

CANADIAN ASSOCIATION OF RESEARCH ETHICS BOARDS L'ASSOCIATION CANADIENNE DES COMITES D'ETHIQUE DE LA RECHERCHE

# Virtual REB Case 1: Influenza Transmission in Hutterite Communities

# Background

The dynamics of how influenza transmits through populations of people are not well understood. One theory is that children play a key role in transmitting influenza in communities and that reducing the number of cases in children will reduce the number of cases among adults. By immunizing healthy children who do not have a high risk for complications you indirectly protect those at highest risk who are not healthy enough to handle a vaccine. Results from a study testing this theory could have important implications in years in which there are influenza vaccine shortages.

## **Research Question**

Dr. Green is performing Agency-funded research on the transmission of influenza. Her hypothesis is that vaccinating large numbers of school age children against influenza will prevent influenza in other community members.

#### **Participants**

The research proposal is to conduct a study across 50 Hutterite colonies in western Canada and United States. Hutterites provide a unique research group because they live in distinct communities, have limited exposure to the outside world and have a large percentage of children in their community (25%) all of which make it easier to see patterns of how influenza spreads between children and adults. The participants include 1,000 children from ages 3 to 15 and 2,000 adult community members.

# **Proposed Method**

The children in half of the colonies will receive influenza shots and the 500 children in the other half will receive placebo shots. The incidence of influenza cases will be tracked for a 12-month period with the 1,000 children and the 2,000 community members to see if fewer cases occur in the communities in which the children receive the vaccine.

# Risks

The risks to the children include possible adverse reactions to or emotional distress associated with receiving an influenza shot. The research does not expose the adult participants to risks beyond their everyday activities.

## **Potential Benefits**

The children receiving the influenza vaccine benefit from the protection it provides. Hutterite and non-Hutterite communities will benefit from the intended research outcome of more effective influenza vaccination programs in the future.

## Recruitment

Knowing Hutterite colonies are hierarchical in their organization, Dr. Green will be approaching the leaders of the colonies to seek their approval for the research and to request they ask the teachers to recruit students for the research in the manner best suited to their culture.

## **Consent Process**

Dr. Green will be seeking consent for the research from each community leader on behalf of the members of his community.

#### **Data Security**

The data will be anonymized and the research files safeguarded in keeping with the research institution's privacy and confidentiality policy.

#### Dissemination

The research results will be published in the Canadian Medical Association Journal.

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