

## **Cross-cultural perspectives on research participation and informed consent**

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## **ABSTRACT**

This study examined Portuguese Canadian and Caribbean Canadian immigrants' perceptions of health research and informed consent procedures. Six focus groups (three in each cultural group) involving 42 participants and two individual interviews were conducted. The focus groups began with a general question about health research. This was followed by three short role-plays between the moderator and the assistant. The role-plays involved a fictional health research study in which a patient is approached for recruitment, is read a consent form, and is asked to sign. The role-plays stopped at key moments at which time focus group participants were asked questions about their understanding and their perceptions. Focus group transcripts were coded in QSR NUDIST software using open coding and then compared across cultural groups. Six overriding themes emerged: two were common in both the Portuguese and Caribbean transcripts, one emphasized the importance of trust and mistrust, and the other highlighted the need and desire for more information about health research. However, these themes were expressed somewhat differently in the two groups. In addition, there were four overriding themes that were specific to only one cultural group. In the Portuguese groups, there was an overwhelming positive regard for the research process and an emphasis on verbal as opposed to written information. The Caribbean participants qualified their participation in research studies and repeatedly raised images of invasive research.

### **Key Words**

Canada; Informed consent; Research participation; Portuguese; Caribbean; Immigrants

### **Introduction**

The importance of including participants from various cultural backgrounds in health research cannot be understated. The most obvious reason is that research findings may not apply to all ethnic groups equally. This may be especially relevant for social science research where social mediators can play a large role. For

instance, racial and ethnic differences have been found with respect to delays for therapy with cardiac patients (Bradley et al., 2004). Moreover, individuals from different cultural groups have the right to participate in research in order to benefit from any medical gains, and in order to provide information about their cultural group (Elks, 1993). The purpose of the present study was to investigate Portuguese Canadian and Caribbean Canadian immigrants' perspectives on research participation and the informed consent process.

Most literature critiquing the informed consent process has focused on the consent forms. They are

generally too complex (Goduka, 1990; Harth & Thong, 1995; Leach et al., 1999), the literacy is too high (Paasche-Orlow, Taylor, & Brancati, 2003) and participants do not understand the research terminology (Freimuth et al., 2001). One can imagine that the complexity of these forms would be particularly problematic for people reading them in their second language. In addition, emphasizing disclosure, individual decision-making, and signed consent can be considered culturally insensitive and can further deter minority individuals from participation (Gostin, 1995).

The problems with culturally insensitive recruitment and consent procedures are particularly relevant given the decreasing number of ethnic minority individuals participating in medical research (Murthy, Krumholz, & Gross, 2004). Some of the reasons for the exclusion of ethnic minority individuals in research include researcher bias (e.g., belief that minorities will not agree to participate or adhere to protocols) and researcher perception of costs (e.g., expensive to translate materials) (Swanson & Ward, 1995). There are also less obvious impediments to recruitment such as participant fear of exploitation or mistrust of researchers or of medicine (Areán, Gallagher-Thompson, 1996; Baker, 1999; Freimuth et al., 2001; Harris, 1996; Robertson, 1994). This mistrust may be compounded by consent procedures that are foreign to participants and require a signature, which may connote a legal obligation to come.

Although it may be tempting to justify minority exclusion because of these difficulties, this justification is clearly unacceptable (Freimuth et al., 2001; Swanson & Ward, 1995). Difficulty with recruitment does not justify an ethically homogeneous sample when the community clearly serves a culturally heterogeneous population. A number of authors have successfully, and often creatively, overcome recruitment challenges (Areán & Gallagher-Thompson, 1996; Coleman et al., 1997; Preloran, Browner, & Lieber, 2001).

Informed consent is particularly important as a safeguard against the exploitation of minority participants, which has occurred in the past (Dula, 1997). However, a balance needs to be reached between overprotection to the point of exclusion and the right to participate in health research (Elks, 1993). We need to understand how different minority groups perceive the informed consent process so that it can proceed without undue anxiety that heightens mistrust and discourages participation.

The current study sought the perspectives of Portuguese and Black Caribbean immigrants living in Canada on participating in a mildly invasive medical study with an emphasis on the informed consent process. We wanted to compare two very different immigrant groups. These two ethnic groups were selected for both practical and theoretical reasons. First, we had encountered problems in the recruitment of Portuguese

participants in past research that seemed to stem directly from our consent procedures. Second, because much of the literature available has examined African American perspectives, we were interested in including a comparable group that was also a visible minority but that would not have language difficulties. Our hospitals serve a large number of Caribbean patients whose first language is English because they are originally from English speaking islands. Our interest lay in how research protocols may be contributing to recruitment problems with ethnic minority groups. There were two research questions:

- (1) What are the main issues that Portuguese and Caribbean individuals express with regards to research participation and the informed consent process (specifically, the consent form and the signature requirement)?
- (2) Are there similarities and differences between groups on these issues?

## Method

Focus group methodology is particularly advantageous for topics that participants have not thought out in detail because it stimulates dialogue (Morgan, 1997). Three focus groups within each ethnic group were conducted. In addition, a Caribbean man and a Caribbean woman who did not want to participate in the focus groups were interviewed. An additional focus group was organized, but invitees refused to formally participate when they arrived. Instead an informal discussion with the moderator took place and participants allowed us to take notes for our research purpose. We included these notes in the analysis because the research question was specific to research participation and it was important to understand why this group did not want to participate. Unfortunately this means we did not collect demographic data from this group, but they were recruited from a senior's group and they were all women. An institutional research ethics board approved this study.

Adult men and women over age 18 who had immigrated to Canada from Portugal or an English-speaking Caribbean country were eligible to participate. Initially, two English speaking female recruiters who were African-Canadian and Asian-Canadian approached potential participants in the waiting rooms of various outpatient clinics in three hospitals. This recruitment strategy was not very effective. Only one Caribbean focus group and the two people interviewed were recruited in this manner. The remaining groups were organized by service providers in community centers serving Portuguese and Caribbean communities in Toronto and surrounding areas.

### *Topic guide*

We followed Morgan and Scannel's (1998) guidelines for designing the focus group topic guide and used a funnel approach for questions. Our first question asked participants for their perceptions about "health research." To help engage focus group participants in the specifics of recruitment and informed consent, we introduced a fictional scenario for a research study titled, "Cross-cultural risk factors for heart disease." This fictitious research study was mildly invasive and involved filling out a questionnaire in language of preference on diet, physical exercise, drinking patterns, smoking patterns, and stress levels. It also involved measuring heart rate, blood pressure, body weight, and cholesterol levels, which they were told would involve taking a small amount of blood from a finger with a "pin prick test." The only remuneration provided in the fictitious study was bus tickets and a lottery ticket.

Participants watched three short role-plays between the moderator and her assistant, which were followed by focus group questions. The first involved the recruitment of a participant who was waiting for a doctor's appointment. After watching the role-play, focus group participants answered questions about their own participation. In the second role-play the pretend participant listened to the consent form being read aloud, while the focus group participants followed along. This consent form (see Appendix A) followed our research ethics board's guidelines for consent. It began by telling participants that they should read the form carefully and be sure that they understand it, and it contained specific sections on the study purpose, procedure, risks, benefits, confidentiality, voluntary participation and withdrawal, and payment. Participants explained what they understood from the form and whether or not it would influence their decision to participate. In the final role-play, the pretend participant was asked to sign the consent form. Here, the final statement on the form was read; it stated a willingness to participate and requested a signature. The participants then explained how they would feel about being asked to sign, whether or not they would sign, and what they believed the signature meant. The real participants in this study were not asked to sign the fictitious consent form or any other consent form. Finally, participants were asked what they believed would encourage others from their ethnic community to participate in health research.

The topic guide for the two individual interviews was exactly the same, but participants were only told about the scenarios and did not watch a role-play.

### *Procedure*

The Portuguese focus groups were conducted in Portuguese and the Caribbean focus groups were

conducted in English. The moderator began by explaining the purpose of the focus group and emphasized the voluntary nature of their participation. Focus groups were audio taped with the participants' verbal consent. At the end of each focus group, participants filled out a one-page demographic questionnaire, and received a debriefing form and subway tickets. The individual interviews followed a similar format, but only the interviewer and the participant were present.

### *Analysis*

All focus group discussions were transcribed and the Portuguese ones were also translated into English. Following open coding procedures (Strauss & Corbin, 1998), meaningful sections of the transcript were assigned to preliminary themes. These themes were then grouped together or assigned to subthemes as meaningful units emerged and changed when new information was added (Lincoln & Guba, 1985). The transcripts were analyzed by ethnic group so that general comparisons could be made between the two groups. Themes were first identified by content area, which was largely determined by the questions asked in the focus group protocol. Second, transcripts were compared across content areas to identify overriding themes that transcended both content area and focus groups. Finally, the overriding themes in each cultural group were compared to identify differences (group specific themes) and similarities (cross-cutting themes) between the two groups. The first author used QSR NUDIST version 6 to help sort and identify themes. The second author read through all the transcripts and examined the coding. These two authors met, discussed discrepancies, and agreed on the final themes.

## **Results**

### *Demographics*

The demographics of the focus group participants are listed in Table 1. Overall, the average age of the Portuguese participants was 56.36 years ( $SD = 18.07$ ) and they had lived in Canada for an average of 20.57 years ( $SD = 12.22$ ). The average age of all Caribbean participants was 45.88 years ( $SD = 13.28$ ) and they had lived in Canada for an average of 15.00 years ( $SD = 10.28$ ). The Caribbean woman who was interviewed was 50 years old and had lived in Canada for 28 years. She had never been married and held a university degree. The Caribbean man who was interviewed was 63 years old and had been in Canada for 32 years. He was married and had a college education. It should be noted that all of the Portuguese participants and 13 of the 16 Caribbean participants were women. Unfortunately, in



Table 1  
Participant demographics

Demographics	Portuguese #1 <i>N</i> = 5	Portuguese #2 <i>N</i> = 12	Portuguese #3 <i>N</i> = 11	Caribbean #1 <i>N</i> = 4	Caribbean #2 <i>N</i> = 4	Caribbean #3 <i>N</i> = 6
<i>Age in years</i>						
Mean	28.40	55.67	69.81	59.25	36.00	40.00
SD	3.44	13.52	9.22	14.64	10.13	3.74
Range	25–33	26–71	21–81	39–74	21–43	35–45
<i>Years in Canada</i>						
Mean	7.20	23.92	23.00	20.00	8.00	11.33
SD	5.85	11.88	11.18	15.03	1.63	3.61
Range	3–17	2–40	4–36	7–34	6–10	7–17
Country of birth	All Portugal	67% Portugal 25% Brazil 8% Mozambique	All Portugal	All Caribbean but not specified	All Jamaica	83% Jamaica 17% Grenada
Gender	All female	All female	All female	50% female	All female	All female
<i>Education</i>						
Grade 4 or less	0%	42%	82%	0%	0%	0%
Grade 5–12	80%	25%	9%	25%	50%	50%
Graduated	20%	17%	9%	0%	0%	17%
secondary						
Post secondary	0%	17%	0%	75%	50%	33%
<i>Marital status</i>						
Married	100%	42%	36%	100%	25%	50%
Separated/ divorced	0%	42%	18%	0%	25%	0%
Widowed	0%	17%	36%	0%	0%	0%
Single, never married	0%	0%	9%	0%	50%	50%

the first Caribbean focus group we asked if they were born in an English-speaking Caribbean island, but did not ask participants to specify which one, so this information is missing.

#### *Overriding themes*

Some of the overriding themes, called cross-cutting, dominated in both the Portuguese and Caribbean groups; however, these themes were not expressed in exactly the same way and important differences were noted in the analysis. Other overriding themes were group-specific in that they dominated in only one of the two ethnic groups. However, even within these themes there were sometimes similarities between the two ethnic groups, which were also noted and appear in the similarities column in Table 2.

In the quotes, the abbreviations “PF1”, “PF2”, and “PF3” refer to the three Portuguese focus groups. Conversely, CF1 etc. refer to the Caribbean focus groups. “M” and “P” indicate moderator and participant.

#### *Crosscutting theme: the importance of trust and mistrust*

Trust and mistrust were discussed at length by both Portuguese and Caribbean participants. However, within the two cultural groups, trust takes on a particular meaning.

#### *Portuguese: interpersonal trust and validity*

In the Portuguese groups, establishing interpersonal trust and confirming the validity of the research was very important. Suspicion of strangers and concerns about being tricked were apparent in many places throughout the transcripts. For instance, most agreed that they would participate in the fictitious study, but the following dialogue occurred:

- P1: I would accept. I would accept to participate.  
P2: I would accept, I would look at your face and make sure it not...  
P3: Make sure it is not a deception (laughs).

Table 2  
Similarities and difference in overriding themes

Overriding themes		Similarities		Differences	
		Portuguese	Caribbean	Portuguese	Caribbean
Cross-cutting	Importance of trust and mistrust	Interpersonal trust and validity	Fear, anxiety, and mistrust of research	<ul style="list-style-type: none"> <li>the person recruiting must be trusted</li> </ul>	<ul style="list-style-type: none"> <li>general mistrust of research and medicine that causes fear and anxiety</li> </ul>
	Need and desire for more information about health research	Lacking knowledge and appreciating more information	Correcting misconceptions and providing details	<ul style="list-style-type: none"> <li>saw focus groups as providing information and recommend this for recruitment.</li> <li>saw participating in research as a way to acquire information</li> </ul>	<ul style="list-style-type: none"> <li>need to correct mis-conception that all research is highly invasive</li> <li>want the details of the study before they decide</li> </ul>
	Group specific	Portuguese	Caribbean	Portuguese	Caribbean
Group specific		Portuguese	Caribbean	Portuguese	Caribbean
	Positive regard for research and for the research process		N/A	<ul style="list-style-type: none"> <li>most willing to participate in fictitious study</li> <li>saw consent form as informative.</li> </ul>	<ul style="list-style-type: none"> <li>a dominant reoccurring theme</li> <li>a number of negative things were also said about research</li> </ul>
	Verbal and written information		N/A	<ul style="list-style-type: none"> <li>no similarities</li> </ul>	<ul style="list-style-type: none"> <li>not a dominant theme</li> <li>not discussed</li> </ul>
	N/A		Invasive notions of research	<ul style="list-style-type: none"> <li>risks are mentioned only in passing or as a joke</li> </ul>	<ul style="list-style-type: none"> <li>a dominant reoccurring theme that causes fear and anxiety</li> </ul>
	N/A		Qualified participation early	<ul style="list-style-type: none"> <li>rarely qualified their participation</li> </ul>	<ul style="list-style-type: none"> <li>often qualified their participation especially with regards to invasive research</li> </ul>

M: Normally the person would have an identification.

P1: I only wouldn't talk if it was not a sure thing, if it was a thing under the cloth [under the cloth translates roughly as seemingly sneaky], but if it is something public, a study, I would accept to do the research.

P2: You have to look at their face [to see if you can trust them]. (PF2)

This dialogue continued with participants discussing their suspicion of strangers who came to the door or phoned to ask questions, but the intentions of our fictitious study was also suspect as is apparent in the following quotation:

"Here it refers to problems of the heart and cholesterol etc. Now suppose this is a front so that they are able to ask other questions. Going beyond these questions. To ask about other things, other illnesses...I think that sometimes they look like one thing, but they aren't. It's always more than what it looks like." (PF2)

One woman explained that Portuguese people were less trusting and thus difficult to recruit. Having the research validated by a trusted source was discussed at length. For instance, one group said that a radio announcement about the study could give it validity, and another group indicated that recruiting in a doctor's office would garner legitimacy to a study. However, establishing interpersonal trust was particularly important. Participants in two focus groups noted that they had only come that day because someone familiar and trusted had invited them. One woman summed up this sentiment when she said, "I trust you (to the moderator) because you look like an honest person." (PF2)

#### *Caribbean: Fear, anxiety, and mistrust of research*

For the Caribbean participants fear and anxiety about participating was a recurring theme in their discussions. This sentiment appeared to be compounded by a general mistrust of research and medicine. A number of people expressed a fear of the medical risks associated with participation or emphasized that they would have to make sure things were "clean" before they agreed to take part. Logistic barriers were seen as problems, but the more important barrier to participation was clearly fear, which is expressed in the following dialogue.

P1: Try to convince people that when you say research it's not a bad word. Some people tend to

get scared from the word research. Educate them [on] what research is all about.

P2: Try to tell them that it's not scary, as they tend to get mixed up with different kinds of research against the simple ones....

P3: Once you say research everything gets so scary. Just the things that you don't want to know, especially blood tests and then after you start thinking about the transportation, the money." (CF3)

Mistrust was also connected to ethnicity in the informal discussion where two women were particularly adamant that they would not do research that targeted Caribbean people because it would be used to stigmatize the community. Their mistrust of the moderator and assistant (neither of whom were Caribbean) was also apparent in their unwillingness to take part in the organized focus group, although as indicated they were willing to engage in an informal discussion. Like the Portuguese participants, establishing trust was very important for recruitment, as is evidenced by this woman's explanation of her willingness to do the fictitious study, "I can see that you guys are straight forward..." (CF1) Also like the Portuguese women, the Caribbean participants discussed the fact that they had only shown up because a trusted community member had called them to set up the focus groups.

#### *Crosscutting theme: Need and desire for more information about health research*

In both ethnic groups there was a perceived lack of information about health research and a genuine desire to know more. This theme was similar in the two ethnic groups, but they began with a different knowledge base that impacted the dialogue around this issue.

#### *Portuguese: lacking knowledge and appreciating more information*

Portuguese participants did not seem to know very much about health research. This was first apparent in the lack of dialogue stimulated in response to the first question. Later, participants themselves noted this lack of information. They explained that people do not know very much about medical research and therefore feel insecure getting involved. For instance, one woman said, "they would be scared to get involved in something when they don't know what they are getting involved in" (PF1). When information was provided, it was highly valued. A number of women saw the fictitious study as an opportunity to get information, and many women praised the consent form because it was so informative.

In the following dialogue a direct link between being well informed and agreeing to participate was made.

- P1: I would sign.  
 P2: I would sign without any problem.  
 Ps: (other agree).  
 M: You wouldn't feel intimidated...  
 Ps: No, no, no.  
 (a little later)  
 P1: We have a lot of information about what is going to happen.  
 P2: There is no reason not to sign. Nothing, nothing.  
 M: So you would feel comfortable because you would be informed, is that it?  
 Ps: Yes, yes, yes (PF1).

Participants also spoke of increasing knowledge as a recruitment strategy. Interestingly, some saw our focus groups as an information session, which could itself increase recruitment.

- P1: This is good, what you've done now... Informing people and getting the information you need from the people.  
 P2: Yeah.  
 P1: Group information sessions, telling people that there aren't any risks, that there are more advantages... (PF3)

#### *Caribbean: Correcting misconceptions and providing the details*

Unlike the Portuguese participants, the Caribbean participants had an idea about what medical research involved. They talked about health research as involving drugs, injections, and blood tests, which could put them at risk. The need for knowledge about research took on two different forms. First, participants saw educating people and correcting misconceptions about research in general as an important way to improve recruitment.

- "Just talking to you, though, I was negative on doing research but you here, being here kinda enlighten me about to like go and do research...it kinda changed my mind because I used to get a lot of negative feedback about research because people would say 'Oh, I'm not going. They want to test us or this or that...or kill us or something like that, but you here and talking to us I'm feeling different.'" (CF2)

The Caribbean man who was interviewed emphasized that others might not understand that research also provided societal or culture specific benefits. He said "You'd have to...you know...you'd have to explain... Look...it's really for the benefit of, maybe not you per

se, but for the Caribbean people in general... the more we know about it the better we're able to help people."

Second, information about the details of specific research studies was also seen as important. Some participants spoke of having to seek out more information before deciding whether or not to participate. When asked about willingness to participate, a person said, "Not necessarily. I would like to know what the research is all about and going back to whether they have to inject anything and the time duration." (CF1)

#### *Specific themes*

##### *Portuguese specific theme: positive regard for research and for the research process*

Overall, the Portuguese participants were very positive about research in general, the specific fictional research study, and the informed consent process. In response to the question "what comes to mind when you think about health research?" a participant said, "I feel pleased because it is betterment. When you are exploring medical issues, you are trying to find something that we need. It is something that is going to be better" (PF2). In each focus group there was an overwhelming willingness to participate that did not wane after reading the consent form as one woman explains, "I don't think there's anything negative [in the form] for the person to say, I don't want to [participate]... It doesn't seem like there's very complicated questions here..." (PF3). Interestingly a number of women pointed out that the risks listed in the consent form were not actually risks (i.e., anxiety over learning that you are at risk for heart disease and discomfort due to pin prick).

Most women genuinely liked the details in the consent form as illustrated by the following quote, "It has everything, everything. It's completely marvelous." (PF3). There was a lot of dialogue about the specific things that women liked about the consent form like the emphasis on the voluntary nature of participation. The positive regard for the research process was also expressed in women's willingness to sign the form.

It is important to note that some of the Caribbean participants also felt positively about health research especially towards the end of the focus groups when they had had time to consider the issues in more detail. However, the Portuguese transcripts were unique in their overwhelming positive regard for research, which was consistent in all the focus groups and across content areas.

##### *Portuguese specific theme: verbal and written information*

In the Portuguese focus groups the importance of verbal information and the problematic nature of written forms and surveys became apparent. This theme did not generate as much dialogue as some of the other



themes, but it was important in that it emerged in every focus group and in different content areas. For instance, the problem of illiteracy came up when one woman admitted that she could not read the consent form (although it was in Portuguese). When the moderator tried to assure her that she could listen to the consent form being read she said, "It's a problem, it's necessary to know how to read" (PF3). The illiteracy in focus group 3 became much more apparent when participants were asked to fill out the one page demographic form (in Portuguese) at the end of the focus group. Nine of the eleven participants had no more than a grade four education and many needed help with this form. The importance of verbal communication was even more apparent in dialogue around recruitment. Here participants emphasized the importance of word of mouth and other form of oral communication (i.e., radio, TV, friends) and indicated that, "written information is ignored by people." (PF2)

#### *Caribbean specific themes*

##### *Caribbean specific theme: qualified participation early*

Unlike the Portuguese participants who readily agreed to participate in the fictitious study, the Caribbean participants qualified their participation almost immediately. As mentioned earlier, many women said they would first have to obtain more information before deciding to participate. Other individuals emphasized that they would have to make sure the research was not invasive. Many talked about participating only if they could see benefits or if it applied to them personally. One person said, "I would think about it....if I had heart problems or diabetes I probably would but if I didn't it would be something I have to think about." (CF1) Participating for the benefit of others, especially family or friends, was also expressed. One woman said, "If results would benefit society I would take part. I have people in my family, my dad, who have heart problems, that's why I would participate." (CF2)

The Portuguese participants mentioned many of these same things when asked to explain their willingness to participate, but the difference was that they did not qualify their own participation. When asked if they would participate, almost everyone simply answered that they would participate.

##### *Caribbean specific theme: Invasive notions of research*

Caribbean participants immediately presented what we came to describe as invasive images when asked the first question about what comes to mind when you hear the words health research: "a group of doctors together have some medications that they like to experiment on different people." (CF1) "...injection and pills...that I am scared of." (CF2) "Poking and scraping, needles, blood." (CF3) These images then reemerged throughout

the focus groups in response to different questions. In every focus group and in the informal discussion group, some participants explained that they would not participate in invasive research, but would in other kinds of research. One woman said, "If it have anything to do with just talking and answering questions and ...asking questions, fine, but if they going to say to me, 'let me try some injection or some pills to see whatever...', then no it wouldn't work for me that way." (CF2) In the informal discussion group, there was a concern that medical research uses people as "guinea pigs." For some women there was a fear of medicine that explained their dislike of medical research.

P: I get scared like the doctors, the testing, finding a cure

M: Why does it scare you?

P: Oh! First of all I don't like to go to doctors, I don't like medicine, injection, pills. (CF3)

There were also a number of discussions about the perceived risks of participating, which caused anxiety. After reading the consent form one woman said, "it leaves me with just anxiety, and provoking. The reason why people most people don't want to participate is because of anxiety. If you are healthy right now why would you go down the road and do this?" (CF3) The risks of medical research were also discussed in passing in the Portuguese groups, but they did not generate the same anxiety. For instance, in one group a woman joked about making sure that the needle for the pin prick test was clean, which generated laughter.

#### **Discussion**

Establishing trust was clearly an important issue for both Portuguese and Caribbean participants, which is consistent with existing literature on minority participation in research. Fear of exploitation and issues of mistrust have repeatedly surfaced (e.g., Corbie Smith, Thomas, & St. George, 2002; Corbie-Smith, Thomas, Williams, & Moody-Ayers, 1999; Fouad et al., 2001; Freimuth et al., 2001; Harris, 1996; Shavers, Lynch, & Burmcister, 2001, 2002; Robertson, 1994). In particular, establishing trust and overcoming fear and mistrust have been emphasized for the successful recruitment of minority participants (Areán & Gallagher-Thompson, 1996).

In our study Portuguese and Caribbean participants did not view trust in the same way. Portuguese participants emphasized establishing interpersonal trust and voiced their suspicion of strangers (but not of research or medicine per se). This may be explained somewhat by understanding the roots of the Portuguese

immigrant community in Toronto. Portugal was under a dictatorship from 1926 to 1974 (Grosner, 1995) at which time the population became very fearful of voicing their opinions and suspicious of government institutions and strangers. In addition, education was very limited during the dictatorship and so few people had more than a grade four education —especially among those who immigrated (Anderson & Davis, 1990). Thus the few who were educated (e.g. doctors, priests, teachers, etc.) were highly respected. This may explain both the underlying trust participants seemed to give to the research process, and the need to have the research verified by an authority figure like their family doctor.

For the Caribbean participants, establishing trust served to verify the legitimacy and, more importantly, the safety of the research. A possible explanation is that dangerous research may be especially salient for visible minority participants who are more conscious of racial discrimination. For example, Black Americans are more aware of previous examples of unethical or dangerous research conducted on minorities (Harris, 1996; Shavers et al., 2002). Unethical studies make headline news and can have a particularly detrimental affect on the already eroded trust that some minorities have of medical research. For instance, a relatively recent article on the perils of medical research appeared in *Time* magazine titled, "At your own risk" (Lemonick & Goldstein, 2002).

It is interesting that the participants in our study did not specifically link their mistrust and fear to discrimination within the wider society or within the medical establishment. Black Caribbean Canadians do experience racism in Canada in both public and private sectors (Henry, 1994) and these experiences are likely to play a role in their thinking about research. However, our participants might not have felt comfortable discussing this with a non-Caribbean moderator. A similar reluctance to speak about these issues was noted by Curtis and Lawson (2000) who used a White moderator in a study with Caribbean participants.

The fact that the Caribbean participants repeatedly brought up images of invasive research and often qualified their willingness to participate is likely related to issues of trust and mistrust. Both of these issues have been noted in previous research with African Americans. For instance, Corbie-Smith et al. (1999) found that their participants expressed concerns about the risks of participating in research especially with regards to unknown viral agents, injections, needles, and being treated like "guinea pigs". In addition, Fouad et al. (2001) found that African Americans qualified their participation by specifying that they would not participate in invasive research.

The need for information emerged as an important issue in both cultural groups and has also been found to be important in past research (e.g., Arcán & Gallagher-

Thompson, 1996; Brown, Fouad, Basen-Fingquist, & Tortolero-Luna 2000b; Brown, Long, Gould, Weitz, & Milliken, 2000a; Freimuth et al., 2001; Leach et al., 1999; Robertson, 1994). In a study with African Americans, Hispanics, and Native Americans, all three groups mentioned a lack of information as a reason why people do not participate in research (Robertson, 1994). This includes both a lack of knowledge about research more generally, which has been termed a "conceptual barrier", and a lack of accessibility due to fewer opportunities to hear about individual research projects, which has been termed a "structural barrier" (Killien et al., 2000). The Portuguese and Caribbean participants in this study discussed both of these information barriers. However, information as a conceptual barrier was even more pronounced in the Portuguese groups, who seemed to have little understanding of what health research entailed. The Caribbean participants on the other hand had some knowledge about health research but also had a number of misconceptions. Corbie-Smith et al. (1999) conducted focus groups with African Americans and noted that their participants voiced myths and misconceptions, including a number of conspiracy theories, about not only research, but also the medical system more broadly.

### *Implications*

The need for trust and knowledge were clearly important, but were not exactly the same in the two communities and a next step may be to further explore those differences and create multifaceted strategies. For instance, recruiting and providing informed consent through a trusted community member would likely be important for both cultural groups, but may not be enough for Caribbean individuals who are going into the research with very specific preconceived notions about invasive research. It seems particularly important that a wider trust be established between the Caribbean community and researchers/medical professionals. Participatory research goes beyond community recruitment, and also involves community participation in developing the research question and methods used; thereby, fostering a trusting relationship between participants and researchers (e.g., Minkler & Wallerstein, 2003). Providing study results to participants and other community members would also help demonstrate the benefits of health research, which seem to be important considerations in deciding whether or not to participate. We need to move away from thinking that establishing trust is only important in the recruitment phase. Indeed trust should be fostered before, during, and after the study is complete.

The results of this study suggest that consent letters provide valuable information that participants use in their decision making process and can actually encour-

rage participation. The Portuguese participants in particular saw the consent letter as reinforcing their decision to participate because it provided so much information. However, a written form may not be enough and a verbal explanation of the study that allows participants to ask more questions seems important in both groups. The Caribbean participants voiced a desire for more details about the study, which would be better addressed in a discussion between the participant and the researcher. For many Portuguese participants, low literacy would make even reading the form difficult and a discussion of the information essential. Poor health literacy is a growing concern in a number of communities because it is related to poorer health status (Lee, Arozullah, & Cho, 2004). Health literacy is also likely to be important in participants' understanding and willingness to participate in health research; therefore, the strategies that have been used to cope with low health literacy in general may also be useful to researchers working with low literacy communities such as the Portuguese. For instance, being ready and willing to help patients fill out paper work, speaking to patients in plain language that is free of medical jargon, and using the teach back-method after explaining important points (Rothschild, 2005).

Truly viewing informed consent as a process, rather than as a discrete event that ends with the signing of a consent form, may go a long way in establishing trust between participants and researchers. Kuczewski and Marshall (2002) see informed consent as a "social process that is influenced by myriad factors" (p.45). For instance, they suggest that delaying consent so that participants can involve their family in the decision-making process can accommodate some cultural norms. In addition, informed consent protocols may require more flexibility to facilitate communication and negotiation with participants (Gostin, 1995; Mulder, Rance, Suarez & Condori, 2000).

The signature requirement was not problematic for either cultural group. This is somewhat surprising because others have described it as a problem (Lykes, 1989; Singer, 1978; Wendler & Rackoff, 2001) and we have observed this anecdotally in previous studies with some Portuguese Canadian participants. Perhaps the real problem we had encountered in past research was not the signature requirement per se, but a lack of understanding and trust.

### *Limitations*

We used a fictitious study that participants knew they would not be taking part in it, so it may have been easier for them to indicate a willingness to participate. Future research should aim to understand the consent process as it happens in real medical studies. That is, data about the informed consent process and about recruitment

could be collected when participants are approached. It may be particularly useful to conduct short interviews with participants who initially seem interested in participating, but who later refuse to sign the consent form. It is also problematic that all of the participants may have been predisposed to research participation because they agreed to take part in our focus groups; however, this is less of a problem considering that participants still voiced the issues that concerned them.

We first attempted to recruit for the focus groups in a hospital setting, but had to seek help from community leaders when this strategy failed. This was both positive and negative. On the positive side, we likely heard from people who would never have otherwise talked to us, but on the negative side, we lost some control over the recruitment process. For example, in one of the Portuguese groups we had three women from Brazil and one from Mozambique. We also ended up with a very uneven distribution of women to men because all of the community groups were made up of women.

The fact that we did not have a Caribbean researcher on our team and did not have a Caribbean moderator or note taker is perhaps the most serious limitation to this study. Participants may not have felt as comfortable opening up to someone that was not a member of their cultural group. This may be particularly important in understanding the lack of discussion that emerged around racism and discrimination. It therefore brings into question the level of trust that we established with the participants. A Caribbean member of the research team may also have added a layer to the analysis that was not possible without that experiential knowledge. However, it has also been argued that an "outsider" researcher can see things in the data that an "insider" researcher may overlook (Finlay, 2002).

### **Conclusion**

This study is strengthened by the inclusion of two very different cultural groups that have not been researched extensively in the past and by the comparative analysis that was conducted. The subtle differences that emerged between groups with respect to trust and the need for knowledge suggests that future research should explore these issues in more detail with other cultural groups because subtle differences may impact how we proceed with recruitment and consent procedures. The group-specific themes highlight the fact that different ethnic groups have different concerns and that slightly different approaches to recruitment and to the informed consent process are needed. We anticipate that future research and debate will highlight the intricacies of these issues and propose solutions that will help researchers truly represent and give voice to multiethnic communities.



## Appendix A

### Consent to Participate in Research

Investigators: Drs. \_\_\_\_\_ and \_\_\_\_\_

### Title: Cross-cultural risk factors for heart disease

You are being asked to take part in a research study from the Women's Health Program at the University Health Network. Before agreeing to participate in this study, it is important that you read and understand the following explanations of the proposed study procedures. The following information describes the purpose, procedure, benefits, discomforts, and risks associated with this study. You should understand this information before you decide whether or not you want to participate. This is known as informed consent. Please ask the research assistant to explain anything that you do not understand. Make sure all your questions have been answered to your satisfaction before signing this consent form.

#### Purpose

This study is designed to help us understand how risk factors for heart disease may vary cross-culturally.

#### Procedure

If you volunteer to participate in this study, you will be interviewed in your language of preference (Chinese, English, Portuguese, Spanish, or Tamil) about your diet, physical exercise, drinking patterns, smoking patterns, and stress levels. Your heart rate, blood pressure, and body weight will be measured. Your cholesterol level will be measured with a finger prick test, which will involve pricking your finger to draw a little bit of blood. The whole procedure should take about 30 min.

#### Risks

There are no anticipated risks with this study for most people. Some people may learn that they are at risk for heart disease, which may be anxiety provoking. The finger prick test may be uncomfortable.

#### Benefits

This study may forward our understanding of how risks for heart disease may differ cross-culturally. We hope to use this information to better target prevention programs in different ethnic communities.

#### Confidentiality

All the information obtained during this study is confidential. There is no identifying information on the questionnaires and the consent forms are stored separately from the questionnaires. No names or identifying information will be used in any publication or presentation.

#### Voluntary Participation and Withdrawal

You can choose whether or not you want to participate in this study or not. If you volunteer in this study, you may withdraw at any time without consequences, and you may refuse to answer any question you don't want to answer and still remain in the study. Once your questionnaire is pooled with other partici-

pants' questionnaires you will be unable to withdraw your data because we will have no way of tracking down your questionnaire.

#### Payment for participation

You will receive bus tokens to compensate you for transportation costs and a 649 ticket as a thank-you.

#### Questions

If you have any questions about the study, please call Dr. \_\_\_\_\_ or \_\_\_\_\_ at phone number \_\_\_\_\_. If you have any questions about your rights as a research participant, please call Dr. \_\_\_\_\_, Chair of the University Health Ethics Board at \_\_\_\_\_.

#### Consent

I understand the information provided for the study "Cross-cultural risk factors for cardiovascular disease" described in this form. My questions have been answered to my satisfaction and I consent to take part in the study with the understanding that I may withdraw at any time. I have received a signed copy of this consent form. I voluntarily consent to participate in this study.

Name of Participant	Participant's Signature	Date
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