

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

- WHEREAS,** the Tribal Council of the White Mountain Apache Tribe is composed of elected members of the Council who serves as representatives of their respective districts and of the constituents of their respective district; and
- WHEREAS,** the Tribal Council has been supportive in the past of research projects which seek to find ways to prevent illnesses in infants which have high rates of morbidity and mortality; and
- WHEREAS,** the *Streptococcus pneumoniae* (pneumococcus) bacteria is responsible for a number of serious illnesses in people of all age groups, especially infants and the elderly; and these illnesses include pneumonia, ear infections, blood infections, meningitis, and others; and
- WHEREAS,** infants have pneumococcal infections much more than the elderly, and in certain American Indian tribes, such as Navajos and Apaches, the rates of pneumococcal diseases are 8-10 times worse than in infants throughout the U.S.; and
- WHEREAS,** although older children and adults can be given a licensed pneumococcal vaccine, there is currently no licensed vaccine available for infants to protect them from pneumococcal diseases; and
- WHEREAS,** the treatment for pneumococcal diseases has become more difficult in recent years because the bacteria has increasingly become resistant to antibiotics which formerly were very effective in killing the bacteria, and this makes it more important to seek ways to prevent these illness, such as by use of vaccines; and
- WHEREAS,** the meningococcus is another germ which causes diseases on certain reservations, and occurs only rarely among White Mountain Apaches, and these diseases are the same as those caused by pneumococcus; and, in this proposed study, a meningococcal vaccine will be used to help determine the efficacy of the pneumococcal vaccine; and
- WHEREAS,** infants and young children 2 to 23 months of age who are enrolled in this project will, in a double-blind manner, be randomly assigned to receive 2 to 4 doses of either an investigational pneumococcal conjugate vaccine (IND #5832) or an investigational meningococcal conjugate vaccine (IND #5290), depending on their age at enrollment; and all children will be diligently monitored for all types of pneumococcal infections; and project personnel will also administer all well-baby immunizations at the times they are due; and

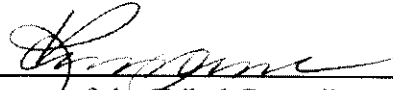
- WHEREAS,** blood specimens will be obtained from each participants approximately 2 months after each vaccination and will be tested for antibodies against pneumococcus; and
- WHEREAS,** to determine “indirect [herd] immunity”, specimens from the back of the nose will be collected from a certain number of young children in the community and will be tested for the presence of pneumococci, and this will help determine if the vaccine “spreads” protection to children who were not vaccinated; and
- WHEREAS,** the pneumococcal and meningococcal vaccines have been found to be safe and immunogenic in previous evaluations in other locations in the U.S., and no serious adverse effects are anticipated beyond local reactions such as the usual pain of the injection and possible redness and mild swelling; and
- WHEREAS,** there is the potential that infants receiving the pneumococcal vaccine can benefit by being protected from pneumococcal infections caused by serotypes incorporated in the vaccine, and infants receiving the meningococcal vaccine may benefit by being protected from meningococcal infections; and
- WHEREAS,** participation in this project is totally voluntary and will require the signatures of parents of all infants taking part in the study; and parents are free to withdraw their child from the study at any time without penalty.

BE IT RESOLVED by the Tribal Council of the White Mountain Apache Tribe that, based on the foregoing, it hereby grants approval to the Johns Hopkins Program to conduct the scientific trial to evaluate the efficacy of a seven-valent pneumococcal conjugate vaccine to protect infants from invasive pneumococcal infections and that a determination be also done to assess the extent to which the vaccine confers indirect immunity to unvaccinated individuals.

BE IT FURTHER RESOLVED by the Tribal Council that all information obtained from or about anyone taking part in this project will be treated with the strictest confidence. All printed materials which identifies participants will be kept in locked files with access limited to only John Hopkins personnel involved in this study. All data collected from participants will be entered into a computer using a coded identifier, and access to computers and the breakout of the code will be limited only to authorized study personnel. Publications resulting from this study will not identify any participants by name, and analyses of data will be done in aggregate.

Resolution No. 03-97-046

The foregoing resolution was on March 12, 1997, duly adopted by a vote of nine for and zero against by the Tribal Council of the White Mountain Apache Tribe, pursuant to authority vested in it by the White Mountain Apache Tribal Constitution, including Article IV, Sections 1 (a), (i), (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).



Chairman of the Tribal Council



Secretary of the Tribal Council