

Appendix E: STOP with Addictions Mail-Out Model

In this model, Nicotine Replacement Therapy (NRT) will be mailed directly from CAMH to the client via courier. All clients will receive the same type and length of treatment – a pre-packaged 10-week kit containing a standard course of NRT patches. The 10-week kit will contain:

- 6 boxes of 21mg patch (Step 1)
- 2 boxes of 14mg patch (Step 2)
- 2 boxes of 7mg patch (Step 3)
- Information sheet

There are a couple of significant differences to the instructions described in this Operations Manual, primarily:

1. All references to storing, dispensing, and tracking NRT products do not apply (including the “Visit Form”).
2. This model has a Screening Form for inclusion and exclusion criteria prior to enrollment (see below).

Screening Form

Before enrolling a client into the STOP Program, implementers must first screen potential participants for the eligibility criteria using the Screening Form (see attached). Implementers must inform clients that there are eligibility criteria for participating in the STOP Program, and that they may or may not qualify.

The eligibility criteria are based on the other STOP Program protocols, as well as the product monographs for NRT. For this model of the study, it is necessary to adhere to the contraindications listed on the NRT package and the product monograph. The criteria include:

Inclusion Criteria

- Individuals 18 years of age or older
- Ontario resident (This study is open only to current residents of Ontario)
- Current daily smoker
- Smokes 10 or more cigarettes per day
- Has smoked more than 100 cigarettes in their lifetime
- Wants to quit smoking (i.e. start using the patches) within next 30 days
- Capable and willing to provide informed consent and comply with the study protocol

Exclusion Criteria

- Individuals under the age of 18 years
- Have a medical condition that would make participation medically hazardous as determined by the list of contraindications in the product monograph:
 - Heart attack in the past two (2) weeks
 - Life-threatening arrhythmias
 - Severe or worsening angina pectoris
 - Recent cerebral vascular incident (i.e. stroke)
- Intolerant or allergic to NRT
- Pregnant or lactating women
- Have been enrolled in another component of the STOP program/study within the past 6 months

When filling in the Screening Form, ask the client all of the questions in the order that they appear. You will notice that all responses that would make a client Eligible are in the left-hand answer column. Thus, any response that falls in the right-hand answer column would mean the client is Not Eligible. Even if a client is not eligible, you should still ask them all of the questions to complete the screening. You should not reveal to a potential participant the reason(s) that they are not eligible to participate.

(Eligible)

(Not Eligible)

Ask the client:	↓	↓
1. How old are you? <i>Enter age:</i> _____	<input type="checkbox"/> 18 or older	<input type="checkbox"/> 17 or younger
2. Are you an Ontario resident?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3. Are you pregnant or breastfeeding?	<input type="checkbox"/> No	<input type="checkbox"/> Yes
4. Are you a daily smoker?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
5. Have you smoked at least 100 cigarettes in your life?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
6. How many cigarettes do you smoke per day? <i>Enter # of cigarettes per day (CPD):</i> _____	<input type="checkbox"/> 10+ CPD	<input type="checkbox"/> 0-9 CPD
7. Are you willing to set a “quit date” (i.e. start using the NRT) in the next 30 days? <i>Enter quit date:</i> _____ (day/month/year)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
8. Do you have a life-threatening arrhythmia, or severe or worsening angina pectoris, or have you had a heart attack or cerebral vascular incident (e.g. stroke) in the past 2 weeks?	<input type="checkbox"/> No	Yes (<i>select which one</i>): <input type="checkbox"/> Heart attack in past 2 weeks <input type="checkbox"/> Stroke in past 2 weeks <input type="checkbox"/> Life-threatening arrhythmia <input type="checkbox"/> Severe or worsening angina
9. In the past 6 months, did you receive free Nicotine Replacement Therapy through another component of the STOP Program (i.e. In the mail, through a workshop, or from a Family Health Team, Community Health Centre or Addictions Agency)?	<input type="checkbox"/> No	<input type="checkbox"/> Yes

Once the Screening Form is complete, you will know if the client is Eligible or Not Eligible to participate.

- If Eligible: Proceed with program enrollment (Consent, Registration Questionnaire, and Baseline Questionnaire) using a paper Consent Form and the STOP Portal.
- If Not Eligible: Thank the client for their interest in participating, and explain that unfortunately they are not eligible to participate in the STOP Program at this time.

The Screening Forms for Eligible participants should be scanned and emailed in to STOP once enrollment is complete, to ensure timely delivery of the NRT kit. The email address is stop.addictions@camh.ca. Alternatively, you can fax the Screening Form to **(416) 599-8265**.

STOP research staff will then confirm the client's eligibility, and review the enrollment information on the STOP Portal. We will arrange to mail the 10-week Patch Kit directly to the client via courier service, to the mailing address provided on the Consent Form (which appears on the Patient Profile on the STOP Portal). If the client does not have a home address for delivery, you may use your agency's address; it will be addressed to the client for them to pick up.

Documentation Pick-Ups

All original Screening Forms, for both Eligible and Not Eligible participants, must be sent back to STOP for study records. Screening Forms must be included with your monthly documentation pick-ups, in a separate envelope from the Consent Forms.