

## **The Role of Consumers in Research and the Expectations and Responsibilities of Researchers**

### Introduction:

It is only recently that the consumer role in research has expanded beyond that of the human subject. As consumer involvement has changed there have been few if any guidelines to help define what the consumer role(s) should or can be, or how the researcher – and the research project - can benefit from consumer inclusion on the research team. This guide has been prepared to help address these questions. Rather than a wide ranging discussion on all possible areas of consumer participation in research we have focused on the problems we have observed and experienced from our own varied participation in research studies, when assisting researchers in contacting consumers for possible recruitment, and in facilitating productive working relationships between researchers and consumers. We have initiated this workshop in the belief, as expressed in the CAN renewal document, that consumer participation improves the relevance, outcomes and overall quality of research. It is our intention that these guidelines be modified, edited and enlarged upon as required, because we don't have all the answers either. We're here to share what we know, to help you to help us through collaboration and cooperation in our mutual aim of conducting well designed research.

The following appears in the CAN NCE Renewal Document:

#### *Strategic objective 1:*

- *Consumer involvement in every CAN funded research project*
- *Consumer involvement in all Network commercial development activities*

## Part I - The Basics

To be most valuable, *consumer involvement must be appropriate, substantial and occur at every stage of research, beginning with participation in setting the research agenda.* Arthritis consumers live with pain, disability, deformity and resulting employment, economic, family and personal problems. Over the years, in addition to learning about their disease and how to cope with it, arthritis consumers have learned things about human nature, and the health care and social welfare systems that clinicians, researchers and the general public don't know. Their knowledge and experience, gained the hard way, is invaluable. Consumer participation increases the legitimacy of health research, which is a public good. This includes the principles of democracy and the moral right to participate in decisions that may directly affect the health and lives of consumers. (Caron-Flinterman, et al, 2004; Caron-Flinterman, et al, 2005)

*Consumer knowledge is not limited to what is acquired through disease experience.* Consumers are individuals first with unique personalities and abilities. They come equipped with knowledge gained from life experiences, formal education, family, culture, religion, employment and their larger communities. They may be very accomplished and successful, with the 24-365 experience of living with arthritis providing additional levels of expertise. This entire 'package' is brought to the research table. Some consumers also undertake additional training (e.g. Reading protocols, statistical analysis, knowledge translation and exchange, ethics in human research) from recognized institutions, from organizations to which they belong, or through self-study. This can further enhance their value to the research project. Some projects call for consumers with specialized and/or narrowly defined qualifications, while others do not. Appropriate selection of consumers is therefore important. It may seem obvious, but it needs to be said: **Consumers are unique. They are not interchangeable.**

CAN's objective is to have consumer involvement in every CAN funded research project. Other funders also look favourably on consumer involvement. It's therefore understandable that researchers should want to include 'a patient' to improve the chances of receiving funding. However, *merely listing the name of a consumer in a grant proposal is not evidence of consumer involvement.* Moreover, *no consumer – or researcher – should be listed in a protocol, grant proposal or LOI without written confirmation that they have agreed to be part of the research team.*

*A clear description of the function or role of the consumer* on the research team must be defined before the grant application is written, and the protocol is developed. A clear statement on how many consumers will be involved and the roles they will play, including expected time commitments, is needed prior to consumer recruitment. Potential consumer roles are many and may vary from collaboration in designing the study, acting as advisers throughout the project, helping with the analysis of results, assisting with dissemination of resulting knowledge, and in project evaluation.

Consumers may play an important role in the dissemination of knowledge gained from research. In fact, knowledge translation and exchange is considered by some to be the major, if not only, suitable activity for consumer involvement. In this traditional view, consumers may be little more than messengers that take packages of prepared materials back to their fellow consumers or organizations. Sometimes 'advocacy' is also expected. But this approach ignores the consumer knowledge of their organizations and the knowledge requirements of their fellow consumers, and it allows any activity that may be stamped 'advocacy' to suffice, however effective or ineffective it may be. Another traditional activity that is viewed with favour is recruitment of research subjects. Consumers act in all these areas. To restrict consumers to the most rudimentary of KTE, advocacy and recruitment activities is to overlook valuable consumer input that may assist in ensuring relevance and acceptance of the aims of the research study, and effective and productive dissemination of research results.

There are three arguments that pop up from time to time in opposition to active consumer involvement in research. The first is that the well informed, experienced consumer *knows too much* and therefore cannot represent the 'typical', presumably uninformed patient/consumer, at the research table. The second is that consumers are too naïve and *know too little* and therefore are unable to make valuable and relevant contributions at the research table. And the third is that an individual can only represent their own experience and therefore cannot represent or speak on behalf of others at the research table.

In the first example of participation by well informed, experienced and articulate consumers,- what might be called *proto-professional* consumers (Caron-Flinterman, et al 2004) – it should be apparent that no amount of knowledge and experience possessed by these consumers cures the disease or eliminates pain, disability or deformity. However well informed these consumers are they still live with arthritis 24 hours a day. Their experiential knowledge is valuable.

The third argument proposes that consumers can only really represent their own experiences, which are a waste of time to bring to the research table. In our society we depend on representation by others, examples being in government and judicial systems, and in peer review. We expect these representatives to have good credentials for the job. Examining the credentials of consumer representatives invariably shows a high degree of experiential and other knowledge, the ability to clearly articulate consumer perspective and a close association with large numbers of similarly affected individuals with whom they share and compare information. They ably represent the consumer perspective.

The second argument about consumers not having sufficient knowledge can perhaps be best articulated by the quote from a European researcher, collected during interviews by Caron-Flinterman, et al, for their 2004 article that appeared in the Journal, *Social Science and Medicine*:

“Patients should not interfere in processes of which they know nothing about.”

This view acknowledges the nature of the technical expertise of the researcher, but rejects the objective knowledge of the consumer. The phrase, 'patients *should not interfere*', would seem to imply that patients involved in research get in the way, or somehow prevent legitimate research activity from occurring, and might also suggest the notion that only the researcher knows what research ought to be done. It also implies a significant level of apprehension about consumer involvement that is also implicit in the other two arguments. If true, this is unfortunate as consumers bring legitimacy and relevance to the table, and are the only ones who can contribute experiential knowledge. Because health care is considered a public good, and research contributes to health care, the decisions about the direction and execution of health care must be made by all stakeholders. It is particularly important for patients/consumers to be included as stakeholders because the results of these decisions may directly affect the physical well being and lives of patients/consumers. Researchers need not be apprehensive about having consumers at the table. We are already familiar with the research process, know the white coat is a costume, and understand that outcomes are not the result of a series of miracles. As consumers and volunteers we're prepared to take our seat at the research table to join with you in our common purpose of making life – and health – better for people living with arthritis. (Entwhistle, VA, et al, 1998; Williamson C, 2001)

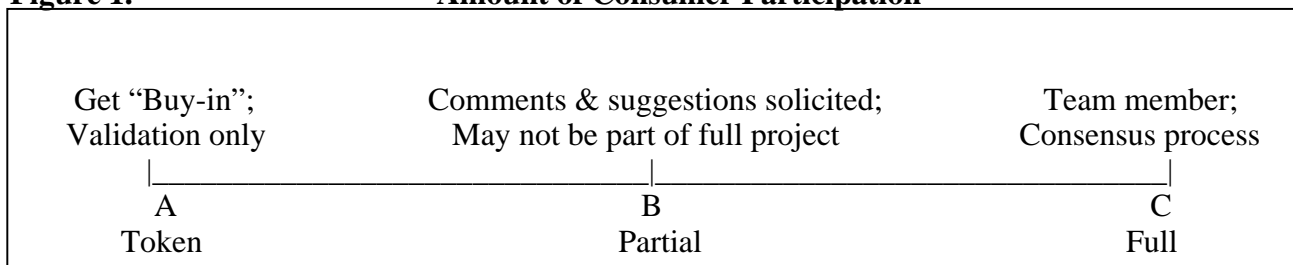
No matter how many different areas there may be for consumer participation in research, it's important for consumers and researchers alike to understand that research projects *don't* have to include consumers on the research team. We are not suggesting otherwise. We are also not suggesting that consumers would supplant any other project team member. The consumer contribution to research is

as separate and distinct as that of other disciplines that may join together to conduct research. What we *are* saying is that consumer experience and hard-won knowledge *can only be contributed by consumers*, and to carry out relevant and innovative research, it ought not be ignored.

## Part 2 – Consumer involvement

Before looking more closely at the different roles a consumer may play in a research project, it may be useful to take a quick look at the spectrum of the **amount** of possible interactive involvement between consumers and researchers.

**Figure 1. Amount of Consumer Participation**



For the sake of simplicity, we've limited the discussion to three loosely defined ideas on the appropriate **amount** of consumer interaction with researchers. Figure 1, shows the spectrum of consumer participation running between Token (A) and Full (C) participation. Depending on the project, full participation, and in some instances partial participation, provides the greatest opportunities for exchange of information between consumer and researcher. Because the amount of interaction between consumers and research team members helps to determine how the project will be carried out, it must be determined at the outset.

An example of token participation might be a group of consumers who are brought together to 'comment' on a health related policy or project that has already been decided upon but not yet officially 'announced'. The purpose of 'consulting' the consumers is to get 'buy-in' so the project can be said to be 'approved' and/or 'supported' by the consumers. But the consumers may have had nothing to do with the development of the project or policy, have no input during the meeting, may not approve of what has been decided and have no way of making their disapproval clear, or of presenting suggestions for improvement. This extreme degree of tokenism is sometimes seen when policies or projects are developed in isolation by organizations or governments with a particular agenda. (Ard and Natowicz, 2001; Stevens et al, 2003) It leads to consumer discouragement and distrust of the groups who initiate such projects, and the reluctance or refusal to participate in any future initiatives.

An example of full participation might be when consumers are consulted at the outset of a project, participate in writing the LOI and grant proposal, and act throughout the project with the same degree of involvement and responsibility as other team members, with consensus used for project decision making wherever possible.

An example of the mid-point (B), might be where additional consumers are brought into an existing project to provide comment and/or suggestions. There are times when having someone come in 'cold' can provide a fresh perspective and/or new information. This can be built into a full participation project. For example, it may be helpful to 'user test' material under development. Or, an *ad hoc*

addition to a study may be advisable - perhaps to illuminate glitches that may have developed because of team familiarity with the project. However, when such limited activity is the sole extent of consumer participation in a project, the benefits of consumers experience may be limited.

**Figure 2. Types of Participation**

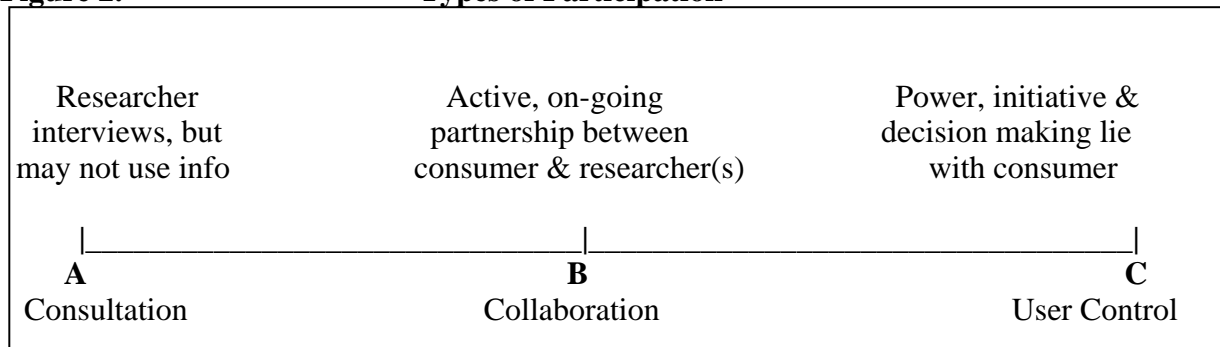


Figure 2, illustrates only three of many possible examples of **types** of consumer participation in research. An example of Consultation (A) might be talking to one or more consumers about a subject before initiating a research project, and/or similarly consulting during any phase of research. This is the most commonly seen model of consumer involvement. The project is clearly controlled by the researcher who might not make use of any information or opinion gained from consumers, or alternatively may extensively use the information, for instance to set the parameters of the project. It's important that the consumers being consulted understand how their information will be used so they don't become discouraged or feel marginalized or even angry should they believe their input has been ignored, misinterpreted or misused. Should this occur, results of the research may not be accepted by consumers and consumer recruitment to future research projects may be hampered. (Boote et al, 2002; Hanley et al, 2000)

Collaboration (B), is the active, on-going partnership between consumer and researcher, and consumer roles may vary widely according to the research design. It is a balanced relationship between all team members to maximize the efficiency and effectiveness of the research process.

In User Control (C) the power, initiative and decision making for the research project lie with the consumer. It doesn't necessarily mean that consumers undertake the research themselves, although that's a possibility. In fact, an example of this might be the survey that determined the research priorities of people living with arthritis that was successfully carried out by four consumers in 2002. Consumers might also define the research project, recruit researchers to develop and carry it out, and or seek funding for the project. (Williamson C, 2001; Hanley B, et al, 2004)

### **Part 3 - Appropriate Consumer Roles:**

*Types of consumer roles in research are limited only by the needs of the projects, the imagination of the researcher(s), and by the availability of the consumers who fill the requirements.* For instance, if a researcher plans on having a *focus group* as part of the research, consumer team roles may include helping to develop the questions; assist with planning (how, where and when to hold the sessions); conduct or assist in conducting the sessions; and help with information processing following the sessions. However, to prevent any implication of conflict of interest and questioning of research

results, consumers who help with focus group design and implementation must not participate as subjects in the focus group sessions.

Other possible areas for consumer participation might be in helping to identify and prioritize research topics, or perhaps in assisting with research design by providing consumer experience and perspective. (Stevens T, et al, 2003; Tallon D, et al, 2000). More specifically, consumers can help to define outcome measures, help with analysis, interpretation and dissemination of results; and also play a significant role in helping to evaluate the research project. There are also times when consumers may be involved in the area of research management. In this instance, consumer roles might include active 'how-goes-its' to make sure the project stays on course, ongoing comment and suggestions that may improve project outcomes, and sometimes in serving as a member of the research steering committee, which may involve working with confidential subject information. This points out the necessity of dealing with ethical requirements early to ensure that no conflict of interest issues exist, and that all requirements for confidentiality and security of personal information are met.

Other, more defined areas of consumer involvement include assisting in the consent process, and roles in knowledge translation and exchange. Consumer knowledge and experience can be particularly valuable in the development of the consent form for participating research subjects, and possibly also – when consumers become involved early enough - the method by which consumers agree to indicate their willingness to collaborate on the study. This may vary from a full letter of agreement and support written by the consumer, to a common form signed by the consumer that may also include pertinent information about role(s) the consumer is expected to play.

KTE is an important part of any research project. It requires expertise to be done well. Without appropriate communication, research results gather dust on a shelf, and the time, effort and money that went into the project is largely wasted. Consumers are frequently expected to play a major role in the dissemination of information at the completion of a research study. Sometimes it even appears that they may be expected to 'do' the KTE. But, a consumer will not morph into a communication guru just because he/she is expected to play that role, nor will they sort out what kind of knowledge translation and exchange the project requires. Planning the KTE segment is the work of the research team – including consumer members, particularly when they will play a significant role. If active advocacy is also expected, targets and methods should be included in the design and planning stage with major input by consumer team members. Methods of assessing short and long-term achievement of KTE goals are necessary, a process that emphasizes that KTE is effectively a dialogue. If researchers are serious about appropriate dissemination of information and the involvement of consumers in this role, then it might also be appropriate for them to consider sponsoring one or more consumers to attend a Cochrane Colloquium or Symposium, and also to encourage membership in the Cochrane Consumer Network (CCnet). (Entwhistle VA, et al, 1998)

In the area of ethics, we've touched on the consent process, privacy and confidentiality of information, and conflict of interest. Another concern, closely aligned with conflict of interest, is also important to be aware of. Because it is usually invisible during consumer recruitment it may not be taken into consideration. It is coercion – real or imagined – and researchers, and consumers who assist in recruiting others for research projects, need to be aware of it. It can occur if there is a perceived power imbalance between the researcher, or research community, and the potential consumer participant. A request to become part of a research study of any type may be interpreted – for any number of reasons – as being an offer that cannot be refused. One of the best ways of trying to avoid this is to present adequate information on the project, including on the expected role of the consumer, in sufficient time for questions to be asked and solid decision making to take place.

There are other less common roles for consumers in research, and two in particular deserve to be mentioned. The first is in the critically important situation of research proposed to take place within groups or communities of individuals whose ethnic, cultural, linguistic, social, religious or other beliefs differ greatly from that of the researchers. One or more consumers who are members of this group or community may be of great assistance as a fully involved member of the research team. They may be able to help bridge the gap in understanding about beliefs, about barriers to successful research that may exist, and about the requirements that must be met prior to, during and following the projected study as well as bringing the patient perspective to the table. These consumers may also help the members of the groups or communities to understand the relevance and importance of the research and its benefits. However, while consumers acting in this role may be very helpful in facilitating understanding, the burden of initiating relationships, discussions and agreements with leaders within these communities must not fall on the shoulders of these individuals.

The second, is in the area of peer review and is one of the most significant of all contributions that consumers make to research. The consumer's chief contribution in grant peer review is generally thought to be in helping to determine the relevance of proposed research. However because of their greater knowledge in their chosen disciplines, and their specific training for peer review, consumer contributions are frequently much greater. The consumer brings an area of expertise to the panel that is every bit as relevant and important as that of all other panel members. The work load and responsibility of consumers is the same for all panel members, and all panel members should have a vote. CAN accepts the importance of the consumer role, acknowledges the principle of equity and of the moral right for the consumer to fully participate, and recognizes and respects consumer knowledge. Consumers on CAN peer review panels are full voting members. (Goodare H and Lockwood S, 1999; CDRP website)

As a matter of practicality, it is important that the peer review panel receive grant proposals in sufficient time for a thorough review and rating to take place. In the case of consumers, because they may not 'speak' the scientific language of the proposal, a **lay or plain language summary of what the research proposes to determine, must be included with all grant proposals.** This is also a welcome aid for other panel members from differing disciplines. Think of it as an exercise in KTE. To ensure that all listed members of the research team have consented to participate in the project, a signed and dated statement to this effect should accompany each grant proposal. In the case of consumer team participants, the statement should also indicate that they understand what their role in the project will be, and provide their contact information. Signed conflict of interest statements by each team member – including consumers - should also be included. To accommodate individual schedules all peer reviewers must receive notice of at least one month for TEC teleconferences, and documents for the teleconference must be in hand at least two weeks prior to the teleconference.

#### **Part 4 - Practical considerations:**

It's a good idea to build consumers into your team early. Decide on how consumers can best aid your project. Decide on how many consumers you think are necessary, and be realistic in your assessment. Also decide if there are special requirements for your consumer team members, such as having a specific disease type, having arthritis for a certain period of time, being on a certain treatment, possessing certain technical knowledge, living within a certain geographic area, or being available at certain times.

When it comes down to recruiting, decide how you will recruit. Will you use local contacts to assist you or will you require outside assistance that may include the help of organizations like CAC, CAPA, ACE, CAB or TAS. If you have used a consumer organization you already know that we usually bend over backward to help, but what you may not know is that the advocates you speak with volunteer their

time to find consumers for you and may not be reimbursed for phone calls or other expenses they may incur on your behalf. There is a cost to advocates for advocating.

Because of PIPEDA regulations, the potential consumer team member recruit will first be contacted by the advocate recruiter to determine if they are interested in participating, and to get their permission to pass his/her contact information to the researcher. When discussing the project, the consumer must receive a clear statement – *in lay language* – of what the research proposes to determine. They must know who the principle investigator is and the other investigators on the team, the proposed time element for the project, the consumer time commitment and what meetings – if any - will take place. Each consumer must be asked – and give permission – to be listed as a participant and consumers must be aware of what is required of him/her prior to agreeing to participate. **Grant proposals should include letters of consent from consumers named in the proposal that include the degree of consumer involvement, any special expertise expected from the consumer and the consumer's contact information.** And there must be opportunity for the potential recruit to ask questions of the PI, or delegated team member(s).

It is important to remember that consumers you recruit are volunteers. They may be unemployed, under-employed or retired, or may be fully employed, but all may have tight schedules. Many have a high degree of expertise in their chosen fields, and most are happy to help. This does not mean, however, that they should be asked to do a job that you would normally pay a professional to do – even if they have the knowledge and skills to do it. To avoid potentially nasty conflict of interest issues, some serious talking needs to happen in any situation where this is a possibility.

Every effort should be made to involve consumers from across Canada, regardless of the location of the principle investigator. To always dip into the same 'gene pool' of consumers in the larger centres risks continued use of 'local' information that may challenge the accuracy or reliability of the results. A wide variety of consumer experience and expertise is required.

Meetings and teleconferences are a given, but sometimes these may interfere with consumer schedules or responsibilities. For instance, 'the boss' may take an understandably dim view of an employee who participates in a conference call on company time, or leaves the office to attend a research meeting. This situation should be anticipated and talked about at the time of recruitment. It may be that juggling schedules and/or a little PR - by both consumer and researcher - may be necessary, with the possible additional benefit of increasing knowledge about arthritis in the workplace. Where in-person meetings are required the consumer may need to travel across town from home or place of employment, and may need assistance with gas and parking, or with commercial transportation. Other consumers may require travel arrangements, hotel accommodation and food if they must travel from more distant locations.

As we said at the outset, we don't have all the answers. Also, we have only identified the major problem areas and hit the high spots. It's a beginning. Now, in the finest tradition of KTE, we want your feedback. What are your views, your experiences with consumers – good, bad and indifferent? What are your comments and suggestions about the expectations and responsibilities of consumers in research?

Anne Dooley, CAC Allied Member and CAPA Research Chair,  
in collaboration with the members of CAC.

Acronyms used:

ACE	Arthritis Consumer Experts
ARC	Arthritis Research Centre of Canada
CAC	Consumer Advisory Council (of the Canadian Arthritis Network)
CAB	Consumer Advisory Board (of the Arthritis Research Centre of Canada)
CAN	Canadian Arthritis Network
CAPA	Canadian Arthritis Patient Alliance
KTE	Knowledge Transfer and Exchange
PI	Principle Investigator
TAS	The Arthritis Society
TEC	Training and Education Committee

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