RESOLUTION OF THE WHITE MOUNTAIN APACHE TRIBE OF THE FORT APACHE INDIAN RESERVATION

- WHEREAS, members of the Tribal Council of the White Mountain Apache Tribe support programs that prevent diseases which afflict many tribal members such as hepatitis; and
- WHEREAS, hepatitis A infection has been endemic on the White Mountain Apache Tribe Reservation in past years, but because of intense vaccination efforts beginning in 1995, rates of hepatitis A disease have come down a lot; and
- WHEREAS, rates of hepatitis B infections among White Mountain Apaches have remained low, but hepatitis B disease can have more serious outcomes; and
- WHEREAS, separate hepatitis A and hepatitis B vaccines have been developed and licensed (1995 and 1981, respectively) to protect people against these forms of hepatitis, especially people at high risk such as a number of American Indian tribes; and
- WHEREAS, currently, hepatitis B vaccine is routinely given to newborns and young infants as a regular "well-baby" shot, and hepatitis A vaccine is recommended for at-risk persons 2 years of age and older such as populations which have high rates of disease; and persons fully vaccinated with these two vaccines receive 5 injections (3 hepatitis B shots and 2 hepatitis A shots); and
- WHEREAS, recently, a combination hepatitis AB vaccine (Twinrix) was licensed in the U. S. and was made by combining the hepatitis A vaccine and the hepatitis B vaccine, and, based on previous evaluations, the vaccine was found to be effective and safe; and the vaccine has also been licensed in more than 70 countries, including all of Europe and Canada; and
- WHEREAS, additional information about Twinrix is needed to fully complete licensure and the information needed relates to local reactions such as pain, redness, and swelling at the injection site and possible fever, headache, and diarrhea; and a study has been developed to obtain this information from adult participants; and
- WHEREAS, for this study, recruitment will target healthy males and females 18 years of age and older who have never had the hepatitis illness and have never been vaccinated with either or both of the hepatitis A or hepatitis B vaccine; and

WHEREAS, this study is also being conducted at a number of locations throughout the U.S., and before taking in this study, which is totally voluntary, each participant must sign and date an informed consent; and all information concerning each participant will be kept confidential.

WHEREAS the Tribal Health Board has reviewed and approved the proposed study and its parameters.

BE IT RESOLVED by the Tribal Council of the White Mountain Apache Tribe that it hereby grants approval to the Johns Hopkins University to conduct the study to collect safety information about the recently licensed new combination hepatitis AB vaccine (Twinrix) among adult tribal members.

The foregoing resolution was on <u>June 7, 2001</u>, duly adopted by a vote of <u>EIGHT</u> for and <u>ZERO</u> against by the Tribal Council of the White Mountain Apache Tribe, pursuant to authority vested in it by Article IV, Section 1 (a), (b), (s), (t) and (u) of the Constitution of the Tribe, ratified by the Tribe on September 30, 1993, and approved by the Secretary of the Interior on November 12, 1993, pursuant to Section 16 of the Act of June 18, 1934 (48 Stat. 984).

Dallas Massey, Sr.

Chairman of the Tribal Council

Cyndy Harvey-Burnette

Secretary of the Tribal Council