Date: Wednesday, July 03, 2013 8:56:18 AM

The University of British Columbia
Office of Research Services
Behavioural Research Ethics Board
Suite 102, 6190 Agronomy Road
Vancouver, BC V6T 1Z3

H08-01170 **Rights, Risks & Smoking (Version 3.0)**

Principal Investigator: Kirsten Bell

1. Principal Investigator & Study Team - Human Ethics Application [View Form]

1.1. Principal Investigator Please select the Principal Investigator (PI) for the study. Once you hit Select, you can enter the PI's name, or enter the first few letters of his or her name and hit Go. You can sort the returned list alphabetically by First name, Last name, or Organization by clicking the appropriate heading.	Last Name: Bell; First Name: Kirsten; Employer.Name: Anthropology; Email: kibell@interchange.ubc.ca
Enter Principal Investigator Primary Department and also the primary location of the PI's Institution:	
1.2. Primary Contact Provide the name of ONE primary contact person in addition to the PI who will receive ALL correspondence, certificates of approval and notifications from the REB for this study. This primary contact will have online access to read, amend, and track the application.	Last Name: [redacted]; First Name: [redacted]; Rank: [redacted]
1.3. Co-Investigators List all the Co-Investigators of the study. These members WILL have online access which will allow them to read, amend and track the application. These members will be listed on the certificate of approval (except BC Cancer Agency Research Ethics Board certificates). If this research application is for a graduate degree, enter the graduate student's name in this section.	Last Name / First Name / Institution/Department / Rank: [redacted]
1.4. Additional Study Team Members - Online Access List the additional study team members who WILL have online access to read, amend, and track the application but WILL NOT be listed on the certificate of approval.	Last Name / First Name / Institution/Department / Rank: [redacted]
1.5. Additional Study Team Members - No Online Access Click Add to list study team members who WILL NOT have online access to the application and will NOT be listed on the certificate of approval.	Last Name / First Name / Institution / Department / Rank / Job Title / Email Address
Tri Council Policy Statement2 (TCPS2) Tutorial All undergraduate and graduate students and medical residents are required to complete the TCPS2	Yes

Tutorial (CORE) before submission. This tutorial provides an essential orientation to Canadian human research ethics guidelines. The Principal Investigator and all Co-Investigators must be familiar with the TCPS2. Indicate completion of the TCPS2 (CORE) tutorial below: 1.6.A. All Undergraduate/Graduate Students:	
1.6.B. All Medical Residents:	N/A (no medical residents participating in this study)
Comments:	
1.7. Project Title Enter the title of this research study as it will appear on the certificate. If applicable, include the protocol number in brackets at the end of the title. If this is a class-based project, see guidance on the right.	Rights, Risks and Smoking
1.8. Project Nickname Enter a nickname for this study. What would you like this study to be known as to the Principal Investigator and study team?	Rights, Risks & Smoking
2 Study Dates and Funding Information - Human Ethics Application [View Form]	
You plan to start collecting data immediately after obtaining ethics and any other required approvals (the start date on the ethics certificate will reflect the approval date),	
You plan to start data collection at a later date i.e., 2 months or more after approvals are obtained. Click the calendar icon below to select the dates (Internet Explorer) or enter the dates manually using the format yyyy-mm-dd. Estimated start date:	July 1, 2008
2.1. B. Estimated end date:	July 1, 2009
2.2.A. Types of Funds Please select the applicable box(es) below to indicate the type(s) of funding you are receiving to conduct this research. You must then complete section 2.3 and/or section 2.4 for the name of the source of the funds to be listed on the certificate of approval.	Grant
2.2.B. For Industry Sponsored studies, please provide a sponsor contact.	
2.3. Research Funding Application/Award Associated with the Study that was Submitted to the UBC Office of Research Services Please click Add to identify the research funding application/award associated with this study. Selecting Add will list the sources of all research funding applications that have been submitted by the PI (and the person completing this application if different from the PI). If the research funding application/award associated with this study is not listed below, please enter those details in question 2.4.	UBC Number / Title / Sponsor 07-2522 / Rights, risks and smoking: How 'denormalisation" mediates patient-provider interactions in primary health care settings / Canadian Institutes of Health Research (CIHR)
2.4. Research Funding Application/Award Associated with the Study not listed in question 2.3. Please click Add to enter the details for the research funding application/award associated	UBC Number / Title / Sponsor

with this study that is not listed in question 2.3. When you press Add you can do a search for your funding award by doing a search in the Sponsor box - over 7000 options are listed	
2.5.A. Is this a DHHS grant? (To view a list of DHHS funding agencies click on add in 2.5.B below)	
2.5.B. If yes, please select the appropriate DHHS funding agency from the selection box, and attach the grant to box 9.8. of the application.	
Attach DHHS Grant Application for each sponsor listed above	
2.6. Conflict of Interest Do any of the following statements apply to the Principal Investigator, Co-Investigators and/or their partners/immediate family members? Receive personal benefits in connection with this study over and above the direct cost of conducting this study. For example, being paid by the funder for consulting. (Reminder: receiving a finders fee for each participant enrolled is not allowed). Have a non-financial relationship with the sponsor (such as unpaid consultant, advisor, board member or other non-financial interest). Have direct financial involvement with the sponsor (source of funds) via ownership of stock, stock options, or membership on a Board. Hold patent rights or intellectual property rights linked in any way to this study or its sponsor (source of funds).	no
4. Study Review Type - Human Ethics Application [View Form]	
4.1. UBC Research Ethics Board Indicate which UBC Research Ethics Board you are applying to and the type of study you are applying for:	UBC Behavioural Research Ethics Board
4.2. Institutions and Sites for Study A. Enter the locations for the institutions and sites where the research will be carried out under this Research Ethics Board approval (including specimens processed by pathology, special radiological procedures, specimens obtained in the operating room, or tissue requested from pathology). Click Add and enter the appropriate letter to see the locations for the institutions and sites where the research will be carried out under this Research Ethics Board approval: B for BC Cancer Agency C for Children's and Women's Health Centre of BC P for Providence Health Care U for UBC Campus V for Vancouver Coastal Health (VCHRI/VCHA). If you are NOT using any of these sites select N/A from the list.	Institution: N/A Site: N/A
B. Please enter any other locations where the research will be conducted under this Research Ethics Approval (e.g. private physician's office, community centre, school, classroom, subject's home, in the field - provide details).	People who smoke: a location they designate to be convenient - e.g. coffee shop, researcher's office. If people choose to take part in a focus group, it will be held at a local community centre. GPs: a location they designate to be convenient - e.g.

	their office, or researcher's office. If GPs choose to take part in a focus group, it will be held at the BC Cancer Agency.
4.3. A. If this proposal is closely linked to any other proposal previously/simultaneously submitted, enter the Research Ethics Board number of that proposal.	
B. If applicable, please describe the relationship between this proposal and the previously/simultaneously submitted proposal listed above.	
C. Have you received any information or are you aware of any rejection of this study by any Research Ethics Board? If yes, please provide known details and attach any available relevant documentation in question 9.8.	
4.4. If this research proposal has received any independent scientific/methodological peer review, please include the names of committees or individuals involved in the review. State whether the peer review process is ongoing or completed. A. External peer review details:	Canadian Institutes of Health Research (CIHR) Health, Ethics, Law & Humanities Committee
B. Internal (UBC or hospital) peer review details:	
C. If this research proposal has NOT received any independent scientific/methodological peer review, explain why no review has taken place.	
4.5. After reviewing the minimal risk criteria on the right, does your application fall under minimal risk (and therefore is eligible to be considered for Delegated Review, executive review or review by an Undergraduate Research Review Committee)?	no
4.6.A. Pandemic Research Does this study involve research concerning H1N1 or any other urgent public health event such that it requires urgent review and approval? [if no, move on to 5, if yes, answer 4.6B]	
4.6.B. Does this pandemic study require review and approval by multiple Canadian Research Boards (i.e. more than those covered under the certificate of approval for this application) [If no, move on to 5, if yes, answer 4.6.C]	
4.6.C. Are you the Lead Investigator for this pandemic study? (i.e. the pandemic study involves numerous co-investigators from various sites external to UBC and you have been selected as the lead investigator for the entire project) [If YES, move on to 5, if NO move on to 4.7]	
4.7. Pandemic Research Lead PI REB Please review the guidance note on the right and then answer the following question: If the study has NOT been approved by the Lead PI's REB, UBC's REBs will not proceed to review the study independently. They will be participating in the Lead REB approval process and accordingly, your	

application is premature. Please discontinue this application and submit a new application as soon as the study approval by the Lead PI REB has been obtained. If the study HAS been approved by the Lead PI's REB, UBC's REBs will make every effort to review your study as quickly as possible. In order to ensure that the required documentation is incorporated into the RISe system, you will be directed to respond to Question 9. For more information please see the accompanying guidance note. Has this study been reviewed and approved by the Lead Principal Investigator's REB?	
5. Summary of Study and Recruitment - Human Ethics Application for Clinical Study [View Form]	
5.1. Study Summary 5.1.A Provide a short summary of the project written in lay language suitable for non-scientific REB members. DO NOT exceed 100 words and do not cut and paste directly from the study protocol.	
5.1.B Summarize the research proposal:	1) PURPOSE The purpose of this study is to explore the ethical implications of tobacco 'denormalisation' as a population-based risk management strategy, through an examination of how this strategy informs patient-provider interactions involving smokers in primary health care settings. 2) HYPOTHESIS N/A 3) JUSTIFICATION 'Denormalisation' is the fourth goal of Canada's national tobacco control strategy and underpins the other three pillars of prevention, cessation and protection (National Clearinghouse on Tobacco or Health 1999). Although social denormalisation strategies underpin the Canadian tobacco control movement at both national and provincial levels (e.g. BC Ministry of Health Services 2004), recent critics have argued that these strategies have fostered a social transformation that involves the active stigmatisation of smokers (Bayer & Stuber 2006; see also Kim & Shanahan 2003). The stigma attached to smoking is evident in recent efforts to frame health care as a privilege that smokers have negated the 'right' to access, as recent media reports suggest that some doctors are choosing to withhold treatment from smokers and to exclude smokers from their practice (Kohler & Righton 2006). These attitudes and practices illustrate how successful denormalisation efforts have been in changing social norms, values and attitudes regarding smoking and smokers. However, this emphasis on the individual responsibility for health disguises the fact that 'risk' behaviours such as smoking are increasingly confined to low socio-economic status (SES) groups and that smoking-related morbidity and mortality are heavily

concentrated amongst these groups (Bayer & Stuber 2006).

Despite the ethical issues raised by such policies and practices, denormalisation policies have received little scrutiny from ethicists in the Canadian context. The proposed pilot project will tackle these ethical issues in detail through an exploration of both the macro-level policy environment and its impact on micro-level primary health care interactions. This intersectional approach stems from our mutual recognition that health care interactions must be examined within a wider set of social relations, which, though not typically visible, profoundly influence access to health care (Ahmad 1993; Singer & Baer 1997; Waitzkin 1991).

4) OBJECTIVES
a) Understand how stigma interacts with tobacco denormalisation to impact public health messaging and treatment, as evident in patient-provider interactions;
b) Analyse the primary health care experiences and expectations of smokers and physicians who treat them;
c) Include the voice of smokers into discussions about risk-management policies and practices, as their views, opinions and experiences are notably absent in tobacco research and policy;
d) Examine the opinions of physicians regarding the ethical dimensions of decisions to provide or withhold treatment for people who smoke;
e) Apply these findings in developing more comprehensive and effective population-based risk management strategies targeting smoking-related illnesses and related health promotion interventions for people who smoke.

To achieve these objectives, and in keeping with the Interagency Panel on Research Ethics First Principles of transparency, community engagement, and consultation, this pilot project will be guided by the following research questions:

Research Questions
1) How do people who smoke characterise their interactions with physicians when seeking support and treatment for health concerns (including those which are and are not smoking related)?
2) How do physicians characterise their interactions with patients who are smokers? What issues do they face in providing effective treatment for people who smoke?
3) How does knowledge of smoking status affect physicians' decisions about treatment and support for patients' health concerns (both smoking and non-smoking related)?
4) How would people who smoke like to interact with primary-care providers? What role do they see for physicians (if any) in supporting smoking cessation?
5) How could population-based risk management strategies relating to smoking be reconfigured to respond

	more effectively to potential smoking-related harms without stigmatising smokers? 6) Is it possible to reconcile possible conflicts in individual and societal interests when responding to public health issues presented by smoking? 5) RESEARCH METHODS This pilot project will utilise a variety of qualitative research methods: individual interviews, focus group interviews. Given the parallels between smoking and obesity in terms of how both are framed (see Kohler & Righton 2006), the study will draw on methods that have successfully been used to study patient-provider interactions in the context of obesity and draw on the insights these studies have produced (see Parham 1999; Joanisse & Synnott 1999; Teachman & Brownell 2001; Ferraro & Holland 2002; Oberrieder et al. 1995). According to their comfort and preference, the two target populations (smokers and GPs) may choose to be interviewed individually or as part of a focus group. As we are interested in ascertaining the role that gender (of both the smoker and the GP) plays in the treatment of smokers, we aim to recruit relatively equal numbers of men and women into the project. Individual interview questions will reflect the six primary research questions guiding this project, and will invite smokers and GPs to reflect on their respective experiences in the context of their interactions around smoking. Focus groups will address topics similar to those found in the individual interview schedule, although they differ from interviews in that they rely on group interaction to generate data. Thus, they are ideal for exploring how accounts are articulated, censured, opposed and changed through social interactions, and are particularly appropriate when investigating complex behaviours and motivations (Litosseliti 2003). The individual and focus group interviews will all be tape recorded and transcribed verbatim and the text of these transcripts will be coded and analysed using the NVivo qualitative data analysis program. 6) STATISTICAL ANALYSIS N/A
5.2. Inclusion Criteria Inclusion Criteria. Describe the participants being selected for this study, and list the criteria for their inclusion. For research involving human pluripotent stem cells, provide a detailed description of the stem cells being used in the research.	Inclusion Criteria for people who smoke 1) ex-smokers who have quit smoking within the past year 2) current smokers who have not been to a GP in the last 12 months 3) current smokers who have been to a GP no more than 4 times in the last 12 months 4) current smokers who have been to a GP more than 4 times in the last 12 Inclusion criteria for GPs

	1) GPs need to be currently practising
5.3. Exclusion Criteria Exclusion Criteria. Describe which potential participants will be excluded from participation, and list the criteria for their exclusion.	Participants who are not fluent in English will be excluded from the study as this is a pilot study only and we do not have the funds to hire interpreters and have materials translated. No exclusions will be made on the basis of class, ethnicity, gender or age.
5.4. Recruitment Provide a detailed description of the method of recruitment. For example, describe who will contact prospective participants and by what means this will be done. Ensure that any letters of initial contact or other recruitment materials are attached to this submission on Page 9.	Recruitment methods for people who smoke a) standard third party recruitment methods - posters and advertisements in coffee shops, in local newspapers, in staff rooms, at shopping malls, at health clinics, etc b) snowball sampling - initial participants will be asked if they know of others who might be interested in taking part in the study. If they respond affirmatively, they will be given copies of the study poster to disseminate to these other potentially interested parties. c) approaching people smoking in designated smoking sections in public places such as coffee shops and workplaces - recent articles (e.g. Henison & Haines 2006) highlight some of the problems with standard opt-in approaches, which can be particularly problematic when trying to recruit participants of low socio-economic status into studies. We thus request approval to go beyond standard third party recruitment methods. Operating under the assumption that people smoking in public places are willing to define themselves publicly as 'smokers', the researcher will approach people smoking and ask if they have a few moments to hear about a study on smoking they might be interested in taking part in. If people indicate a lack of interest, the researcher will thank them for their time and leave. If they express interest, she will briefly explain the project and hand them the project poster - asking them to get in touch if they are interested. Recruitment methods for GPs a) standard third party recruitment methods - advertisements in the BC Family Practice Oncology Council and Network newsletters, and the BC College of Physicians newsletters b) Recruitment through the [redacted] - which runs [redacted] Program [redacted] for healthcare professionals to provide them with training in delivering smoking cessation. The [redacted] will be asked to disseminate the poster on its mailing list, place a copy on its notice board, and include a copy of the poster with its training materials. [redacted] c) snowball sampling - initial participants will be asked if

	they know of others who might be interested in taking part in the study. If they respond affirmatively, they will be given copies of the study poster to disseminate to these other potentially interested parties.
5.5. Recruitment of Normal/Control Participants Describe how prospective normal/control participants will be identified, contacted, and recruited, if the method differs from the above.	N/A
5.6. Use of Records If existing records (e.g. health records, clinical lists or other records/databases) will be used to IDENTIFY potential participants, please describe how permission to access this information, and to collect and use this information will be obtained.	
5.7. Summary of Procedures	When participants contact the research assistant to express an interest in being interviewed, they will be initially screened to see whether they fit the inclusion criteria for the two study populations (people who smoke, GPs). We intend to purposively sample smokers to attempt to obtain relatively equal representation from all four categories of interest. We also would like to ensure that we have relatively equal numbers of men and women from both target groups. Once screening is completed, people will be asked if they would prefer to take part in an interview or focus group. If they express an interest in being interviewed, an interview date, time and location will be scheduled. If they express a preference for taking part in a focus group, their name will be put on a list and they will be told that they will be contacted when there are enough names on the list to hold a focus group. They will be asked to get in touch if their contact details change in the meantime. Interviews Participants will take part in a formal, semi-structured interview of 1-2 hrs (smokers) or 30mins-1hr (GPs) duration. If the participant provides permission, the interview will be recorded. If not, written notes only will be taken. Smokers or ex-smokers will be asked about their history of smoking, their views on smoking and their interactions with GPs. GPs will be asked about their views on smoking, their own smoking history, and their interactions with patients who smoke. Focus Groups Participants will take part in a focus group of between 8-10 people. Depending on levels of interest, there may be one focus group for GPs and 2-3 for smokers/ex-smokers. With the permission of the participants, the focus group will recorded - if anyone expresses discomfort with the recording, written notes only will be taken. The questions asked will be similar to those asked in the individual interview.
6. Participant Information and Consent Process - Human Ethics Application for Clinical Study [View Form]	

6.1. Time to Participate How much time will a participant be asked to dedicate to the project beyond that needed for normal care?	An interview or focus group of between 1-2 hours
6.2. Time to Participate – Normal/Control Participants If applicable, how much time will a normal/control volunteer be asked to dedicate to the project?	N/A
6.3. Risks/Harms Describe what is known about the risks (harms) of the proposed research.	The research does deal with a somewhat sensitive subject as people who smoke and GPs will be asked to discuss their views on the topic. Smokers/ex-smokers: smoking has become an increasingly stigmatised and they some people therefore feel discomfort in discussing this topic with researchers. However, this study will by definition only enroll smokers who are willing to talk about this subject as it will be very clear from the recruitment materials and study title what the interview/focus group content will explore. Moreover the study poster will make it clear that the research is non-judgmental and seeks to explore participants' views and opinions. Importantly, participants will also be given the choice of whether to participate in an interview or a focus group - the latter method has been shown to be effective in dealing with other stigmatised topics such as weight issues (see Cosrow et al. 2001), where participants may feel uncomfortable expressing their views one-to-one. However, in the event that participants become distressed during the course of the interview/focus group, the interviewer will acknowledge this and ask if the participant/s would like to take a 'time out', prefer to reschedule at another time, or withdraw from the study altogether. GPs: for GPs smoking is also a sensitive topic because they often have very high patient loads and they are increasingly being placed under pressure to conduct smoking cessation with their patients - although some patients may be resistant to such attempts. Popular articles which have highlighted discriminatory practices by GPs against smokers may also mean that some GPs might feel sensitive about attempts to explore their perceptions of patients who smoke. Once again, by definition, this study will only include GPs who are willing to discuss this topic. Although it is very unlikely that a GP would become distressed about the topic during the course of an interview or focus group, if this occurs, the same procedures outlined above will be used.
6.4. Benefits Describe any potential benefits to the participant that could arise from his or her participation in the proposed research.	There are no explicit potential benefits to participants for taking part in this research. However, this research will provide smokers with a rare opportunity to voice their views on smoking and how they would like this issue to be dealt with (or not) in a primary care setting. For GPs who participate in the study, it will similarly provide an opportunity for them to voice their experiences (including pressures and frustrations) when addressing the topic of smoking with patients.
6.5. Reimbursement Describe any reimbursement	Smokers will be provided with a $25 honorarium for

for expenses (e.g. meals, parking, medications) or payments/incentives/gifts-in-kind (e.g. honoraria, gifts, prizes, credits) to be offered to the participants. Provide full details of the amounts, payment schedules, and value of gifts-in-kind.	taking part in the interview/focus group, which will cover any costs incurred, such as parking or childcare. On the advice of [redacted], a GP consultant for the project, the GP honorarium will be $50.
6.6. Obtaining Consent Specify who will explain the consent form and consent participants. Include details of where the consent will be obtained and under what circumstances.	The consent form will be provided to people who contact the researcher and express an interest in being interviewed - either via email or post. They will be asked to go over the form prior to the interview to obtain a sense of their rights as participants and the interview content. They will be encouraged to get in touch if they have any questions about the information or consent form or if they change their mind about being interviewed upon reading it. On the day of the scheduled interview, prior to starting the interview, the interviewer/focus group facilitator (Kirsten Bell, [redacted]) will go through the consent form with the participant/s and ask if he/she/they have any questions about it.
6.7.A. Waiver/Alteration of Consent If you are asking for a waiver or an alteration of the requirement for participant informed consent, please justify the waiver or alteration and explain how the study meets all the criteria on the right. Please address each criterion on the right individually.	
6.7.B. Waiver of Consent in Individual Medical Emergencies If you are asking for a waiver or an alteration of the requirement for participant informed consent in individual medical emergencies, please justify the waiver or alteration and explain how the study meets all the criteria on the right. Please address each criterion on the right individually.	
6.8. Time to Consent How long after being provided with detailed information/consent form about the study will the participant have to decide whether or not to participate? Provide your rationale for the amount of time given.	The participant will have from the period they make initial contact expressing their interest in taking part in the study to the day of the scheduled interview to decide whether or not to participate. While some interviews may be scheduled 24 hours after the initial phone call, in most cases it is likely to be several days to one week later.
6.9. Capacity to Consent Will every participant have the capacity to give fully informed consent on his/her own behalf? Please click Select to complete the question and view further details.	Will the participant have the capacity to give fully informed consent? / Details of the nature of the incapacity / If not, who will consent on his/her behalf? / If not, will he/she be able to give assent to participate? / If Yes, explain how assent will be sought. Yes [Details]
6.10. Renewal of Consent Describe any situation in which the renewal of consent for this research might be appropriate, and how this would take place.	It is unlikely that renewal of consent would be required as only single interviews/focus groups are anticipated with each participant. However, in the event that participants who have already been interviewed contact the researchers to provide an update of their situation,

	the researcher/s will ask if it is okay that the information being provided can be used in the study.
6.11. Provisions for Consent What provisions are planned for participants, or those consenting on a participant's behalf, to have special assistance, if needed, during the consent process (e.g. consent forms in Braille, or in languages other than English).	N/A
6.12. Restrictions on Disclosure Describe any restrictions regarding the disclosure of information to research participants (during or at the end of the study) that the sponsor has placed on investigators, including those related to the publication of results. Also, indicate any plans for communicating study results to participants.	N/A
7. Number of Participants - Human Ethics Application for Behavioural Study [View Form]	
7.1. External Approvals External approvals for research involving other institutions and other jurisdictions: Provide written proof of agency approval for projects carried out at other institutions and, when applicable, other jurisdictions. Indicate external approvals below: A. Other Institutions:	no
B. Please select Add to enter the name of the institution and if you have already received approval attach the approval letter.	Name of Institution
C. Other Jurisdiction or Country (if answer is No go to 7.1.G):	no
D. Please select Add to enter the name of the jurisdiction or country and if you have already received approval attach the approval letter.	Name of Jurisdiction or Country
E. Has a Request for Ethics Approval been submitted to the institution or responsible authority in the other jurisdiction or country? (Send a copy to the Research Ethics Office when approval is obtained).	
F. If a Request for Approval has not been submitted, provide the reasons below:	
G. Does this research focus on aboriginal peoples, communities or organizations?	
If Yes, ensure that you are familiar with the guidance documents linked on the right. Also attach a copy of the research agreement with the community (if available) in question 9.7. Please describe the community consent process. If no community consent is being sought, please justify.	
H. Registration for Publication of Clinical Trials. Does this study fall within the clinical/intervention trial definition stated on the right (in the guidelines)?	
If 'Yes', click 'Add' to enter the following information. (Please note that registration by UBC	

ORS administration requires the prior ethical approval of the study. In that case, registration information should be added when it becomes available).	
7.2. Number of Participants A. How many participants will take part in the entire study (i.e., the entire study, world-wide)?	Approximately 30 smokers & 10 GPs
B. How many participants will take part at institutions covered by this Research Ethics Approval (i.e., only at the institutions covered by this approval)?	
7.3. Researcher Qualifications Who will actually conduct the study and what are their qualifications to conduct this kind of research? (e.g., describe relevant training, experience, degrees, and/or courses).	Fieldwork will be conducted by Kirsten Bell, [redacted] Kirsten Bell has a PhD in cultural anthropology and is an experienced qualitative researcher. Aside from her experience in teaching qualitative methods courses to both undergraduate and postgraduate students, she has conducted over 85 individual and group interviews. [redacted]
8. Confidentiality - Human Ethics Application for Behavioural Study [View Form]	
8.1. Security of Data During the Course of the Study How will data be stored? (E.g., computerized files, hard copy, videotape, audio recordings, personal electronic communications device, other.) How will security of the data be maintained? (For example, study documents must be kept in a secure locked location and computer files should be password protected and encrypted, data should not be stored or downloaded onto an unsecured computer, back up files should be stored appropriately.) If any data or images are to be kept on the Web, what precautions have been taken to prevent them being copied?	Hard copies of study documents and CD-ROMs containing interview recordings will be kept in the principal investigator's (Kirsten Bell) locked office filing cabinet. Although computer files will be shared with the research team, they will be stored on password protected computers and will not be uploaded into communal storage drives.

8.2. Access to Data Who will have access to the data (e.g., co-investigators, students or translators)? How will all of those who have access to the data be made aware of their responsibilities concerning privacy and confidentiality issues?	Co-investigators and the project research assistant will have access to the data. At the first team meeting the responsibilities of team members to ensure the privacy and confidentiality of data will be discussed - along with the provision of a project document outlining these responsibilities.
8.3. Protection of Personal Information Describe how the identity of research participants will be protected both during and after the research study, including how participants will be identified on data collection forms.	
8.4. Transfer of Data Will any data that identify individuals be transferred (available) to persons or agencies outside of the University?	no
If YES, describe in detail what identifiable information is released, to whom, how the data will be transferred, how and where it will be stored and what safeguards will be used to protect the identity of participants and the privacy of their data. Attach the data transfer agreement if applicable.	
8.5. Retention and Destruction of Data UBC policy requires that data be kept for at least 5 years within a UBC facility. If you intend to destroy the data at the end of the storage period describe how this will be done to ensure confidentiality (e.g., tapes should be demagnetized, paper copies shredded). UBC has no explicit requirement for shredding of data at the end of this period and it may be kept indefinitely. Please note that the responsibility for the security of the data rests with the Principal Investigator.	The project data will be stored indefinitely via hard copy in a lockable filing cabinet and electronically on a password protected computer.
8.6. Future Use of Data Are there any plans for future use of either data or audio/video recordings? Provide details, including who will have access and for what purposes, below.	No future uses are presently planned for the data. However, it is possible that the data may be re-analysed in at some point in light of future research interests and projects. This information will be provided in the information/consent form.
8.7. Feedback to Participants Are there any plans for feedback on the findings or results of the research to the participant? Provide details below.	Research participants will be asked to provide their contact details at the time of the interview or focus group if they are interested in receiving feedback on the findings. At the end of the study, a presentation will be organised in conjunction with the [redacted] where the two differing perspectives on smoking (that of people who smoke and that of GPs) will be outlined - participants who provided their contact details will be invited along to the presentation.
9. Documentation - Human Ethics Application for Behavioural Study [View Form]	
9.1. Research Proposal Examples of types of proposals are listed on the right. Click Add to enter the required information and attach the documents.	Name / Version / Date Research Proposal / January 6, 2007 [View]
9.2. Documentation of Consent Examples of types of consent documents are listed on the right. Click Add to enter the required information and attach	Name / Version / Date Letterhead GP consent form / V2 / October 3, 2008 [View]

the documents.	Letterhead Consent Form for Smokers V1 June 2, 2008 [View]
9.3. Documentation of Assent Examples of types of assent documents are listed on the right. Click Add to enter the required information and attach the documents.	Name Version Date
9.4. Advertisement to Recruit Participants Examples are listed on the right. Click Add to enter the required information and attach the documents.	Name Version Date Recruitment poster for GPs V2 October 3, 2008 [View] Recruitment poster - smokers V1 June 5, 2008 [View]
9.5. Questionnaire, Questionnaire Consent Cover Letter, Tests, Interview Scripts, etc. Please click Add to enter the required information and attach the documents.	Name Version Date Sample Interview Guide - smokers V1 June 3, 2008 [View] Sample Interview Guide - GPs V1 June 3, 2008 [View]
9.6. Letter of Initial Contact Please click Add to enter the required information and attach the forms.	Name Version Date
9.7. Other Documents A. Other documents: Examples of other types of documents are listed on the right. Click Add to enter the required information and attach the documents.	Name Version Date CIHR review of proposal January 2, 2008 [View]
B. If a Web site is part of this study, enter the URL below. Since URL's may change over time or become non-existent, you must also attach a copy of the documentation contained on the web site to one of the sections above or provide an explanation.	
10. Fee for Service - Human Ethics Application for Behavioural Study [View Form]	
Mechanism for Submitting Fee. Please indicate which of the following method of payment will be used for this application:	
Contact information regarding where to send the invoice.	
12. Save Application - Human Ethics Application [View Form]	

6303 N.W. Marine Drive
Vancouver, B.C., Canada V6T 1Z1

Tel: (604) 822-2878
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Consent Form for GPs 'Rights, Risks and Smoking'

Principal Investigator: Dr Kirsten Bell, Anthropology Department, University of British Columbia. Ph: 604 877 6000 ext. 2160; email: kbell@bccancer.bc.ca.
Co-Investigator(s): [redacted]
Research Assistant: [redacted]

Sponsor:
This project is funded by the Canadian Institutes of Health Research (CIHR).

Purpose:
Smoking has become a highly charged issue in primary care settings in recent years, with GPs under increased pressure to conduct smoking cessation with patients, and patients experiencing attendant pressure to quit smoking. The goal of this research is to understand more about the primary health care experiences and expectations of both smokers and the physicians who treat them. By exploring the perspectives of both groups, we anticipate that this research will lead to improved communication between patients and their GPs around the topic of smoking.

Study Procedures:
Your involvement will entail an interview or focus group of 30mins-1 hour where you will be asked about your perspective on smoking as a physician and your interactions with patients around smoking. With your permission the interview/focus group will be recorded and then transcribed to accurately record your views and opinions. If you would prefer the interview/focus group not to be recorded, written notes alone will be taken.

Project Outcomes:
Although the project outcomes will be determined by the research findings, possible research products will include: journal articles, a report, a brief for health care providers, and plain language summaries. Data from the project may also be re-analysed at a later point if they connect with the researchers' future projects.

Potential Benefits:
There are no explicit benefits to you by taking part in this study. However, the interview or focus group will provide you with the opportunity to voice your opinion on your experiences and will hopefully raise awareness of GPs' experiences around dealing with smoking in primary care settings.

If you are interested in learning about the results of this study, please provide your contact details at the bottom of this form. We will be in touch at the end of the project to provide a copy of the report and information on when we will be presenting the results.

Potential Risks:
Although the interview or focus group will deal with topics that you are likely to discuss with your patients in everyday practice, if it raises issues or feelings that you would like support in dealing with, the researcher can refer you to a counsellor, or to other resources in the community. You can terminate the

interview at any time, and you do not have to answer any questions that make you feel uncomfortable. You can also withdraw your participation in the project at any time.

Confidentiality:
All hard copies of documents and recordings will be identified only by code number and kept in a locked filing cabinet. You will not be identified by name in either the recording or the interview transcript. Hard copies of the interview notes and transcripts will be stored in a locked filing cabinet in the office of the Principal Investigator and electronic copies will be kept on the local hard drives of team members' computers – all of which are password protected. Participants will not be identified by name in any reports of the completed study.

If you choose to take part in a focus group, only limited confidentiality can be offered. Although we encourage all participants to refrain from disclosing the contents of the discussion outside of the focus group, we cannot control what other participants do with the information discussed.

Remuneration/Compensation:
In order to acknowledge the time you have taken to be involved in this project and defray the costs of transportation, each participant will receive an honorarium in the amount of $50.

Contact for information about the study:
If you have any questions or desire further information with respect to this study, you may contact Kirsten Bell (604.877.6000 ext. 2160; email: kbell@bccancer.bc.ca) or [redacted]

Contact for concerns about the rights of research subjects:
If you have any concerns about your treatment or rights as a research subject, you may contact the Research Subject Information Line in the UBC Office of Research Services at 604-822-8598 or if long distance e-mail to RSIL@ors.ubc.ca.

Consent:
Your participation in this study is entirely voluntary and you may refuse to participate or withdraw from the study at any time.

Your signature below indicates that you have received a copy of this consent form for your own records.

Your signature indicates that you consent to participate in this study.

_____
Subject Signature Date

Please provide your contact details if you are interested in attending a presentation on the results of this study:

Address: _____
_____
Phone #: _____
Alternative #: _____
Email: _____

Consent Form for Smokers
'Rights, Risks and Smoking'

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Research Assistant: [redacted]

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This project is funded by the Canadian Institutes of Health Research (CIHR).

Purpose:
Smoking has become a highly charged issue in primary care settings in recent years, with GPs under increased pressure to conduct smoking cessation with patients, and patients experiencing attendant pressure to quit smoking. The goal of this research is to understand more about the primary health care experiences and expectations of both smokers and the physicians who treat them. By exploring the perspectives of both groups, we anticipate that this research will lead to improved communication between patients and their GPs around the topic of smoking.

Study Procedures:
Your involvement will entail an interview or focus group of 1-2 hours where you will be asked about your history of smoking, your personal perspective on smoking, your visits to your GP, and your interactions with your GP. With your permission the interview/focus group will be recorded and then transcribed to accurately record your views and opinions. If you would prefer the interview/focus group not to be recorded, written notes alone will be taken.

Project Outcomes:
Although the project outcomes will be determined by the research findings, possible research products will include: journal articles, a report, a brief for health care providers, and plain language summaries. Data from the project may also be re-analysed at a later point if they connect with the researchers' future projects.

Potential Benefits:
There are no explicit benefits to you by taking part in this study. However, the interview or focus group will provide you with the opportunity to voice your opinion on your experiences, and will hopefully raise awareness of how smokers and recent ex-smokers would like to interact with GPs in primary care settings, especially around the topic of smoking.

If you are interested in learning about the results of this study, please provide your contact details at the bottom of this form. We will be in touch at the end of the project to provide a copy of the report and information on when we will be presenting the results.

Potential Risks:
As the interview or focus group will deal with the topic of smoking and your experiences in primary care settings, it is possible that it may raise issues or feelings that you would like support in dealing with. If this happens, the researcher can refer you to a free counselor, or to other resources in the community

that can help you. You can leave the interview or focus group at any time, and you do not have to answer any questions that make you feel uncomfortable. You can also withdraw your participation in the project at any time.

Confidentiality:
All hard copies of documents and recordings will be identified only by code number and kept in a locked filing cabinet. You will not be identified by name in either the recording or the interview transcript. Hard copies of the interview notes and transcripts will be stored in a locked filing cabinet in the office of the Principal Investigator and electronic copies will be kept on the local hard drives of team members' computers – all of which are password protected. Participants will not be identified by name in any reports of the completed study.

If you choose to take part in a focus group, only limited confidentiality can be offered. Although we encourage all participants to refrain from disclosing the contents of the discussion outside of the focus group, we cannot control what other participants do with the information discussed.

Remuneration/Compensation:
In order to acknowledge the time you have taken to be involved in this project and defray the costs of transportation, each participant will receive an honorarium in the amount of $25.

Contact for information about the study:
If you have any questions or desire further information with respect to this study, you may contact Kirsten Bell (604.877.6000 ext. 2160; email: kbell@bccancer.bc.ca) or [redacted]

Contact for concerns about the rights of research subjects:
If you have any concerns about your treatment or rights as a research subject, you may contact the Research Subject Information Line in the UBC Office of Research Services at 604-822-8598 or if long distance e-mail to RSIL@ors.ubc.ca.

Consent:
Your participation in this study is entirely voluntary and you may refuse to participate or withdraw from the study at any time.

Your signature below indicates that you have received a copy of this consent form for your own records.

Your signature indicates that you consent to participate in this study.

_____

Subject Signature Date

Please provide your contact details if you are interested in attending a presentation on the results of this study:

Address: _____
_____
Phone #: _____
Alternative #: _____
Email: _____

Do you smoke or have you quit recently?

Are you interested in talking about your health care experiences with GPs?

If so, we would like to hear from you.

You are invited to participate in a **1-2 hour interview or focus group** where you will be asked questions about your interactions with GPs around smoking and your experiences as a patient.

You will receive a $25 honorarium for your time.

The researchers conducting this study are: Dr. Kirsten Bell (University of [redacted]

To find out more about the Rights, Risks and Smoking study please contact [redacted]

This project is funded by the Canadian Institutes of Health Research

Version 1: 5 June 2008