Remote Consenting:
IC.8 COV-IMMUNO Case Study

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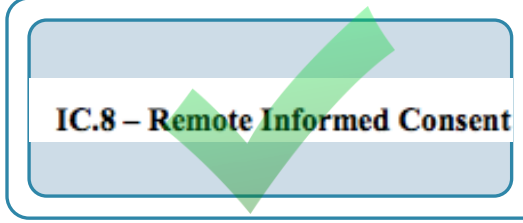
IC.8 Study Summary

- CCTG IC.8 Cov-Immuno: A Randomized, Phase III Trial of Immunization With IMM-101 Versus Observation for the Prevention of Severe Respiratory and COVID-19 Related Infections in Cancer Patients at Increased Risk of Exposure

IC.8 Trial Activation



Sponsor Approval

- CCTG approved use of remote consenting for IC.8
- Wet-ink signed consent forms still required

Planning Meetings

- Multiple meetings with study coordinator, trials activation coordinator, clinical leader/manager, pharmacy/lab, and principal investigator to confirm new process.
- Consulted Health Canada website for guidance and institutional policies

Strategize on Technology

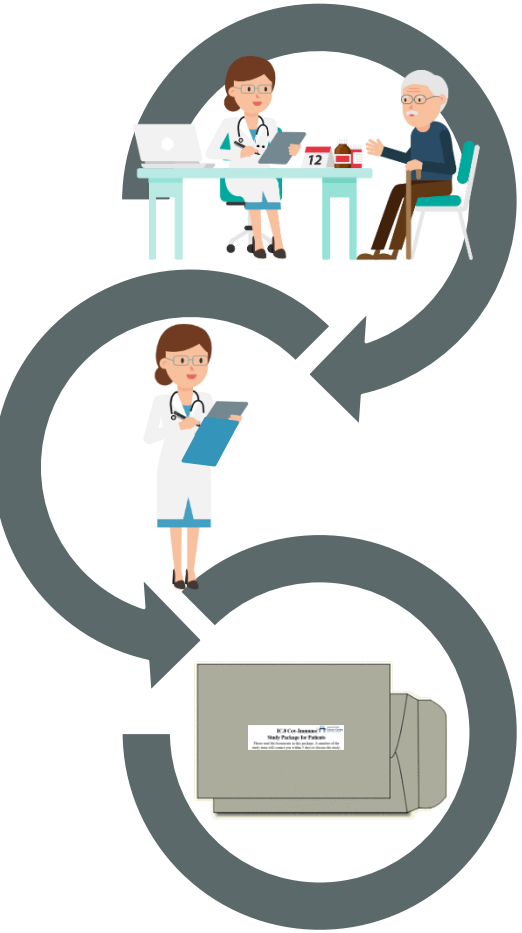
- Used general clinical trials email for self-referrals and patient contact
- Identified and used approved technology at site (e.g., Zoom, telephone)

ocreb HiREB
Hamilton Integrated Research Ethics Board

Submission to REB

- Communicated with REB prior to submission and included in person and remote consenting
- Created verbal consent script, draft email templates, and content that was given to patients

IC.8 Recruitment Process at the Juravinski Cancer Centre



1. Patient learned about the study through health care provider or poster

2. Health care provider completed the eligibility sheet on the front of the study package. Placed the completed sheet in the yellow IC.8 Study folder.

3. Gave the patient the study package to take home and read through or the coordinator sent a virtual study package through email.

   The coordinator contacted the patient by phone within 5 days to complete remote consent

Juravinski Cancer Centre
Clinical Trials Department

Eligibility Sheet – IC.8 Cov –Immuno
COVID-19 and Severe Respiratory Study

To complete this form:

1. Please mark a 'Y' for YES or 'N' for NO beside each eligibility criteria in table below
2. If patient is eligible, add the patient label to the sheet and sign/date at the bottom
3. Give the patient the IC.8 study package and put this sheet in the yellow IC.8 Study folder. Thank you!

If criteria #1 to #4 is 'N' patient is ineligible:

1._____ Patient must be undergoing (or be planned to undergo) active treatment for one or more solid malignancy, lymphoma or myeloma, requiring them to present to the hospital or cancer clinic **at least twice/month for assessments and/or treatments, anticipated for at least 3 months.**

2._____Patients must have **one or more** of the following risk factors for a severe COVID-19 infection **(check at least one):**

- ☐ Age > 65 years old;
- ☐ Hypertension (on medication);
- ☐ Type 1 or 2 Diabetes (on medication);
- ☐ A relevant chronic condition:
  - Heart (e.g. heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
  - Chronic obstructive pulmonary disease
  - Emphysema
  - Chronic bronchitis
  - Moderate to severe asthma
  - Idiopathic pulmonary fibrosis
  - Cystic fibrosis
  - Other lung condition:
  - Liver cirrhosis
  - Serious kidney disease requiring dialysis
- ☐ Receiving systemic therapy (such as cytotoxic chemotherapy, immunotherapy or targeted agents excluding single agent hormonal therapy);
- ☐ Body Mass Index > 40;
- ☐ Living in a nursing home or LTC facility.

3._____ Patient must have a life expectancy of > 6 months

4._____ Patient must have an ECOG Performance Status ≤ 2

If criteria #5 to #10 is 'Y' patient is ineligible:

5._____ Patient has previously experienced an allergic reaction to any mycobacterial product, including the BCG vaccine.

6._____ Patients with superficial bladder cancer or any other condition currently receiving or planned to be treated with BCG.

7._____ Patient has a known history of Human Immunodeficiency Virus (HIV) (HIV 1/2 antibodies) or a known history of or is known to have a positive test for Hepatitis B (HBsAg reactive) or Hepatitis C (HCV RNA [qualitative]).

8._____ Patients with prior or concurrent leukemia.

9. Patient has had a prior bone marrow transplant.

10._____ Patient has documented history of clinically severe autoimmune disease or a syndrome that requires systemic steroids or immunosuppressive agents (e.g., >10 mg daily prednisone/ depot corticosteroids/ azathioprine/ tacrolimus/ cyclosporine etc.)

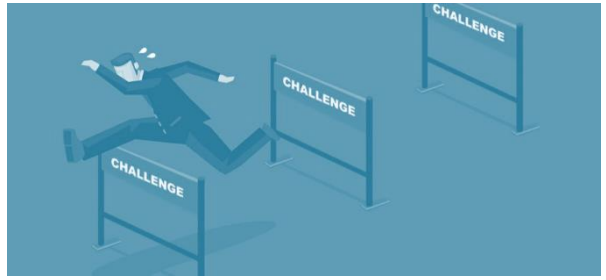
Comments:

☐ (***If applicable***) Please check to indicate that the treating physician has been informed that the patient is being referred for the IC.8 study and has reviewed/agrees with this pre-screening assessment

HCP Signature: _____ **Date:** _____

Remote Consenting Challenges / Considerations

- **Data Documentation:** Tracking telephone calls, collection and filing of scanned/ original consent forms and virtual communication
- **Follow-up Calls:** Multiple telephone calls may be required before a patient is ready to review consent
- **Investigator Availability:** Ensure study investigator is available when you are conducting remote consent for oversight/ to answer any questions
- **Access to Technology:** Processes need to be in place for patients who have access to email and those who do not
- **No Visual Cues During Consent:** Pause throughout consent discussion for questions and to confirm understanding
- **Patient Preference:** Some patients prefer in person consent



Remote Consenting Benefits

- ✓ **Informed Consent:** Patients can read consent form in its entirety prior to consent discussion
- ✓ **Patient-Centred Care:** Speaking with patients in their homes, significant others able to be present, can schedule it at a convenient time for patient, avoid extra trips to Cancer Centre
- ✓ **Sensitive Topics:** Patients may be more open when speaking about sensitive topics
- ✓ **Improved Recruitment.** Patients are not as overwhelmed and may be more willing to discuss involvement in the study
- ✓ **Aligns with Remote Clinic Visits.** Many health care providers conduct virtual visits with patients. Remote consenting would help ensure no potential participants are missed for studies

Final Thoughts and Learnings

- Create clear documentation process and keep information up-to-date
- Consent discussion can take longer for those who are interested but quick conversations for those who are not interested
- Try to meet patients in person after remote consent to establish a connection
- Train staff and investigators on remote consenting process prior to study activation
- Can take time to create a process for remote consenting at your site especially if existing in person process meets all of Health Canada's requirements
- Worth the effort to consider and implement a remote consenting process (if approved by the sponsor and REB)

Questions?