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PLANNING FOR MULTI-SITE ETHICS REVIEW

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Abstract: This article is a brief report that draws on the literature and interviews with CMHEI investigators to explore the challenges of obtaining research ethics board approval for multi-site studies. It goes on to suggest how the complexity of multi-site approval could be addressed in terms of study budget, staff time, and study timelines.

Résumé: Cet article est un bref rapport qui puise dans la littérature et des entrevues avec les chercheurs de la MESCSM afin d'explorer les défis que doivent relever les chercheurs pour obtenir l'approbation des comités d'éthique en recherche pour des études multisites. Il suggère ensuite des façons d'aborder la complexité liée à l'approbation des études multisites du point de vue du budget, du temps consacré par le personnel, et des échéanciers de l'étude.

The Community Mental Health Evaluation Initiative (CMHEI) was the one of the first multi-site evaluations of community mental health programs in Canada. It involved six separate program evaluations of 17 community mental health programs and one methods study; all were linked through use of a common data collection protocol (Dewa et al., 2002).

The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Interagency Advisory Panel on Research Ethics, 2003) sets Canada's standard for ethical conduct for research involving human subjects. It requires multi-site protocols, like all research, to be approved by each site's local research ethics board (REB) before investigators can proceed. This means studies affiliated with

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both hospitals and universities must be granted REB approval at both institutions.

At the end of the CMHEI study, CMHEI investigators discussed their related experiences with REBs. The purpose of this paper is two-fold. First, it reviews how the variability in REBs could impact multi-site projects. Second, it suggests ways to adjust timelines and budgets to accommodate this variability.

BACKGROUND

There is a growing recognition of the value of the multi-site study design in health services program evaluation. One of the strengths of the multi-site design used in CMHEI is that it can take advantage of variations in interventions to identify the effects of their similarities and differences on outcomes. However, a cost of this research design is the complexity associated with coordinating the various sites (Dewa et al., 2002). Not the least of the complications involves obtaining ethics approval from each site and program. Because this aspect of conducting a study is considered a necessary step for any research project, it is often taken for granted and the added complexity often is not appreciated. As a result, timelines and budgets frequently do not adequately account for this step.

When queried about their experiences with the multi-site ethics review, the CMHEI investigators responded with several recurring themes that included frustration with inconsistent feedback from the various REBs to which they applied and the amount of time and money invested in responding to the various REBs.

One investigator commented: "Every time we applied [for ethics review], we had to apply to two boards — and just because something was an issue with one doesn't mean it was an issue with the other. The other would often have issues of its own."

Others agreed. "Every REB has its own take on things…[You] get different feedback from different boards, and they all want different information," said one investigator.

"Right now, we have to get reviews from *every* institution in the project," said another. "I mean, think of all the person hours involved. And then it's one committee says put this in, another says take it out — it can be very frustrating."

Said another,

> The hours spent on ethics are unbelievable — the number of forms, it's unbelievable when all are supposed to follow the same guidelines. It's layer upon layer, with different interpretations. I just want to highlight how much time and effort has been taken up by ethics [on this project]. The amount of energy, of time commitments — it's phenomenal. I'm all for making sure what we do is ethical, but is seems like the time, energy — it's just so much.

Another echoed, "It would be fabulous not to have to go through different levels of time-consuming, often inconsistent review."

These conversations raised the question of whether this experience was unique to the CMHEI investigators or was it universal? In the Canadian setting, one of the contributors to the variability is the fact that the *Tri-Council Policy Statement* has no official legal status. While most Canadian institutions have adopted the Statement, it is not mandatory. Thus, some of the variation in interpretation of the *Tri-Council Policy Statement* by REBs may be a result of this.

A review of the literature indicated that the experience was not unique. Indeed, one of the main difficulties described in the literature and by investigators with respect to multi-site ethics approval relates to the variability among REBs (e.g., Ah-See, Mackenzie, Thakker, & Maran, 1998; Burman et al., 2003; Middle, Johnson, Petty, Sims, & Macfarlane, 1995).

WHAT TO PLAN FOR IN A MULTI-SITE ETHICS REVIEW

Studies consistently report that both the application and review processes vary considerably across ethics boards. The inconsistency among REBs affects both the application and review process. This has important implications with regards to overall time, staffing, and financial costs.

Initial Submission Costs

The resources required to prepare an initial submission varies. This primarily arises from a lack of standardization of application forms

and review processes among REBs. Based on the reports in the literature, it can take from 55 minutes to 2.2 hours to prepare a single REB submission (Burman et al., 2003; Middle et al., 1995).

However, these are not the only costs associated with the submission. Expenses related to photocopying must also be considered. Middle et al. (1995) estimated they were required to submit 1,095 copies of their protocol and 1,116 forms; this translated into about 8 copies per REB. At the end of the day, the total cost of photocopying, staff time, and postage was approximately £4,606 (CDN $11,241) or CDN $78 per submission.

In another British study (Tully, Ninis, Booy, & Viner, 2000), a total of 105,888 pages were generated to apply to 125 different ethics boards. This translated into approximately 850 pages per submission. In total, costs were £6,133 (CDN $14,971) for paper, photocopying, and postage or CDN $120 per submission. The researchers were forced to apply for extra funding to cover the unanticipated expenses.

Review Costs

Additional costs are often incurred once the submissions are reviewed and revisions are requested. Furthermore, these revisions result in delays to the commencement of the project. The review process for each application can take from 39 to 182 days with a median of 78 days (Ah-See et al., 1998). The causes for delays have been attributed to revisions that are infrequently related to either the study's scientific merit or ethics. Instead, the majority of the revisions are often stylistic in nature (Ah-See et al., 1998; Burman et al., 2003; McWilliams et al., 2003; Middle et al., 1995; Silverman, Hull, & Sugarman, 2001). Sometimes, the process requires an investigator to appear before the REB. This can result in travelling a long distance for a very short meeting (Ah-See et al., 1998).

How to Plan for Ethics Review

In planning a project, REB review should be accounted for in project timing and costs. Ethics review can have a significant impact on the timing of a multi-site project. As the project timeline is being developed, adequate time should be allotted to the completion of the review process. In practical terms, this has two implications. First,

investigators should expect to wait from one to six months for the REB approval. Second, all investigators on the multi-site study must agree on contingency plans. For example, should commencement of data collection at each site be staggered as approval is granted? If so, what impact will that have on the larger study?

Second, the project budgets should also reflect potential administrative expenses. Preparing the submission and responding to the reviews can add significant expenses. Thus, there should be adequate funds apportioned for copying, printing, and postage with a rule of thumb of $78 per submission.

Third, there are psychic costs associated with the variability in REB reviews and the accompanying frustration related to delays and responses to REB queries. Investigators encountering these types of difficulties might find solace in the fact that they are not alone. An increasing number of authors have questioned the effectiveness of the current system of local REB review (Christian et al., 2002; Gold & Dewa, 2005; Tully et al., 2000). As a result, change is afoot; there are several initiatives to address the system inefficiencies (Alberti, 2000; Christian et al., 2002).

Until change arrives, it may be important to note the Tri-Council Policy Statement recognizes the potential burden of the multi-site review and recommends a coordinated review with communication among the different REBs involved (Interagency Advisory Panel on Research Ethics, 2003). It may be helpful to call the participating REBs' attentions to the *Tri-Council*'s recommendations to see if such a process could be arranged for the project.

CONCLUSION

Recent years have seen a shift away from studies performed at single academic centres to larger, multi-site projects involving numerous institutions in disparate geographic locations. This has created a new set of complications for investigators who are subject to multiple ethics boards. Though there have been movements toward centralized reviews for multi-site projects (Alberti, 2000; Christian et al., 2002), the procedures have not yet been agreed to. Until they do, it is critical not to underestimate the investment associated with the present system.

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