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REQUEST FOR PROPOSAL (RFP)

Reference Number: 1000151842

CLOSING DATE: August 21, 2013 **CLOSING TIME and TIME ZONE:** 2 p.m. EST

PROJECT TITLE Outdoor Physical Activity and Health (OPAH) Study

Branch/ Directorate

Population Studies Division
Environmental and Radiation Health Sciences Directorate
Healthy Environments and Consumer Safety Branch
Health Canada

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RFP Issue Date: August 1, 2013

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1. 1 Title

Outdoor Physical Activity and Health (OPAH) Study

1.2 Introduction

The study will be conducted in Prince George, British Columbia during January through April 2014.Prince George is the preferred site for the purposes of this study based on geography, air quality characteristics, availability of air quality information at study sites of interest, and size of the community.

Health Canada is seeking a contractor to conduct a panel study involving repeated measurements of respiratory and cardiovascular health outcomes on 35-40 adults 55 years of age and older.

Subjects will participate in light exercise (e.g. walking) for 30 minutes each day, before and after which respiratory and cardiovascular measures will be performed.

The following physiologic measurements will be made: spirometry; heart rate variability; endothelial function; exhaled nitric oxide (FeNO); blood pressure; pulse rate, and oxygen. Urine samples will be taken.

The services provided by the contractor include: hiring, scheduling and supervising the daily work of field staff; ensuring that staff follow all standard operating procedures; setting up and safeguarding the study site and all related equipment; recruiting study participants and overseeing their safety during the study; providing a storage and laboratory space and safeguarding documents and computers; shipping documents and laboratory samples to Health Canada and designated laboratories; and assisting in communications with community stakeholders.

1.3 Estimated Value

The total value of any contract(s) resulting from this RFP shall not exceed $130,000.00, including travel and living expenses (if applicable), fees paid to study participants, other expenses and all applicable taxes. There will be an option to extend the contract for two additional years at $130,000.00 per year.

1.4 Objectives of the Requirement

The primary objective of the study is to examine the association between individual air pollutants, the AQHI and cardiovascular and respiratory physiological measures in a panel of older adults, in rural, and small urban areas.

Should this study indicate that air pollutants are associated with adverse health effects outside large urban centres, but this is not accurately reflected by the AQHI, an additional objective is to employ the results of the study to develop alternative AQHI formulations for rural and smaller urban areas.

By the completion of the contract, all clinical measurements must be completed according to standard operating procedures, and Health Canada must receive all consent forms and questionnaires completed by participants, and laboratory samples.

1.5 Background, Assumptions and Specific Scope of the Requirement

The Air Quality Health Index (AQHI) is a risk communication tool intended to provide information to the public on current and forecasted air quality conditions. It is based on a weighted sum of concentrations of nitrogen dioxide (NO2), ozone (O3), and particulate matter of median aerodynamic diameter ≤ 2.5 μm (PM2.5), where weights are based on an analysis of the association between air pollution and mortality in Canada's 12 largest cities (Stieb et al. 2008). The AQHI is believed to be a valid measure of health risk in urban settings because the AQHI formula was derived directly from analysis of the association between air pollution and mortality in urban areas; this analysis was validated using a split sample technique in which coefficients derived from half the data were used to construct a three pollutant additive index that was a significant predictor of mortality in the other half of the data; and three recent analyses have reported significant associations between the AQHI and morbidity measures for selected circulatory and respiratory conditions (Chen et al. 2012, To et al. 2012, Stieb et al. unpublished data). One of these studies found that the AQHI model fit the data better than models using individual pollutants (Chen et al. 2012).

However, stakeholders have expressed concerns that owing to differences in the mix of pollutants between these large cities and smaller cities, or rural areas, the AQHI may not accurately predict health risks outside large urban centres. Conducting health studies outside large centres is challenging because small populations in small urban centres or rural areas mean that administrative data on health outcomes such as mortality or hospital admissions are likely to have low statistical power and routine air pollution monitoring in these areas is often not available. These challenges underlie a general paucity of evidence linking air pollution and health in rural areas, compared to the evidence base pertaining to urban areas. Nonetheless, these areas may be subject to significant air pollutant exposure from local industry, woodsmoke or long range transport of regional secondary pollutants, and residents may have greater potential for exposure as a result of greater time spent outdoors for work or recreation. They could thus benefit from provision of information on air pollution and its associated risks, and how to reduce exposure in the context of advisories or air quality index programs.

The elderly are a primary target group for AQHI health messages. Elderly individuals have a higher prevalence of respiratory and cardiac disease which predisposes them to adverse health effects of air pollution exposure. Nonetheless, many elderly individuals remain physically active outdoors and are therefore likely to be exposed to outdoor air pollution and to benefit from advice provided through the AQHI.

In order for the AQHI to be a valid tool outside large urban centres, it must first be established that it is in fact associated with health outcomes in these areas.

A number of panel studies have been conducted of the association between air pollution and repeated measures of cardiovascular and respiratory physiological parameters in older adults.

Heart rate variability
Heart rate variability (HRV) is a measure of autonomic nervous system control of the heart. Decreased HRV is believed to reflect an imbalance between sympathetic and parasympathetic control, indicative of potentially increased vulnerability to adverse events. HRV is commonly analysed in either time or frequency domain. In time domain analysis the intervals between successive normal beats is measured (normal-to-normal (NN) intervals). The most common time domain variables are the standard deviation of the NN interval (SDNN), the number of pairs of NN

intervals differing by more than 50 ms divided by the total number of NN intervals (pNN50), and the square root of the mean of the sum of the squares of differences between adjacent NN intervals (r-MSSD). SDNN represents overall variability of heart rate and has been shown to be a predicator of cardiac death in various patient populations (Zareba et al. 2001). Frequency domain analysis determines the power distribution across frequencies and the most commonly used variables include the low frequency (LF) and high frequency (HF) spectral components. The HF represents parasympathetic modulation of the heart, whereas LF power reflects modulation of sympathetic and parasympathetic tone but with strong dominance of sympathetic influence.

Gold et al. (2000) examined the association between air pollution and HRV in a study of 21 residents of an apartment building in Boston. Subjects were 53-87 years old and completed up to 12 days of measurements, which included a 5 minute period of outdoor activity. Mean 4-hour PM2.5 levels ranged from 3 to 49 µg/m3, 1-hour ozone levels from 1 to 77 ppb and 24h average NO2 from 3-41 ppb. Both PM2.5 and ozone were associated with reduced SDNN and r-MSSD. Also in Boston, using a similar protocol to Gold et al., Schwartz et al. (2004) conducted a study of air pollution and HRV among 28 adults aged 61-89. Each subject completed up to 12 measurements of HRV. Mean concentrations of PM2.5, ozone and carbon monoxide (CO) were respectively 10 µg/m3 (24h), 34 ppb (1h) and 0.45 ppm (24h). The strongest associations were with black carbon, which was associated with reduced SDNN, followed by PM2.5, which was associated with reduced r-MSSD and PNN50 as well as with CO and ozone. The same protocol was also employed in a study of 32 adults aged 54-90 in Steubenville (Luttmann-Gibson et al. 2006). PM2.5 concentrations were higher than in Boston, averaging 20 µg/m3. In this study, the strongest associations were of sulphate (SO4) and PM2.5 with reduced SDNN and r-MSSD.

Pope et al. (2004) conducted a study of 89 adults aged 54-89 in Utah, with an average of approximately 3 observations per subject. Various measures of PM2.5 averaged approximately 20 µg/m3 with maximal values of approximately 70 µg/m3. Unlike the Gold, Schwartz and Luttman-Gibson studies, Pope et al. conducted 24 hour Holter studies without a prescribed schedule of activity. Associations were again observed between PM2.5 and reduced SDNN and r-MSSD. In a study of 34 adults aged 57-87 in Seattle, 20 minute resting Holter monitoring studies on up to 3 days per subject did not detect any associations between PM2.5 and HRV (Sullivan et al. 2005). Median concentrations of PM2.5, CO, and NO2 were respectively 10.7 µg/m3, 1.2 ppm and 21 ppb with maxima of 40.3, 2.5 and 46. Dales (2004) reported a study of 36 adults with heart disease aged 51 to 88 in Toronto, each subject undergoing Holter monitoring one day per week for up to 10 weeks. Personal air pollution monitoring was also conducted. Mean concentrations of PM2.5 and CO were respectively 19.9 µg/m3 and 2.4 ppm (daily 95th percentile for CO), with maxima of 146 and 16.5. A positive association was observed between CO and SDNN. In another Canadian study, Brauer et al. studied 16 subjects with chronic obstructive pulmonary disease in Vancouver, measuring HRV as well as blood pressure and spirometry on 7 days per subject. Exposure was assessed using both ambient and personal monitoring. Ambient PM2.5 concentrations averaged 11.4 µg/m3 compared to 18.2 µg/m3 based on personal monitoring. No consistent associations were observed between PM and any health outcome measures.

Finally, Fan et al. (2008) reported a study of the association between PM2.5 and heart rate, heart rate variability and lung function in 11 crossing guards (mean age 61) in Paterson New Jersey. Exposure was characterized as increase in personal exposure during morning and afternoon shifts compared to baseline. Changes in morning and afternoon average exposure were respectively 35 and 24 µg/m3 and in peak exposures were 71 and 64 µg/m3. Decreases in SDNN were noted after the morning shift

and were associated with change from baseline in PM2.5 exposure during the shift. No associations of exposure with heart rate or lung function were observed.

Oxygen saturation

Arterial oxygen saturation is a measure of the adequacy of oxygenation of the blood – one dimension of gas exchange in the lungs. It can be measured non-invasively using a finger probe which detects transmission of light through a vascular bed in the finger (Goldberg et al. 2008, Pope et al. 1999). Employing the same subjects as Schwartz et al. (2004) above, Demeo et al. reported associations between air pollution and reduced O2 saturation at rest. Mar et al. (2005) conducted a study in Seattle of personal PM2.5 exposure and O2 saturation, heart rate and blood pressure among 88 adults 57 or older. Mean personal, indoor and outdoor PM2.5 concentrations averaged around 10 µg/m3. Results were heterogeneous among healthy subjects, those with heart or lung disease, and according to use of medication. Pope et al. (1999) examined associations between oximetry, heart rate and air pollution in a dual panel of 52 older adults (mean age 77) living in private homes and 38 living in a retirement home. Subjects took twice daily measurements of O2 saturation and pulse rate over several weeks. Air pollution was associated with elevated heart rate but not with O2 saturation. Goldberg et al. (2008) examined a panel of 31 patients with heart failure aged 50-85, taking daily measurements of O2 saturation over a 2 month period. Only sulphur dioxide (SO2) was associated with reduced O2 saturation, while both PM2.5 and SO2 were associated with increased heart rate.

Blood pressure

Increased blood pressure is a well documented risk factor for adverse cardiovascular events including myocardial infarction and stroke, in relation to both acute and chronic elevation of blood pressure. Brook and Rajagopalan (2009) recently reviewed the literature on studies of air pollution and blood pressure, concluding that short term PM2.5 exposure is associated with increased blood pressure in epidemiological studies, and these findings are corroborated in human clinical and animal toxicological studies. Several studies are relevant to our proposed design. In a study of nursing home residents in Windsor, Canada, Liu et al. (2009) measured blood pressure, heart rate, vascular reactivity and blood markers of inflammation and oxidative stress in 28 subjects with a mean age of 78. Up to 16 daily measurements were taken. Median personal, indoor and outdoor PM2.5 concentrations were 6.3, 6.8 and 15.3 µg/m3 respectively. They found that black carbon and PM2.5 were associated with increased blood pressure, as well as heart rate, endothelin-1, vascular endothelial growth factor, and oxidative stress marker thiobarbituric acid reactive substances (TBARS), and a decrease in brachial artery diameter. Also in Windsor, in a panel study of 25 diabetic patients (mean age 47), Liu et al. (2007) found that PM10 was associated with increased blood pressure among those not taking vasoactive medications. Among all subjects, it was also associated with flow-mediated vasodilation and TBARS and inversely associated with end-systolic basal brachial arterial diameter. Personal PM10 exposure averaged 25.5 µg/m3. In a study of 65 adults, age 19-80, in Detroit, Brook et al. (2011) measured blood pressure together with personal PM2.5 exposure on 5 consecutive days. Mean personal and ambient PM2.5 concentrations were 21.9 and 15.4 µg/m3 respectively. Personal but not ambient PM2.5 was associated with increased systolic blood pressure. Zanobetti et al. (2004) extracted blood pressure readings from patient records for participants in a cardiac rehabilitation program in Boston. Sixty two patients age 39-90 had an average of 8 measurements over a 2 year period. At PM2.5, SO2 and ozone concentrations averaging approximately 10 µg/m3, 6 ppb and 20 ppb respectively, all three pollutants were associated with increases in systolic and/or diastolic blood pressure. In another study in Boston, Hoffman et al.

(2012) measured blood pressure on up to 5 occasions among 70 adults with type 2 diabetes, aged 45-86. Mean PM2.5 and ozone concentrations were 8.6 µg/m3 and 25 ppb respectively. PM2.5 and black carbon were associated with increased systolic blood pressure, while ozone was associated with reduced systolic blood pressure. Ibald-Mulli et al. (2004) measured blood pressure every two weeks on an average of approximately 10 occasions per subject in 131 patients with coronary artery disease in a multicentre study in Amsterdam, Erfurt and Helsinki. In contrast to the other studies, they found negative associations between PM2.5 as well as ultrafine particles and systolic and diastolic blood pressure.

Endothelial function

Microvascular endothelial function is believed to be a mediator of adverse cardiovascular effects of air pollution including morbidity and mortality. Allen et al. (2011) conducted a study of the impact of HEPA filter air cleaners on endothelial function, measuring the reactive hyperemia index (RHI) using peripheral artery tonometry. Use of the filter device reduced indoor particulate matter (mean PM2.5 concentrations were 4.6 and 11.2 µg/m3 with and without HEPA filtration), which was associated with improved RHI. In two other studies, exposure to particle rich air from a busy street (mean PM2.5 concentration 10.5 µg/m3) (Brauner et al. 2008) did not affect endothelial function in young adults, nor did exposure to environmental tobacco smoke (mean PM2.5 concentration 315 µg/m3) (Bard et al. 2010). However, Brauner et al. (2008) did find a significant effect of HEPA filtration on improvement of endothelial function, measured using EndoPAT in a sample of 42 older adults aged 60-75. In a chamber study of 26 young adults, Pope et al. (2011) found no association between in-chamber exposures and peripheral artery tone, but did find an association with ambient exposures in the preceding days.

Lung function

Spirometry measures including forced expiratory volume in one-second (FEV1) and the forced vital capacity (FVC), are the most widely studied of physiological parameters in relation to air pollution exposure. Fraction of Exhaled Nitric Oxide (FeNO) is a clinical and research test measuring eosinophilic lung inflammation. It has been used clinically as a measure of airway inflammation, especially as a result of allergic responses. We are aware of only one panel study of the association between air pollution and lung function in the elderly. Lee et al. (2007) conducted a study in three panels of approximately 30 subjects each from a seniors residence in Seoul (age 61-89). In each panel, subjects recorded peak expiratory flow rate (PEFR) three times per day (morning, afternoon and evening) for approximately 1 month. PM2.5 concentrations measured on the roof of the residence averaged between approximately 50-60 µg/m3 with a maximum of 133 µg/m3. Significant negative associations were detected between PM2.5 and PEFR. Several panel studies have reported associations between air pollution and increased FeNO in asthmatic children (Delfino et al. 2006, Mar et al. 2005). One study reported higher FeNO in adults 65 and over (Olin et al. 2006).

Oxidative stress markers

Increased oxidative stress, defined by the imbalance in levels of reactive oxygen species and antioxidants, has emerged as a potential mechanism implicated in the pathogenesis, progression and cell dysfunction of the development of diabetes complications (Kawano et al. 1999;King and Brownlee 1996). Oxidative stress-inducing reactive oxygen species are physiologically active mediators that can be induced by air pollutants. PM2.5, SO2, NO2 and O3 have been demonstrated

to cause formation of excessive amounts of reactive oxygen species in airways and in the cardiovascular system in experimental animals, leading to tissue inflammation and cell death (Dye et al. 1997;Meng et al. 2003;Persinger et al. 2002). Oxidative stress has been linked to clinical phenotypes such as asthma and atherosclerosis (Chuang et al. 2007;Walter et al. 2004).

Markers of oxidative stress include Malondialdehyde (MDA), 8-Isoprostane, 8-hydroxy-2'-deoxyguanosine (8-OHdG), and vascular endothelial growth factor (VEGF). MDA is a low-molecular-weight chemical formed during the decomposition of lipid peroxidation products (Halliwell and Chirico 1993), and thus is often used as an index of lipid peroxidation and oxidative stress (Kodavanti et al. 2000; Rhoden et al. 2004;Walter et al. 2004). In a study of 560 elderly Korean subjects, Kim et al. (2012) found that urinary MDA was associated with PM10, but that this association was confined to those with specific polymorphisms of the endothelial nitric oxide synthase (eNOS) gene. Another Korean study found that PM2.5 was associated with urinary MDA among 38 elderly subjects, but not 51 children (Kim et al. 2009). 8-Isoprostane is a prostaglandin F2α-like compound produced by free radicals via the non-enzymatic peroxidation of arachidonic acid in membrane phospholipids (Morrow et al. 1990). Barregard et al. (2006) reported that healthy adults exposed to woodsmoke in a chamber study experienced increases in urinary isoprostane. 8-OHdG is formed from hydroxyl radical attack of guanine residues in DNA (Brown et al. 1979;Park and Floyd 1992). Huang et al. (2012) found that urinary 8-OHdG as well as other biomarkers decreased significantly with air pollution control measures implemented during the Beijing Olympics, and increased once these measures ceased following the Olympics in a panel of 125 young adults. An analysis of data for 320 Boston men aged 69-96 from the normative aging study found that urinary 8-OHdG was associated with PM2.5, NO2, O3, sulphate and organic carbon (Ren et al. 2011). VEGF is an endogenous vasodilator (Ashrafpour et al. 2004) and increases microvascular permeability (Ribatti 2004).

Overview of the procedure:

A panel study design will be used involving repeated measurements of respiratory and cardiovascular health outcomes in 35-40 adults 55 years of age and older. Subjects will participate in light exercise (e.g. walking) for 30 minutes each day, before and after which respiratory and cardiovascular measures will be performed. Subjects will be required to devote approximately 1 ½ hours per day to the study, plus 4 hours once per week. The study will be conducted between June and August of 2012.

Routinely collected air quality data from government monitoring sites will be supplemented by a co-located Airpointer monitor providing continuous measures of CO, NO2, O3, PM2.5 and SO2, as well as a cascade impactor collecting weekly filter based PM2.5 samples for speciation analysis by inductively coupled plasma mass spectrometry (ICP-MS). Monitors will be provided by Health Canada. Speciation data will be used to qualitatively assess differences in PM exposure by study week and between sites. Daily average and maximum values as well as selected hourly values of CO, NO2, O3, PM2.5 and SO2 as well as calculated AQHI values will be employed as the primary independent variables. Daily maximum temperature will be included as a covariate.Daily weather data will be obtained from Environment Canada.

The following physiologic measurements will be made: spirometry, heart rate variability, endothelial function, exhaled nitric oxide (FeNO) (weekly); peak flow, blood pressure, pulse rate, and oxygen saturation (daily). Urine samples will also be taken weekly.

Consent forms and questionnaires: Candidates will be given detailed information on the study, and give consent for participation. Once enrolled into the study, participates will complete several questionnaires, including: (1) a health-based baseline questionnaire to obtain basic socio-demographic information regarding the participant's current and past health status, prescription drugs taken, tobacco smoking, family medical history, and characteristics of the home; and (2) a daily diary for recording measurements and symptoms as well as factors that contribute to the participant's exposure to various pollutants (e.g. grilling food); and (3) a weekly questionnaire obtaining information on dietary factors and medications that can influence weekly physiological measures

Ethical and privacy considerations: The study protocol has been reviewed and approved by Health Canada's Research Ethics Board, and any involved contractor would have to acquire all required local ethics approvals (such as university and regional ethics boards) before the study starts. Privacy considerations have been assessed and privacy obligation guidelines for researchers and field technologists and technicians have been developed. Participation in the health study is voluntary. Both spoken consent provided on the telephone for initial recruitment and written consent during the information session prior to the first day of exposures will be required for participation. Field staff hired by the contractor will provide detailed information about the study presented in non-technical language and answer any questions or concerns.

All participant data must be kept secure and confidential. This will be achieved by a number of steps:

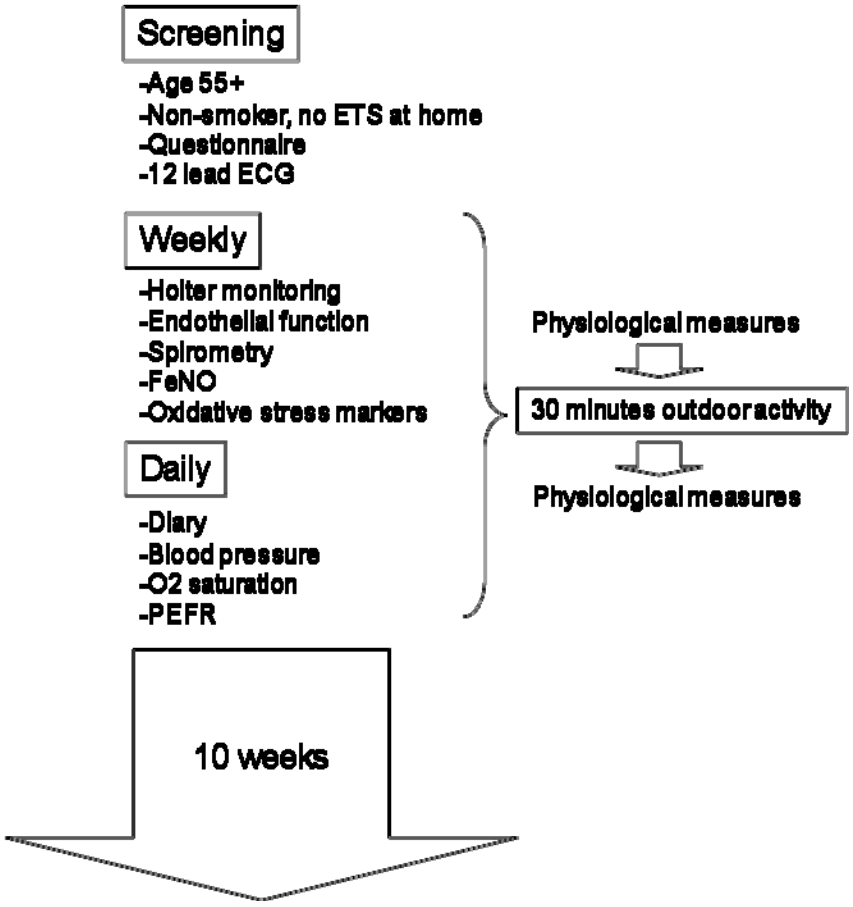
- field staff will undergo security clearance by PWGSC's Canadian Industrial Security Directorate (CISD) before they start work;
- field staff will undergo training on ethics and privacy;
- participants' names/numbers will be coded;
- computers owned by Health Canada containing data will be password protected; a security software program, such as SecureDoc, will need to be enabled on all study computers; only research personnel will have access to the passwords; and
- paper copies of data will be locked in a file cabinet on Health Canada/Public Health Agency of Canada premises to which only research personnel will have access

2.0 Requirements

2.1 Tasks, Activities, Deliverables and Milestones

STUDY PROCEDURE:

Flow chart of study protocol:



The target population is older adults who are at greater risk of clinically apparent or unrecognized cardiac or respiratory disease, but who are healthy enough for outdoor activity and thus likely to benefit from following exposure reduction advice provided through the AQHI. Subjects will be recruited through posters and information sheets at fitness or sports clubs (eg. golf, tennis, curling, pools), community centres, seniors programs, newspaper advertisements, social media, advertising through community job-posting sites, and using Canada Post AdCards through un-addressed postal code identified mail-out. To avoid introducing bias, the study hypothesis will not be disclosed, rather, prospective subjects will be told that this is a study on outdoor physical activity and health.

In order to determine eligibility for inclusion, subjects responding to the advertising campaign will go through an initial screening using a telephone script designed for the study (Encl. 12), and after obtaining written consent (see page 24), a 12 lead ECG. In order to be included in the study, participants must be 55 years of age or older, non-smokers, nonexposed at home to environmental tobacco smoke and without seasonal allergies. Subjects with unstable angina, atrial flutter, atrial fibrillation, paced rhythm, left bundle branch block or implanted cardioverter-defibrillator (ICD) will be excluded. Exclusion of individuals with certain arrhythmias/ conduction disturbances, ICD and unstable angina is required to facilitate interpretation of Holter monitoring data and for subject safety, and exclusion of smokers/smoking households and those with seasonal allergies is intended to reduce confounding from sources other than outdoor air pollution. Those with allergies to latex or adhesives will also be excluded because of exposures during clinical testing.

Information collected on the baseline health questionnaire will comprise demographic information, smoking history, presence of respiratory or cardiovascular disease, medications, and housing characteristics. Daily and weekly questionnaires will also be completed to document recent medication use, outdoor activity, symptoms and indoor exposures (cooking, burning, hobby activities).

Subjects will serve as their own controls based on repeated measurements. Measurements will be carried out daily (blood pressure, PEFR, oximetry) and weekly (Holter monitoring, hyperemia index, spirometry, FeNO, oxidative stress markers). Each subject will be monitored for up to 10 weeks with weekly measurements carried out at the same time of day and day of the week. Daily measurements of blood pressure, oximetry and peak flow rate will be carried out before and after a prescribed 30 minute outdoor activity. During weekly sessions each subject will be fitted with a Holter monitor. They will then undergo the daily measures plus measurements of hyperemia index, spirometry, FeNO and oxidative stress markers. Subjects will be instructed to walk outdoors on the prescribed route for 30 minutes. Following this, they will continue wearing the Holter monitor, and they will again undergo measurements of blood pressure, finger oximetry, reactive hyperemia index spirometry, FeNO and oxidative stress markers. The entire weekly measurement day will take approximately 4 hours A single saliva sample will also be collected for analysis of genetic variation.

Sample schedule of weekly measurements at central site

		Participant						
		1	2	3	4	5	6	7
check in, urine sample		9:30	10:00	10:30	11:00	11:30	12:00	12:30
apply holter		9:40	10:10	10:40	11:10	11:40	12:10	12:40
rest	quiet room	9:45	10:15	10:45	11:15	11:45	12:15	12:45
holter	quiet room	10:00	10:30	11:00	11:30	12:00	12:30	13:00
hyperemia	quiet room	10:15	10:45	11:15	11:45	12:15	12:45	13:15
ox, BP		10:30	11:00	11:30	12:00	12:30	13:00	13:30
Feno, peak flow		10:45	11:15	11:45	12:15	12:45	13:15	13:45
spiro		11:00	11:30	12:00	12:30	13:00	13:30	14:00
10 min set up to walk		11:10	11:40	12:10	12:40	13:10	13:40	14:10
walk		11:25	11:55	12:25	12:55	13:25	13:55	14:25
walk		11:40	12:10	12:40	13:10	13:40	14:10	14:40
5 min set up to test again		11:55	12:25	12:55	13:25	13:55	14:25	14:55
rest		12:00	12:30	13:00	13:30	14:00	14:30	15:00
ox, BP		12:15	12:45	13:15	13:45	14:15	14:45	15:15
Feno, peak flow		12:30	13:00	13:30	14:00	14:30	15:00	15:30
spiro		12:45	13:15	13:45	14:15	14:45	15:15	15:45
rest	quiet room	13:00	13:30	14:00	14:30	15:00	15:30	16:00
holter	quiet room	13:15	13:45	14:15	14:45	15:15	15:45	16:15
hyperemia	quiet room	13:30	14:00	14:30	15:00	15:30	16:00	16:30
remove holter, urine sample		13:45	14:15	14:45	15:15	15:45	16:15	16:45
finish time		13:55	14:25	14:55	15:25	15:55	16:25	16:55

Heart rate variability. Electrocardiograms will be recorded for approximately 4 hours each study visitday using three-channel (seven-lead) digital Holter monitors. Data will be analyzed on a GE Medical Systems Information Technology workstation (MARS version 7.2. A five minute reading from the end of 15 minute rest periods will be examined before and at 3 intervals after exercise.

Oximetry will be measured using a pulse oximeter with a finger sensor. The oximeter will be run

continuously for 3 minutes to obtain each measurement and the average O2 saturation and heart rate during this period will be recorded.

Microvascular endothelial function will be measured via peripheral artery tonometry using the portable EndoPAT 2000 instrument (Itamar Medical Ltd, Cesari, Israel). Reactive hyperemia index (RHI) will be determined based on a computer algorithm.

Blood pressure will be measured in the dominant arm with the subject seated, using an automated sphygmomanometer, taking the average of the last two of three readings 1 minute apart in keeping with clinical recommendations (Daskalopoulu et al. 2012). A sensitivity analysis will be conducted taking an average of all three readings as has been done in some previous panel studies.

Respiratory outcomes. KoKo Legend spirometers (nSpire Health, Longmont, CO, USA) will be used to measure forced expiratory volume in 1 sec (FEV1), forced vital capacity (FVC), and forced expiratory flow at 25–75% of vital capacity (FEF25–75). Single-breath on-line measures of Fraction of Exhaled Nitric Oxide (FeNO) will be carried out using a Niox Mino (Aerocrine AB, Solna, Sweden). Prior to performing a slow vital capacity maneuver over at least 6 seconds at 0.05 L/sec, subjects will take three tidal volume breaths through a NO scrubber which contains a NOx absorber cartridge to scrub the ambient air to a value of between 0 and 1.5 ppb. The test will be repeated a maximum of eight times in an attempt to obtain at least two acceptable plateau FeNO values within 10%. The value assigned to the subject will be the mean of the two values. Exhaled nitric oxide statistics will be calculated using spiroWare 88 software (Eco Medics AG, Duernten, Switzerland). Spirometry measures and FeNO will be obtained by trained technicians according to American Thoracic Society criteria and European Respiratory Society Guidelines and each subject will be assigned to the same instrument and technician on all visits. Subjects will use mini-Wright peak flow meters to measure daily peak expiratory flow rates. Results of 3 trials will be recorded daily before and after exercise.

Urine Samples will be analyzed for vascular endothelial growth factor (VEGF), 8-isoprostane (oxidative stress marker), malondialdehyde (MDA, oxidative stress marker), and 8-hydroxydeoxyguanosine (8-OHdG, a marker of oxidative damage on DNA). Biomarkers in urine will be corrected for creatinine level. Urine will be collected before and after exercise at the beginning and end of a four hour period during which the other health measure data are being collected. Approximately 20 ml of mid-stream urine specimen is collected in a urine collection cup (e.g. Fisher Scientific, cat. 14-375-127). The specimen is immediately transferred in approximately equal volumes to conical centrifuge tubes with screw cap (e.g. BD tubes from Fisher Scientific, cat.14-959-53A). They will be stored at - 20° C and shipped in dry ice to a laboratory at Health Canada for analysis.

Genetic variation: Selected polymorphisms of GSTM1, P1 and eNOS genes will be identified using DNA extracted from saliva samples. As other potentially relevant polymorphisms are identified in the literature, we may examine these in the future. Saliva samples will be collected using an Oragene DNA selfcollection kit (DNA Genotek), Subjects will wash their mouth once with water and wait 30 s, spit in a container, cap it and gently shake the sample. Samples can be stored at room temperature (stable for up to 5 years) until DNA extraction which will be carried out as described by the manufacturer.

TASKS AND ACTIVITIES FOR THE CONTRACTOR:

(1) Apply and obtain all required approvals
   a. Local ethics committee(s)
   b. Apply for PWGSC's Canadian Industrial Security Directorate (CISD) Security clearance.

(2) Organize a research team at Prince George to conduct the field work:

Hire the necessary staff required to collect the exposure and health data described in this proposal (site coordinator ~18 weeks, 5 days per week 8 hours per day; field staff ~13 weeks of work, 5 days per week, 8 hours per day).

The chosen study coordinator must visit the clinic site every day during testing periods. During study days, the coordinator will be first point of contact with Health Canada study coordinators.

At least one field staff with training in first aid must be present at the clinic site at all times during testing.

Hire sufficient field staff to carry out the study which includes: obtaining questionnaire information, collecting urine samples, measuring blood pressure and oxygen saturation, applying and recording data using the Holter monitor, and measuring pulmonary function, exhaled nitric oxide, and endothelial function. We expect that a minimum of 3 research assistants will be necessary to be on site at all times during data collection.

Prepare documentation to have PWGSC CISD conduct security clearance on the staff, and work with Health Canada research team to train the staff on ethical, privacy, professionalism and technical aspects

Field staff must demonstrate proficiency and provide evidence of competency (be able to follow the SOPs). Specifically, Holter leads need to be placed accurately and applied correctly preferably by an individual experienced with these procedures. Spirometry and FENO require someone preferably experienced with respiratory testing who understands the importance of coaching participants to achieve maximal efforts. Endothelial testing needs to be done in a quiet, dark room with a calm technician.

(3) Set up and safeguard a facility and the equipment at the clinic site; these include:
- Provide washrooms
- Make available first aid to staff and participants
- Provide a laboratory and storage space for processing and storing biological and air samples, equipment and paper documents

- Ensure the security of the equipment from theft or damage. If the equipment is damaged or stolen during the study and the contractor has not kept the equipment in a locked facility, or allowed equipment to be exposed to precipitation, or has damaged the equipment through improper handling, the contractor will be liable for the cost of replacing the damaged equipment.
- Set up equipment for air pollution monitoring and take the air samples needed for the study.
- Safeguard all documents (consent forms, questionnaires) in a locked cabinet in a locked room

(4) Liaise with community groups, provide information, organize community meetings with researchers

(5) Recruit and retain study participants, and ensure the safety and privacy of the participants

- A total of up to 35 participants will be studied. To ensure the size of the study group, need to recruit 40 participants to make up for dropout participants
- Advertise the study, and provide information on the study
- Conduct interviews
- Receive informed consent
- Collect questionnaire information
- Schedule their site visits, and arrange for clinical tests, download data onto password protected USB keys
- Must provide proof of insurance and will be responsible for any injury sustained by the subjects or the research assistants while on the study site
- Compensate subjects at a rate and time approved by Health Canada ($500 per participant). Subjects will be entitled to $500 in compensation; to be paid once 10 weeks of daily monitoring and 10 weekly measurements have been completed. If subjects withdraw before the end of the study, they will be entitled to $45 per week they participated in the study.
- Ensure privacy, confidentiality and safety of the participants. All participants' data must be secure and confidential. Staff will undergo a security clearance including criminal record check before being hired, and undergo training on ethics and privacy. Participants' names/numbers will be coded. Files and folders will be password protected. Computers containing the data will be password protected. A security software program, such as SecureDoc, will be enabled on all study computers. Only research personnel will have access to the password. Paper copies of data will be locked in a file cabinet to which only research personnel will have access.
- Keep a record of how many subjects were contacted, how many were eligible, how many were ineligible, what reasons for ineligibility were, how many agreed to participate, how many agree but did not sign consent, how many signed consent but did not come for first visit, how many did not finish study and when dropout occurred and reason for it.

- Weekly ship samples on dry ice to Health Canada laboratories in Ottawa. (This will require Transport of Dangerous Goods Certification).
- Scan questionnaires and log sheets to create a backup copy.
- Weekly ship questionnaires, log sheets and password protected USB keys to Health Canada offices in Ottawa using protocols for shipping Protected information provided by Health Canada.

(6) Schedule and supervise field staff's daily work, ensuring that staff follow all standard operating procedures. Equipment must be calibrated daily.

(7) Develop a system to identify each subject (without using personal information such as names), measurements collected, samples collected, pieces of equipment used for each subject on each day, so that all the data can be matched together and with the subject and with the day of the test.

(8) Calibrate equipment daily, record the calibration results in a log, and make it available to Health Canada's researchers.

(9) Collect all health test data, back them up daily and store them in a secure location.

(10) Collect and store urine samples according to the standard operating procedures, and ship them to the designated laboratories.

TIMELINES:

Table 3. Timelines

Time	Activities
December 1, 2013	Contract is signed off between Health Canada and the contractor
Early December, 2013	■ Site ethics approval completed prior to recruitment ■ Field staff interviewed, security checked and hired ■ Field staff trained ■ Clinic space rented
January 15, 2014	■ All participants recruited ■ Complete pre-screening of participants ■ Clinic facilities are fully operational
February 1, 2014	Start fieldwork
End of April, 2014	Complete all field testing of 35 subjects
Early May, 2014	Complete the delivery of all paper documents and biological samples to designated laboratories, ship all Health Canada's equipment back to Health Canada
End of August, 2014	Deliver final report

DELIVERABLES AND MILESTONES:

Table 4. Deliverables and Milestones		
Milestone	**Deliverable**	**Date**
Milestone 1	Progress report on status of: 1. the employment of field staff, including their security status, availability status 2. training of field staff' 3. recruitment of study subjects, including advertisement methods, number of candidates being interviewed, accepted and rejected 4. clinic space rental 5. local ethics board approval The report is written in English, sent by email	December 31, 2013
Milestone 2	Progress report on: 1. recruitment of study subjects, including advertisement methods, number of candidates being interviewed, accepted and rejected. 40 subjects should be recruited 2. status of the facility and the security measures The report is written in English, sent by email	January 31, 2014
Milestone 3	Progress report on: 1. status of recruitment and retention of study subjects 2. status of the health testing 3. status of communications with community members 4. status of the facility The report is written in English, sent by email	February 28, 2014
Milestone 4	Progress report on: 1. status of recruitment and retention of study subjects 2. status of the health testing 3. status of the sample delivery The report is written in English, sent by email	March 31, 2014
Milestone 5	Progress report on: 1. status of the health testing 2. status of the facility at study site 3. status of delivery of samples The report is written in English, sent by email	April 30, 2014
Milestone 6	Progress report on: 1. status of the health testing 2. status of the facility at study site 3. status of delivery of samples The report is written in English, sent by email	May 31, 2014

Table 4. Deliverables and Milestones		
Milestone	**Deliverable**	**Date**
Milestone 7	Final report Summarize all work including study subjects, questionnaires, testing data, samples The report is written in English, sent by email	August 31, 2014

2.2 Specifications and Standards

See section 2.1

2.3 Technical, Operational and Organizational Environment

- The contractor and its employees must follow all standard operating procedures provided by Health Canada

- The Contractor shall ensure that all necessary resources will be available to meet the standards for the work completion.

- The Contractor will ensure that all reports are delivered in accordance with the requirements identified under Section 2.1.

- The contractor will ensure that all personal information collected during the study is protected according to the requirements specified in Annex A.

2.4 Method and Source of Acceptance

- The scientific authority will make on-site visits and have consultants with expertise in these measures also making on-site visits to ensure the quality of the work

- Data will be checked on an ongoing fashion for completeness and adherence to agreed upon guidelines and published guidelines on data collection and quality control of data, and standard operating procedures. Guidelines and operating procedures will be provided to the contractor.

- All data and samples are delivered according to the methods described in Sections 2.1

- Milestone deliverables and invoices are reviewed based on the requirements of this Contract (Refer to Section 2.1), the current Health Canada technical environment

and time frames identified in this Statement of Work.

2.5 Reporting Requirements

The data must be submitted in electronic format in an excel spreadsheet with a data dictionary. The Contractor shall maintain regular contact with the technical authority at Health Canada, identifying issues that may have arisen and which may require approval or decision-making from Health Canada. The Contractor will also submit written confirmation of completion of each deliverable with the applicable invoice, as outlined in the Section 2.1.

Specific reporting requirements are identified in specific deliverables listed in Section 2.1 herein, Table 4.

2.6 Contractor Project Management Control Procedures

The Scientific and Technical Project Authority shall monitor the progress of the work as well as review progress reports to ensure that the work under this contract is on target. In addition to the measures outlined in section 2.1, the reports for this Contract may be submitted, at the Departmental Representative's discretion, to an internal and/or external peer review prior to acceptance.

2.7 Change Management Procedures

No changes to the final protocol may be made without first obtaining the approval of the Health Canada representative and all research ethics boards which reviewed the original study protocol.

Any change in scope (Section 2.1) and the schedule for the work will need to be presented in writing for the consideration of Health Canada's designated Departmental Representative and Contracting Authority. In identifying a suggested change in the scope or any element of the Statement of Work, the Contractor will need to specify clearly why the change is being recommended, and if it is not within the estimated cost and time lines of this Statement of Work. Health Canada will respond within five (5) working days regarding the decision to approve or not the identified change. If the change is approved, a formal proposal will be received from the Contractor for the review and acceptance by Health Canada and the contract amended accordingly.

2.8 Ownership of Intellectual Property

The Crown will own Copyright

The primary purpose of the proposed contract is to collect samples and conduct a study whose results will be available for public dissemination. Section 6.4 of the Treasury Board Policy on *Title to Intellectual Property Arising Under Crown Procurement Contracts* stipulates that the Crown may retain copyright:

6.4 where the main purpose of the Crown Procurement Contract, or of the deliverables contracted for, is:

6.4.1 to generate knowledge and information for public dissemination.

3.0 Other Terms and Conditions of the SOW

3.1 Authorities

Contract Officer:
Robert Merrick
Materiel and Assets Management Directorate
Chief Financial Officer Branch
Health Canada
Telephone: 613-960-4625
Robert.Merrick@hc-sc.gc.ca

3.2 Health Canada's Obligations

(1) Establish tasks and activities, timelines, deliverables and milestones, and funding for the contractor

(2) Receive approval from Health Canada's Research Ethics Board, and report on adverse events during the study

(3) Ensure appropriate Privacy Assessments have been performed, and develop Privacy Obligations sign off document for field personnel

(4) Work with the contractor to communicate with the public on the purpose and procedure of the study

(5) Provide all the health testing and air sampling equipment for the study and make arrangements to replace faulty equipment.

(6) Provide the contractor with the standard operating procedures for the equipment and methods of sampling, and methods of testing, and testing protocols.

(7) Provide security check on coordinators and field staff.

(8) Provide training on methods of
- conducting health testing

- conducting air sampling
- verifying proper functioning of all equipment
- using questionnaires
- correct ethical conduct
- ensuring privacy of personal information

(9) Provide participant information sheet and consent form, and all the questionnaires.

(10) Once collected and prepared for storage and transport, Health Canada will assume responsibility for the laboratory analysis biologic samples of urine.

(11) Conduct statistical analyses on the data, and interpret findings

(12) Provide the computer equipment on which all data and personal information will be stored.

(13) Provide equipment used for testing. All equipment must be returned to Health Canada in good condition at the end of the study.

3.3 Contractor's Obligations

As per Section 2.1 herein.

The Contractor will be responsible for the deliverables of the Contract.

The Contractor will identify an individual (or prime individuals) who is (are) to act as the prime contact for the Departmental Representative throughout the life of this Contract.

The Contractor shall treat all information that comes to his/her attention by virtue of carrying out the work under this agreement as privileged and confidential and will not disclose it to any third party either during the course of or after termination of this agreement except as may be necessary to perform the duties hereunder. All personal information must be kept on Health Canada computers, backed up on Health Canada memory sticks, and kept in a secure area when not being used.

Title to the equipment/furnishings charged against this Contract shall vest in Canada upon payment of invoiced amounts and shall remain so vested at all times.

For each item of equipment/furnishings that is purchased, the Contractor is to record the name, manufacturer, model number, serial number, optional equipment, supplier and price and forward this information to the Project Authority.

The Contractor shall label all equipment/furnishings (excluding rental facility) as being the property of Canada.

Notwithstanding the fact that the equipment/furnishings under this Contract become vested in

Canada, the equipment/furnishings shall remain within the custody and control of the Contractor until such time as the Project Authority provides instructions for its delivery. During this period of time, the Contractor shall take reasonable and proper care of the equipment/furnishings.

3.4 Location of Work, Work Site and Delivery Point

Location of the work: The work is expected to be completed in Prince George, British Columbia.

Any contract resulting from this RFP will be interpreted and governed by the laws of the Province of Ontario .

Due to existing workload and deadlines, all personnel assigned to any contract resulting from this RFP must be ready to work in close and frequent contact with the Departmental Representative and other departmental personnel.

3.5 Language of Work

The work described in Section 2.1 will be performed in English. Milestone deliverables are to be prepared in English.

3.6 Special Requirements

Health professionals who are hired to conduct clinical testing must hold an up-to-date practising license, and be insured.

3.7 Security Requirements

3.7.1 The Contractor/Offeror must, at all times during the performance of the Contract hold a valid Designated Organization Screening (DOS), issued by the Canadian Industrial Security Directorate (CISD), Public Works and Government Services Canada (PWGSC).

3.7.2 The Contractor/Offeror personnel requiring access to PROTECTED information, assets or sensitive work site(s) must EACH hold a valid RELIABILITY STATUS, granted or approved by CISD/PWGSC.

3.7.3 The Contractor/Offeror MUST NOT remove any PROTECTED information or assets from the identified work site(s), and the Contractor must ensure that its personnel are made aware of and comply with this restriction.

3.7.4 Subcontracts which contain security requirements are NOT to be awarded without the prior written permission of CISD/PWGSC.

3.7.5 The Contractor/Offeror must comply with the provisions of the:

Security Requirements Check List and security guide (if applicable), attached at Appendix __
Industrial Security Manual (Latest Edition).

3.7.6 If the successful bidder does not hold a valid **Designated Organization Screening** (DOS), issued by the Canadian Industrial Security Directorate, Public Works and Government Services Canada, prior to performance of any obligation under any contract resulting from this RFP, Health Canada will sponsor the security screening process.

3.8 Insurance Requirements

It shall be the Contractor's sole responsibility to determine whether specific insurance coverage is required for its own protection to fulfill obligations under this Contract and to ensure compliance in the federal, provincial/territorial or municipal laws, by-laws and regulations. Any such insurance shall be provided and maintained by the Contractor and at the Contractor's own expense. The Contractor will ensure collaborating organizations and individuals have all work-related insurance in place, including coverage if collaborators are going to operate or ride in a vehicle for the purposes of their contribution of this Contract.

3.9 Travel and Living Expenses

Travel and living expenses associated with attending meetings with the Technical Authorities and with conducting field work must be calculated in accordance with current Treasury Board policies and directives, and must be included within the cost proposal. The current Treasury Board Travel Directive (http://www.tbs-sct.gc.ca/pubs_pol/hrpubs/tbm_113/td-dv1_e.asp) applies.

4.0 Project Schedule

4.1 Expected Start and Completion Dates

The services of the Contractor will be required for a period commencing on or about December 1, 2013. The expected completion date of this project is August 31, 2014.

4.2 Schedule and Estimated Level of Effort (Work Breakdown Structure)

Refer to Section 2.1, Tables 3 and 4, for the schedule. Refer to Section 2.1, TASKS AND ACTIVITIES FOR THE CONTRACTOR, for an estimated level of effort.

5.0 Required Resources or Types of Roles to be Performed

The contractor shall have accounting and contracting infrastructure.

The project team shall consist of an experienced study coordinator and field staff capable of adhering to all standard operating procedures.

The project team may include, but not necessarily be limited to, key personnel or project members with the following qualifications:

- A study coordinator to be responsible for setting up the facilities, hiring field staff (research assistants), recruiting participant, as well as coordinating public communications

- At least three research assistants capable of adhering to all standard operating procedures.

6.0 Applicable Documents and Glossary

6.1 Applicable Documents

Applicable documents will be provided to the successful bidder at the project initiation meeting only, as they are subject to amendments by Health Canada and are presently undergoing review. Documents to be provided at this time include:

Detailed Protocol
Letter of Invitation, consent form, questionnaires
Ethic approval document

6.2 Relevant Terms, Acronyms and Glossaries

Airpointers	fixed-site ambient air quality monitors
BP	blood pressure
CO	carbon monoxide
ECG	electrocardiogram
eNO/FeNO	exhaled nitric oxide
FEV1	one –second forced expiratory volume
HRV	heart rate variability
NO_2	nitrogen dioxide
O_3	ozone
$PM_{2.5}$	particles smaller than 2.5 μm in median aerodynamic diameter
SO_2	sulfur dioxide
SOP	standard operating procedure

6.3 References

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Annex A

Interpretation

"Personal Information: means information about an individual, including the types of information specifically described in the *Privacy Act*, R.S. 1985, c. p-21.

Ownership of Personal Information and Records

To perform the work, the Contractor will be provided with and /or work be collecting Personal Information from third parties. The Contractor acknowledges that it has no rights in the Personal Information. On request, the Contractor must make all the Personal Information available to Canada immediately in a format acceptable to Canada.

Use of Personal Information

The Contractor agrees to create, collect, receive, manage, access, use, retain and dispose of the Personal Information only to perform the work in accordance with the contract./

Statutory Obligations

1. The Contractor acknowledges that Canada is required to handle the Personal Information in accordance with the provisions of Canada's *Privacy Act*, *Access to Information Act*, R.S. 1985, c. A-1, and *Library and Archives of Canada Act*, S.C. 2004, c.11. The Contractor agrees to comply with any requirement established by the Contracting Authority that is reasonably required to ensure that Canada meets its obligations under these acts and any other legislation in effect from time to time.

PART II PROPOSAL REQUIREMENTS

7.0 Administrative Instructions for Completion of the RFP

7.0 Administrative Information

7.1 General Information

7.1.1 Components, Language and Number of Copies

You are invited to submit an electronic copy of your Technical and Cost Proposal in either official language (English or French) to the attention of **Robert Merrick** using the following e-mail address:

robert.merrick@hc-sc.gc.ca

The RFP Reference Number must be in the subject line of your e-mail. The technical proposal must be a separate document from the cost proposal.

If the size of the soft-copy file that contains the proposal **is greater than 20mb** then the bid submission **must be submitted by courrier** to the address below (7.2) **AND an email shall be sent to the Departmental Representative** stating that the bid has been sent by courier. The RFP Reference Number and the name of the Departmental Representative must be marked on all documents, binders, CDs (or memory sticks) and respective envelopes. Your proposal must be structured in the following manner:

- one covering letter, signed by an authorized representative of your firm;
- four (4) copies of the Technical Proposal (if presented in hard copy); and
- two (2) copies of the Cost/Price Proposal, contained in a separate sealed envelope.

7.1.2 Bid Validity Period

See Appendix "A"

7.1.3 No Payment for Pre-Contract Costs

No payment will be made for costs incurred in the preparation and submission of a proposal in response to this RFP. No costs incurred before receipt of a signed contract or specified written authorization from the Departmental Representative can be charged to the proposed contract.

7.2 Delivery Instructions for Bid / Proposal that is greater than 20mb

Health Canada Bid Receiving Unit
Federal Records Centre Building,
161 Goldenrod Driveway (Loading Dock),
Ottawa, Ontario K1A 0K9
Attention: Robert Merrick
RFP Reference Number: 1000151842

Hours of Operation: 07h30 to 16h30 (EST) Monday to Friday

1. All bids must be time stamped at the Bid Receiving Unit. Each bid submission envelope must include
2. the RFP reference number and
3. the name of the Departmental Representative

The onus for submitting bids on time at the specified location rests with the bidder. It is the responsibility of the bidder to ensure correct and timely delivery of the entire bid to the Crown, including all required information and proposal pages.

7.3 Non-Acceptance of Proposal by Facsimile or Electronic Means

Proposals sent by fax or telex will **not** be accepted.

7.4 Closing Date and Time

All proposals must be received by the date and time specified on the front page of this RFP. Proposals received after this time will be returned unopened.

7.5 Time Extension to Closing Date

Due to tight timelines for this study, requests for a time extension to the closing date will not be considered.

7.6 Non-Compliance / Unacceptable Proposals

Failure to meet the mandatory requirements of this RFP will result in your proposal being declared non-responsive.

Proposals received after the proposal closing time will not be considered and will be returned unopened to the bidder. Further, for any proposals which are found to be non-compliant, the financial part of the bid or proposal will be returned unopened with a letter from Health Canada indicating that the bid/proposal was non compliant.

7.7 Bidders Conference / Site Visits (not mandatory)

Not applicable.

7.8 Announcement of Successful Contractor

The name of the successful bidder will be announced on PWGSC's Tender Management Application (TMA) only upon contract award and sign-off.

7.9 Rights of the Crown

The Crown reserves the right to:

- reject any or all proposals received in response to this RFP;
- accept any proposal in whole or in part; and
- cancel and/or re-issue this requirement at any time.

7.10 Sample Long Form Contract

The successful bidder for this requirement will be expected to enter into agreement with Health Canada as per departmental contract terms and conditions. See Appendix "B" for sample contract clauses.

7.11 Employment Equity

See Appendix "A", Certifications

7.12 Procurement Business Number (PBN)

Public Works and Government Services Canada (PWGSC) has adopted the Procurement Business Number (PBN) for all its purchasing databases, and now requires that its suppliers have one for each of their offices that may be awarded contracts. Register with Contracts Canada's Supplier Registration Information (SRI) service to obtain your PBN. As an existing or potential supplier to the Department, you must obtain a PBN to avoid possible delays of any contract award. It is Health Canada's intention to use this sourcing system for all its procurements of goods and services to which the trade agreements do not apply.

SRI is a database of suppliers who have registered to do business with the Government of Canada. The PBN is created using your Canada Customs and Revenue Agency Business Number to uniquely identify a branch, division or office of your company. Unlike many existing departmental vendor databases, your information in SRI is accessible to all federal government buyers. SRI can help to open up new opportunities with the federal government for requirements not posted on the electronic tendering service, MERX™.

Visit the Contracts Canada Internet site at http://contractscanada.gc.ca/en/busin-e.htm for information and registration procedures. Alternatively, you may contact a Supplier Registration Agent at: 1-800-811-1148 or, in the National Capital Region, at 956-3440.

7.13 Order of Precedence

In the case of any dispute which may arise during the period which may be covered by any ensuing contract, the following documents will be considered in order of precedence in terms of importance in resolving any disputes between the parties:

- The Health Canada Contract;
- Any changes to the terms and conditions contained herein which have been approved by General Counsel for Health Canada;
- The Statement of Work in this RFP; and
- The terms identified in this RFP.

8.0 Technical Proposal

8.1 General Information

Your technical proposal must address all the requirements of the SOW and demonstrate that you are capable of meeting all obligations of the contractor specified in the same.

Your technical proposal must meet **all of the Mandatory Requirements** listed in Section 12.0, as well as the **minimum score identified for the Point Rated Requirements** in Section 13.0.

Furthermore, your technical proposal should include the following:

8.2 Understanding of the Requirements

A brief statement that demonstrates that the contractor understands the requirements of the SOW, including the objectives, scope of work and deliverables.

8.3 Approach and Methodology:

8.3.1 General Approach

A description of the overall approach and strategy to this project.

8.3.2 Methodology

Identify methodologies and techniques to be used, including identifying any proprietary information which is proposed to be used in the program.

8.3.3 Work Plan / Project Schedule

Break down the work by task - show phases, planned start, completion dates and the estimated level of effort (i.e. person days) needed to complete the task. The work plan may include a matrix and/or time line charts. A project schedule structured in weeks, reflecting milestones and deliverables, should be included.

8.3.4 Performance and Quality Control

Specify how you propose to deal with the performance and quality assurance of the work

provided by your organization to the Crown. Include information about quality control methods and reporting mechanisms.

8.4 Proposed Team

8.4.1 Personnel

Identify the proposed personnel, including **Project Manager**, who will be assigned to this contract, describe the role they will be performing, including the amount of direct time dedicated to the project by principals and/or senior personnel, and explain why they are well suited for the work, referring to their qualifications, certifications, education and experience.

If applicable, include a list of proposed sub-contractors, with reference to their capabilities, experience and degree of involvement in the work.

The bidder must certify in the technical proposal that the information provided in all the personnel résumés has been verified to be true and accurate. In addition, for every resource proposed by the bidder who is not an employee of the firm, the actual resource must certify that they are aware that they are being bid as part of the bid/ proposal and state their relationship with the firm.

8.4.2 Contingency Plan

If the contract cannot be completed by the assigned personnel, the following individual(s) will complete the work. *Attach résumés.*

8.5 Contractor Profile

8.5.1 Organization

Provide background information about your company, including its legal name and the province in which the company is incorporated.

8.5.2 Relevant Work Experience

Describe your company's capacity and experience in this field.

8.5.3 References

References are required for items M1 and R2 and R3 of the Mandatory and Point-Rated Criteria in Sections 12.2 and 13.2. The references will only be used to confirm the information you provide to support your assertion that your firm meets the specific mandatory or point-rated criteria.

8.6 Résumés of Personnel

Attach résumés of proposed personnel.

9.0 Cost / Price Proposal

9.1 General Information

The Price Proposal must contain a detailed breakdown of the **total quoted price**, by phase, or by major tasks, or both. The Price Proposal should address each of the following, if applicable:

9.1.1 *Per Diem*

For each individual and/or labour category to be employed on the project, including subcontractors, indicate the proposed time rate and the estimated time requirement. Although detailed support for the rates is not requested at this time, you should be prepared to substantiate the proposed rates.

9.1.2 Travel

Estimate the cost of travel using the current Treasury Board Travel Directive.

9.1.3 Other Expenses

List any other expenses which may be applicable, giving an estimated cost for each (e.g. long distance communications, reproduction, shipping, equipment, rentals, materials, etc.).

9.1.4 Goods and Services Tax / Harmonized Sales Tax

Various items in your cost proposal may be subject to GST / HST or custom duties, and this charge must be included in the cost estimates where applicable.

10.0 Enquiries

All enquiries or issues concerning this procurement must be submitted **in writing only** to the Departmental Representative named on the front cover page of this RFP document **not later than seven (7) working days prior to the bid closing date.**

To ensure consistency and quality of information to Bidders, the Departmental Representative will provide, simultaneously to all bidders to which this solicitation has been sent,

- any information with respect to significant enquiries received, and
- the replies to such enquiries without revealing their sources,

provided that such enquiries are received no less than seven (7) days prior to the bid closing date.

All enquiries and other communications with government officials throughout the solicitation and evaluation period are to be directed **only** to the Departmental Representative named on the front cover page of this RFP document. **Non compliance with this condition during the bid solicitation and**

evaluation period may be sufficient reason for bid disqualification.

PART III BID SELECTION PROCESS

11.0 Introduction

This RFP has both mandatory and point-rated criteria against which each bidder will be evaluated.

12.0 Mandatory Requirements

12.1 Method of Evaluation

Mandatory requirements are evaluated on a simple pass or fail basis. Failure by bidders to meet any of the mandatory requirements will render the bidder's proposal **non-responsive**. The treatment of mandatory requirements in any procurement process is absolute.

Proposers must meet **all** the mandatory requirements described below. This will be evaluated as either "**Yes**" or "**No**". Proposals not receiving "**Yes**" for any mandatory requirement will ***not*** be considered further.

12.2 Mandatory Requirements

Attention Bidders: Write beside each of the criteria the relevant page number(s) from your proposal which addresses the requirement identified in the criteria.			
Criteria	**Page #**	**Yes**	**No**
M1. The bidder must demonstrate that within the last 10 years, members of the Study Team have undertaken at least one project using people as subjects of the study. The bidder's study team must have been responsible for the project management including recruiting of volunteer participants. Provide a summary of 250 words or less for each project, and provide references (these may be contacted).			
M2. The bidder's technical proposal must include a detailed plan/strategy for recruiting and retaining qualified study personnel as well as 35 participants for the study.			
M3. The bidder must make a commitment that research staff will be present in Prince George throughout the duration of the study. The bidder must also make a commitment to have the study coordinator visit the site at least 90% of the days and be available to ensure the study runs smoothly on all study days.			
M4. The bidder's technical proposal must include a communication plan that addresses how enquiries from the community will be handled (i.e. the news media, politicians, public health officials, members of the public,			

etc.)			
M5. The bidder must acknowledge that it is their sole responsibility to ensure they have sufficient liability coverage.			
M6. The bidder must include in their technical bid the applicable certifications found in Appendix "A" of this RFP, signed by a duly authorized representative of the firm.			

13.0 Point Rated Requirements

13.1 Method of Evaluation

A proposal with a score less than the specified minimum for technical compliance for any one criteria will be considered **non responsive**, and eliminated from the competition. To be considered responsive, a bid must obtain the required minimum of 39 points for the criteria which are subject to point rating. The rating is performed on a scale of 80 points.

13.2 Point Rated Requirements

Attention Bidders: Write beside each of the criteria the relevant page number(s) from your proposal which addresses the requirement identified in the criteria.

Criteria	Page #	Points allocated for the criteria	Minimum points required	Score
R1. Bidders should indicate the level and extent of education of its team relevant to carrying out this type of project. Relevant education would include PhD or MSc/MA involving a substantial fieldwork component (data collection and analysis), or a health professional degree or diploma (medicine, nursing, related fields) *One point is assigned for each member that has a relevant qualification up to a maximum score of 5.*		5	2	
R2. Bidders should list previous research projects carried out by team members involving recruiting human subjects. Provide references including project title, funding source/ sponsor, contact person, (name, title and telephone number).		10	1	

Each project is awarded one point to a maximum of 10.				
R3. Bidders should list research projects the proposed research team has conducted involving multiple stakeholders: the general public, industry, politicians, public health, colleges and universities, and press. Provide references including project title, funding source/ sponsor, contact person, (name, title and telephone number). *Each project is awarded one point to a maximum of 10.*		10	1	
R4. Bidders should list research projects the proposed research team has conducted involving air pollution. *Each project is awarded one point to a maximum of 10.*		10	0	
R5. The Bidder should clearly outline the approach and proposed methodology to meet the technical requirements described in the Statement of Work. Sufficient detail should be provided to demonstrate the Bidder's grasp of the requirements and the Bidder's competence to meet them. Approach and proposed method must be clearly described and address the following (points will be allotted as indicated following each item): ▸ Recruiting an experienced study coordinator who can be relied upon to manage all aspects of study logistics (1 point for recruitment plan, up to 2 points for detailed plan for ensuring sufficiently experienced, up to 2 points for detailed plan for establishing ability to manage study logistics to overall maximum 5 points) ▸ Recruiting research assistants who can carry out the study as per protocol. (1 point for recruitment plan, up to 2 points for detailed plan for ensuring sufficiently qualified, up to 2 points for detailed plan for establishing ability to carry out study as per protocol to overall maximum 5 points) ▸ A plan/timetable to start and end the study on schedule. (up to 2 points for detailed plan for pre-data collection activities, up to 3 points for detailed plan for daily data collection activities to overall maximum 5 points) ▸ Detailing methods of locating and renting suitable clinic space (up to 3 points for detailed suitability criteria, up to 2 points for detailed search strategy to overall maximum 5 points)		45	35	

▸ Successfully recruiting and retaining at least 35 eligible subjects. (1 point for list of organizations to be contacted, 1 point for list of locations where study posters/brochures will be posted/made available, 1 point for strategy for employing social media, up to 2 points for detailed methods for retaining subjects up to overall maximum 5 points) ▸ Ensuring data completeness (1 point), quality (1 point), integrity (1 point), security (1point) and confidentiality (1 point) (Maximum 5 points) ▸ Ensuring biological samples are appropriately collected (1 point), identified (1 point), processed (1 point), stored (1 point), and shipped (1 point) (Maximum 5 points) ▸ Responding to community and stakeholder queries/ concerns. (up to 2 points for detailed community involvement plan, up to 2 points for detailed community response plan, 1 point for mechanism for logging queries, concerns and responses up to overall maximum 5 points) ▸ Dealing with any unforeseen circumstances such as weather (0.5 points), illness (1 point), resistance to the study by the community or industry or union (1 point), vandalism of equipment (0.5 points), injury at the worksite (1 point), difficulty recruiting subjects (1 point). (Maximum 5 points)				
Total Points		80	39	

14.0 BASIS OF AWARDING CONTRACT

Highest Rated Within Budget:

To be considered responsive, a bid must:

(a) meet all the mandatory requirements of the bid solicitation; and

(b) obtain the required minimum of 39 points for the criteria which are subject to point rating specified in the bid solicitation. The rating is performed on a scale of 80 points.

Bids not meeting (a) or (b) above will be given no further consideration. The responsive bid that scores the highest number of rated points will be recommended for award of a contract, provided that the estimated total price does not exceed the available budget for this requirement.

CERTIFICATIONS

1. **Bidder Certification**

We hereby offer to sell to Her Majesty, in accordance with the Health Canada terms and conditions referred to herein or attached hereto, the goods and/or services listed herein and on any attached sheets at the prices set out therein.

We certify that all information provided herein is accurate. Furthermore we have satisfied ourselves that the personnel proposed by us for this requirement are capable of satisfactorily performing the requirements described herein. In addition, we certify that individuals proposed will be available until completion of the project. Also, that the work specified herein can be met in a timely manner, and will be achieved with the time frame allocated.

_____ _____

Signature of the Authorized Representative of the Bidder Date

2. **Bid Validity Certification**

We certify that all pricing identified in the bid/ proposal will be valid for a period of one hundred twenty (120) days from the closing date of the RFP.

_____ _____

Signature of Authorized Representative of the bidder Date

3. **Employment Equity Certification**

The Federal Contractors Program for Employment Equity requires that some organizations bidding for federal government contracts make a formal commitment to implement employment equity, as a pre-condition to the validation of their bids. All bidders must check the applicable box(es) below. **Failure to do so may render the bid non-responsive.**

Program requirements do not apply for the following reason(s):

( ) bid is less than $1,000,000;

( ) this organization has fewer than 100 permanent part-time and/or full time employees across Canada;

( ) this organization is a federally regulated employer;

or, program requirements do apply:

( ) copy of signed Certificate of Commitment is enclosed; or

( ) Certificate number is _____

NOTE: *The Federal Contractors Program for Employment Equity applies to Canadian-based bidders only. The Certificate of Commitment criteria and other information about the Federal Contractors Program for Employment Equity are available in the PWGSC Standard Acquisition Clauses and Conditions (SACC) Manual, Section 2, and on the Government Electronic Tendering Service.*

4. **Joint Venture Information** (if applicable)

A joint venture is an association of two or more parties who temporarily combine their money, property, knowledge, or other resources in a joint business enterprise. There are two primary types of joint ventures, the incorporated joint venture and the contractual joint venture, i.e. formed through a contractual agreement between the parties.

If a contract is awarded to a contractual joint venture, all members of the joint venture shall be jointly and severally or solitarily liable for the performance of the Contract.

If the Bidder is submitting a type of joint venture, the Bidder must provide the following information in the proposal:

a) indicate the type of joint venture:
- incorporated joint venture
- limited partnership joint venture
- partnership joint venture
- contractual joint venture
- other (explain)

b) provide the legal names and addresses of all of the members of the joint venture (i.e. the legal name of the firm associated with the Business Number (BN) or Social Insurance Number (SIN) for sole proprietorships), aswell as the legal name and address of the joint venture business entity.

SAMPLE CONTRACT CLAUSES

GC1.0 Interpretation

GC1.1 In the contract,

GC1.1.1 "Minister" includes a person acting for, or if the office is vacant, in place of the Minister and the Minister's successors in the office, and the Minister's or their lawful deputy and any of the Minister's or their representatives appointed for the purpose of the contract;

GC1.1.2 "Departmental Representative" means the officer or employee of Her Majesty who is designated by the Articles of Agreement and includes a person authorized by the Departmental Representative to perform any of the Departmental Representative's functions under the contract;

GC1.1.3 "work", unless otherwise expressed in the contract, means everything that is necessary to be done, furnished or delivered by the Contractor to perform the Contractor's obligations under the contract.

GC2.0 Successors and Assigns

GC2.1 The contract shall inure to the benefit of and be binding upon the parties and their lawful heirs, executors, administrators, successors and assigns.

GC3.0 Assignment

GC3.1 The contract shall not be assigned in whole or in part by the Contractor without the prior written consent of the Minister and any assignment made without that consent is void and of no effect.

GC3.2 No assignment of the contract shall relieve the Contractor from any obligation under the contract or impose any liability upon Her Majesty or the Minister.

GC4.0 Time of the Essence

GC4.1 Time is of the essence of the contract.

GC4.2 Any delay by the Contractor in performing the Contractor's obligations under the contract which is caused by an event beyond the control of the Contractor, and which could not have been avoided by the Contractor without incurring unreasonable cost through the use of work-around plans including alternative sources or other means, constitutes an excusable delay. Events may include, but are not restricted to: acts of God, acts of Her Majesty, acts of local or provincial governments, fires, floods, epidemics, quarantine restrictions, strikes or labour unrest, freight embargoes and unusually severe weather.

GC4.3 The Contractor shall give notice to the Minister immediately after the occurrence of the event that causes the excusable delay. The notice shall state the cause and circumstances of the delay and indicate the portion of the work affected by the delay. When requested to do so by the Departmental Representative, the Contractor shall deliver a description, in a form satisfactory to the Minister, of work-around plans including alternative sources and any other means that the Contractor will utilize to overcome the delay and endeavour to prevent any further delay. Upon approval in writing by the Minister of the work-around plans, the Contractor shall implement the work-around plans and use all reasonable means to recover any time lost as a result of the excusable delay.

GC4.4 Unless the Contractor complies with the requirements of GC4.3, any delay that would constitute an excusable delay shall be deemed not to be an excusable delay.

GC4.5 Notwithstanding that the Contractor has complied with the requirements of GC4.3, Her Majesty may exercise any right of termination contained in GC7.0.

GC5.0 Indemnification

GC5.1 The Contractor shall indemnify and save harmless Her Majesty, the Minister and their servants and agents from and against all claims, losses, damages, costs, expenses, actions and other proceedings, made, sustained, brought, prosecuted, threatened to be brought or prosecuted, in any manner based upon, occasioned by or attributable to any injury to or death of a person or damage to or loss of property arising from any wilful or negligent act, omission or delay on the part of the Contractor, the Contractor's servants, agents or subcontractors in performing the work or as a result of the work.

GC5.2 The Contractor shall indemnify Her Majesty, the Minister and their servants and agents from all costs, charges and expenses whatsoever that Her Majesty sustains or incurs in all claims, actions, suits and proceedings for the use of the invention claimed in a patent, or infringement or alleged infringement of any patent or any registered industrial design or any copyright or other intellectual property right resulting from the performance of the Contractor's obligations under the contract, and in respect of the use of or disposal by Her Majesty of anything furnished pursuant to the contract.

GC5.3 The Contractor's liability to indemnify or reimburse Her Majesty under the contract shall not affect or prejudice Her Majesty from exercising any other rights under law.

GC5.4 The Contractor agrees that Her Majesty shall not be liable for, and agrees to protect and indemnify Her Majesty with respect to, any injury or damage (including death) to the Contractor or to the person of any officer, servant or agent of the Contractor or for the loss of or damage to the property of the Contractor or its officers, servants or agents in any manner based upon, occasioned by, or in any way attributable to the performance of the said work unless the injury, loss or damage is caused by the negligence of an officer, servant or agent of Her Majesty while acting within the scope of his or her employment.

GC6.0 Notices

GC6.1 Where in the contract any notice, request, direction, or other communication is required to be given or made by either party, it shall be in writing and is effective if delivered in person, sent by registered mail, telegram, facsimile or electronic mail addressed to the party for whom it is intended at the address mentioned in the contract and any notice, request, direction or other communication shall be deemed to have been given by registered mail, when the postal receipt is acknowledged by the other party; by telegram, when transmitted by the carrier; and, by telex, facsimile or electronic mail, when transmitted. The address of either party may be changed by notice in the manner set out in this provision.

GC7.0 Termination or Suspension for Convenience

GC7.1 The Minister may, by giving notice to the Contractor, terminate or suspend the work with respect to all or any part or parts of the work not completed.

GC7.2 All work completed by the Contractor to the satisfaction of Her Majesty before the giving of notice shall be paid for by Her Majesty in accordance with the provisions of the contract and, for all work not completed before the giving of notice, Her Majesty shall pay the Contractor's costs as determined under the provisions of the contract and, in addition, an amount representing a fair and reasonable fee in respect of the work not completed.

GC7.3 In addition to the amount which the Contractor shall be paid under GC7.2, the Contractor shall be reimbursed for the Contractor's cost of, and incidental to, the cancellation of obligations incurred by the Contractor pursuant to the notice and obligations incurred by the Contractor or to which the Contractor is subject with respect to the work.

GC7.4 Payment and reimbursement under the provisions of GC7.0 shall be made only to the extent that it is established to the satisfaction of the Minister that the costs and expenses were actually incurred by the Contractor and that the same are fair and reasonable and are properly attributable to the termination or suspension of the work or the part of the work terminated.

GC7.5 The Contractor shall not be entitled to be reimbursed any amount which, taken together with any amounts paid or becoming due to the Contractor under the contract, exceeds the contract price applicable to the work or the particular part of the work.

GC7.6 The Contractor shall have no claim for damages, compensation, loss of profit, allowance or otherwise by reason of or directly or indirectly arising out of any action taken or notice given by the Minister under the provisions of GC7.0, except as expressly provided.

GC8.0 Termination Due to Default of Contractor

GC8.1 The Minister may, by notice to the Contractor, terminate the whole or any part of the work if:

GC8.1.1 the Contractor becomes bankrupt or insolvent, or a receiving order is made against the Contractor, or an assignment is made for the benefit of creditors, or if an order is made or resolution passed for the winding up of the Contractor, or if the Contractor takes the benefit of any statute for the time being in force relating to bankrupt or insolvent debtors; or

GC8.1.2 the Contractor fails to perform any of the Contractor's obligations under the contract, or, in the Minister's view, so fails to make progress as to endanger performance of the contract in accordance with its terms.

GC8.2 In the event that the Minister terminates the work in whole or in part under GC8.1, the Minister may arrange, upon such terms and conditions and in such manner as the Minister deems appropriate, for the work to be completed that was so terminated, and the Contractor shall be liable to Her Majesty for any excess costs relating to the completion of the work.

GC8.3 Upon termination of the work under GC8.1, the Minister may require the Contractor to deliver and transfer title to Her Majesty, in the manner and to the extent directed by the Minister, any finished work which has not been delivered and accepted prior to such termination and any materials or work-in-process which the Contractor has specifically acquired or produced for the fulfilment of the contract. Her Majesty shall pay the Contractor for all finished work delivered pursuant to the direction and accepted by the Minister, the cost to the Contractor of the finished work plus the proportionate part of any fee fixed by the contract and shall pay or reimburse the Contractor the fair and reasonable cost to the Contractor of all materials or work-in-process delivered pursuant to the direction. Her Majesty may withhold from the amounts due to the Contractor the sums that the Minister determines to be necessary to protect Her Majesty against excess costs for the completion of the work.

GC8.4 The Contractor shall not be entitled to be reimbursed any amount which, taken together with any amounts paid or becoming due to the Contractor under the contract, exceeds the contract price applicable to the work or the particular part of the work.

GC8.5 If, after the Minister issues a notice of termination under GC8.1, it is determined by the Minister that the default of the Contractor is due to causes beyond the control of the Contractor, the notice of termination shall be deemed to have been issued pursuant to GC7.1 and the rights and obligations of the parties shall be governed by GC7.0.

GC9.0 Records to be Kept by Contractor

GC9.1 The Contractor shall keep proper accounts and records of the cost of the work and of all expenditures or commitments made by the Contractor including invoices, original receipts and vouchers, which shall at reasonable times be open to audit and inspection by the authorized representatives of the Minister who may make copies and take extracts.

GC9.2 The Contractor shall afford facilities for audit and inspection and shall furnish the authorized representatives of the Minister with such information as the Minister or they may from time to time require with reference to the documents referred to in GC9.1.

GC9.3 The Contractor shall not dispose of the documents referred to in GC9.1 without the written consent of the Minister, but shall preserve and keep them available for audit and inspection for the period of time specified elsewhere in the contract or, in the absence of such specification, for a period of six years following completion of the work.

GC10.0 Ownership of Intellectual and Other Property Including Copyright

Crown to Own Copyright

GC11.0 Conflict of Interest

GC11.1 The Contractor agrees that its signature on the contract certifies that the government's rules on conflict of interest, summarized below, have been discussed with the Contractor, and that the Contractor complies in every respect with the rules.

The government has adopted a policy to ensure that hiring and contracting of suppliers of goods and services will meet the highest ethical standards. Health Canada wishes to make it clear that these standards will be scrupulously observed. The relevant portion of the policy precludes appointment not only of a Minister's immediate family, that is, Minister's spouse, parents, children, brothers and sisters, but also any member of the immediate family of his or her spouse, the immediate families of other Ministers and of party colleagues in the House of Commons and the senate. It applies, as well, to organizations outside of government in which such family members are employed in senior positions of authority including membership on Boards of Directors. Your signature on this contract or agreement certifies that this aspect of the government rules on conflict of interest has been discussed with you and that you and your firm comply in every respect with these rules.

GC11.2 It is a term of this contract that no individual, for whom the post-employment provisions of the *Conflict of Interest and Post-Employment Code for Public Office Holders* or the *Values and Ethics Code for the Public Service* apply, shall derive a direct benefit from this contract unless that individual is in compliance with the applicable post-employment provisions;

GC11.3 The Contractor declares that the Contractor has no pecuniary interest in the business of any third party that would cause a conflict of interest or seem to cause a conflict of interest in carrying out the work. Should such an interest be acquired during the life of the contract, the Contractor shall declare it immediately to the Departmental Representative.

GC12.0 Contractor Status

GC12.1 This is a contract for the performance of a service and the Contractor is engaged under the contract as an independent contractor for the sole purpose of providing a service. Neither the Contractor nor any of the Contractor's personnel is engaged by the contract as an employee, servant or agent of Her Majesty. The Contractor agrees to be solely responsible for any and all payments and/or deductions required to be made including those required for Canada or Quebec Pension Plans, Employment Insurance, Worker's Compensation, or Income Tax.

GC13.0 Warranty by Contractor

GC13.1 The Contractor warrants that the Contractor is competent to perform the work required under the contract in that the

Contractor has the necessary qualifications including the knowledge, skill and ability to perform the work.

GC13.2 The Contractor warrants that the Contractor shall provide a quality of service at least equal to that which contractors generally would expect of a competent contractor in a like situation.

GC14.0 Member of Parliament

GC14.1 No member of Parliament shall be admitted to any share or part of this contract or to any benefit to arise from this contract.

GC15.0 Security and Protection of Work

GC15.1 The Contractor shall keep confidential all information provided to the Contractor by or on behalf of Canada in connection with the Work, including any information that is confidential or proprietary to third parties, and all information conceived, developed or produced by the Contractor as part of the Work where copyright or any other intellectual property rights in such information (except a licence) vests in Canada under the Contract. The Contractor shall not disclose any such information to any person without the written permission of the Minister, except that the Contractor may disclose to a Subcontractor information necessary for the performance of the Subcontract, on the condition that the Subcontractor agrees that it will be used solely for the purposes of such Subcontract. Information provided to the Contractor by or on behalf of Canada shall be used solely for the purpose of the Contract and shall remain the property of Canada or the third party, as the case may be. Unless the Contract otherwise expressly provides, the Contractor shall deliver to Canada all such information, together with every copy, draft, working paper and note thereof that contains such information, upon completion or termination of the Contract or at such earlier time as the Minister may require. This section does not apply to any information that:

GC15.1.1 is publicly available from a source other than the Contractor; or

GC15.1.2 is or becomes known to the Contractor from a source other than Her Majesty, except any source that is known to the Contractor to be under an obligation to Her Majesty not to disclose the information.

GC15.2 When the contract, the work, or any information referred to in GC15.1 is identified as TOP SECRET, SECRET, CONFIDENTIAL or PROTECTED by Her Majesty,

GC15.2.1 the Contractor shall, at all times, take all measures reasonably necessary for the safeguarding of the material so identified, including any other instructions issued by the Minister.

GC15.2.2 the Minister shall be entitled to inspect the Contractor's premises and the premises of a subcontractor at any tier for security purposes at any time during the term of the contract, and the Contractor shall comply with, and ensure that any subcontractor complies with, all written instructions issued by the Minister dealing with the material so identified, including any requirement that employees of the Contractor or of any subcontractor execute and deliver declarations relating to reliability screenings, security clearances and other procedures.

GC16.0 Certification - Contingency Fees

GC16.1 The Contractor certifies that it has not directly or indirectly paid or agreed to pay and covenants that it will not directly or indirectly pay a contingency fee for the solicitation, negotiation or obtaining of this contract to any person other than an employee acting in the normal course of the employee's duties.

GC16.2 All accounts and records pertaining to payments of fees or other compensation for the solicitation, obtaining or negotiation of the contract shall be subject to the accounts and audit provisions of this contract.

GC16.3 If the Contractor certifies falsely under this section or is in default of the obligations contained in this section, the Minister may either terminate this contract in accordance with the default provisions of this contract or recover from the Contractor by way of reduction to the contract price or otherwise the full amount of the contingency fee.

GC16.4 In this section:

GC16.4.1 "contingency fee" means any payment or other compensation that is contingent upon or is calculated upon the basis of a degree of success in soliciting or obtaining a government contract or negotiating the whole or any part of its terms;

GC16.4.2 "employee" means a person with whom the Contractor has an employer/employee relationship;

GC16.4.3 "person" includes an individual or group of individuals, a corporation, a partnership, an organization and an association and, without restricting the generality of the foregoing, includes any individual who is required to file a return with the registrar pursuant to section 5 of the *Lobbyist Registration Act*, R.S.C. 1985, c. 44 (4th Supp.) as the same may be amended from time to time.

GC17.0 Work Force Reduction Programs

GC17.1 The Contractor acknowledges and agrees that any person, including the Contractor, carrying out this contract, shall make available to the Departmental Representative any details of the status of the person with respect to cash out benefits as well as details of any pension payments under Work Force Reduction Programs.

GC17.2 The Contractor shall, if asked in writing and where necessary, sign or cause to have signed on behalf of any person, a waiver of privacy with respect to any and all information in relation to any such benefits and payments.

GC18.0 Amendments

GC18.1 No amendment of the contract nor waiver of any of the terms and provisions shall be deemed valid unless effected by a written amendment.

GC19.0 Entire Agreement

GC19.1 The contract constitutes the entire agreement between the parties with respect to the subject matter of the contract and supersedes all previous negotiations, communications and other agreements relating to it unless they are incorporated by reference in the contract.