

<p>10410-01(101)(New) – “A Multicenter, Randomized Dose Response Study of the Safety, Clinical and Immune Responses of Dry® Administered to Children 2 to 5 Years of Age” NIH Institutional Consent Forms (2) & Harbor-UCLA Medical Center Consent Form</p>	<p>stepped in during the presentation of this project.</p> <p>The committee reviewed this protocol to evaluate a vaccinia-based vaccine in eliciting an immune response in children either at full strength or in diluted form.</p> <p>After presentation of the protocol by two reviewers, who differed markedly in their enthusiasm for the protocol, a motion was made and seconded to approve the protocol as 46.405, with minor stipulations regarding payment and corrections to the consent form.</p> <p>The committee discussed and clarified a number of issues related to whether recruitment was likely (yes), whether recruitment might target children from lower socioeconomic backgrounds (no), why the vaccine was originally withdrawn from use (side effects from vaccine were considered more risky than the risk of smallpox in this country) and the anticipated likelihood of a smallpox attack (not impossible, but only one of a vast number of possible agents that could be employed by terrorists). The committee questioned regarding various aspects of the protocol. She was then asked to withdraw.</p> <p>A lengthy discussion ensued as to the propriety of approving as 46.405 a vaccine with known side effects whose likelihood of providing direct benefit to an individual child depended on an assessment of the likelihood of a terrorist-inspired smallpox attack. The committee was divided regarding this issue and the question was called.</p> <p>For – 5 Against- 5 Abstentions – 1</p> <p>As a result of the tie vote, the chair exercised his right to vote. According to the chair’s understanding of Roberts’ Rules, the function of the chair in the event of a tie vote is to vote to preserve the status quo; consequently, the chair voted against the motion which was then defeated</p> <p>For- 5 Against – 6 Abstentions - 1</p> <p>Following the defeat of this motion, the committee reviewed into what category of research the proposed study might fall.</p> <p>The committee reviewed the various categories of research in children that are permitted:</p> <ol style="list-style-type: none"> a. 46.404 was considered inappropriate since the vaccine itself has side effects which make its use greater than minimal risk; b. 46.405 was considered inappropriate since the vaccine would not offer the prospect of direct benefit to the individual child, except in the highly remote (with the information available to the 	<p>A motion was made and seconded to APPROVE this project as risk category 45CFR46.407 and to refer the protocol to the Secretary of the Department of Health and Human Services (DHHS) for further action. Should the Secretary of DHHS’s action indicate approval, the approval period is to expire July 15, 2003.</p> <p>Total: 11 Vote: For – 11 Opposed – 0 Abstentions – 0</p>
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committee) possibility that the individual child was exposed to smallpox. The committee noted that smallpox was eradicated in the 1970's, save for stocks in the CDC and in Russia.

- c. 46.406 was considered inappropriate because the committee did not find the risk of the vaccine to be a minor increase over minimal risk (see point (a) above), nor did the committee believe that generalizable information about the subjects disorder or condition would be obtained that had not previously been known

The committee agreed that the category which best fit the proposed research was 46.407. The research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of children.

The committee noted, under that category, that a finding of 46.407 meant that the protocol should be referred to the Secretary of Health and Human Services for his decision, following consultation with a panel of experts in pertinent disciplines and public review and comment to determine whether:

The research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of children.

The research will be conducted in accordance with sound ethical principles; and adequate provisions are made for soliciting the assent of children and permission of their parents or guardians.

returned after the vote on this project.