



10/18/76

723923

ARGONNE NATIONAL LABORATORY

REPOSITORY Argonne/Chicago Federal Records Center

Office of the Director

COLLECTION Laboratory Director's Files October 18, 1976

BOX No. Accession # 434-93-0012, box 18

FOLDER Use of Human Subjects for Research



Dr. James L. Liverman, Director
Division of Biomedical and Environmental Research
U. S. Energy Research and Development Administration
Washington, D. C. 20545

Dear Dr. Liverman:

I am responding on behalf of Argonne National Laboratory to the notice of proposed regulations, 10 CFR part 705, Energy Research and Development Administration - "Protection of Human Subjects", dated August 10, 1976.

It is stated that "the policies and procedures provided by the proposed regulation are substantially the same as those adopted by the Department of Health, Education and Welfare for the protection of human subjects (40 FR 11854, March 13, 1975)."

There is at least one significant difference which we feel requires further consideration. It is contained in paragraph 705.6 item (4), "No Board shall consist of a majority of persons who are officers, employees, or agents of, or are otherwise associated with, the institution, apart from their membership on the Board."

There are obvious disadvantages in having different agencies setting forth different regulations for the same activities. Dissimilar constraints on the membership of the Board would be especially troublesome. Furthermore, it is not clear to us what the advantages of the proposed change will be. Indeed, there would seem to be definite disadvantages. Obviously, there should be members of the Board who are not staff members of the institution but to have a majority requirement for these members seems unwieldy in practice and questionable in concept. It is unwieldy because (a) experience shows that staff members of the institution attend meetings better than do others and an enlarged membership would inevitably be necessary, (b) given areas of

1168058

ERDA - Protection of Human Subjects

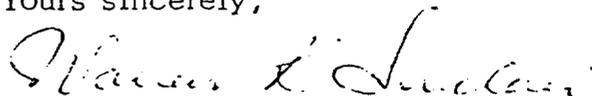
Dr. James L. Liverman
October 18, 1976
Page two

expertise (in some localities) are sometimes hard to find outside the staff of the institution. More important is the matter of the propriety of having a minority of staff people. It is not clear to us what the responsibility of a review board would be in those circumstances where the majority are not responsible to the institution in other ways. It is the institution that has the responsibility for the protection of human subjects (as noted in paragraph 705.2 and etc.) and it is not inconceivable, that with a majority of outside members, its own Institutional Review Board could actually render the institution unable to carry out this responsibility.

It is suggested that the phrase "of a majority" appearing in 705.6 (4) be amended to read "entirely", to agree with the current DHEW regulations.

We urge that this aspect of the proposed regulations be reconsidered.

Yours sincerely,



W. K. Sinclair
Associate Laboratory Director for
Biomedical and Environmental Research

WKS:nw

bcc: C. L. Chernick ✓
M. V. Nevitt
R. G. Sachs

1168059