

DEPARTMENT OF THE AIR FORCE
 USAF SCHOOL OF AEROSPACE MEDICINE (AFSC)
 BROOKS AIR FORCE BASE, TEXAS 78235



REF ID: A111130

SMBP

21 March 1966

Request for Human Subjects--Modification of Original Experimental Protocol

TO *Allen*
 SMBP SMB SMG

1. Title of experiment: The prevention of altitude sickness with Acetazolamide (Diamox). Original human subject request submitted on 21 Feb 1966.
2. Methods: The original experimental protocol will be modified as follows: Each group of four subjects will be placed in the low pressure chamber one time only for a period of 24 rather than 48 hours. This 24-hour period will be spent either at ground level or 14,000 feet (447 mm. Hg). Preexperimental control runs will no longer be necessary. Approximately 2 hours prior to the conclusion of the flight, an arterial puncture will be made with the subjects at rest. Simultaneously with the arterial puncture, a lumbar puncture will be done and approximately 10 cc. of cerebral spinal fluid withdrawn. These samples will be analyzed for P_{O_2} , P_{CO_2} , pH, lactate, and standard bicarbonate. The subjects will also be asked to breathe into a CO_2 meter for analysis of their end-tidal P_{CO_2} periodically during the flight and at the time of the arterial puncture and spinal tap. Other measurements as outlined in the original protocol will remain unchanged.
3. Potential Hazards: In addition to those hazards outlined in the original protocol, certain new hazards associated with the arterial puncture and spinal tap will be incurred. The dangers of arterial puncture are principally those of hemorrhage and occlusion of the circulation. A pressure dressing will be applied for a minimum of 5 minutes following the puncture to prevent hemorrhage. Arterial occlusion is a rare complication which would require hospital treatment if it should occur. Wilford Hall USAF Hospital is available for this purpose. A carefully-done spinal tap under sterile conditions presents no serious hazard to the healthy individual. The presence of intracranial and/or lumbar spine pathology will be ascertained before the flight and will be cause for elimination of that subject. In approximately 1 - 6% of individuals a severe, incapacitating headache, lasting up to 7 days, will occur following a spinal tap. This can be uniformly relieved by having the subject lie down. It is hoped that this complication can be kept to a minimum by using a small diameter needle and keeping the subjects horizontal for a minimum of 2 hours after the tap.

4. Type of subjects needed: No change from original protocol.
5. The individuals responsible for the planning of the experiment:
No change from the original protocol.
6. Responsible medical officers: William Brown, Major, MC, USAF, is
to be added to the list of assisting physicians.

R. S. Kronenberg

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