

## Partners for Healthier Weight

### Participant Informed Consent - The Program

#### The Program

The Partners for Healthier Weight (PfHW) Program is a medically and psychologically focused Program to treat participants who have a Body Mass Index (BMI) of 30 or greater and may have significant medical problems related to obesity. Such problems may include but are not limited to high blood pressure, coronary heart disease, diabetes, lung disease, and/or joint or bone disease.

#### The PfHW Program includes the following:

Phase	Timetable	Purpose	Activities
Pre-Program Preparation	Referral & Assessments prior to program start	<i>To assess your readiness for treatment and determine if you are appropriate to participate in the Program</i>	<ul style="list-style-type: none"> <li>• 30 minute nutrition assessment</li> <li>• 45 minute psychological assessment</li> <li>• 30 minute medical</li> <li>• Initial blood work</li> <li>• Online Questionnaire</li> </ul>
Introduction	Weeks 1-4 (3hrs weekly)	<i>To prepare for dietary and lifestyle changes</i>	<ul style="list-style-type: none"> <li>• Welcome &amp; Introduction Session (baseline activity &amp; biometric measurements)</li> <li>• Preparation of social support (e.g., family, friends) and environments (e.g., home, office)</li> <li>• 1200 calorie meal plan and awareness building activities (Weeks 2 to 4)</li> <li>• Week 1, 3 &amp; 4, visits with Program nurse and concurrent group discussion (1.5 hours)</li> <li>• Weekly PfHW team facilitated or group facilitated modules and activities (1.5 hours)</li> </ul>
Meal Replacement	Weeks 5-16 (3hrs weekly)	<p><i>To produce optimal weight loss while preserving lean body mass (muscle)</i></p> <p><i>Develop and practice new lifestyle skills and gain insights to enable long term weight management.</i></p>	<ul style="list-style-type: none"> <li>• Optifast® 900 calorie meal replacements used in replace of solid food</li> <li>• Weekly visits with Program nurse and concurrent group discussion (1.5 hours)</li> <li>• Weekly PfHW team facilitated or group facilitated modules and activities (1.5 hours)</li> <li>• Blood work at specified times</li> </ul>
Transition	Weeks 17-22 (3hrs weekly)	<i>To gradually re-introduce solid foods while giving the opportunity to practice and refine skills learned during the meal</i>	<ul style="list-style-type: none"> <li>• Progressive re-introduction of food with modified use of Optifast® 900 meal replacement</li> <li>• Weekly visits with Program nurse and concurrent group discussion (1.5 hours)</li> </ul>

		<i>replacement phase</i>	<ul style="list-style-type: none"> <li>• Weekly PfHW team facilitated or group facilitated modules and activities (1.5 hours)</li> <li>• Blood work at specified times</li> <li>• Consult with Program dietitian (1 hour)</li> </ul>
<b>Stabilization</b>	Weeks 22-26 (3hrs weekly)	<i>To stabilize your weight before completion of the weekly phase of the Program and prepare for long-term weight maintenance.</i>	<ul style="list-style-type: none"> <li>• Week 22 &amp; 26, visits with team nurse and concurrent group discussion (1.5 hours)</li> <li>• Weekly PfHW team facilitated or group facilitated modules and activities (1.5 hours)</li> <li>• Blood work at specified times</li> </ul>
<b>Maintenance</b>	Weeks 27-52 (3hrs biweekly)	<i>To maintain and stabilize your weight and to continue to reinforce long-term lifestyle changes</i>	<ul style="list-style-type: none"> <li>• Biweekly sessions facilitated by a PfHW team member</li> <li>• Biweekly group discussion &amp; activities</li> <li>• Week 52 end of Program assessment.</li> </ul>

The required commitment for this Program is three (3) hours, weekly, for 27 weeks and then biweekly for the remaining part of the Program.

During the first 26 weeks, participants will engage in group discussion while the team nurse assesses each group member (1.5 hours). The second half of the weekly session (1.5 hours) is spent in a group directed activity or with a PfHW team member in a group module. Some weekly sessions require participants to engage in scheduled group led activities. Group members will be responsible for engaging in information gathering and leading discussion on these weeks without a PfHW facilitator present.

The sessions during the remaining weeks of the Program will occur biweekly. Participants will engage in group discussion & activities for half of each session (1.5 hours) and will attend a module facilitated by a PfHW team member (1.5 hours). **Please note that the Program nurse does not complete medical assessments after week 26 of the Program.** Participants are responsible for scheduling their own family physician appointments as recommended by their family physician.

### **The Optifast® Product**

The Optifast® meal replacement is a safe and nutritionally complete powder formula, when used as prescribed by the team, under medical supervision. The PfHW Program advises that only water be consumed in addition to the meal replacement. During the meal replacement phase, all usual activities of daily living are permitted. However, as a precaution, (due to a decrease in blood volume / blood pressure) some activities that can further reduce your blood volume/blood pressure are not recommended, including but not limited to: hot steaming baths, whirlpool baths, sauna, scuba diving, and piloting an airplane. Strenuous activity, particularly with associated increased perspiration (especially during hot weather) is also not recommended. Prior to taking part in any activities that may be of concern, please consult with a member of the PfHW team.

The participant will be re-introduced to solid food in a carefully regulated and programmed fashion. Any deviation from use of Optifast® meal replacement as prescribed could cause additional medical complications.

Due to a low calorie diet and weight loss, some participants may experience side effects. These are usually temporary and include, but may not be limited to: headache, dry skin/nails, formation of gallstones, dizziness when standing in position for too long or standing up quickly, fatigue, diarrhea or constipation, muscle cramps, bad breath, dry mouth, frequent urination, hair loss, sensitivity to cold and changes in menstrual patterns. As a

participant in this Program, you agree to strictly adhere to the physical activity restrictions given to you by the PfHW team. Failure to do so may result in withholding the Optifast® product or, in cases of continued non-adherence, dismissal from the Program.

### **Dispensing of Optifast®**

The Optifast® product is dispensed on a weekly basis as needed, with the prescribed medical guidelines recommending four packages consumed daily. On week seven (7) of the Program, participants will receive a seven (7) package emergency supply of Optifast® to be used in the event of an unforeseen circumstance (e.g., storm days, unexpected absences, etc). The seven (7) packages are **not extra** and will be used during the transition phase.

In some circumstances some participants may require more than the allotted supply for the meal replacement and transition phase. Any additional Optifast® needed during the Program must be purchased, at an additional cost to the participant.

Subsequent to the transition phase, participants of the PflHW Program are given the opportunity to utilize Optifast® as a partial meal replacement product after at least 4 weeks of full food intake, when deemed appropriate. As a partial meal replacement, Optifast® may only be used to replace one full meal per day and is intended *for the purpose of weight maintenance, not weight loss*. PflHW never recommends the use of Optifast® more than once per day without medical supervision. Any deviation from use of Optifast® meal replacement as prescribed could cause additional medical complications.

### **Potential Medical Risks**

As with any medical treatment, participating in the PflHW Program with the presence of any significant disease or co-morbidity may increase your risk of experiencing an unexpected medical event. Participants with obesity (BMI 30 or greater), particularly those with significant hypertension (high blood pressure), coronary artery disease (poor circulation to the heart), kidney disease, and diabetes mellitus have a statistically higher chance of suffering sudden death than normal weight people without such medical problems. Instances of death have occurred while obese subjects were undergoing weight reduction with supplemented fasting. The possibility cannot be excluded that some undefined or unknown factor in the Program could increase the risk in a medically vulnerable participant due to individual physiology. Participants are therefore required to notify the medical team of any changes to their medication or medical status.

### **Participant Health Record**

The participant's health record serves as a legal document for recording healthcare service provided to the participant. The health record provides a vehicle for clinical communication and care planning and serves as a resource for health care practitioner education as appropriate. PflHW compiles and stores your information for 10 years as part of your health record in a confidential manner. PflHW stores participant's health records electronically through *Nightingale on Demand Electronic Medical Records* (EMR), which is supported by the Nova Scotia Department of Health and Wellness Primary Health Care Information Management (PHIM) Program. Any paper records, including financial records are stored securely in a locked file room. PflHW may also compile your information without your name for quality assurance purposes. Your records will only be accessible to PflHW team members.

Throughout the course of the Program (i.e., before enrollment, 3 months, 6 months and 12 months), you will be asked to complete online questionnaires for the purpose of ongoing medical, nutrition, and psychological assessment, as well as for quality assurance purposes. The results of this questionnaire will become part of your health record with PflHW. The survey program is administered by Capital District Health Authority (CDHA) and responses are stored in Nova Scotia and are not transferred to other entities. While this survey is

administered and stored utilizing CDHA resources, the information is not accessible to persons outside of PfHW and its contractors. Completing the questionnaires is voluntary and you may opt out of doing so without penalty to your ongoing medical care.

Services provided to participants enrolled in PfHW, including their initial assessment and weekly medical assessment, will be documented for purposes of the participant's health record.

### **Authorization to Treat**

I consent to be treated with the meal replacement described in this consent. Therefore, I hereby authorize and direct PfHW, their team members and other health care professionals selected by them, to administer any healthcare or treatment(s) necessary while in the Program in order to ensure my health and safety. I agree that PfHW does not take sole responsibility for any medication adjustment or primary medical care during the Program unless urgent adjustment or care is needed. I am aware that my medical care will be the responsibility of my family physician and/or specialists involved in my care.

I understand that the purpose of my participation is to be treated for obesity.

I acknowledge that no guarantee can be made concerning the expected results of the product and Program described above. I hereby acknowledge that the above-described information has been disclosed to me and all questions, which I have asked about the treatment described, have been answered in a satisfactory manner.

### **Termination of Participation**

I understand that I am free to discontinue participation in the Program at any time, either verbally or in writing without fear of prejudice in other treatments I may receive by the staff of PfHW.

I understand that this consent extends to the original period of participation in the Program.

I understand that I may be requested to return to a regular food diet before the completion of the twelve (12) full weeks of meal replacement if:

- a) I am losing too much weight or lean body mass (muscle).
- b) I am not following the PfHW Program as prescribed.
- c) I am away from the Program for more than one (1) week.
- d) The Program team deems it necessary for medical reasons.

I understand that I may be asked to leave the Program due to non-compliance with recommendations from the PfHW team. For example, if I fail to attend my weekly medical assessment.

### **Release of Information**

I agree to have a copy of my blood work results sent to PfHW as ordered by my family physician. I agree to allow the PfHW team to communicate information pertaining to my participation in the Program to my family physician including but not limited to: medical status, attendance, medication changes, and discharge status.

I understand that attendance at the lifestyle sessions is mandatory. Please note that these sessions are not psychotherapy sessions. Should individual issues arise during the course of the Program, I understand that I should discuss this with the Program nurse or my family physician who will provide guidance with the appropriate referral process.

**Email Correspondence**

PfHW team members only use secure and encrypted Capital Health/NSHealth network email accounts for purposes of email correspondence for Program-related matters involving your personal health information. However, PfHW also sends general Program information through an email, password protected service called Mail Chimp for reminders, announcements, and news. You may opt in or opt out of either of these options.

I understand that personal information sent through the use of my personal email account (e.g., gmail, yahoo, etc) for purposes of corresponding with PfHW may not be secure and may be stored on servers outside of Canada. I understand that providing PfHW with a personal email address for purposes of corresponding regarding Program-related matters is optional.

PfHW will not release your e-mail address to third parties.

I consent for PfHW to correspond with me through the following email address:

\_\_\_\_\_ (optional) By providing an email address, you are consenting.

Initial one: \_\_\_only correspond with me using the Capital Health network account  
\_\_\_please communicate with me using Capital Health network for personal information and using Mail Chimp for any other general Program information. I acknowledge I can unsubscribe from Mail Chimp at any time.

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***I have read and understand this informed consent.***

*I understand and acknowledge that Partners for Care, Nestle Nutrition, PfHW and PfHW staff are not responsible for any harm or other injury I may experience as a result of deviating from the stated Program.*

**Date:** \_\_\_\_\_

**Participant Name:** \_\_\_\_\_  
(please print)

**Participant Signature:** \_\_\_\_\_

**Witness Name:** \_\_\_\_\_  
(please print)

**Witness Signature:** \_\_\_\_\_

## Partners for Healthier Weight

### Participant's Responsibilities - The Program

I, \_\_\_\_\_, understand that my responsibilities and obligations as a PfHW participant are as follows:

1. I have viewed and understand the Partners for Healthier Weight *Information Session* videos. I have read and understand the “Related Documents” including the *Program Information Booklet* and *Next Steps to Enroll*. I have had any questions that I had answered by a PfHW team member.
2. If a participant chooses not to participate in the PfHW Program following their initial medical, nutritional and/or psychological assessment, they must inform the Program Coordinator **at least one week** prior to **Pre-Program Clinical Team Rounds** to allow for additional prospective participants to be assessed. If a participant fails to provide at least one week notice prior to **Pre-Program Clinical Team Rounds**, they will be responsible for the cost of the lifestyle component of the Program due to inadequate notice given to fill their spot in the group.
3. Participants must be willing to make participation in the Program and the resulting long-term lifestyle changes a priority.
4. Participants must be prompt in attendance for each session. Participants understand that each session is approximately THREE (3) HOURS LONG and may include the medical assessment, group discussion, and group activities and modules.
5. Participants must have their weekly medical assessment form completed prior to attending their session.
6. Participants are expected to read the manual and complete all assignments before each session. They understand that these assignments are an important aspect of this Program and are beneficial to progress.
7. Participants are required to notify the medical staff regarding any changes in medications or changes in their medical status.
8. Participants must accurately report weekly consumption of Optifast® and other food and beverage.
9. Participants are expected to adhere strictly to the medical portion of this Program. This includes seeing the Program nurse, attending family physician appointments as recommended, following medical advice, and having necessary blood tests done according to schedule, including other tests that the medical team or their family physician deem necessary.
10. Participants are required to notify the PfHW team if they will be absent from a weekly session and book required assessments with their family physician.

11. Participants must attend each scheduled group session. These sessions permit the participants to work on improving eating, exercise, and other health behaviours and are an essential part of treatment.
12. If participants choose to discontinue the Program at any time, they must inform the PfHW at the time of the decision. Under some circumstances (non-compliance, absenteeism, etc.) the PfHW team may ask a participant to leave the program. Monies for services and products are nonrefundable.
13. If a participant is required to discontinue the program due to medical reasons, they will receive a prorated refund from PfHW for the lifestyle fee and will also be issued a refund for any Optifast® product not yet dispensed according to the payment balance that PfHW has received at the time of leaving the Program.
14. Participants are required to pay for services according to the prescribed payment schedule. Failure to follow the payment schedule will result in temporary suspension of the Program until monies owed are paid. This cost includes the meal replacement product, group sessions, and associated Program costs.
15. PfHW does not guarantee insurance reimbursement.
16. Participants will receive, upon completion of the Program or at regular intervals, a receipt(s) outlining the amount paid and the services rendered for the Program.

**Date:** \_\_\_\_\_

**Participant Name:** \_\_\_\_\_  
(please print)

**Participant Signature:** \_\_\_\_\_

**Witness Name:** \_\_\_\_\_  
(please print)

**Witness Signature:** \_\_\_\_\_