Tri-Council Policy Statement
Ethical Conduct for Research Involving Humans

1. Province: Ontario, Canada

2. Affiliation: Independent health researcher (see attached inventory of references)

3. Submission of comments: Published Health Researcher

4. Main discipline: Health Sciences

I agree to have my comments posted.

The Tri-Council team enjoys a high order of expertise and ethical values.

I am sharing my research experiences for your consideration regarding a complex research subject, i.e., risk to human health associated with industrial wind energy development.

I agree with the Tri-Council’s acknowledgement that ethics evolves and appreciate the opportunity to contribute to the proposed revisions.

Purpose of this submission:

- to share experiences regarding the complexities of researching the topic of industrial wind energy facilities and risk to health;
- to discuss opportunities to consider these factors;
- to consider rural residents as a vulnerable population group; and
- to consider enhancing the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans ethical requirements, including that of disclosure for informed consent.

Proposals

Smith (2016) commented in the British Medical Association Blog about what questions potential research participants should ask when invited to participate in a clinical trial. Some interesting points were raised such as “whether the trial will be published together with the full dataset so that everybody can access the results and reanalyse and reuse the data”; Smith suggested if the answer is no to any part of this question, the patient decline to participate. Another consideration is whether “the trial addresses a question that is clinically or scientifically important and will benefit other patients”. He indicates the hardest question is “will the trial provide a confident answer to the question being asked?”

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1 Smith R (October 21, 2016). What should a patient ask before entering a clinical trial?
British Medical Journal Blog.
These comments provide useful guidance for considering the following proposals towards enhanced disclosure for informed consent and to assist with managing expectations of research participants.

- identify known research/knowledge gaps which are not yet resolved;

- emphasize risk/benefits risks of exposure associated with the study;

- to assist with managing expectations, emphasize participants of the limitations of the research outcomes;

- consider rural populations in Canada as a vulnerable population group as they are bearing the burden for renewable energy being imposed on residents who are non-participants in a renewable energy project, without consent;

- ensure that all government funding support associated with the research is declared;

- since typically ethical decisions are not shared either through an Freedom of Information request or other process, consider enhancing transparency associated with the ethics approval process;

- clarify the ownership of data, both from the point of view of the research participants and that of the researcher and University;

- in order to contribute towards improved research designs and ethics review, ensure that both the researchers and peer reviewers have an understanding of the research challenges and variables.

I trust these observations and suggestions are helpful for enhancing the understanding of the research challenges and knowledge/research gaps associated with wind energy research, and will contribute towards considering these factors during the ethics approval process while assisting with future research on this topic.

I have provided reference sources in support of my suggestions.

**Background: Carmen Krogh, BScPharm (retired)**

As background, I am a retired pharmacist from Ontario and have been researching adverse health effects associated with industrial wind energy development since October, 2008. I am an independent, full time volunteer and published researcher and share information with: communities; individuals; researchers; federal, provincial and public health authorities, wind energy developers; the industry; and others. Other activities include: an author / co-author of peer reviewed articles and of conference papers presented at wind turbine noise scientific conferences and other references relating to this complex topic; numerous invited presentations to community groups in California, Vermont, Massachusetts, Alberta, Saskatchewan, Ontario, Quebec, and Nova Scotia;
presentations to the Standing Committee, Green Energy Act, Ontario (2009), Canadian Centre for Health and Safety in Agriculture Research Seminar, University of Saskatoon, Saskatchewan (2011), Government of Canada Standing Senate Committee on Energy, the Environment and Natural Resources (2011) and the House of Commons Standing Committee on Health (2015).

During my career, I have held senior executive positions at a teaching hospital (Edmonton, Alberta), as a drug information researcher (Ottawa, Ontario), a professional organization (Ottawa), and Health Canada (PMRA - Ottawa). I am a former Director of Publications and Editor in Chief of the Compendium of Pharmaceuticals and Specialties (CPS), the book used by physicians, nurses, and health professionals for prescribing information in Canada.

Appendix A provides a brief summary of Krogh publications and other references related to wind energy health research. It is not exhaustive and does not include the numerous community group presentations and meetings held with Federal, Provincial, Municipal and various environmental and health authorities.

Background: industrial wind energy research

The topic of exposure to wind energy facilities and the risk to human health is controversial and debated globally. Due to the many variables, conducting human health research associated with wind energy development is complex.

Ethical considerations evolve. Since it is expected future research on this topic will occur, there is an opportunity to consider the current research/knowledge gaps and challenges during the revision process of the Tri-Council Ethical Conduct for Research Involving Humans.

Risk of harmful exposures to wind energy development has been known for some time. Based on international research, some rural family members living in proximity to wind facilities are reporting adverse health effects such as sleep disturbance, effects on quality of life, annoyance and shadow flicker. Research indicates

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occupational workers in the field of industrial wind energy can also be negatively affected. In some cases, families residing in proximity to IWTs have effectively abandoned their homes, been billeted by wind project developers or
successfully negotiated financial agreements with developers.\textsuperscript{23} Audible and inaudible noise, visual impacts, stray voltage and socio-economic impacts are identified as plausible causes of adverse effects.\textsuperscript{24} Some have lost trust in government processes and are sensitive to social injustice.\textsuperscript{25}

The Ontario government established a renewable energy policy\textsuperscript{26} and funded studies that researched the potential outcomes of the exposures.\textsuperscript{27}

While research participants can opt out of research, in the case of wind energy exposure, unless they remove themselves from the exposure, they remain in a potentially harmful environment. During clinical trials, the Principal Investigator can stop the experiment or exposure; however, wind turbine researchers are unable to do so.

In Ontario, industrial wind energy facilities are imposed without consent on residents who are non-participants in the project by governmental policy and statute.\textsuperscript{28} However, those who are participating in a project, typically through contractual agreements agree to accept/consent to potential risk factors such as increased noise, nuisance, and shadow-flicker.\textsuperscript{29}

A number of knowledge gaps regarding the health and safety of residents associated with wind energy development were identified by the Ontario Chief Medical Officer of Health (2010)\textsuperscript{30}, Rideout et al (2010),\textsuperscript{31} and the Council of Canadian Academies (2015).\textsuperscript{32}

\begin{thebibliography}{10}
\url{http://www.ncbi.nlm.nih.gov/pubmed/24398354}.
\url{http://bst.sagepub.com/content/31/4/321}.
\url{https://www.ontario.ca/laws/statute/09g12}.
\url{http://cou.on.ca/articles/cou-announces-new-ontario-research-chairs-in-environmental-science/}.
\bibitem{28} Green Energy Act, 2009. S.O. 2009, CHAPTER 12, SCHEDULE A.  
\url{https://www.ontario.ca/laws/statute/09g12}.
\bibitem{29} Sample contract available on request.
\end{thebibliography}
In addition, in 2011 Health Canada drafted interim guidelines on IWT noise.\textsuperscript{33} However, the guidelines were not released due to lack of agreement by all members of the working group regarding the overall content of the draft voluntary guidelines.\textsuperscript{34} In 2012, during a presentation to Health Canada’s Science Advisory Board, Health Canada representatives commented: “Place hold on Guideline finalization. HC will explore research options and release guidelines only when knowledge gaps are filled.”\textsuperscript{35}

Many of the knowledge gaps associated with human health research remain unresolved. Some residents have indicated a perception of feeling like “lab rats”\textsuperscript{36} or “guinea pigs”\textsuperscript{37} As well, some have requested to stop experimenting on humans\textsuperscript{38} without their consent.\textsuperscript{39, 40}

**Human variables/knowledge gaps include:**

The variety of individual human responses in general and risk factors to various emissions such as: audible and inaudible noise - low frequency/infrasound, tonal, etc, radio/electromagnetic energy); noise sensitivity; a variety of pre-existing medical conditions (cardiac, immune disorders, migraine etc); vulnerable population groups (rural, children, elderly, those with pre-existing medical condition including special needs); prevalence of abandoned homes; lack of vigilance monitoring and long term surveillance; lack of metrics regarding intensity and length of time of exposure; lack of research on risks associated with acute and chronic exposure; and social-economic impacts on rural communities and residents (property values and costs of electricity).

**Wind turbine variables/knowledge gaps and their role on human responses include:**

The variety of industrial wind turbines available and the diversity of their siting and operational processes such as: brand/trade models and blade design; the range of

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\textsuperscript{34} Krogh personal correspondence (February 6, 2012). Health Canada. Assistant Deputy Minister Geller.


\textsuperscript{38} Horner B (March 21, 2013). Request that the Government of Canada discontinue Health Canada’s ongoing experiment on Canadians exposed to wind turbines. \url{https://mothersagainstturbines.files.wordpress.com/2013/09/request-stop-health-canada-experiment-on-canadians-march-21-2013.pdf}

\textsuperscript{39} Anne Cat, (November 12, 2013). Experiment: Falmouth Wind Turbines. \url{http://anne12.bloggles.info/2013/11/12/falmouth-wind-turbines/}

MWatt (sound power); wind speed and direction in relation to a family home; prevailing winds; seasonal (spring, summer, fall, winter); atmospherics (rain, fog, snow); siting array and density (number of turbines) near family homes; siting distances from homes; population density; terrain (hilly, flat, soil composition); noise guidelines and compliance limits established by authorities; noise standards and methodologies for assessing operational status and emissions (low frequency/infrasound, amplitude modulation, tonal, night time abatement, rural ambient noise); house construction; use of predictive noise models verses actual noise measurements; acoustical measurement challenges; and local and other policy conditions.

Ownership of raw study data is unclear. I am in contact with a family who participated in one of the government sponsored studies and have requested the raw data related to their home only. It appears to be denied due to confidentiality concerns. However, the family has no interest in obtaining any data other than that which were generated during their participation. The disclosure agreed to by the family for informed consent did not appear to consider data ownership, both from the standpoint of the research participant and that of the researcher/institution.

There is an opportunity to clarify data ownership and/or the sharing of personal data during the disclosure for informed consent.

There is a perception of inequity between rural and urban residents. Industrial wind turbines are typically installed in quiet rural areas with low population densities. Wind turbine-specific prevalence information is limited and is complicated by the limited population densities in rural areas as compared to urban. For example, a square kilometre of an urban area sampled indicates a population of about 6,100 while several random samples of a square kilometre taken in an operating wind facility indicates 9 people and 6 (2 of them children). However, when one considers population densities and the typically low ambient noise levels in rural areas, the use of urban comparisons may distort the results. These differences should be factored into the research design and reporting of outcomes. An addition knowledge gap is that children, which includes all stages of development (fetus to youth), have yet to be studied regarding wind energy. Children were excluded in the Health Canada wind turbine noise and health study.\(^{41}\) Research on other vulnerable population groups such as the elderly, those with pre-existing medical conditions and/or special needs is also lacking.

Health Canada presented its study design to the Science Advisory Board (SAB) and were advised “Don't waste time on measuring the prevalence of reported health effects from wind farms; assume that they are going to proliferate in the future. There doesn't seem to be value in trying to gauge the annoyance factors associated with aesthetics of the turbines, rather the important thing is to measure the health effects due to noise.”\(^{42}\)

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Research indicates some numbers which are helpful regarding risk factors. If the examples of the indicators below were applied to an urban area, it is likely there would be concerns about the risk of exposure.

Janssen et al (2011) conclude: “... regions with a highest allowed immission level of 45 dB(A) equivalent level [corresponding to Lden 49.7 dB(A) in this study] such as Denmark could expect less than 14% of the exposed population to be highly annoyed indoors by wind turbines and less than 29% to be highly annoyed outdoors.\(^{43}\)

The Ministry of the Environment of Ontario, Canada commissioned a low frequency noise review which concluded the sound from wind turbines, at the levels experienced at typical receptor distances in Ontario, Canada was expected to result in a non-trivial percentage of persons being highly annoyed and that research had shown that annoyance associated with sound from wind turbines can be expected to contribute to stress related health impacts in some persons.\(^{44}\) During an Ontario Environmental Review Tribunal, the author of the low frequency noise review was qualified as an expert and testified under oath. He stated: “...two or three fairly comprehensive studies in Europe on annoyance versus sound levels, they have found that in the range of about 35 to 40 dBA...about six percent of people will be annoyed or very annoyed, as the term is considered, and above 40 dBA, that number jumps to about 20 percent” [p. 189].\(^{45}\) The author also agreed during testimony that six percent is “not trivial” [p. 257].

Annoyance may seem of little consequence in everyday language; however, in terms of health, the term annoyance is acknowledged as an adverse health effect.\(^{46, 47, 48, 49}\)

Health Canada’s comments on its 2.1 million dollar wind turbine noise and health study indicates the challenges associated with this topic:

... the results will not provide a definitive answer on their own.\(^{50}\)

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... this design does not permit any conclusions to be made with respect to causality.\textsuperscript{51}

... results may not be generalized to areas beyond the sample as the wind turbine locations in this study were not randomly selected from all possible sites operating in Canada.\textsuperscript{52}

These factors have challenged the research and ability to obtain resolution. Due to the range of variables associated with the operations of wind energy facilities, the knowledge gaps and associated research challenges, ethical considerations regarding this research appear to be evolving.

Again, thank you for this opportunity to comment on the revisions for conducting ethical research.

Respectfully,

Carmen Krogh, BScPharm (retired)
Submitted February 17, 2017.

APPENDIX A

Summary of references: Carmen Krogh, February, 2017

Peer reviewed


Robert Y McMurtry and Carmen ME Krogh, Diagnostic criteria for adverse health effects in the environs of wind turbines.
http://shr.sagepub.com/content/5/10/2054270414554048.

\textsuperscript{52} Michaud DS. Self-reported and Objectively Measured Outcomes Assessed in the Health Canada Wind Turbine Noise and Health Study: Results Support an Increase in Community Annoyance. Proceedings InterNoise 2015, San Francisco (August).


Canadian Medical Association Journal (CMAJ) Blog


Western University: From the Selected Works of Grace L Howell


Seminars

Krogh C. Industrial Wind Turbines and Health: A Case Study (December 6, 2011). Canadian Centre for Health and Safety in Agriculture Research Seminar. University of Saskatoon, Saskatchewan.

Krogh C. Harm from Wind Turbines: What has been known for decades (May 7, 2014). University of Waterloo Seminar. Ontario.

Krogh C. Industrial wind turbines can harm humans (October 31, 2016). Ryerson University, Ontario.


Government Hearings


Krogh C and Harrington B (October 18, 2011). Standing Senate Committee on Energy, the Environment and Natural Resources. Industrial Wind Turbines and Health. Wind Turbines Can Harm Humans.


53 Carmen Krogh (retired), is a peer reviewed IWT health researcher and former Director of Publications and Editor-in-Chief of the CPS.
54 Dr. McMurtry is Professor Emeritus (Surgery) of Western University (formerly University of Western Ontario). Dr. McMurtry was also an ADM at Health Canada 2000-02
Conference papers


Wind Turbine Facilities’ Perception: A Case Study from Canada Peter N. Cole MD, MHSc, FRCP(C) and Carmen Krogh, BScPharm 5th International Conference on Wind Turbine Noise Denver 28 – 30 August 2013 (published in proceedings but not presented).


Carmen ME Krogh, Roy D Jeffery, Jeff Aramini, Brett Horner, Wind turbines can harm humans: a case study, Paper presented at Inter-noise 2012, New York City, NY.


Carmen ME Krogh, Roy D Jeffery, Jeff Aramini, Brett Horner, Annoyance can represent a serious degradation of health: wind turbine noise a case study, Paper presented at Inter-noise 2012, New York City, NY.