DEPARTMENT OF THE AIR FORCE
AIR FORCE RESEARCH LABORATORY
WRIGHT-PATTERSON AIR FORCE BASE OHIO 45433

MEMORANDUM FOR 711 HPW/RHDR (b) (6) [redacted]

FROM: 711 HPW/IR (AFRL IRB)

SUBJECT: IRB approval for the use of human volunteers in research

1. Protocol title: Thermal and Behavioral Effects of Exposure to Moving Small-Diameter, 95-GHz Millimeter Wave Energy Spots

2. Protocol number: FWR20120147H

3. Protocol version: 3.00

4. Risk: Greater than Minimal

5. Approval date: 24 September 2014

6. Expiration date: 24 September 2015

7. Scheduled renewal date: 24 August 2015

8. Type of review: Continuing Review-Expedited

9. Assurance Number and Expiration Date:
   a. AFRL DoD Assurance 50002: 6 March 2017
   b. General Dynamics FWA #00015890, DoD F50415: 24 June 2018

10. CITI Training: Completed

11. The above protocol has been reviewed and approved by the AFRL IRB via expedited review procedures. All requirements, as set by the IRB and its legal counsel, have been fully complied with. The study involves identification of effective pain response levels for various 95-GHz millimeter wave (MMW) energy beam exposures at varying diameters of size and exposure intensity levels. The exposures will be monitored by measuring the rise in skin temperature of the illuminated human upper anterior and posterior skin surfaces. The research will enhance basic scientific understanding and will quantify the effects of previously tested systems. **Progress**: Study is partially complete. Nothing unexpected has been encountered. Status of subjects specified in protocol: 33, total# of subjects enrolled in study: 11 unique subjects (6 enrolled in experiment IA, 10 enrolled in experiment 1B). 2 Female/9 male subjects. No adverse events were encountered. Total withdrawals: 0.

12. HIPAA authorization is not required, since no HIPAA protected information will be recorded in the execution of this protocol.

13. FDA regulations do not apply since no drugs, supplements, or unapproved medical devices will be used in this research. Evaluation by the convened Board determined no medical devices are used in the study.

14. This approval applies only to the requirements of 32 CFR 219, DoDI 3216.02, AFI 40-402, and related human research subject regulations. If this project is a survey, attitude or opinion poll, questionnaire or interview, consult AFI 38-501, AF Survey Program, for further guidance. Headquarters AFPC/DPSAS is the final approval authority for conducting attitude and opinion surveys within the Air Force. If the survey, attitude or opinion poll, questionnaire or interview is hosted on a .com server, consult AFI 33-129, Web Management and Effective Use of Internet-based Capabilities, for further guidance. If the study is being conducted under an Investigational New Drug (IND) or Exemption Device (IDE), a copy of the FDA IDE or IND approval letter must be submitted by the Principal Investigator to the IRB.

15. With this approval comes the expectation that the Principle Investigator has the funding to fully execute the protocol. Partial protocol funding, particularly with Greater than Minimal Risk studies, should prompt a re-examination of the protocol by both the Principle Investigator and the IRB with specific emphasis on the risk-benefit evaluation.

16. Any serious adverse event or issues resulting from this study should be reported immediately to the IRB. Amendments to protocols and/or revisions to informed consent documents must have IRB approval prior to implementation. Please retain both hard copy and electronic copy of the final approved protocol and informed consent document.

17. All inquiries and correspondence concerning this protocol should include the protocol number and name of the primary investigator. Please ensure the timely submission of all required progress and final reports and use the templates provided on the AFRL IRB web site http://www.wpafb.af.mil/library/factsheets/factsheet.asp?id=7496.

18. For questions or concerns, please contact the IRB administrator, (b) (6) (b) (6) All inquiries and correspondence concerning this protocol should include the protocol number and name of the primary investigator.

(b) (6)

cc:
AFMSA/SGE-C

1st Indorsement to 711 HPW/RHDR (b) (6) Memo, 24 September 2014, Continuing Review, Full Board Approval FWR20120147H

MEMORANDUM FOR 711 HPW/IR (b) (6)

I have reviewed the hardcopy and electronic records and found them to be complete and accurate.

(b) (6)

2nd Indorsement to 711 HPW/RHCP (b) (6) Memo, 24 September 2014 IRB Human Research Approval, Initial Review, Expedited Approval FWR20140111H

MEMORANDUM FOR AFMSA/SGE-C

This protocol has been reviewed and approved by the AFRL IRB. I concur with the recommendation of the IRB and approve this research.

(b) (6)

0 8 OCT 2014