STREAMLINING MULTISITE ETHICS REVIEWS: LESSONS FROM THE “CANCER IN YOUNG PEOPLE IN CANADA” PROGRAM

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INTRODUCTION

The Cancer in Young People in Canada (CYP-C) surveillance program was launched in 2009 to contribute to the control of cancer in children, adolescents, and young adults in Canada. CYP-C includes diagnostic, treatment, and outcome data from all children diagnosed and/or treated at one of seventeen pediatric oncology centers across the country (Figure 1 and Table 1). Multisite ethics approval was required for the CYP-C program.

Figure 1: Pediatric oncology centers participating in the CYP-C program.

METHODS

CYP-C is a minimal risk study that meets the Tri-Council Policy Statement criteria for a waiver of consent (Box 1). A CYP-C research ethics board (REB) review committee was established in December 2009 to streamline multisite REB approvals (Box 2). Twelve separate REB applications were submitted by participating hospitals and the Health Canada REB between December 2009 and September 2010. Data on time to study approval and REB issued change requests were collected and analyzed.

Box 1: How CYP-C meets the Tri-Council Policy Statement criteria for a consent waiver

• The research involves no more than minimal risk to the subjects
• The waiver is unlikely to adversely affect the rights and welfare of the subjects
• The research could not practically be carried out without the waiver or alteration
• Whenever possible and appropriate, participants are provided with pertinent information after participation
• The waived consent does not involve a therapeutic intervention

Box 2: Steps taken to streamline the multisite ethics reviews for the CYP-C program

• The CYP-C research ethics board review committee met on a monthly basis to review REB applications completed at each participating pediatric oncology center.
• The committee prepared guidelines on how to approach REB applications for CYP-C based on the Tri-Council Policy Statement principles.
• The committee provided personalized feedback on each REB application.
• Relevant requirements were meticulously disseminated and posted on an electronic, password-protected portal.
• The committee received regular updates on the status of the applications and assisted with answering REB questions until full approval was received.

RESULTS

Seven out of the twelve centers (58%) received uncontested REB approval. Of the remaining five centers that required conditional REB approval, most requested information pertaining to non-local changes (Table 2). Three of the five remaining centres provided REB approval after additional information was provided. For the remaining two centres, further negotiating was required over requested changes before REB approval was given. By the end of 2010, all centres had secured full ethics approvals. The time taken for full approval varied greatly among the REBs (Range = 13 to 304 days; Median = 74 days, Mean = 43 days) (Figure 2). Delays in receiving ethics approval delayed the commencement of data collection by 4 months.

Table 2: Local and non-local changes requested by research ethics boards

<table>
<thead>
<tr>
<th>Non-local changes on comments</th>
<th>No. of times requested</th>
<th>Local changes on comments</th>
<th>No. of times requested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information on recruitment</td>
<td>0</td>
<td>Local changes to patient information sheet</td>
<td>2</td>
</tr>
<tr>
<td>Request for updated study documents</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Information on legal authority to conduct research</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Information on inclusion of volunteer participants</td>
<td>1</td>
<td>Request for annual report on data use at the center</td>
<td>1</td>
</tr>
<tr>
<td>Changes to be required for a consent waiver</td>
<td>1</td>
<td>Information on local process for resolving patient complaints</td>
<td>1</td>
</tr>
<tr>
<td>Information on change of personal information</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Figure 2: Time to full ethics approval by research ethics boards

CONCLUSIONS

The CYP-C program overcame some of the challenges of requiring multisite ethics approval by the establishment of an REB review committee. Notably, the emphasis on establishing channels of communication between the REBs and local researchers and continual efforts in streamlining ethics reviews proved highly successful. Still, ethics approval from all the centres was achieved at considerable administrative and logistical cost and led to delays in the launch of the study. A consistent, balanced, and timely approach to receiving ethical approval for multi-site studies is recommended. The effort will ameliorate the administrative and financial burden of ethics reviews, yield timely research, and improve consistency in decision-making among REBs.

ACKNOWLEDGEMENT

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CONTACT

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The Cancer in Young People in Canada (CYP-C) program is a national, population-based research initiative, studying all children diagnosed with cancer in Canada. CYP-C collects data on cancer cases, treatments, complications and outcomes with the aim of better understanding the causes of cancer, improving cure rates, enhancing the quality and accessibility of care, and minimizing late effects. The program is a partnership between the Public Health Agency of Canada and the C1 Council, the network of all the seventeen pediatric cancer hospitals across the country.