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cc: WJ Bair
GM Dalen
SJ Farmer
CE Newton, Jr.
WD Norwood
JM Selby-RH Scott

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NOV 21 1969

H. M. PARKER

DATE November 20, 1969

TO H. M. Parker

FROM 
C. E. Newton, Jr.

SUBJECT Human Subjects Committee Meeting - November 19, 1969

At your request I called a meeting, Wednesday, November 19, 1969, of the Human Subjects Committee to review and make recommendations on the proposal to the Air Force entitled "A Study Relating Dose Levels from Laser Radiations to Threshold Effects in Skin."

Attending were:

W. J. Bair

S. J. Farmer

C. E. Newton, Jr.

W. D. Norwood

J. M. Selby (for R. H. Scott)

REPOSITORY PNL, ENG. BLDG.
AREA 3000
COLLECTION LASER IRRADIATION
BOX No. 2947
FOLDER HSC 69-3

Absent was G. M. Dalen who submitted his views per attached letter.

The Committee recommends:

- 1) Unqualified approval of phase one (animal and equipment studies).
- 2) Phase two (human testing) not be initiated until the Committee has thoroughly reviewed and specifically recommended the conduct and extent of this phase based upon phase one findings.
- 3) The potential sponsor should be notified that BNW will conduct a full review and evaluation of the data obtained in the animal phase before extending its support to the human testing phase and if, in the opinion of BNW personnel, sufficient adverse findings appear as not to justify human testing, BNW may terminate or withdraw from the study without penalty.

Items which must be of concern to personnel making these types of proposals, which have come up in the past and did so again, and which will be of concern to the Committee in a phase 2 review are:

- 1) The submissions to the Committee must provide a plan of implementation so technical aspects can be reviewed, i.e., calibration procedures, equipment limitation, method of data evaluation, literature reviews, etc.

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- 2) Type and extent of liabilities. In particular, that of the scientist who calibrates the equipment. What are his risks, has he been advised, does he accept? Are BNW and/or the Committee members sufficiently covered for each particular proposal?
- 3) Who operates the equipment when used on humans? (A past ruling by Paul Santilli was BNW personnel may not.)
4. What restrictions on volunteers? (A past ruling of Paul Santilli was that BNW personnel may not participate.)
5. Does the medical organization conducting the experiment have a Human Use Committee so composed and functional as to make our subcontracting to them advisable?

CEN:es

Enc.

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W. D. Richmond
D. D. Mahlum

DATE November 18, 1969
TO H. M. Parker
FROM G. M. Dalen
SUBJECT Human Subjects Committee Review of a Study Relating
Dose Levels from Laser Radiation to Threshold Effects
in Skin

If proposal is accepted by the Air Force, we should work with the sponsor in making a public announcement. There is some possibility of misunderstanding (if an editor or reporter really wanted to) on the difference in sensitivity of black and white skin. However, this presents no major difficulty and I can see no public relations problems with such a research project.

GMD:drr



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