Hatching CHRPP: Developing an e-learning Tutorial for Research Ethics

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Abstract

A need for a new approach to research ethics education was identified at Queen's University. The goals were to ensure all graduate students involved in research with human participants were aware of the national standard of research ethics, The Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS), and to improve their approach to the research ethics review process at Queen's University. Existing resources (hard copy of the guidelines, in-house forms, and the TCPS online tutorial) were generally considered by students to be unappealing. A team of experts in research ethics, e-learning, and pedagogy worked together to produce an engaging, interactive online tutorial focused on the practical application of TCPS regulations to real research situations . The development of the design specifications, the adoption of the ICE (ideas, connections, and extensions) learning model, the process of content creation and review, and the issues arising from programming challenges and usability testing are described in this paper.

Keywords: e-learning; online tutorial; research ethics; design specifications; usability testing; ICE model; interactive; learning objects

Introduction

For novice researchers, typically graduate students, an important but often overlooked component of conducting good research is becoming knowledgeable about research ethics regulations and learning to prepare applications for research ethics review. Unfortunately, many students, caught up in the creative process of designing their research, neglect their ethics review application until the last minute and then suffer delays to their research plan. More rarely, it has been discovered that a research project has been conducted without benefit of ethics review at all.

In 2005, the School of Graduate Studies at Queen's University introduced the idea of offering a formal ethics education program for graduate students conducting research with human subjects. Efforts to provide research ethics education at this time were limited to annual presentations and several departmental education sessions given by the Chair of the General Research Ethics Board (GREB) to Humanities and Social Science students, and by the Chair of the Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB) to Health Science students. Some of these presentations were general and voluntary, while others were specific to a research area and students' attendance was required by their course instructor or department head. Aside from these lectures, many students (who would be eventually doing research with human participants) would receive no further training in research ethics, depending upon whether their department or graduate supervisor offered additional guidance.

In contrast, students who would be engaging in research with animal participants were (and still are) required to complete a compulsory, non-credit course focused on the ethical treatment of animals in research. It was recognized by the University that offering meaningful research ethics education for graduate students involved in human participant research was important, not only in meeting the mandate of providing adequate training, but also in ensuring high standards of ethical conduct for all research conducted by graduate students.

The Structure of Research Ethics in Canada

In Canada, a research ethics policy for research involving human participants was developed by the three main granting agencies (The Natural Sciences and Engineering Research Council; The Social Science and Humanities Research Council, and the Canadian Institute of Health Research). In 1998 they released the Tri-Council Policy Statement (TCPS): The Ethical Conduct for Research Involving Humans. This 'living document' is considered to be the working standard of the ethical treatment of human research participants in Canada. Like the Belmont report and the Declaration of Helsinki, the TCPS contains the fundamental principles of respect for human dignity through the provisions of informed consent, respect for privacy and confidentiality, and respect for the rights of vulnerable populations. It offers definitions of research that must have ethics review and specifies exemptions from review (e.g. public policy research, literary criticism, archival projects). The TCPS is meant to provide an ethical framework for research across all disciplines.

In this document, the duties of local REBs include the responsibility for both "educational and review roles". For institutions receiving research funding from the Tri-Council agencies, all research, whether it is conducted by a novice or veteran researcher, whether it is funded or unfunded, must be reviewed by a Research Ethics Board before it can proceed (unless it qualifies for a TCPS review exemption). At Queen's University, due to the large volume of research, there are two 17 member REBs, the GREB for Social Sciences and Humanities Research and the HSREB for Health Sciences Research. There are also 11 Unit REBs for departments with a high volume of undergraduate research, such as Psychology, Business, and Education. All faculty supervising research students are expected to introduce their students to the research ethics review process and to model ethical research practices themselves. However, the lack of a mandatory, standardized approach to research ethics education has allowed for the possibility of some students not being aware of or following TCPS regulations. The overarching goal was to foster a culture of research ethics at Queen's University through a new approach to research ethics education.

First Steps

To investigate the reasons why existing sources of information about research ethics regulations and processes were not engaging students and to come up with a fresh approach, the GREB, HSREB and School of Graduate Studies at Queen's assembled a team of experts in research ethics and pedagogy, with faculty and graduate student representatives from several departments (Psychology, Geography, Health Sciences, Education and Kinesiology). This ad-hoc committee established an agenda to:

1. Investigate and evaluate research ethics educational programs in Canada and the United States.
2. Choose a model program from another institution or Design an independent program.

The rather ambitious goal was to have a research ethics education program in place within one year of the committee's initial meeting (fall, 2006). The name that was eventually chosen for this tutorial was the Course on Human Research Participant Protection (CHRPP).

In Search of a Model Program

The committee examined other research ethics educational programs including the current TCPS educational program and initiatives at other Canadian and American institutions. They found that most Canadian institutions relied upon an online tutorial on the TCPS website: (http://www.pre.ethics.gc.ca/english/tutorial/) as a resource in conjunction with one or more educational sessions on research ethics. As completion of this tutorial is not mandatory, many students do not follow

through unless they are directed to do so by their department or supervisor. The possibility of making completion of the TCPS tutorial mandatory for students doing research involving human participants was considered. However, a survey of research ethics members and current graduate students from several departments on campus revealed that the TCPS tutorial, a text-driven replication of the guidelines broken into sections with quizzes, was not well liked. The committee's student members in particular advocated the need for a more engaging approach to research ethics education that would focus more on the practical application of the guidelines and offer more relevance to students in the Social Sciences and Humanities.

In the United States, the committee saw that a large number of universities and research institutions were using an online educational program developed by the Collaborative Institutional Training Initiative (CITI). The CITI Program was initiated in 2000 by Dr. Paul Braunschweiger (University of Miami) and Dr. Karen Hansen (The Fred Hutchinson Cancer Research Center). This web-based program has served 830 institutions in the United States and around the world. CITI offers several online courses on research ethics, responsible conduct of research, and good clinical practice. The course material is updated by a team of volunteer content developers from over 25 universities and/or research institutions.

Several members of the committee travelled to CITI developer meetings and were impressed with the program's content and organization. However, the differences in policies and practices between Canada and the United States prompted a proposal that Queen's create a Canadian version of the CITI basic research ethics program. This suggestion was welcomed by the CITI team and for the first six months of CHRPP's initial development the goal was to create a Canadian version of their program that would be hosted on the CITI site. Unfortunately, technical difficulties ensued as the CHRPP design involved television and radio news excerpts, visits to external sites, interactive exercises, and a unique quiz format. Some of these features were incompatible with the existing CITI architecture. Several solutions to these issues were tried but ultimately the technical difficulties left the committee little choice but to end the partnership with CITI and move towards designing an independent delivery system.

The experience with CITI was extremely valuable as the Queen's development team was able to meet with other research ethics education developers from around the world and exchange information and ideas. It also imbued the project with the momentum needed to develop design specifications and content. The committee was fortunate to have an e-learning specialist on the team who led them through the early steps of this process.

Design Specifications

The initial concept was to follow previous online examples which were mainly text-based with some interactivity in the form of quizzes at the end of each module. This was a fairly straightforward approach that was cost effective and easy to implement. However, the committee wanted to go beyond this paradigm to offer more opportunities for student engagement with the content. The primary goal for the development of this program was for students to transfer the content learned online to their everyday research practices. It was perceived that a text-based online course without interactivity would engage students only at a surface level with no lasting transfer of knowledge effect (i.e., Biggs, 1989; Biggs, 1999; Entwistle, 2005).

To achieve this move away from a text-based model, and on the recommendation of the specialist, the committee embarked on a software design process that would help to ensure that their goals were met. The design specification process was adapted from the work of Driscoll (1998) and Driscoll and Carliner (2005). The following are excerpts from the CHRPP design specifications:

Scope Statement

The goals of the Queen's University Research Ethics Educational Program are:

1. To provide the Queen's community (especially graduate students) with a deeper understanding of research ethics and the ethical principles identified in the TCPS and follow-up documents

2. To increase awareness and improve interaction with human research subjects and participants

3. To help protect the researchers from making an inadvertent error in the ethics process; and to improve understanding of research ethics, and quality of research ethics applications.

Target Audience

Given the nature of university research, it was recognized that there would be a diverse population of potential users, and the structure and content of the modules was planned to reach the following target personas.

Target Persona A: Eager Ethics Neophyte.

Keen to learn as much as possible, the eager ethics neophytes will be engaged in the required materials, follow all links so they can read extra materials and will wish to perform well on the tests at the end of the Modules.

Target Persona B: Need-to-know Minimalist.

Although they wish to be informed to prevent mistakes, the Need-to-know Minimalist will not want to apply any more time or energy than needed to complete the task. They will want to take as little time as possible to learn only what is necessary to their purpose.

Target Persona C: Grumpy Critical Antagonist.

Very resistant to taking any research ethics educational program, the Grumpy Critical Antagonist will believe that it is unnecessary, an insult to their intelligence, and will only do it if it is forced upon them by management. Typically, members of this group believe they are the best judge of whether their research design is ethically appropriate.

Program Goals/Objectives

By the end of the program Modules, the participant should:

1. have an improved appreciation for the value of an ethical approach,
2. have improved judgement skills in regard to ethical issues,
3. know the TCPS Guidelines and be able to apply them,
4. have a better appreciation for the rights of the participants,
5. have a better understanding of their role in protecting research subjects,
6. understand the ethics process at Queen's University, and
7. have an appreciation of emerging ethical issues.

Pedagogical Approach

The pedagogical approach that was chosen for these Modules is called ICE which stands for Ideas, Connections and Extensions (Fostaty Young & Wilson, 2000). The ideas component is the presentation of facts, principles and rules. The connections component shows how the facts can be connected with situations relevant to the student. The extensions component gives the student an opportunity to apply the material just reviewed to a plausible scenario, typically in the form of an exercise involving judgement and/or decision-making. In conjunction with this approach it was agreed that the content should include a variety of learning objects (interactive elements, video and audio material, and graphics) to support the fundamental material and to appeal to students with different learning styles. The content developer was charged with applying these guidelines to the presentation of research ethics material.

Content Development

To create the draft content in such a way that the elements of the online tutorial would be evident, each of the eight planned modules was rendered in a series of PowerPoint slides. Using PowerPoint tools such as animation and clickable audio and video excerpts allowed reviewers to get a better sense of the

dynamic components that would be featured in the online version. For example, clicking bulleted text to see a pop-up window was easily mimicked using multiple windows and object animation.

Following the design specifications, a master template for the modules was created to provide a consistent look and sequence for the entire tutorial. Each module begins with a title page listing three objectives. That is, three things the user should be able to do after completing the module. Objectives were drawn from the content of the module and how the user would interact with the content. Typically, the three objectives included one related to the Ideas component of the ICE model (e.g. Describe the guiding principles of research ethics); one related to the Connections component (e.g. Recognize ethics violations); and one related to the Extensions component (e.g. Evaluate strategies for creating ethical research designs).

The objectives drove the subsequent content of the module. The ideas component was satisfied by presenting the information from the TCPS in small chunks with bulleted lists and clickable examples. A section on respect for privacy and confidentiality, for example, explains the fundamental principle and provides a link to a Canadian Broadcasting Corporation (CBC TV) report about a stolen laptop containing patients' medical records and the reaction of the privacy commissioner (see Figure 1). A later module deals in depth with the TCPS regulations related to privacy and confidentiality.

Figure 1. CHRPP Sample Page 1

The connections component aims to get the student to think about how the regulations apply to actual research by presenting scenarios drawn from real research incidents. The extensions component engages the student in interactive exercises that require them to apply the information they have been given. For example, provided with a research scenario in which an ethics dilemma has three possible solutions, students are asked to rank the solutions in order of preference (see Figure 2). When they submit their selection they get to see how research ethics experts would order the solutions and why.

Relevance to Social Sciences and Humanities Researchers

An important goal of the tutorial was to make research ethics more accessible to Humanities and Social Science researchers. When the TCPS was first developed, it was focused on a biomedical model of research. Much of the language is geared towards Health Sciences researchers and many of the scenarios described (e.g. clinical trials) have no relevance to researchers outside this area. As a result, researchers from the Social Sciences and Humanities have often complained that their research methods are not properly addressed and that they have difficulty finding the relevance of many research

ethics regulations to their work. To address this need, every module contains examples and interactive exercises from all three major research areas (see Table 1). The content developer sought to include as many disciplines that typically involve research with human participants as possible. There are 32 different disciplines represented in the first seven modules.

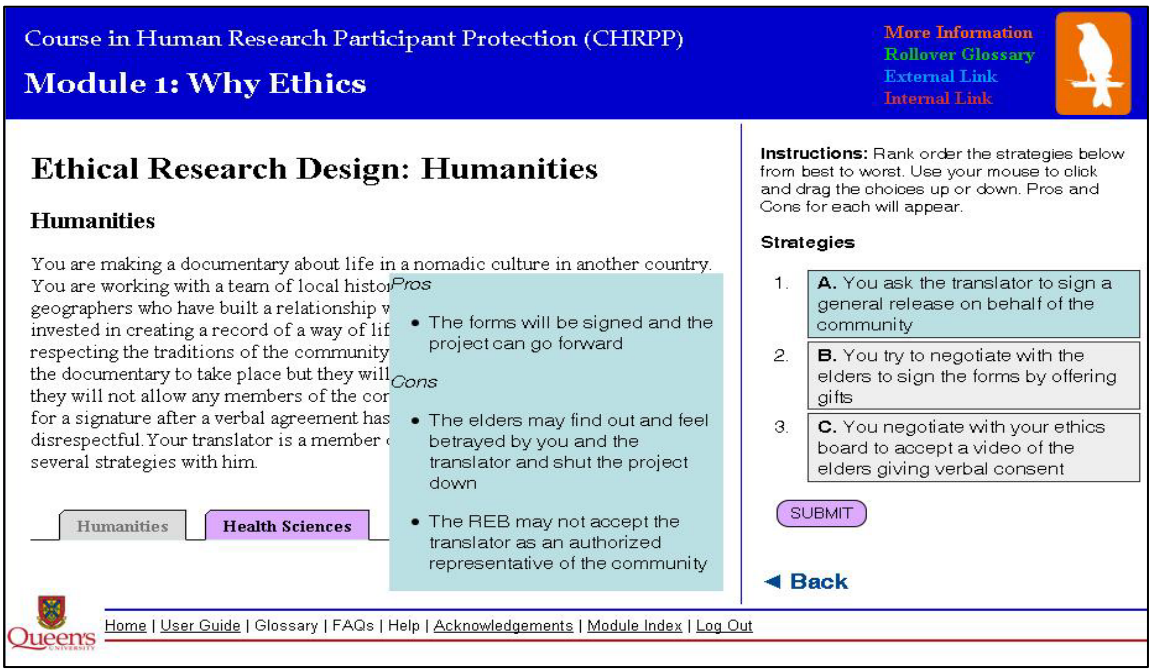

Figure 2. CHRPP Sample Page 2.

Table 1. Partial List of Research Areas and Disciplines Represented in the CHRPP Modules

1	Humanities Health Science Social Science	History Cardiology/Genetics Education
2	Humanities Health Science Social Science	Public Policy Forensics Business
3	Humanities Health Science Social Science	Theology Neurology Psychology

On each page where the three major areas are represented, users have the option of viewing one, two, or all three examples/exercises. This allows users who wish to focus solely on material related to their research area (the Need-to-Know Minimalists and the Grumpy Critical Antagonists) to go through the tutorial in the most efficient manner, while those who wish to explore material from more than one research area are free to do so (the Eager Ethics Neophytes and interdisciplinary researchers).

The examples and scenarios in each module were sourced in a variety of ways. Throughout the development period, members of the Queen's research ethics boards (GREB, HSREB, and Unit REBs) were asked to generate scenarios based on their own experience designing, supervising and/or reviewing research projects. A search of research projects that had been funded by the three major granting agencies (CIHR, SSHRC, and NSERC) also provided inspiration and source material (with names, locations, and other identifying details altered). The examples and scenarios in each module deal with different aspects of the main topic. For example in the Vulnerable Populations module, there

are scenarios illustrating some of the issues that can arise in research with prisoners, indigenous peoples, children, and elderly people (e.g. violations of informed consent; exclusion from research; use of unclear language, among others).

Going Beyond the Text

To avoid the text-heavy approach of other tutorials, the following design decisions were made (see Figure 3):

1. Lots of white space, clean and colourful graphics, and almost no scrolling. Text material was presented in small paragraphs with graphic elements, and, with few exceptions, did not extend beyond the borders of an 8.5" X 11" (landscape) viewing screen.
2. Additional or highlighted information was presented in pop-up windows that could be opened and closed at the discretion of the user.
3. Options for more detailed information on particular topics were presented as external links, PDF documents, video and audio reports, that could be activated at the discretion of the user.

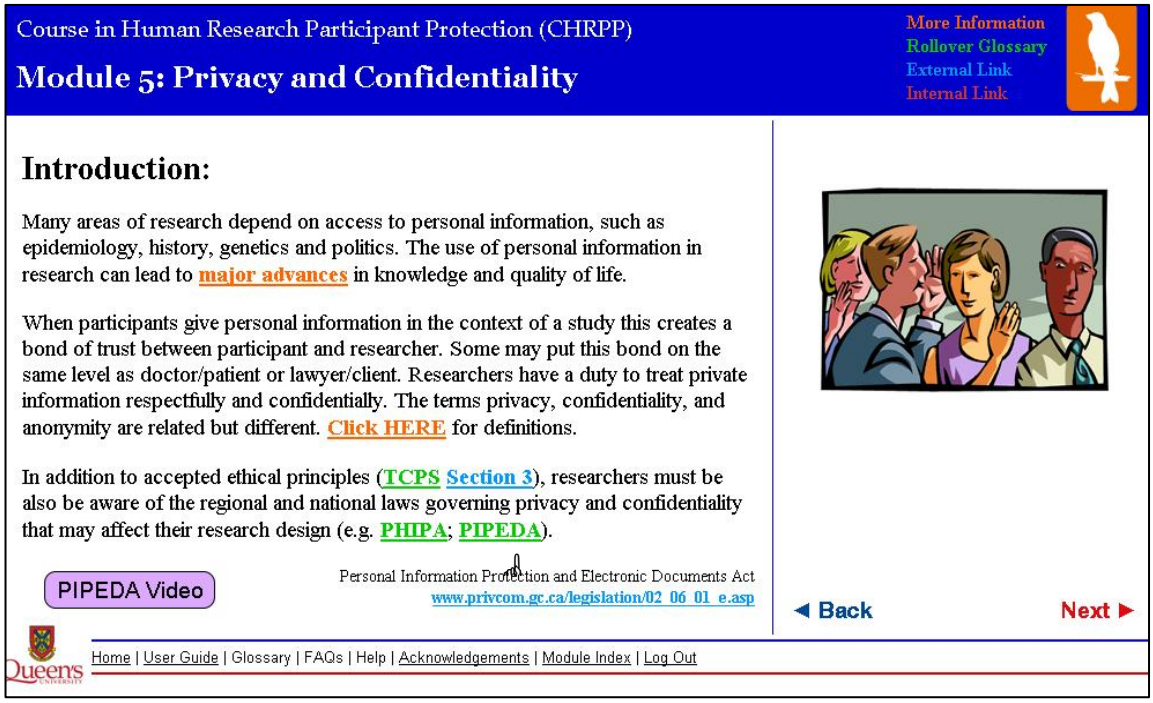

Figure 3. CHRPP Sample Page 3.

The decision to include excerpts of CBC television and radio news reports about research ethics issues was motivated by the committee's desire to take research ethics out of the realm of the theoretical and make it real to the students. It was also an excellent means of ensuring the CHRPP tutorial was truly relevant to Canadians. For example, in module one, the fundamental principle of informed consent is highlighted by a CBC radio report on the case of a group of researchers pressuring members of a family with a rare genetic heart defect to provide blood samples. In return, the researchers promised to use the blood to find a treatment or a cure. The research team flew in from Texas, took as many blood samples as they could get (without going through ethics review at the local university), and flew out – thus earning them the nickname "The Texas Vampires". The report includes interviews with members of the family and with local research ethics officials, and describes the family's fight to get the blood returned to local researchers (who would put it to the use the family had originally agreed to). This piece and several other television and radio pieces highlighting real life violations of research ethics were licensed from the CBC's educational division.

Programming

The content developer worked with a number of part-time programmers on this project with expertise in PHP and MySQL. Their task was to transform the PowerPoint prototypes for each module into HTML pages with links to embedded audio and video as well as to external sites. The challenge of getting the audio and video to play from a pop-up window was solved by creating a separate QuickTime pop-up from within the text window, allowing users to refer back to the text as they listened to a radio report or watched a video.

The design of the interface was intended to provide users with a relatively simple and predictable format. Navigation was controlled primarily by "next" and "back" buttons in the bottom right corner of each page. On occasion these buttons would be hidden until the user followed the directions on the page to access a particular piece of information. Although one of the design objectives was for the program to be easy to go through, another equally important objective was that the users not find it easy to skip through the content. Several "stops" or "slow-downs" of this nature were implemented to give users every opportunity to benefit from the information presented. For example, in the quizzes at the end of the module, selecting a response does not immediately indicate whether it is correct or incorrect. Instead the user sees a scrollable feedback window that discusses the pro's and con's of the response selected and then, in the last few lines, lets the user know whether the response was correct or whether they should select again. Users cannot exit the quiz until they have found all of the correct answers.

Another feature of the interface is that the user can quit the program at any time and return to where they left off the next time they log in. Each user's progress through the tutorial is tracked, not only for their convenience, but also so that the average length of time it takes to complete the tutorial can be analyzed, and to derive a statistical picture of how deeply users are engaging with the material (e.g. whether only one area of content is consistently explored or whether more than one information option are being accessed).

Usability Testing

On the advice of the e-learning specialist, usability testing was conducted after two modules were completed in HTML. This proved to be an invaluable investment. Three students with no previous experience with the tutorial viewed it on three computers, a PC laptop, a PC desktop, and a MacIntosh laptop. The lead tester prepared a report identifying navigation issues and recommending solutions. Table 2 provides a partial list of the issues identified in usability testing and the solutions that were implemented.

Table 2: Usability Testing Issues and Solutions

ISSUE	SOLUTION
Text and graphics are too large causing more scrolling than is absolutely necessary	Reduced text and graphics to limit the need for scrolling without compromising aesthetic appeal
Sections with subheadings lack clear markers or reminders of what sections have already been seen; too easy to skip to the last heading	Implemented consistent use of navigational markers such as bulleted lists of sections in the side bar. Previously visited section bullets change colour. Disabled the 'next' button until each section on a page has been visited sequentially
External or pop-up connections to new information do not always provide clear path back to the main window	Implemented consistent use of closing window instructions on all external links and pop-up boxes to enable users to return to the tutorial

After implementing these and several other solutions to the first two modules, the lessons learned were applied to the HTML and content development of the next six modules. Another round of usability testing

was conducted with four independent testers on modules one through five. Two of the testers had been involved in the first round and were very pleased with the changes made according to their recommendations. Very few issues were raised in the second round of testing but one suggestion that was very much appreciated was to provide a tutorial on the tutorial (See Figure 4). This led to the creation of a more extensive welcome page with links to a brief guide on the tutorial structure and features, frequently asked questions (FAQs), acknowledgements, copyright information, and access to the help request form. The development team also followed another suggestion to include a legend of colour-coding on each page of the tutorial (highlighted on Figure 4) to remind users of the following text-click features:

Green text: Rollover glossary (as cursor rolls over text, word or acronym definition is revealed

Blue text: External link (clicking on this text opens an external site with related information)

Red text: Internal link (clicking on this text opens a related section of the tutorial.

Orange text: More information (clicking on this text activates a pop-up window containing related text, video and/or audio information

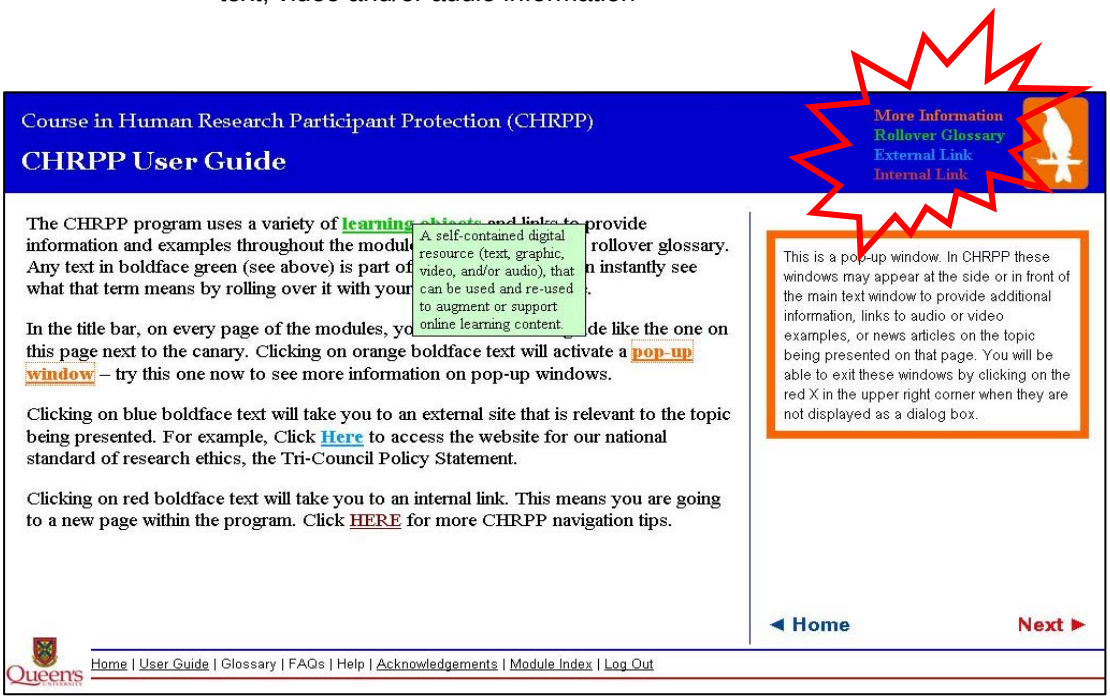

Figure 4: CHRPP Sample Page 4

Security Audit

With the usability testing complete and eight modules completed in accordance with the testers' recommendations, the committee was ready to start pilot testing the program with groups of graduate students. Upon contacting the university's IT department, however, they discovered that the program could not be made accessible on the Queen's server until it had gone through a security audit. This was a relatively new policy implemented due to the recognition of how student and staff data could be vulnerable to unauthorized third party viewers, even in the context of completing an online course about research ethics.

This was a serious setback for the projected timeline but it was a necessary step in the process. Over a period of five weeks, the CHRPP programmer worked with the IT department to ensure that the program was in compliance with the security measures required by the university and made sure it would function

properly in its new home on a secure server. Finally, in spring of 2008 the development team was able to begin pilot testing just as the majority of students were leaving for the summer. Although a few students did do the tutorial over the summer months the team decided to plan a well-publicized open house in the fall to introduce CHRPP to staff, students, and faculty with a follow-up schedule of "getting started" seminars.

Summary

Although the initial intent was not to create an independent research ethics program, the committee and the development team found the process immensely stimulating and informative. The lessons the authors would like to share with others who find themselves embarking on this type of e-learning development project are:

1. Take your initial concept through the invaluable process of creating design specifications before doing any content development. Identify your target audience, decide on your pedagogical approach, create your objectives, and then build your content to meet those objectives.

2. Consult with your IT department or an IT professional before setting any timelines. Find out the full details of the security requirements your program will have to meet and make sure your programming staff is aware of these requirements and is capable of fulfilling them.

3. Involve representatives from all of your stakeholder groups. In this case it was faculty, students, ethics experts, e-learning experts, and upper level administration. In hindsight the committee should have had someone from IT at the table.

4. Consider a variety of learning styles in the presentation of your material. Offer the same information in various forms – video, audio, graphics and/or text. Engage the user in exercises that require the use of recently presented material. Don't make it easy for the user to skip over important information.

5. Design and implement usability testing early in the content development process and repeat it at regular intervals. By getting user feedback at the two module stage and again at the fifth module stage a tremendous amount of revision work was avoided.

CHRPP was formally launched in October, 2008 and is currently available to the Queen's University community. It will become a mandatory course for all graduate students engaging in research with human participants as of September, 2009. From October to November the development team hosted CHRPP seminars for graduate students to take them through the first three modules and give them an opportunity to ask questions and give feedback to the people involved in designing the program. These students were encouraged to finish the course on their own and complete the user satisfaction survey so additional improvements could be made before the next update of the program in summer, 2009.

CHRPP has been presented during the last stages of its development at several research ethics conferences and, as a result, other institutions have expressed interest in obtaining the course for their own research community. Plans are being made to make CHRPP available to research institutions across Canada in 2009. Another series of modules dealing with specific areas of research ethics (e.g. research with aboriginal communities, international research, digital data collection, stem cell research, research with prisoners, among others.) are currently in development. It is anticipated that CHRPP will need to be updated when the next version of the TCPS is released and the authors expect to involve many more stakeholders from the research community nationwide in this process.

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