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FROM: SGS

6 March 1979

SUBJECT: Minutes of the Institutional Review/Animal Use Committee Meeting, 6 March 1979

TO: WRMC Executive Committee

1. The Institutional Review/Animal Use Committee met in the General's Conference Room at 1400, on 6 March 1979.

2. The following members were present:

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| Lt Col Wild, Acting Chairman | Lt Col Foshee |
| Lt Col Van Riper, Recorder | Maj Savoy |
| Lt Col Boddie | Capt Sweeney for Capt Palagi |
| Lt Col Perez for Maj Shaffer | Dr Bloom |

Members absent:

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|---|---|
| Lt Col Hauth | Col DeLemos |
| Lt Col Floyd | Maj Shaffer |
| Maj Dolwick | Capt Palagi |

Others present:

| | |
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| Lt Col Brady | Maj May |
| Maj Donovan | |

3. Old business: None.

4. New business:

a. The following protocols were presented:

(1) F-87, "Clinical Evaluation of the Oral Antifungal Drug," Principal Investigator, Maj Donovan. Dr Donovan explained that this study would be to furnish patients to an on-going study with two major universities. The study consists of giving patients who have already failed on two chemo-drugs, the experimental drug R41-400 for treatment of severe fungal diseases.

Q. Some of the systemic fungal infections are very severe problems and somebody has to be the guinea pig so to speak but it seems that you ought to have some stratification so you are not giving them something you are not sure of.

A. Past experience with the use of approximately 50 human subjects has been shown to be effective, but this is a small number.

Comment: If this is true, then you possibly should make reference to this in your introduction.

Comment: People you propose to use this drug on have failed to respond at all to the other two agents. If this drug is effective there will be a tremendous desire to use it as a first line medication.

A. The idea was to have the latitude of using it as a third line medi-

cation originally and if it shows promise, then possibly as a first line drug.

Q. Does FDA list this as an experimental drug?

A. Yes, Phase II study.

Comment: The protocol does not state that this will be used as a third line drug and then with good results, possibly a first line drug. You would be better off to spell this out from the beginning.

A. The way it stands right now, is as a third line drug. One of our patients has refused to use Myconazol. The only way that Myconazol has been studied has been after Amphoteracin. We've been locked into Amphoteracin just because it came along first.

Comment: I frankly feel that if you don't explain the whole story in your protocol the IRC and possibly the FDA down stream will cause some trouble.

Comment: Why not talk with whoever has the IND number and see what they understand are the restrictions from FDA.

Comment: It won't take long before patients hear about an oral drug and they will be hollering for it versus the others.

Comment: There are still restrictions on who you give what to.

Q. Do you plan to measure drug levels?

A. We have a patient already on the drug through a one-time use and we have studied the blood level and were able to determine he is absorbing it at a level to kill the bug. Not all of our potential patients are growing it so it will not be easy. We will get a reasonable blood level.

Q. How fast will you be able to generate patients?

A. That's why this is a multi-institutional effort; so far, we have had three at WHMC and four at UTSA.

Comment: An alternative to this protocol would be to treat each patient on a one-time basis which will not give you the exact information you need.

Q. Who is the statistician mentioned?

A. I assume he is in New Brunswick.

Q. The protocol talks about record forms, number of tests, and a large amount of data - I would like to know what the record form looks like.

A. I took it to Jansen at the VA but I can get a copy of it.

Q. You talk about 25 different tests and yet the lab has not been notified - we are unclear as to the number of patients.

A. Right now there are only three and we do not expect a lot more.

Q. How long will the study last?

A. The drug has never been used over six months on a human and that's the only information I have.

Q. When will the Wilford Hall portion be completed?

A. It will be open ended.

After further discussion it was the unanimous decision of the committee that this protocol be changed to include the following information:

1. Define the status of the patients, i.e., number and what drugs, if any, already administered.

2. Submit data collection sheet for review.

3. Statement of criteria for documentation.

4. Statement of how and when drug will be used

(2) I-162, "Alterations in Ventilation, Oxygen Saturation and Arterial Blood Gases During Medical Peridoneoscopy," Principal Investigator, Lt Col Charles Brady. Dr Brady stated that the purpose of this study will be to determine whether significant changes occur in ventilation, oxygen saturation, or arterial blood gases during routine medical peritoneoscopy and why.

Q. How many patients are you talking about?

A. A minimum of ten - this is not a very large number.

Q. Will you be getting numerical differences or catagorical?

A. Catagorical.

Comment: Since this relates in part to anesthesology, SGO may want to have an Anesthetist listed as a co-investigator.

A. We have not used them in the past when we do a medical peritoneoscopy; we have been doing them routinely.

Q. What are the chances SGO will ask for this? Don't they usually approve with qualifications?

A. It depends on how the whole protocol is worded.

Comment. Could you make a footnote in paragraph 6 and attach a sheet showing that the T test will be included and measured over what variables.

The committee unanimously approved this protocol and Dr Brady was informed that he could not begin entering patients until it had been approved by the HEC and the SGO.

(3) S-67, "Cryotherapy in the Resolution of Vitreous Hemorrhage," Principal Investigator, Maj Donald May. Dr May explained that vitreous hemorrhage occurs quite often with cycle cell, diabetis and in cases of injuries to the eye. It can clear up on its own or with surgery. We have encountered a patient with a solid vitreous hemorrhage, he is diabetic, and he came in to have the surgery when we discovered neovascular glaucoma in the other eye. We then used a laser treatment to wipe out one-third of the retna. We feel that we have found a new method to dissolve the hemorrhage, strictly by chance. We now want to see if we can get a reliable animal to show what we found in this one patient.

Q. How many rabbits do you plan to use.

A. There will be two groups of 20 for a total of 40.

Q. Can you use chi square for analysis.

A. That's a good point, there will be degrees.

Q. Can you define these degrees?

A. They will be based on clinical observations but they could be defined.

The committee unanimously approved this protocol with the addition of the exact number of rabbits to be used, the method of analysis, and a definition of degrees.

b. The following semi-annual progress reports were reviewed and accepted:

(1) C-22, "A Cooperative Project to Evaluate the Efficacy of Pi Mesons in the Management of Patients with Inoperable Cancer," Principal Investigator, Lt Col Gary West.

(2) D-16, "Evaluation of Hyperbaric Oxygen Treatment of Patients Following Anterior Maxillary Osteomies," Principal Investigator, Maj Melvin Dolwick.

(3) D-21, "Rat Connective Tissue Response to Composite, Amalgam, and Zinc Oxide Eugenol Restorative Material," Principal Investigator, Lt Col James McIlwain.

(4) I-48, "The Radioimmunoassay of Serum Androgens: Testosterone, Androstenedione, and Dehydroepiandrosterone (DHA)," Principal Investigator, Lt Col Wilbur Howard.

c. The following request for termination was reviewed and accepted:

S-60, "The Evaluation of a Microporous Expanded Polytetrafluoroethylene Arterial Prosthesis for Construction of Aortopulmonary Shunts," Principal Investigator, Lt Col Daniel Knauf.

d. Minutes of the Institutional Review/Animal Use Committee Meeting of 27 Feb 1979, were reviewed and approved.

5. There being no further business to come before this committee, the meeting was adjourned at 1530.

Donald C. Van Riper

DONALD C. VAN RIPER, Lt Col, USAF, VC
Recorder, IRC

JAMES H. WILD, Lt Col, USAF, MC
Acting Chairman, IRC