 hours or longer for the skin to return to its normal temperature.

If you choose to continue, you will then start the experiment. We will refer to each exposure, real or not, as an exposure. We will now describe one complete exposure sequence. Your dog will be required to have an exam at the beginning and end of the day. Additionally, the dog's eyes and skin will be briefly examined between exposures. You and your dog will also do performance tasks (obedience course and aggression) in the Lackland kennel area before the exposure. You will then travel to the exposure site where you will do more performance tasks (obedience and odor detection). You will then be exposed. Immediately following the exposure, you will be asked a few questions. Then you and your dog will do performance tasks (obedience and odor detection). You will then travel to the kennel area for more performance tasks (obedience course and aggression). You and your dog will then rest at the kennel site. Approximately 3-6 hours later you will repeat the performance tasks (obedience course and aggression) at the kennel site. You will then travel back to the exposure site where you will do more performance tasks (obedience and odor detection). The dog will then receive a physical exam. At any time during this process if you are concerned about any reaction you may be having to the ADS you can be examined by medical personnel and/or withdraw your participation in the study. This completes one exposure sequence. Your performance in obedience, obedience course, and aggression will use the same handler evaluation criteria that you are used to (the evaluation criteria used by the 341st TRS, WMD School). During detection you will not be evaluated because no handler evaluation criteria exists. The evaluation of your MWD team conducted during this study will not be used as a part of your normal work evaluation.

You will then start another exposure sequence. During one day, we anticipate you and your dog to complete 2 exposure sequences. Thus, the duration of your participation in the experiment may be 10 hours or longer, each day, given that some exposures may be delayed for a few minutes by conditions beyond our control (e.g., aircraft in the area). If an exposure produces skin reddening and/or tenderness that lasts for more than 2 hours, your exposures for that day may be terminated. Although not anticipated, if an eye injury is suspected, you may be referred for further evaluation. Cardiac pacemakers are not affected by millimeter wave energy used in these experiments. If you have any unusual skin conditions or eye surgery that might be aggravated by surface heating, you should decline participation in this experiment. **You are free to discontinue participation at any time.**

During the ADS exposures, a video camera will record the reaction of the MWD team. These recordings may be qualitatively reviewed to assess your reactions while you are actually experiencing the effects of the ADS and during the 5 minutes pre- and post-exposure. These videos may be used later for training purposes. Signing this consent affirms your willingness to release the video footage. After each exposure, you will be asked a series of questions about the exposure. You will be given brief medical and vision screening examinations before the first

exposure, examination of the skin following each exposure, and brief medical and vision examinations after your last exposure.
During two of the four exposures you will be stationary. During the other two you will be moving from one point to another, then will suddenly become stationary as your dog focuses on a decoy.

RISKS/INCONVENIENCES

Participation involves a risk of being bitten or scratched by your dog. There is a potential for injury if the MWD performs inappropriate or unanticipated actions. These include trying to run away, becoming upset and uncontrollable, or perhaps showing aggression as they are trained to do. Additionally there is risk of skin reddening. The affected area might remain slightly tender and red for several minutes after exposure. If the skin remains tender or reddened more than two hours after exposure, this should be reported to the experimenter, and examined by the medical staff. If you feel discomfort in the eyes or the skin around the eyes for more that a fifteen minutes, you should have the area examined by a medical observer. If eye injury is suspected, evaluation may require that ophthalmic staining drops be applied to your eyes. These drops will enable an injury to be seen by the medical provider. Subjects who tolerate the most extreme skin heating may develop skin reddening or a few skin blisters, which will heal within a few days, leaving no aftereffects. You are completely free to decline participation or to terminate your voluntary participation at any time. Many scientific studies have looked for possible detrimental effects (for example: skin cancer and damage to the cornea or lens of the eye) of exposure to microwave energy (which includes millimeter wave exposures). Except for the heating effects, there are no known effects (detrimental or beneficial) of exposure to millimeter wave energy. It is extremely unlikely that brief heating of the skin to painful but non-damaging temperatures will have any short- or long-term deleterious effects. Normal reflexes (closing the eyes, turning the head, protecting the eyes with a hand) will protect the eyes from heating that might cause damage.

PRECAUTIONS FOR FEMALE SUBJECTS

You may not participate in this study if you are pregnant. There is some concern that you could stumble and fall as you are rapidly moving away from the beam. Although there is no reason to believe that exposure to millimeter waves of this type will affect a fetus because the energy is absorbed in by the skin, research on this specific question has not yet been completed. Therefore, if you are a female of childbearing potential, and are not certain whether or not you are pregnant, you should consult with the Medical Monitor, who may ask you to take a pregnancy test.

BENEFITS

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

ALTERNATIVES

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

EVENT OF INJURY

Federal laws and regulations govern your entitlement to medical care and/or compensation in the event of injury. If you have questions about your rights or if you believe you have received a research-related injury, you should contact the Medical Monitor, Rick Allnutt, Col, USAF, MC, CFS, (office 937-255-0311, ext 203 [DSN 787-0311], or a on site medical observer, or one of the investigators listed at the top of this document.

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

OCCURRENCE OF UNANTICIPATED ADVERSE EVENT

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

Next of kin if needed: Name_____ Phone # _____

CONFIDENTIALITY

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. Medical and psychological documentation will be identified only by subject number to maintain your anonymity. However, complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities.

DECISION TO PARTICIPATE

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

SUBJECT STATEMENT

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

Full Name: _____ _____ _____

(Please Print) SSN (optional) Telephone Number

_____ _____

Volunteer Signature Date and Time

_____ _____

Investigator Date

_____ _____

Witness (not involved) Date

Privacy Act Statement

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

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

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

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

Instructions for Subjects-ADS Effects on Trained Dogs
Experiment 2

These experiments involve millimeter wave energy that will heat the skin to painful levels. If you are willing, we will expose you up to 5 times. These exposures will take place with you in your work attire.

During your orientation exposure, we hope that you will stand still until you feel that you need to move to limit the pain. Most subjects will move away from the millimeter wave beam before the end of the maximal exposure duration, either because of involuntary reflex withdrawal or because the pain reaches the subject's tolerance limit. After you move, or the beam is turned off, you may experience "burning" pain that lingers for a few seconds. The exposed area may also be reddened and feel tender for up to a few minutes. We expect that these conditions will disappear within an hour or two at most. If the skin is still red and/or tender after two hours, you should notify the Investigator, who will arrange for the medical staff to examine it and apply any appropriate treatment. Any eye discomfort or concerns that last longer than fifteen minutes should also be reported. There is no reason to expect any aftereffects more serious than a mild sunburn. In contrast to sunburn, which entails some long-term risk from the aftereffects of ultraviolet exposure, millimeter waves have no known long-term effects. The purpose of the orientation exposure is to familiarize you with the effects of the ADS beam. It is hoped this will prevent you from giving inadvertent cues to the dog during the real exposure.

During the next four exposures, you will be exposed with your dog. Two of the exposures will be done with the system turned on and two will be sham exposures meaning no power is applied. You will not know ahead of time if the exposure will be a sham or real exposure. During these exposures, we ask that you try and remain as neutral to the dog as possible. Try not to provide any input to the dog. Keep the leash loose; however, do not allow the dog to pull the leash out of your hands.

During two of the four exposures you will be stationary. During the other two you will be moving from one point to another, then will suddenly become stationary as your dog focuses on a decoy. There will not be a bite involved in this portion of the experiment.

Before and after each exposure you will do performance tasks with your dog. Try to observe and remember if your dog is performing normally or if he has been affected by the ADS exposure. Your answers to assorted questions will be very important.

You should NOT be afraid of the exposure. The most that might happen is that you could be forced to escape the millimeter wave energy because the pain becomes too intense. Additionally, you are at risk of being scratched or bitten by your dog. If you are uncomfortable or if you feel the dog may aggress on you, we can attach a safety line on the dog as an additional safety measure. The minimal skin irritation that may occur (reddening, tenderness) should not last more than a few minutes to two hours. Some subjects who tolerate the most heating may experience minor damage to the skin (for example, redness and a few small blisters). Although this is unlikely, if it should occur, it

will clear up within a few days, leaving no aftereffects. We do not expect any injury to occur to the dog.

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

Handler Questionnaire

1. Did the dog exhibit any aggressive/submissive behavior (growl, hackle, come up leash, cower) during or after exposure?

   a. The dog demonstrated aggression towards the handler (growling, barking, snapping, biting)
   b. The dog attempted to escape from the handler
   c. The dog cowered or crouched
   d. The dog demonstrated aggressive behaviors not directed towards the handler
   e. The dog attempted to avoid the source of the stimulation
   Circle all that apply, Comments here:

2. Did you attempt to calm/correct the dog vocally?

3. What was his/her reaction?

   a. Dog returned to heel/sit/task
   b. Dog demonstrated aggression towards handler
   c. Dog attempted to escape from handler
   d. Dog demonstrated other distracting behavior (describe)
   e. Other (describe)

4. Did the dog-handler rapport immediately return to baseline after exposure to the ADS?

   YES/NO

5. How did the dog respond when exiting the test area?
   a. Tail tucked
   b. Come up leash
   c. Cower
   d. Attempt to escape?
   Circle or add others (describe)

6. How did the dog respond when re-entering the test area?
   a. Growl,
   b. Avoidance
   c. Escape
   d. Cower
   e. Need coaxing
   f. Hackle
   Circle or add others (describe)

Medical Documentation Form
Effects of ADS Exposures on the Performance of Military Working Dog Teams

DATE: _____SUBJECT # _____

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

1. Absolute DQ if: pregnant

2. May require DQ, must check with medical monitor (or alternate), not necessarily because of ADS but because of the environment, if:

   Skin condition: ongoing disease, history of skin cancer, grafts, photosensitivity.

   Other chronic medical problems: cancer, neuropathy, uncontrolled high blood pressure, stroke, heart problems, on heart medications.

3. Current medications:

4. Eye specific:
   --Do you currently have any eye complaints? No___ Yes___
   --Any foreign body sensation (like something is in your eye)? No ___ Yes ___
   --Any eye burning, dryness, discharge? No___ Yes___
   --Any condition requiring eye medication? No___ Yes____
   --Diabetes? No___ Yes___
   --Used contacts 12 hours before exposure? No___ Yes___
   --Impaired blink reflex? No___ Yes___
   --Eye surgery (PRK etc)? No___ Yes___

PRE-EXPOSURE EXAM, AS REQUIRED BY HISTORY

FINAL POST EXPOSURE HISTORY: DATE _____

1. Concerns or complaints: none, other:
2. Eye specific:
   --Do you currently have any eye complaints? No____ Yes____
   --Any foreign body sensation (feel like something is in your eye)? No____ Yes____
   --Any eye burning, dryness, discharge? No____ Yes_____
   --Any complaints? No____ Yes____

POST-EXPOSURE EXAM, AS REQUIRED BY POST EXPOSURE HISTORY:

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
WASHINGTON DC

5 June 2004

MEMORANDUM FOR: AFRL/HEDV, 2509 Kennedy Circle, Brooks AFB, TX 78235-5118
ATTN: Protocol Coordinator, Ms. Teresa Terrell

FROM: Chief, USAF Animal Research Programs
Air Force Medical Support Agency
Division of Biomedical Research & Compliance (AFMSA/SGRC)
5201 Leesburg Pike, Suite 1400, Falls Church, VA 22041

SUBJECT: Animal Research Protocol FBR-2004-0015A, "Active Denial System Effects on the Performance of Military Working Dogs (*Canis familiaris*)"

Principal Investigator: Maj Michelle Bryce, DO, MTM&H
USAF, MC, SFS, AFRL/HEDR

1) Representatives of the Surgeon General's Research Oversight Committee (SGROC) reviewed the subject protocol for compliance with: 1) Title 9 Code of Federal Regulations, "Animals and Animal Products," Chapter 1, Subchapter A, "Animal Welfare," parts 1, 2, and 3; 2) DOD Directive 3216.1, "Use of Laboratory Animals in DOD Programs, 17 April 1995, as amended; and 3) AFMAN (I) 40-401, The Care & Use of Laboratory Animals in DOD Programs," 1 December 2003. The protocol is hereby granted **full approval** that will remain effective until its expiration, significant modification, completion or termination.

2) The SGROC requires annual submission of protocol status reports and all proposed significant protocol modifications, including personnel changes. SGROC review and approval of modifications is required prior to continuation of protocol activities incorporating any proposed change(s).

3) In addition, please notify this office immediately upon completion or termination of research activities and any changes or updates to institutional accreditation status, including the forwarding of all AAALAC and USDA site visit reports.

4) For additional assistance, please contact the undersigned at (703) 681-4132, fax (703) 681-4518, or via e-mail: chris.hanson@pentagon.af.mil

///ORIGINAL SIGNED///

CHRIS E. HANSON, DVM, DACLAM
MAJ, VC, USA
Chief, USAF Animal Research Programs