

Clinical Equipoise and Notions of Expertise: How Law May Inform Ideas in Ethics

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Introduction

Ideas regarding the notion of “expertise” and what it means to be an “expert” traditionally have been discussed in the field of law where courts and jurists have contemplated the admissibility of testimony proffered by witnesses called as experts in a given field. In these cases, judges have applied rules of evidence to assess whether the trier of fact can consider the expert witness’s opinions.¹ Once it is established that a witness’s testimony complies with these rules, it will be admissible, and the judge or jury will be allowed to consider and weigh this opinion, along with all other evidence presented during the trial, to decide the case.

Questions related to the meaning of expertise are interesting not only from a legal standpoint, but also from the standpoint of bioethics. Research ethics boards (“REBs”) in Canada and institutional review boards (“IRBs”) in the United States devote their time to deliberating the ethics of research proposals submitted to them by scientific investigators. The role of these bodies is to ensure that the proposed research meets ethical standards and does not jeopardize the health or safety of research subjects. This usually involves asking questions about the risks and benefits involved in participation or non-participation, and about the competency of the subjects to provide their informed consent.

In a randomized clinical trial, another issue of concern to the REB is ensuring that a state of clinical equipoise exists concerning the relative merits of two or more treatments. In such trials, a patient/subject is randomly assigned to a “treatment arm” of the trial in which he or she may receive one of several selected treatments, or a placebo. In such cases, chance determines the treatment that the subject receives (or non-treatment if he or she receives a placebo) rather than the physician’s opinion about what would be the most therapeutic or beneficial treatment.

To ensure that such randomized clinical trials are ethical, REBs must be certain that a state of “clinical equipoise” exists. The notion of clinical equipoise, introduced by Freedman, requires a genuine uncertainty within the expert community as to whether any of the treatments administered in a randomized clinical trial is to be preferred over the other(s).² Pursuant to this principle, REBs must assess the sentiment of the expert professional community as a whole, rather than just the personal opinion of the individual clinical investigator, to decide whether the trial is ethical.

Although Freedman’s definition of clinical equipoise is central to an REB’s assessment of a randomized clinical trial, the operationalization of this principle is challenged by the ambiguity surrounding who should be included in the “expert” community.³ Gifford has noted the inherent difficulty involved in trying to ascertain what is meant by a “community of experts”, yet has not attempted to define this concept.⁴

Notions of expertise also become significant for REBs in two other circumstances. First, the REB’s overall ethical assessment should include an evaluation of whether the clinical investigator is properly qualified to devise and execute the proposed research. As such, part of an REB’s task is to determine whether this individual possesses the expertise necessary for carrying out the research under review. A second scenario involves the REB’s evaluation of its own expertise. When assessing the ethical merit of a protocol, the REB members, as a group, must be able to understand all of its elements. Although an individual REB member may not grasp the protocol in its entirety, REBs usually are composed of members with diverse backgrounds and professions so that the group will have the collective expertise required to understand and review protocols that come before it. Yet, what if an REB were faced with a protocol that was not fully comprehensible to its members? Should the REB rely on its own expertise as it normally would, or should it call on an “outside expert” on the

relevant topic for assistance? At the present time, it is unclear whether these questions are being raised by REBs in Canada and IRBs in the United States. Nevertheless, because the REB's own expertise may be fundamental to assessing the ethical merit of clinical research, it will be considered as another context in which an REB may grapple with the meaning of expertise.

This brief overview provides a glimpse of three situations in which questions about expertise may become important to REBs. Yet, as discussed above, the bioethics literature provides little guidance for understanding the meaning of this concept. As a student trained in law with an affinity for bioethics, I am interested in asking whether questions that REBs may raise about expertise could be informed by the prolific discourse on this topic within legal circles. I therefore discuss three contexts in which courts and jurists have examined the notion of "expertise" that are analogous to those in which REBs may deal with this concept: the "expert opinion-giver", the "expert community" and the "expert decision-maker".

Although these three legal paradigms of expertise are instructive for REBs seeking to devise a working definition of this concept, this paper also discusses problematic aspects of the legal model of expertise. The way in which the law understands what it means to be an expert is often ambiguous and vague, causing frequent inconsistencies in the ideas advanced by courts and jurists on this topic. The identification of these difficulties is not intended to suggest that the legal model cannot be useful for REBs. While its legal definition requires refinement and clarification, expertise remains a necessary concept in law. Thus, although not flawless, the legal model of expertise may provide bioethicists with insight and guidance for crafting a definition essential for REBs evaluating randomized clinical trials.

Part I: The "Expert Opinion-Giver"

In North America, the trial process is designed to be adversarial in nature, with each party to presenting its own version of facts and arguments. Their propositions may be supported by real evidence (i.e., physical objects), or testimonial evidence (i.e., information provided by witnesses). One of the basic rules of evidence in North America is that testimonial evidence must be fact-based and restricted to recantations of the witness's first-hand observations. Therefore, although a witness may testify to something he or she said, heard, saw or did, he or she may not provide an opinion on the information provided. It is believed that the right and responsibility of drawing

inferences belong solely to the trier of fact (that is, the judge or the jury), and these would be usurped by allowing witnesses to deliver opinion evidence.

While the general prohibition against opinion evidence appears well-founded in the majority of cases, this would not be true where a case involves facts and issues that are very complex and beyond the comprehension of the average person. Therefore, parties may call in witnesses with the necessary expertise to explain certain information to the judge or jury. In these circumstances, restricting the witness's testimony to facts and personal observations would not be helpful, as the resultant testimony would still be meaningless and unintelligible. This "expert" witness thus will be required to draw an inference on the information he or she provides, if the trier of fact does not have the knowledge to do so independently. For this reason, an exception to the general rule against opinion evidence exists with respect to the testimony of experts.

Experts may provide opinions on the facts to which they testify wherever it is found that the average judge or juror would not be able to understand the facts or the evidence without their assistance. This rule is the same in the U.S. and in Canada. In the U.S., it is established by the Federal Rule of Evidence 702⁵ which allows expert testimony to be heard where it "will assist the trier of fact to understand the evidence or to determine a fact in issue." In Canada, the Supreme Court decided in *R. v. Abbey*⁶ that where a matter calls for "special knowledge", an expert is entitled to draw an inference and state an opinion. Expert testimony is considered necessary where it enables the trier of fact to form its own conclusions where it would otherwise be unable due to the technical nature of the information likely to be outside its experience and knowledge.⁷

a) Qualification of an Individual Expert in the Court

Expert evidence becomes an issue in a court of law whenever its admissibility is debated. In Canada and the U.S., the laws related to the admissibility of evidence focus on the qualities of the opinion, rather than those of the opinion-giver. Therefore, while courts have provided long discourses regarding the necessary characteristics of admissible expert *testimony*, there is scarcely any discussion concerning the necessary qualifications one must possess to be considered an expert *witness*. Nevertheless, a review of the leading North American cases on the issue of expert evidence is instructive and sheds some light on how courts and jurists consider the question of qualifying the expert opinion-giver.

i. The American Position

The first formulation of a special rule applicable to expert evidence appeared in the case of *Frye v. United States*,⁸ where a trial court refused to allow the results of a “systolic blood pressure deception test”, the test which preceded the polygraph, into evidence. This holding was confirmed on appeal where the Federal Court adopted the following principle regarding expert evidence:

Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stage is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained *general acceptance* in the particular field in which it belongs.⁹

This rule, although rapidly adopted as the test for determining whether or not a scientific principle proffered by an expert was admissible,¹⁰ was challenged in several respects. First, although it established a standard for determining the admissibility of an opinion proffered by an “expert”, that is, “general acceptance”, it did not discuss whether any qualifications were necessary before a witness could be considered an “expert”. Second, the test addressed only scientific evidence, implying that expert testimony would be necessary only where a case involved a scientific issue that a lay judge or a juror could not understand without explanation from an expert. Finally, the test failed to define the meaning of “general acceptance” and did not indicate how a court should go about identifying the expert community which must be in agreement with the proffered testimony.

The rule in *Frye* continued to operate as the prevailing standard for admissibility of expert evidence until the U.S. Federal Rules of Evidence were adopted in 1975. Rule 702 of the Rules governs the admissibility of expert testimony and provides that:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise.¹¹

Unlike the rule in *Frye*, Rule 702 affirms that the witness presented as an expert must be qualified. Moreover, although *Frye* suggested that the qualifications could be based on scientific knowledge only, Rule 702 establishes that an expert’s opinion can be based on “scientific, technical or other specialized knowledge” which may derive from “skill, experience or training.”

The issue of whether the Federal Rules of Evidence superseded the *Frye* rule was never made clear. Neither the text of the Rules themselves, nor the relevant congressional committee reports address whether Congress had intended for the Rules to perpetuate or to eliminate *Frye*.¹² Although most judgments rendered after 1975 held that the *Frye* test continued to determine the admission of expert testimony, others had abandoned the test in favour of the Federal Rules of Evidence.¹³

This ambiguity was laid to rest by the U.S. Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*¹⁴ The case involved a suit by infants and their guardians against Dow Pharmaceuticals to recover for birth defects allegedly sustained by maternal ingestion of Bendectin, an anti-nausea drug, during pregnancy. While Dow’s experts concluded that maternal use of Bendectin was not proven to be a risk factor for human birth defects, eight experts for the petitioners testified that Bendectin could cause birth defects.

At trial,¹⁵ testimony proffered by the petitioners’ experts was found inadmissible given that the opinions presented were not published nor subject to peer review. The U.S. Court of Appeals affirmed this decision.¹⁶ Citing *Frye*, the Court of Appeals stated that expert opinion based on a scientific technique is inadmissible unless it is generally accepted as reliable in the expert community.

These rulings were overturned by the U.S. Supreme Court which held that the “general acceptance” standard in *Frye* was no longer good law. Rather, it had been replaced by the Federal Rules of Evidence which do not require that an opinion be known to absolute certainty in order for it to be the basis of expert testimony. According to the Court, the inference or opinion proffered by the expert was admissible provided that it was “derived by scientific method”, and “supported by appropriate validation – i.e., ‘good grounds,’ based on what is known. In short, the requirements that an expert’s testimony pertain to ‘scientific knowledge’ establishes a standard of evidentiary reliability.”¹⁷

The Supreme Court also discussed how a trial judge can determine whether proposed scientific testimony is indeed reliable and “derived by scientific method”. It established four techniques for testing the reliability of a given opinion

or theory, including: (i) its subjection to empirical testing, (ii) its submission for peer review and publication, (iii) its known or potential rate of error, and (iv) its rate of acceptance within a relevant scientific community. These factors or techniques became known as the “*Daubert* factors.”

Daubert appeared to create a thorough, yet flexible, test for assessing the reliability of scientific evidence. Yet, while the court fully addressed the issue of what qualities are necessary for the admissibility of expert testimony or *opinion*, it failed to discuss whether the *opinion-giver* must also have any specific qualifications. This could be interpreted as implying that so long as an opinion satisfies the *Daubert* factors, it should be considered admissible expert testimony, even if the witness is not qualified as an expert.

However, a review of American judgments dealing with the issue of expert testimony rendered after *Daubert* indicates that the courts do in fact consider the professional qualifications and skills of witnesses called as experts. In these cases, courts begin their judgments by discussing the credentials of the expert, in particular, by considering his or her academic and work experience. Here, the prestige of the institutions where the witness received his or her education and/or professional training becomes important to the court’s assessment of his or her qualifications as an expert on a given topic. In addition, courts will consider whether the witness and his or her ideas are renowned in his or her professional field. Judicial discussions on the qualifications of an expert witness generally are brief and descriptive, devoid of any analysis on the type of expertise required to provide opinion evidence in a given case. Nevertheless, the fact that the judges initiate their inquiry into the issue of expert testimony by considering the witness’s qualifications indicates the significance of this issue to the courts.¹⁸

Support for this view is found in the U.S. Court of Appeals decision in *Moore v. Ashland Chemicals*¹⁹ which ruled that although the Supreme Court’s decision in *Daubert* did not raise the issue of qualifying the expert opinion-giver, this does not overrule the U.S. Federal Rules of Evidence. The Court pointed out that pursuant to Rule 702, the expert called as a witness must be qualified “by scientific, technical or other specialized knowledge”, by reason of his or her “knowledge, skill, experience, training or education.”²⁰ Therefore, although it is not central to their discussions regarding the admissibility of expert evidence, American courts are bound by statute to ensure that a witness called as an expert has the requisite qualifications to provide an enlightened opinion on the matters in issue.

ii. The Canadian Position

In contrast to the approach adopted by U.S. courts, Canadian judgments dealing with the issue of expert testimony have devoted a significant amount of attention to examining the qualifications a witness must have to be called as an expert opinion-giver. Rather than considering whether his or her opinion meets specific requirements to be considered expert testimony, Canadian courts instead have focussed on whether the witness’s knowledge and experience truly qualify him or her as an expert in a given field. “Expertise” in Canada has been defined as a “modest status achieved when the expert possesses special knowledge and experience going beyond that of the trier of fact.”²¹ From this definition, we see that the Canadian legal view of expertise is broader than the one suggested by the key U.S. cases of *Frye* and ...*Daubert*, as it extends to scientific and nonscientific opinions alike, and to opinions based on knowledge acquired by education or by experience.²²

As part of their consideration of the witness’s qualifications, Canadian courts have stressed the importance of ensuring that the opinion provided falls within the scope of his or her experience.²³ Courts have recognized that although a witness may be properly qualified as an expert, if his or her testimony is beyond his or her training and experience, the witness should no longer be considered an “expert”. In such cases, the general rule against opinion evidence delivered by lay individuals should apply, and the testimony should be ruled inadmissible.²⁴

Furthermore, although Canadian courts have spent far less time than their American counterparts deliberating the scientific merit of expert evidence, scientific reliability has become an issue in some cases, particularly where the evidence is based on a novel or non-traditional scientific theory. For example, in *R. v. Neilsen and Stolar*,²⁵ the court admitted testimony regarding footprint analyses taken from a crime scene even through the scientific validity of this technique was not universally accepted. The Court found this acceptable given that the witnesses confined themselves to their respective areas of technical expertise without advancing any specific scientific theory.²⁶

In *R. v. Mohan*,²⁷ a psychiatrist was called to testify to the personality traits that would be possessed by the perpetrator of the crime of which the defendant was accused. At trial, this evidence was ruled inadmissible, in part because of a lack of scientific data available to support the expert’s conclusions. This decision was upheld by the Supreme Court of Canada in a judgment which directed trial courts to shift their focus from evaluating the expertise of the witness to assessing the legal admissibility of the testimony. Trial courts thus were instructed to concentrate on the



characteristics of the proffered *opinion* rather than the qualifications possessed by the *opinion-giver*. In *Mohan*, the Court enumerated four requirements for the reception of expert evidence in Canada. According to Sopinka J., the evidence must be (i) relevant to a fact in issue, (ii) helpful to the trier of fact, (iii) not excluded by a rule of evidence, and (iv) delivered by a properly qualified expert. This new perspective which insisted that the expert evidence be necessary and reliable bears some similarity to the approach of the U.S. Supreme Court in *Daubert* which focuses on the “scientific reliability” of the proffered testimony. Indeed, Professor Delisle has maintained that “the court in *Mohan*, with no citations to either of the United States cases [i.e., *Frye* and *Daubert*], or to the longstanding controversy, has implicitly adopted the current United States position.”²⁸

Nevertheless, an important distinction between the American and Canadian perspectives on the issue of expert evidence remains. The U.S. Supreme Court in *Daubert* made no mention of what weight, if any, a witness’s qualifications should bear on a trial court’s assessment of the admissibility of expert evidence. In contrast, although the *Mohan* decision indicated that a witness’ qualifications should not be the sole preoccupation of a Canadian trial court, this factor remained one of the Supreme Court’s key considerations in determining the admissibility of such evidence.

Despite this, the Supreme Court in *Mohan* provided little guidance for assessing whether an expert is “properly qualified”, stating only that the evidence must be given “by a witness who is shown to have acquired special or peculiar knowledge through study or experience in respect of the matters on which he or she undertakes to testify.”²⁹ This definition of expertise incorporates all types of knowledge (i.e., both scientific and nonscientific) and recognizes that it may derive from academic endeavours or through experience. As such, it appears to perpetuate the broad notion of “expertise” traditionally found in the Canadian legal context.

Canadian judgments after *Mohan* interpreted Sopinka J.’s brief definition of a “properly qualified expert” and elaborated on the techniques courts may employ to determine the expertise of a witness. In *R. v. Bernardo*,³⁰ the Court, in applying the *Mohan* criteria, had to determine whether four psychiatrists who advanced four different psychiatric theories were “properly qualified experts”. The court enumerated three factors it used to conclude that the witnesses were indeed qualified experts. First, it found that the witnesses had been qualified to give expert testimony in the past. Second, the court looked at the *curriculum vitae* of each witness. Finally, the court mentioned that the theories

they advanced were part of “a valid and recognized area of science”.³¹

The discussion of expertise in *Bernardo*, albeit brief, appears to combine the Canadian and American positions on the issue of expert testimony. In considering their prior experience as “expert witnesses” and *curriculum vitae*, the Court seems to follow the Canadian view that a witness’s expertise should be assessed by examining his or her training and/or experience. Yet, by discussing the scientific validity of the testimony, the court here appears to be influenced by the *Daubert* principle that the proffered theory of inference must be scientifically reliable to be admissible.

iii. Assessing the Meaning of the “individual expert” in American and Canadian Law

The following points summarize the analysis undertaken by American and Canadian courts in the context of the “expert opinion-giver”.

- The first question a court should ask is whether the expert possesses the scientific, technical or other specialized knowledge to assist the judge or jury in understanding the evidence or the facts in issue.
- This knowledge may derive from the knowledge, skill, experience, training or education of the witness. Therefore, the court must undertake a global evaluation of his or her credentials that includes an examination of academic background and personal experiences which may or may not derive from his or her professional activities.
- Once the court ascertains that the witness is properly qualified as an expert, it must proceed to ensure that the proffered opinion or inference is within the realm of his or her area of experience.
- If the testimony exceeds his or her domain of proficiency, then the witness should no longer be considered an expert on the information that is the subject of the testimony. As such, the general prohibition against opinion evidence should apply and the testimony should be ruled inadmissible.
- If the witness is properly qualified as an expert and the testimony remains within the limits of his or her expertise, the court must still verify that the proffered opinion is reliable.
- In the U.S., if the opinion or inference is one based on “hard science”, then the *Daubert* factors are applicable to assess its scientific reliability. If the *Daubert* factors cannot be applied, for example, where the testimony is based on clinical medical opinion, then the court should ask whether the opinion is soundly grounded in the principles and methodology of the discipline.³²

- In Canada, pursuant to *Mohan*, the court also will ensure that the opinion is necessary and reliable. This will be assessed by comparing the testimony to the general sentiment in the expert community.

b) Utility of this Analysis to an REB

The analysis of the meaning of expertise within the framework of the expert opinion-giver might be helpful to an REB wishing to assess the expertise of investigators who have submitted a research proposal for ethics review. Both the expert witness and a clinical investigator must instruct those assessing their ideas (i.e., the trier of fact or the REB) about the hypotheses they advance. Their role as instructors is not limited to the provision of factual information, but also includes inferences and opinions they have derived based on their respective areas of specialization. In this regard, the expert witness and the scientific investigator also share a role as advocates. While their reasons for promoting their theories differ, both present their opinions and ideas for the purpose of convincing their assessors to accept their hypotheses.

These similarities suggest that the scientific researcher, like the expert called during a legal proceeding, also can be considered an “expert opinion-giver”. Therefore, the REB faced with assessing the investigator’s qualifications could follow the steps outlined above in order to complete this evaluation. Its analysis might proceed along the following lines:

- The REB should begin its inquiry by evaluating the investigator’s professional credentials and skills to discover, at the outset of its investigation, whether the researcher and/or research team is properly qualified to formulate the protocol and carry out the proposed research. This should entail, at the very least, reviewing all candidates’ *curriculum vitae* (which, in the majority of cases, is done by REBs currently in place), but may also include interviews with investigators to gain more information about their academic qualifications, practical experiences, and ideas.
- In addition to having “expertise” in a given field, the investigator also must be properly qualified to carry out the research in question. Therefore, the REB should ensure that the proposed research is within the scope of the investigator’s realm of expertise. If it is not, then the proposal should either be rejected or the research team should add an investigator with the necessary expertise.
- Finally, the REB must assess the scientific reliability of the proposed research. If the research is based on

scientific knowledge, as will be true for clinical trials, it would be helpful for an REB to apply the *Daubert* factors in this part of its evaluation. This applies even to Canadian REBs even though *Daubert* is not part of Canadian law, given that it appears to be the soundest test for assessing the reliability of proposed research.³³

As discussed earlier, the *Daubert* test is based in part on asking questions about how a theory or inference is perceived by the relevant expert community. As such, the court or the REB must first identify the members of this community before it can apply this test. The very same question of who should be included within the expert community also arises when REBs seek to determine the state of clinical equipoise on proposed treatments. In these circumstances, the legal paradigm of the “expert community” could be a useful model upon which REBs might base their inquiries.

Part II: The “Expert Community”

a) The Meaning of the “Expert Community” in the Legal Arena

In this section, the way in which the “expert community” has been defined in the law is assessed. Throughout the discussion, the legal paradigm of expertise is criticized because of the ambiguous interpretation it has been given by courts and legal academics. These difficulties are identified as part of a critical analysis of the legal concept of an “expert community”. Yet although this paradigm requires revision and clarification, the ideas on this topic articulated by jurists nevertheless may be helpful to REBs that must identify the “expert community” to determine whether there exists a state of clinical equipoise within it.

i. The rule in *Frye*: in which community is “general acceptance” of the evidence necessary?

Assessing the reliability of expert opinion traditionally has been based on the view that if the opinion is consistent with the thinking of the relevant expert community, then it is reliable. This was the view adopted by the U.S. Federal Court in *Frye* which established the “general acceptance” standard for the admissibility of expert evidence. Yet, one of the main difficulties in *Frye* was that it failed to define what should be considered “general acceptance” in a given field. Does this mean that the opinion expressed must be accepted by all the professionals in the field? By a majority of them? By the most prominent of its members?³⁴ The issue is further complicated by the fact that the *Frye* ruling did not provide any direction for identifying which experts must have

accepted a theory before it may be considered scientifically reliable evidence. In practice, this could lead to unpredictable and problematic results for cases involving expert evidence.

For instance, if an expert witness has a very specialized practice or knowledge in a given field, is it appropriate to consider only the opinions of those who are as specialized, or should the court include the opinions of all members of the witness's profession in general, regardless of their degree or area of specialization in order to assess the reliability of the opinion proffered? As Paciocco and Stuesser note, "[i]f one were to ask sexual assault therapists about the 'science' of repressed memory of sexual abuse, one would get a different answer than if one were to ask many behaviour psychologists."³⁵ In much the same way, finding answers to the question of what is meant by "general acceptance" and who should be included in the "expert community" could be extremely instructive for REBs responsible for assessing the sentiment in a professional community (i.e., whether clinical equipoise exists) vis-à-vis the treatment proposed in a research protocol.

The questions left unanswered in *Frye* were recognized by critics of the rule who frequently argued that the general acceptance test could be reduced to a process of "counting noses" of those the court quite arbitrarily chooses to include within the pertinent field.³⁶ This view was adopted by the Third Circuit Court in *United States v. Williams*³⁷ which pointed out that whether or not "general acceptance" existed depended in each case on who was selected to be included in the "relevant scientific community".

Because the notion of expert community appeared so malleable, the court in *Williams* abandoned this test and instead considered other factors to assess the reliability of the proffered evidence. Five indicators of reliability of a scientific technique were identified.³⁸ These included: (1) its known or potential rate of error; (2) the existence of maintenance standards for the technique; (3) the care and concern with which it has been employed, and evidence that it will not lend itself to abuse; (4) similarity to other types of scientific techniques and results routinely admitted into evidence; and (5) the presence of "fail-safe" characteristics.³⁹

Similarly, in *United States v. Downing*,⁴⁰ the court rejected the *Frye* test as a process of "scientific 'nose-counting'" and instead held that reliability assessment should not require the explicit identification of a relevant scientific community.⁴¹ Yet, while the *Frye* test was rejected, the court went on to say that acceptance by the community was a strong indicator of reliability. Nevertheless, this judgment is devoid of any

discussion concerning whom a court should include when identifying the relevant community of experts.

Canadian courts also were also troubled by *Frye*'s general acceptance standard and thus did not adopt it. In *R. v. Béland*,⁴² Wilson J. preferred a test that considers the relevance and "helpfulness" of the evidence based on its "reasonable reliability".⁴³ Although no Canadian decision has defined the notion of "expert community", the concept has been discussed peripherally in some cases. For example, in *Mohan*, the Supreme Court held that where the scientific community has developed a standard and the expert witness' testimony is consistent with this, the evidence will meet the criteria of necessity and reliability, and will be admissible.⁴⁴ Thus, in *R. v. Lavallee*,⁴⁵ Wilson J. assessed the admissibility of a psychiatrist's testimony concerning Battered Wife's Syndrome by reviewing the academic literature on the topic. Finding the witness's account consistent with the views of prominent members of the North American psychiatric community, his testimony was ruled admissible.

ii. The meaning of "peer review" and "expert community" after Daubert

Although the U.S. Supreme Court's decision in *Daubert* overruled *Frye*'s general acceptance test, the standard which it established to replace the *Frye* rule was also heavily premised on the view that acceptance of a theory by the relevant expert community is a significant indicator of its scientific reliability. Not only did the Supreme Court list "acceptance by the expert community" as one of the four factors that should be used to test reliability, but also held, in discussing peer review and publication, that "scrutiny of the scientific community is a component of 'good science', in part because it increases the likelihood that substantive flaws in methodology will be detected."⁴⁶

Yet, unfortunately, the Supreme Court in *Daubert* did not indicate how a trial court should determine who the members of the expert community are. The Ninth Circuit Court's reconsideration of the case suggests that a professional association might be a source of expertise in a given field and may therefore assist a court in identifying the members of the "relevant expert community."⁴⁷ Moreover, the emphasis on peer review and publication in both the Supreme Court and Ninth Circuit's decisions⁴⁸ suggests that anyone competent to conduct peer review of the study for a reputable journal could be considered a member of the expert community.

However, E.J. Chan identifies two types of peer review: "true peer review" and "editorial peer review", and draws

important distinctions between these.⁴⁹ “True peer review” involves the replication and testing of research results by other scientists after the initial results of a test have been published. The repeated confirmation of results by testing them through peer review allows for the certification of the scientific reliability of a hypothesis, and is the point from which scientific progress can occur.⁵⁰ In contrast, editorial peer review occurs where the members of a professional body provide opinions on a work submitted for publication in a journal or publication.⁵¹

Yet, this distinction does not appear to have been recognized by the courts, not even in the leading case on the assessment of the scientific reliability of expert opinion. In *Daubert*, the U.S. Supreme Court used the term “peer review” in a general manner as one of the criteria for testing the reliability of an opinion proffered by an expert. The Court’s failure to distinguish between “true” and “editorial” forms of peer review may suggest that, if an opinion has been subjected to and accepted by “editorial” peer reviewers, this is sufficient to show its scientific reliability, and thus, its admissibility in a court of law.

However, the Supreme Court’s ruling in *Daubert* insists that testimony presented as expert opinion must conform to the ideas espoused by professionals in the witness’s particular field of expertise. As such, editorial peer review may impose a threshold for review that is too low to meet the standard implied by *Daubert*. The meaning of peer review in this judgment thus may be more closely aligned with Chan’s definition of true peer review, a standard that would allow only those who have replicated and tested a scientific principle to give an opinion on whether it is reliable.⁵²

While true peer review may ensure that the expert community identified by a court or an REB is restricted to genuine experts on a specific topic, the practical application of this standard may present some difficulties. For instance, the actual number of people who have replicated and tested the scientific opinion and/or data in question may be very few in number. As such, the true peer review standard may be too restrictive and might result in a group of experts that are not representative of those whose opinions courts and REBs would want to consider when referring to the expert community. In addition, theoretical problems are raised by the framework of true peer review as described by Chan. On its face, this standard seems to ensure that the expert community will be composed of scientists of the highest caliber whose work is based on testing the researcher’s data to ensure its validity. However, the ability to replicate scientific data may hardly require any form of expertise. One needs only to think of experiments conducted in high school laboratories. If the ability to repeat an experiment alone

could qualify as expertise, students in a very basic physics class technically could be considered experts. Thus, while the capacity to design an experiment may indicate expertise, the ability to test it through its replication does not.⁵³

Given that neither the true peer review nor the editorial peer review model is entirely satisfactory, a separate standard is required for determining who should be included within the expert community. What is proposed, therefore, is a stipulative definition of the expert community that is not based on any absolute criteria. Instead, individuals should be considered as potential members of the relevant community when their background and experience are similar to or surpass that of the person whose opinion is being tested for its scientific reliability.⁵⁴ While the accomplishments and credentials of the potential expert are not “proof” of his or her expertise, they lead to a presumption that expertise exists. This permits the trier of fact or the REB to draw an inference that he or she should be included within the “expert community”. Thus, although this understanding of expertise does not allow the parameters of the community to be strictly defined, it allows courts and REBs to practically proceed where this is necessary.

b) Utility of this Analysis to an REB

The reader will recall that part of the responsibility of an REB is to ensure that a state of clinical equipoise exists with respect to the treatment proposed by the investigator. Where Freedman’s view of clinical equipoise is employed, this involves ascertaining the opinion of the “expert community”. Although the legal discourse on the notion of “expert community” is quite scarce, the analysis presented in this paper may be helpful to an REB.

Based primarily on the principles enunciated in *Daubert* and the ideas set forth by Chan, I would propose the following analysis to assist the REB seeking to identify the members of a community of experts in the investigator’s field:

- The REB should begin by ensuring that the investigator’s proposal is based on “hard science” as defined by the U.S. Supreme Court in *Daubert*, that is, knowledge based on generating hypotheses and testing them for falsification⁵⁵, as opposed to clinical observation. This should not be a problem in almost all cases given that the very purpose of a research protocol is to test the investigator’s hypotheses.
- The distinction between “true” and “editorial” peer reviewer groups should be recognized, however, the inherent difficulties underlying the identification of either as the expert community also must be acknowledged.



- The REB thus may seek to strike a balance between these two forms of peer review. One area that it may look to for guidance is the peer review process for academic funding. In this context, reviewers must have the ability to understand, analyse and criticize the project in question. Employing the concept of peer review from this perspective may ensure that the expert community identified by the REB includes an adequate membership of individuals who are able to comprehend and critique the protocol.
- The REB should consider the accomplishments and credentials of the potential members of the expert community to ensure that their opinions are based on a higher level of knowledge than the average person.

If their qualifications are similar to or surpass the investigator's, this will create a presumption of expertise, suggesting that they should be included in the expert community. This presumption can be rebutted by demonstrating the persons' inability to understand and/or evaluate the proposed research protocol.

Part III: the "Expert Decision-maker"

a) When does the expertise of the legal decision-maker become an issue?

A third paradigm of expertise that figures in law relates to the qualification of the individual(s) charged with deciding the outcome of a case, that is, the judge or jury. In North American law, the trier of fact does not require a special expertise regarding the facts in issue in order to render a judgment. However, as discussed earlier, in many cases specific expertise may be necessary in order to fully comprehend the facts and thereby render a fair decision. In considering the qualifications that the judge or jury must have, North American legal culture appears to place far more emphasis on the importance of neutrality rather than technical expertise. Yet, even though we do not require the trier of fact to be an expert on the issues involved in a case, we believe that its decisions must be enlightened. Therefore, where the facts of the case are technical and beyond the knowledge of the average person, expert testimony is viewed as the means through which the trier of fact receives the

rudimentary education required to enable it to make a fair and sound decision.

All individuals within the court system, including lawyers, litigants and witnesses, have little control over the amount of knowledge possessed by the trier of fact. Where a judge is responsible for hearing and deciding a case, none of these individuals have any say in the selection of the decision-maker, as the ability to do so would surely taint the justice of the trial process. With respect to jurors, although they are selected by the parties, their selection probably will not be based on the candidates' knowledge, skill or background. Indeed, most lawyers will hesitate before selecting a juror that has a special knowledge in the area about which expert

witnesses will testify. According to Hastie *et al.*,⁵⁶ this juror will think that they know more than other jurors and more than the experts, which can distort the case as presented by the litigants.⁵⁷

A lawyer's main concern in jury selection is ascertaining which individuals are likely to render a decision in his or

her client's favour, while at the same time ensuring that the panel created satisfies the characteristics required by law.⁵⁸ Although the juror's profession and skill may be an important consideration, as mentioned, the parties will not necessarily seek an individual with an education or background conducive to understanding the facts or issues of the case. Moreover, other factors, such as the jury candidate's age, gender, race, ethnicity, class and demeanor during the selection process will be just as, if not more, important as his or her occupation and level of education or training.

It thus would appear that the traditional legal arena, that is, the courtroom, does not allow for any real assessment of the decision-maker's expertise. However, a growing movement toward alternative dispute resolution (ADR) mechanisms have made room for some discussion on this topic. Although there are various forms of ADR, arbitration is the one which involves a decision-making process that most closely resembles litigation. In arbitration, the parties have agreed, usually in a prior written contract, to submit any dispute arising in their relationship to the decision of an arbitrator. The arbitrator makes a decision after he or she has either heard oral arguments with evidence, or after reading the parties' written submissions. The parties may agree that the arbitrator's decision is binding or non-binding.

In light of the technical and scientific nature of the questions that REBs generally face, it may be more appropriate to think about the expertise of an REB in a manner similar to the way this concept is considered in arbitration.

The popularity of arbitration, primarily evident in commercial relationships, is due in large part to the fact that it appears to be a quicker and less expensive way to resolve disputes than litigation.⁵⁹ Another major advantage of arbitration is that, unlike a judge, the arbitrator⁶⁰ is selected by the parties. The arbitrator is not required to have any legal background and may be selected for his or her other professional credentials which render him or her an “expert” on the matter in dispute. For example, in a construction dispute, an engineer may be sought as an arbitrator, or in a dispute involving finances, an accountant may be sought. In this way, the selection of the arbitrator is treated like the selection of the “expert opinion-giver” called as a witness in litigation.

b) Utility of this Analysis for an REB

In the first two paradigms of expertise discussed, that is, the “expert opinion-giver” and the “expert community”, the analogy between the legal models and the REB context was drawn quite easily. However, applying the “expert decision-maker” paradigm to an REB is somewhat more complicated. Although it is clear that in an REB setting, the REB itself acts as the decision-maker, whether its expertise can or should be called into question is not.

The REB’s mandate often exceeds the capacities and/or knowledge of the members who compose it. Therefore, it would appear that its expertise could indeed become an issue in a variety of circumstances. As noted above, where an REB is faced with determining whether there is clinical equipoise, it must determine the sentiment in the expert community on the treatment is proposed in the protocol. Yet, where its members are not fully aware of the community’s position, it may seek outside opinions on this point. In other cases, the REB’s members may not even have the scientific or technical knowledge to understand the proposed research. This is another situation where assistance from the outside expert community may be necessary.

The REB’s identity and role appear closer to that of a judge or jury than of an arbitrator, given that it is not selected by the investigator in the way that an arbitrator is selected by the parties to a legal dispute. However, in light of the technical and scientific nature of the questions that REBs generally face, it may be more appropriate to think about the expertise of an REB in a manner similar to the way this

concept is considered in arbitration. This is not to suggest that the investigator should have the ability to select REB members based on their professional qualifications in the same way that parties can choose an arbitrator. Rather, the REB should have the ability, indeed, the duty, to call into question its own expertise and certify that all the issues involved in any research proposal are fully understood by the committee prior to endorsing any protocol.

As such, the REB should be distinguished from a judge or jury who does not have the ability to call its own expertise into question or defer its decision-making authority simply because it does not consider itself qualified to fully understand the facts in issue. In a trial context, the trier of fact must make a decision based on the evidence it has been presented, including the expert evidence. Where both sides have presented expert testimony that is contradictory, the trier of fact is obliged to weigh the evidence and make a

finding based on the credibility and persuasiveness of the individual witnesses.

If a judge or jury requires more information related to technical or scientific knowledge, it generally does not have the right to recall the witnesses or call in its own experts in for

further clarification. This is also the case where no expert evidence has been called. Although one court in Alabama has opened the door to the use of court-appointed experts to assess the scientific issues involved in the trial⁶¹, this does not necessarily mean that a judge or jury can summon its own experts at any time during a trial. Following the procedure adopted in this case, the court will have to determine whether it will need its own experts and select them at the *outset* of the trial, before the parties’ experts are heard. It cannot simply have its own experts “on call”, available to be summoned any time during the hearing or decision-making process, in the event that some complex scientific or technical point stumps the trier of fact.

In contrast, an REB should not be limited to its own inherent expertise in carrying out its decision-making responsibilities and should have the right and obligation to look to an outside source to assist in its deliberations. Experts could be consulted during the review process, whenever the REB recognizes that it lacks particular expertise to complete a full and fair review. Moreover, the scientific investigator or any other interested person⁶² should also have the right to insist that the REB seek assistance from outside experts where it

An REB should not be limited to its own inherent expertise in carrying out its decision-making responsibilities and should have the right and obligation to look to an outside source to assist in its deliberations.



can demonstrate that its members do not have the requisite expertise for dealing with the issues involved in the protocol under review. The individuals considered for assistance would ideally be selected from the relevant expert community. This group of professionals can be identified by employing the analysis outlined in the previous section.

CONCLUSION

In law, the question of what it means to be an “expert” arises in three contexts which are analogous to those in which REBs may deal with this issue: the “expert opinion-giver”, the “expert community” and the “expert decision-maker”. The similarity between the contexts in which law and ethics interpret expertise suggests that REBs seeking to formulate a working definition of this concept may turn to the legal model for guidance. Although this paper has sometimes been critical of legal notions of expertise, this is not intended to suggest that they should be ignored. Rather, ideas on expertise articulated by lawyers, judges and legal academics remain important to bioethicists and REBs, particularly those concerned with questions of clinical equipoise in randomized clinical trials. Given the breadth of this discussion in the law, and the similar situations in which courts and REBs might consider the meaning of expertise, the legal model may provide the most effective guide for understanding this concept in the context of bioethics.

As shown here, an REB’s assessment of expertise based on legal paradigms will depend on the particular context of its analysis. That is, much like a court of law, its evaluation will depend on whether it is trying to assess the qualifications of the investigator, identify the expert community, or discern its own ability to understand and review a protocol. REBs thus require a definition of expertise that does not have fixed parameters, but rather is stipulative and can be adjusted to fit the particular circumstances in which the issue arises. The legal model of expertise, though not without its difficulties, provides a framework within which REBs can formulate this type of flexible definition.

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1. For a detailed discussion of the law of evidence in Canada and the particular rules which must be adhered to for evidence to be admissible before a court of law, see D.M. Paciocco & S.L. Stuesser, *The Law of Evidence*, (Concord, Ont.: Irwin Law, 1996); J. Sopkina *et al.*, *The Law of Evidence in Canada*, (Toronto: Butterworths, 1992); and Sir R. Cross & C. Tupper, *Cross on Evidence*, 7th ed. (Toronto: Butterworths, 1990).

2.B. Freedman, “Equipoise and the Ethics of Clinical Research” (1987) 317 N. Engl. J. Med. 141.

3. Although some bioethicists have presented their ideas about “expertise”, they have considered this issue mainly from a legal or clinical perspective. As such, they have examined issues such as the role of a bioethicist called as an expert witness, whether ethics may serve as the basis of expert testimony, and the authority of the clinical ethicist. See *e.g.*, D.J. Casarett, “Experts in Ethics? The Authority of the Clinical Ethicist” (1998) 28:6 *Hastings Center Rep.* 6; J.C. Fletcher, “Bioethics in a Legal Forum: Confessions of an ‘Expert’ Witness” (1997) 22 *J. Med. Phil.* 297; and R. Delgado & P. McAllen, “The Moralist as Expert Witness” (1982) 62 *Boston Univ. L. Rev.* 869.

Nevertheless, some scholars in the field of ethics have begun to discuss the meaning of “expert” and “expertise” in the particular context of research ethics. See *e.g.* S.D. Yoder, “Experts in Ethics? The Nature of Ethical Expertise” (1998) 28:6 *Hastings Center Rep.* 11; and B.D. Weinstein, “What is an Expert?” (1993) 14 *Theoretical Med.* 57.

4.F. Gifford, “Community-Equipoise and the Ethics of Randomized Clinical Trials” (1995) *Bioethics* 9:2: 127.

5. *Fed. Rules. Evid. Rule 702*, 28 U.S.C.A. [hereinafter *Rule 702 Fed. R. Evid.*].

6. (1982), 29 C.R. (3d) 193.

7. *Ibid.* at 210. See also *R. v. Mohan* (1994), 29 C.R. (4th) 243 at 254 [hereinafter *Mohan*] where the Supreme Court affirmed that necessity in assisting the trier of fact is one of the four criteria for the admissibility of expert opinion. Necessity is demonstrated where it is shown that the information is “likely to be outside the experience and knowledge of a judge or jury.”

The experience and knowledge of a judge or jury are certainly variable and whether or not a judge or juror can understand particular technical or scientific facts will depend on his or her background and experience. The expertise of the decision-maker is explored in the third part of this paper where I consider the question of whether the trier of fact must be educated about the

facts or evidence presented during a trial, and then examine whether an REB should base its practices on the traditional legal model. In this section, I am more concerned with examining the process through which courts in the U.S. and Canada determine whether a witness called to testify as an expert is duly qualified to provide his or her opinion on the facts in issue.

- 8.293 F.1013 (D.C. Cir. 1923) [hereinafter *Frye*].
- 9.*Ibid.* at 1014 [emphasis added].
- 10.M.M. Horne, "Novel Scientific Evidence: Does Frye Require that General Acceptance Within the Scientific Community be Established by Disinterested Scientists?" (1987) 65 U. Detroit L. Rev. 147 at 151.
- 11.Fed. R. Evid. 702, *supra* note 5.
- 12.A.W. Tamarelli Jr., "*Daubert v. Merrell Dow Pharmaceuticals*: Pushing the Limits of Scientific Reliability - The Questionable Wisdom of Abandoning the Peer Review Standard for Admitting Expert Testimony" (1994) 47 Vanderbilt L. Rev. 1175 at 1182.
- 13.*Ibid.* at 1182-83.
- 14.113 S. Ct. 2786 (1993) [hereinafter *Daubert*].
- 15.727 F. Supp. 570 (S.D. Cal. 1989).
- 16.951 F. 2d 1128 (9th Cir. 1991).
- 17.*Daubert*, *supra* note 15 at 2795.
- 18.For examples of such judgments, see the Ninth Circuit Court's ruling in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F. 3d 1311 (9th Cir. 1995) [hereinafter *Daubert (1995)*], after the case was returned to trial by the Supreme Court for a reconsideration of the experts' testimony. See also *Hopkins v. Dow Corning Corp.*, 33 F. 3d 1116 (9th Cir. 1994) and *United States v. Martinez*, 3 F. 3d 1191 (8th Cir. 1993).
- 19.126 F. 3d 679 (5th Cir. 1997) [hereinafter *Ashland Chemicals*].
- 20.*Ibid.* at 684.
- 21.Paciocco & Stuesser, *supra* note 1 at 119.
- 22.The view that personal experience, unaccompanied by academic training, could be a source of expertise was advanced in early Canadian judgments dealing with the issue of expert testimony. See *e.g. Rice v. Sockett* (1912), 8 D.L.R. 84 at 85 (Ont. Div. Ct.); and *R. v. Silverlock* (1894), 2 Q.B. 755 at 771.
- 23.See *e.g. Preeper v. The Queen*, [1888] 15 S.C.R. 401, particularly the dissenting opinion of Strong J. at 410; and *R. v. Nielsen and Stolar* (1984), 16 C.C.C. (3d) 39 at 69-70 (Man. C.A.).
- 24.See *R. v. Warren* (1995), 35 C.R. (4th) 347 (N.W.T. Sup. Ct.); and *R. v. Marquaard* (1993) 25 C.R. (4th) 1 (S.C.C.).
- 25.(1984), 16 C.C.C. (3d) 39 (Man. C.A.).
- 26.*Ibid.* at 68-70.
- 27.*Supra* note 7.

- 28.R.J. Delisle, "The Admissibility of Expert Evidence: A New Caution Based on General Principles" (1994) 29 C.R. (4th) 267 at 269.
29. *Mohan*, *supra* note 7 at 255.
- 30.(1995), 42 C.R. (4th) 96 (Ont. Ct. J. (Gen. Div.)).
- 31.*Ibid.* at 115.
- 32.*Ashland Chemicals*, *supra* note 20 at 687, 703.
- 33.A question sure to arise at this point is whether the REB has the expertise necessary to judge these factors. Issues related to whether REB members require a specific level of expertise to evaluate research protocols are the focus of Part III of this paper.
- 34.This ambiguity in the meaning of "community of experts" has also been discussed within the context of clinical equipoise. See Gifford, *supra* note 4 at 136.
- 35.*Supra* note 1 at page 124.
- 36.D.L. Faigman *et al.*, "Check Your Crystal Ball at the Courthouse Doors, Please: Exploring the Past, Understanding the Present, and Worrying about the Future of Scientific Evidence" (1994) 15 Cardozo L. Rev. 1799 at 1816.
- 37.583 F. 2d 1195 (2nd Cir. 1978) at 1198.
- 38.*Ibid.* at 1198-99.
- 39.The "fail-safe" factor seems to have been designed particularly for criminal trials. It is predicated on the notion that a scientific technique is more reliable or trust-worthy if the inaccuracies that may result from using it be more likely to result in an error that favours the defendant. In this case, it was found that inaccuracies with spectrograms (i.e., voice analysis for the purpose of identification) were more likely to lead to the conclusion that two voices are different, rather than the same, evidence that would be helpful to an accused in a criminal trial.
- 40.753 F. 2d 1224 (3rd Cir. 1985).
- 41.*Ibid.* at 1238.
- 42.(1987), 36 C.C.C. (3d) 481.
- 43.*Ibid.* at 506.
- 44.*Mohan*, *supra* note 7 at 264.
- 45.(1990), 76 C.R. (3d) 329 (S.C.C.).
- 46.*Daubert*, *supra* note 15 at 2797.
- 47.*Daubert (1995)*, *supra* note 19 at 1318.
- 48.*Ibid.* at 1319.
- 49.E.J. Chan, "Notes, The 'Brave New World' of *Daubert*: True Peer Review, Editorial Peer Review, and Scientific Validity", (1995) 70 N.Y.U. L. Rev. 100.
- 50.*Ibid.* at 113-114.
- 51.*Ibid.* at 116.
- 52.Chan, *supra* note 50 at 117-118.
- 53.I thank Chris Herrera for his very instructive and insightful comments on this point.



54. It should be noted that the concepts of “editorial” and “true” peer review are not discarded here. Rather, the ability to review the theory for academic publication, or the ability to test and replicate the data to ascertain its validity may be considered as relevant, though not exclusive, qualifications for inclusion in the expert community.

55. *Daubert*, *supra* note 15 at 2795-96.

56. R. Hastie, S.D. Penrod & N. Pennington, *Inside the Jury* (Cambridge, Mass.: Harvard University Press, 1983) at 122.

57. See D.M. Tanovich *et al.*, *Jury Selection in Criminal Trials: Skills, science, and the law* (Concord, Ontario: Irwin Law, 1997) at 189.

58. In Canada, the Supreme Court has ruled that jury qualification requirements include: impartiality, competence and representativeness. See *R. v. Sherratt*, [1991] 1 S.C.R. 509; *R. v. Biddle*, [1995] 1 S.C.R. 761 at 787-90; and D.M. Tanovich *et al.*, *ibid.* at 12-15.

59. Teplitzky & Low, “Arbitration - An Alternative”, (1983) 4 *Advocates’ Quarterly* 233.

60. Although a sole arbitrator usually is selected, a board of arbitrators also may be called to hear and decide a case. See *ibid.*, at 237. For example, the arbitration rules of the Québec National and International Commercial Arbitration Centre permit the parties to appoint one or three arbitrators to settle the dispute.

61. *In re Silicone Gel Breast Implants Products Liability Litigation*, 996 F. Supp. 1110 (N.D. Ala. 1997). This new technique for assessing expert evidence was not discussed in the actual judgment. Rather, it was reported in an article about this case published in *The Economist*. See “Science and Technology: Scientific Justice” *The Economist* 69 (July 26, 1997).

62. This could include, for example, a physician whose patients could be recruited into the protocol or any other member of the relevant professional community aware of the protocol under review. It may also be questioned whether it is possible that a potential research subject could be aware of the research proposal at this stage, and if so, whether he or she can be considered an “interested person” in this context.

