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Questions and Answers about the *Sanofi Pasteur Vaccine Challenge Unit* and the Clinical Research Unit

1. **What is the *Sanofi Pasteur Vaccine Challenge Unit*?**
   A: The *Sanofi Pasteur Vaccine Challenge Unit* is a 5,400 sq. ft., ten-bed inpatient unit with single isolation rooms, located in the *IWK Health Centre* in Halifax. It is the first of its kind in Canada and one of a very few such facilities worldwide. It is designed for human vaccine challenge studies which test the efficacy of vaccines at an early stage in the vaccine development process.

2. **What is a vaccine challenge?**
   A: In a typical vaccine challenge study, healthy adult volunteers are vaccinated then exposed to the virus or bacteria against which they were vaccinated. These studies are conducted only for well understood diseases which cause only mild illness or can be treated if the vaccine does not provide sufficient protection. Examples include respiratory viruses (e.g. influenza) and gastrointestinal organisms (e.g. salmonella, campylobacter). Once exposed, the volunteer participants are usually required to stay in the Challenge Unit for days or weeks for observation. The level of protection provided by the vaccine is measured by blood tests, swabs and by looking for any symptoms of infection.

3. **What is the Clinical Research Unit?**
   A: The *Sanofi Pasteur Vaccine Challenge Unit* may also be used for other inpatient and outpatient clinical research. These studies may include, but are not limited to, research on infectious disease transmission, antimicrobial effectiveness and pharmacokinetics. Clinical researchers will have access to full-spectrum infrastructure and resources needed to conduct clinical research, including but not limited to the preparation of ethics/regulatory submissions, statistical and data management support, nursing support for inpatient and outpatient data collection, protocol-specific interventions, and all other trial-related activities.

4. **What is a clinical trial?**
   A: Before any new medicine or medical device is placed on the market, it must be tested through clinical trials. Clinical trials are research studies, which require the participation of volunteer children, adults, and families to evaluate whether a new product is safe and well tolerated and whether it works to prevent or treat the problem for which it was developed. Results are then reviewed to determine if the drug, practice or medical device should be made available to the public. Clinical trials are a vital part of scientific research that play an important role in the development and evaluation of new medicines, treatments, and cures.

5. **Who may use the *Sanofi Pasteur Vaccine Challenge Unit*?**
   A: Researchers from institutions, governments or the private sector who wish to conduct vaccine research requiring inpatient observation or isolation and care may apply to use the facility. Applications will be subject to rigorous oversight, scientific and ethics review.

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6. **Who may use the Clinical Research Unit?**
   A: When the unit is not being used for vaccine research, researchers from institutions, government or the private sector who wish to conduct health research requiring inpatient observation and care may contract the facility and its services. As with the Challenge Unit, applications will be subject to oversight, scientific, and ethics review. In an emergency such as a severe outbreak of an infectious disease, the unit is available to the *IWK Health Centre* for containment and treatment.

7. **Who manages the unit?**
   A: Staff from the *Canadian Center for Vaccinology* will coordinate use of the unit and manage the services available to researchers and participants. A Medical Director and Clinical Operations Coordinator will oversee vaccine clinical trials including challenge studies.

8. **How is the unit staffed?**
   A: Medical staff will be provided by the *Canadian Center for Vaccinology* or by the researcher, depending on the type of study.

9. **How are volunteer participants recruited?**
   There are different eligibility requirements for each clinical trial. When volunteers are needed, print and broadcast advertisements will be used to recruit people who may be eligible. Staff at the *Canadian Center for Vaccinology* will be available to answer questions about the research, determine eligibility, and ensure that participants are well informed about the study before agreeing to participate.

10. **Do research participants get paid?**
    A: For most clinical trials, participants are reimbursed for travel expenses only. However, if overnight or longer observation is required, additional reimbursements will usually be paid as compensation for the participants' time.

11. **What if a participant has an unexpected emergency, such as a death in the family, during a study?**
    A: This will depend on the study and the need for isolation, but staff will make every effort to accommodate the needs of participants.

12. **If a vaccine fails to protect a participant, what happens?**
    A: Participants are closely monitored by physicians throughout the study. The unit is equipped with full physiological monitoring capabilities so that medical staff can quickly detect complications and provide immediate treatment. Because the unit is located in a full service pediatric hospital and adjacent to the QEII hospital for adults, specialists are in close proximity for additional consultation or treatment if required.

13. **In a challenge study, how is the virus or bacteria contained in the unit?**
    A: The unit is specially designed to contain organisms, similar to isolation rooms in hospitals, including HEPA-filtered air exhaust and negative-pressure rooms.

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14. **If the Challenge Unit is the first of its kind in Canada, where were vaccine challenge studies being conducted previously?**
    A: Challenge studies have not been possible in Canada until now. The absence of such a facility has limited Canada's capacity and access to valuable vaccine research. A sister unit is being planned for the *McGill Research Institute* in Montreal. Other vaccine challenge units exist at the *University of Maryland* and *Johns Hopkins University* in Maryland. The *Sanofi Pasteur Challenge Unit* is uniquely positioned to conduct industry-sponsored studies when other units are being used for government-sponsored research.

15. **What research has already been conducted on a vaccine before it is used in a challenge study?**
    A: Vaccines used in challenge studies have usually already undergone studies to evaluate safety and are ready to be tested in a larger number of people.

16. **What services are provided to research participants who stay in the unit?**
    A: The inpatient facility is designed to allow participants in isolation to have access to their own TV, Internet connection, DVD, full-service meals and snacks, hot and cold beverages, and telephone. Each isolation room has natural light through large windows. In the common area participants who are not in isolation may use the fridge, microwave, coffee maker, and lounge area.

17. **What are the regulatory agencies governing clinical research studies?**
    A: All clinical research studies in Canada require review and approval by *Health Canada* and local Research Ethics boards. Some clinical trials in Canada also require approval from the *U.S. Food and Drug Administration.*

18. **How will this unit expand the ability to conduct health research in Nova Scotia and in Canada ?**
    A: Until now there has not been an inpatient facility to conduct health research. Researchers in Halifax can now expand the scope of their research with the capability to do studies which could previously not be done locally. The availability of this facility will attract researchers from other parts of Canada by providing an added dimension to clinical trial capability not available elsewhere. Vaccine manufacturers will be encouraged to bring their research and development to Halifax not just for challenge studies but also for preliminary pre-challenge studies and post-challenge extended phase II, III and IV studies for that vaccine as well. This will offer tremendous benefit not only to Canadian researchers but will also improve Canada's access to new vaccines and vaccine technologies thereby benefiting more Canadians, sooner.