TRAP-HPV STUDY
Transmission Reduction And Prevention with HPV vaccination

TELEPHONE SCREENING PROTOCOL

<table>
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<th>To be filled out by Interviewer:</th>
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<td>Date of initial contact: ____/ ____/ _______</td>
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<td>Initials of Interviewer: ________</td>
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Thank you for your interest in our study. TRAP-HPV is a clinical trial aimed to determine the efficacy of an HPV vaccine in reducing transmission of HPV infection in young, heterosexual couples. It enrolls male-female couples who have recently begun a sexual relationship. Couple must have plans to remain in Montreal for at least one year.

If you are eligible and choose to participate, you and your partner will be asked to visit the McGill Student Health Services Clinic or the Concordia Health Services Clinic to enroll.

Both Men and Women will visit the clinic together six times – Enrolment visit, 2, 4, 6, 9 and 12 months.

Men will provide a sample of penile epithelial (skin) cells, blood, oral, samples, and to complete a survey.

Women will be asked collection of vaginal specimens. This is done by insertion of a swab. (Women do not undergo pelvic exams for TRAP). Women will be asked to provide blood, oral samples and to complete a survey.

The surveys will ask women and men questions about their medical and sexual history, sexual behaviour with their current partner, contraceptives use, smoking habits, and knowledge and attitudes about HPV.

In appreciation of your time, you would each be receiving either Gardasil 9 or Hep. A vaccine and $120 for the first visit and between $60-120 for each subsequent visit, for a total of $1000 per couple if all study visits were completed. At the end of the study, you would also receive the vaccine that you did not receive during the study.

After describing study: “Are you interested in participating in this study? YES NO

If yes: Do you have 5 minutes right now to answer some questions?
If yes: Proceed to section I
If no: Proceed section II

I. General Information

1. How did you hear about the study? Select

   On POSTERS (ask where):
   - McGill
   - Concordia
   - UdeM or UQAM
   - College (which one) ____________
   - Other ________________________

   In ADVERTISEMENT:
   - Classified Ads
   - Website ______________________
   - Facebook
   - Other ________________________

   Through WORD OF MOUTH:
   - By a boy/girl-friend
   - By a friend
   - Other ________________________

   Through OTHER:
   - Specify ________________________

   “it is really helpful for us to know what promotional strategies are working”. 
2. What is your name? ____________________________________________ Gender: M      F

3. What is your partner’s name? ___________________________________________________________

4. How long have you been engaging in sexual activity together? ______
   Interviewer:
   ❌ Stop if answer is over 6 months

5. Do you plan to continue having sexual relationship for the next year with your partner? YES    NO

5. How old are you? _______  
   Interviewer:
   ❌ Stop if answer
   Female and or Male: is/are younger than 18 or older than 45 years old.

6. How old is (partner’s name)? ____________

7. Are you or your partner a student? YES  NO
   If yes, where do you/ him or her study? ____________________________

8. Are you and your partner planning to stay in Montreal for the next year? YES    NO

   Restate that we want both male-female willing to enroll and tell that there are 4 samples that we take, oral, vaginal/penis and blood.
   Let them know ...
   Female: Self-Collection of vaginal sample.
   Male: Rub outside of penis with a Q-tip (cotton swab). Nothing is inserted into ureter.

9. Do you think that your partner is willing to enroll in the TRAP-HPV Study? YES    NO

10. Have you ever been vaccinated against HPV (i.e. Gardasil or Cervarix)? YES    NO

11. Have your partner ever been vaccinated against HPV (i.e. Gardasil or Cervarix)?
    YES    NO    DON’T KNOW

   Female only

12. Are you pregnant or planning to become pregnant in the next 12 months? YES    NO
13. Are you ongoing or planning to participate in any other HPV study? YES  NO

Female only
14. Have you ever had a pap test? YES  NO

* 15. Have you ever redone a pap test because of abnormal results? YES  NO

** 16. Have you ever had gone for colposcopy? YES  NO

If yes: Please write any information related with an abnormal pap results.
_____________________________________________________________________________________________
_____________________________________________________________________________________________

17. Have you ever been diagnosed with cervical (women), penile (men), oral, or cancer? YES  NO

Perception of your life situation as a couple

Most people have problems in their relationships. This following questionnaire is concerned with your perception of your life as a couple. So this is your personal opinion. Do not be concerned about what may or may meet your partner. For each question, please indicate your response by choosing the most appropriate box.

18. Does it happen often or is it you’ve ever considered separation, or terminating your relationship?

       0  1  2  3  4  5
Always                                      Never

19. In general, would you consider that things are going well between you and your partner?

       0  1  2  3  4  5
Always                                      Never
20. Do you have trust in your partner?

0 1 2 3 4 5

Always Never

21. The boxes on the following line represent different degrees of happiness in your relationship. The central square ‘happy’ is the degree of happiness found in most relationships. From scale from 0 to 6 the box that best describes your degree of happiness as a couple.

0 1 2 3 4 5 6

Extremely unhappy Happy Totally happy

II. Contact Information

What is your ...

Cell phone number: _____________________________

Other preferred contact number: _________________________

*** Sometimes it’s easier for us to communicate with participants through emails.

What is your email address: ____________________________________________

What are the best times for our nurse to contact you? (Select all that apply)

Anytime Mornings Afternoons Evenings Other (specify):____________________

According to your availability, on which weekdays could we schedule your first visit? (Select all that apply)

Monday Tuesday Wednesday Thursday Friday

@ what times (specify): ___________________

Do you have any question to ask?

__________________________________________________________________________________

Be willing to answer questions through the conversation. They may wish to have their questions asked before providing you with all this personal information.
If candidate meets criteria after intake:

“So, based on what you’ve told me, it looks like you and your partner meet the eligibility criteria. I will send your contact information to one of our nurses and she will contact you and give you a first clinical appointment where you and your partner will fill out computerized confidential questionnaires and take the samples that I mentioned before. The first visit takes about 1 to 1.5 hours.

Please feel free to contact us if you have any further question regarding the study.

Thank you for your interest in the TRAP-HPV Study!!!!

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