



WHITE MOUNTAIN APACHE TRIBE

A Sovereign Tribal Nation

(Amendment to RSV Pilot Study)

WHEREAS, the Tribal Council of the White Mountain Apache Tribe (“Tribe”) is entrusted by the Tribe’s Constitution to act in all matters that concern the welfare of the Tribe, to manage all economic affairs and enterprises of the Tribe, and to regulate subordinate organizations for economic and other purposes; and

WHEREAS, Johns Hopkins University has been a primary partner with the Tribe on current and past research studies to develop and build capacity within our community to address our priority health problems; and

WHEREAS, the pilot study, *A Phase 3 Study of MEDI-524 (Motavizumab), an Enhanced Potency Humanized Respiratory Syncytial Virus (RSV) Monoclonal Antibody, for the Prevention of RSV Disease Among Native American Infants in the Southwestern United States* approved on April 20, 2016 (resolution # 04-2016-77) was not funded and will not be conducted; and

WHEREAS, funding has been secured to complete the second part of the original RSV study entitled: *A Phase 3 Study of MEDI-524 (Numax), an Enhanced Potency Humanized Respiratory Syncytial Virus (RSV) Monoclonal Antibody, for the Prevention of RSV Disease among Native American Indian Infants in the Southwestern United States*; and

WHEREAS, Johns Hopkins is requesting three amendments to the original RSV study:

- 1) permission from the tribe to test approximately 800 stored NP specimens for the presence of *Streptococcus pneumoniae*, to assess whether RSV prevention reduces the risk of colonization by this bacterium. Prevalence of *S. pneumoniae* colonization and disease has been shown to be high among White Mountain Apache infants in prior studies conducted and will help us to better understand the relationship between these pathogens. This testing would be conducted by the Arctic Investigations Program in Anchorage, Alaska, a CDC field station that has as its mission to improve the health of American Indian and Alaska Native communities.
- 2) permission from the tribe to test stored nasopharyngeal specimens for other (non RSV) respiratory viruses. Observational studies have shown an association between RSV in infancy and increased risk of wheeze in preschool aged children. It was therefore expected that children in the study who received motavizumab would have a reduced risk of wheeze between the ages of 1 and 3. Instead, we observed no difference in wheezing risk between the placebo and treatment groups. We would like to test the specimens of ~600 infants who had experienced medically attended wheezing within this age range, as well as those who did not, so that we may assess the contribution of other viral infections in infancy to risk of preschool wheezing. This will allow us to better understand the risk factors for wheezing in the White Mountain Apache population. This testing would be performed in the laboratory of Jim Gern at the University of Wisconsin.

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- 3) permission from the tribe to test stored nasopharyngeal specimens from the second winter season of life for RSV. To date, only specimens from the first winter season were tested for RSV. Among these specimens, the risk of RSV was significantly lower among infants who received motavizumab. We would like to test approximately 800 specimens from children who experienced medically attended respiratory illness during the second winter season for RSV to determine whether motavizumab has a protective effect beyond the first year of life. This will help us to evaluate the benefit of similar RSV prevention strategies that may be offered to the White Mountain Apache people in the future. This testing would be performed in the laboratory of Jim Gern at the University of Wisconsin.

WHEREAS, the nasal wash samples will not have any personal information on them that links back to the patient. All unused samples will be returned to JHU or destroyed. If the results of this pilot study indicate that some children have immune responses that put them at risk for ear infections, more samples may be requested to further characterize the immune response and understand more effective ways to prevent AOM.

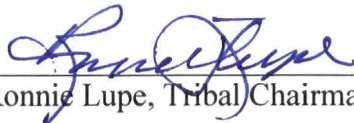
BE IT RESOLVED by the Tribal Council of the White Mountain Apache Tribe that it hereby approves the request to amend the original study previously approved by resolution 04-2016-77 to better understand the severity of RSV and the potential risk of *Streptococcus pneumoniae* bacterium.

BE IT FURTHER RESOLVED by the Tribal Council of the White Mountain Apache Tribe that it hereby directs that in the event this Resolution directly conflicts with the Tribal Constitution, Tribal Ordinances, or any material facts concerning the issues presented are later found to be false, this Resolution shall be deemed null and void and have no legal effect.

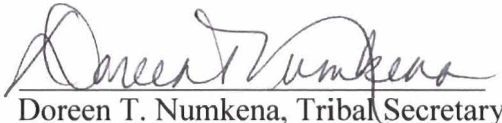
BE IT FURTHER RESOLVED by the Tribal Council of the White Mountain Apache Tribe that it hereby directs that in the event that this Resolution conflicts with a prior Resolution or Policy, this Resolution shall supersede and govern over the conflicting subject matter.

BE IT FURTHER RESOLVED by the Tribal Council of the White Mountain Apache Tribe that the Chairman, or in his absence, the Vice-Chairman, is hereby authorized to execute any and all documents necessary to effectuate the intent of this Resolution.

The foregoing resolution was on **FEBRUARY 8, 2017** duly adopted by a vote of **EIGHT** for, **ZERO** against, and **ONE** abstentions by the Tribal Council of the White Mountain Apache Tribe, pursuant to authority vested in it under the enumerated powers listed in Article IV, Section 1 of the WMAT Constitution, so ratified on September 30, 1993, and federally recognized pursuant to Section 16 of the Indian Reorganization Act of June 18, 1934 (48 Stat. 984).


Ronnie Lupe, Tribal Chairman

9/26/17
Date


Doreen T. Numkena, Tribal Secretary

9/27/2017
Date