Help Researchers Write Participant Information Sheets for Studies with Humans

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Abstract

When the study involves human participants, the researchers need to provide them with a participant information sheet (PIS) to inform them of all the information they need to know about the study such as procedures and potential risks.

However, since many researchers are not familiar with PIS, they may encounter frustrations and make many mistakes in the process of writing PIS. The research question of this project is to explore and analyze their frustrations and the source of mistakes in PIS. At the same time, the project figured out what kind of website to build to make researchers more confident in writing PIS. Here we show the website called "Help Your PIS" can help researchers complete the writing of PIS efficiently and confidently.

Unlike many current similar websites of information collection, this website uses a step-by-step guide based on the user's choice and gives corresponding information and tips. Finally, it provides a personalized downloadable PIS template tex file. Through the evaluation of the System Usability Scale, the entire project has high usalibility and learnability.

This project is based on the ethics rules of the School of infomatics, the University of Edinburgh, so it may not apply to the requirements of other colleges or institutions.

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Declaration

I declare that this thesis was composed by myself, that the work contained herein is my own except where explicitly stated otherwise in the text, and that this work has not been submitted for any other degree or professional qualification except as specified.

(*Souven Chen*)

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Chapter 1

Introduction

1.1 Motivation

People can help researchers figure out the questions explored in their thesis by participating in their study. When a study involves human participants, in order to reflect respect for humans and follow basic ethical principles [3], researchers have to consider how to describe the motivation and procedures of the research in plain language [21], inform the participants of this information and obtain their informed consent. In other words, It is necessary for researchers to provide a participant information sheet(PIS) and consent informed form to the potential human participants before conducting research.

PIS provides all the project related information that participants need to know, including but not limited to the motivation and purpose of the research, the benefits and the risk of this study, the process of the entire study, the confidentiality of their private information, and the methods of data storage. Potential participants can decide whether to participate in this study based on this information sheet. In order for potential participants to have a detailed and comprehensive understanding of what will happen if they participate in the project, the content of PIS needs to be reasonable and understandable.

Because many researchers who are still students are not very familiar with PIS, they do not know how to write an information sheet that meets all the requirements. There are some problems in the PIS they provided which harm to potential participants' understanding, so it is meaningful and important to help solve the mistakes in writing.

1.2 Problem Statement

As mentioned before, to express respect for humans [27], researchers should write a PIS for potential participants before conducting the study. The PIS needs to inform these participants about all they need to know about this project in plain and understandable language [8]. In other words, participants can understand the motivation and purpose of the research through this PIS, the process and steps of experiments that require them to participate, and how their personal privacy information will be protected, etc. At the same time, the PIS provided by the researchers must meet the ethical requirements and regulations of the School of Informatics of the University of Edinburgh.

But at present, many researchers who need human participation in studies do not know how to write a PIS that meets the all requirements of the school. First of all, because some researchers have not received ethical training or only received minimal ethical training, they do not know all the regulations and relevant ethical requirements of the school. Secondly, the ethics-related content provided by the school is very numerous and complex. For zero-based researchers, it is difficult to understand and master all the requirements in a short time.

Due to the above reasons, these researchers have no confidence in how to answer the questions in the PIS, and often use the copy of the text in the PIS template provided by the school in the writing of PIS for granted, without really considering the meaning of these texts. As a result, the content of the PIS they wrote is not completely consistent with the actual experimental operation, and even the context of the PIS may be inconsistent. Such a PIS is difficult to meet the requirements of the school. At the same time, because PIS does not accurately express project information. There is such a possibility that people will participate in research without the correct understanding and judgment of what will happen if participating in this study, which is likely to bring unexpected risks. In this case, it is difficult to show respect for humanity. The consequences of this phenomenon also include increasing workload for the ethics team. What's more, as mentioned before, because PIS needs to meet more ethical requirements, zero-based researchers need to spend a lot of time to learn relevant information from scratch, which means that this will increase the time cost of research and reduce work efficiency to a certain extent.

This project proposes to use the method of building a guiding website to help such researchers complete their PIS writing confidently, efficiently and with high quality.

Specifically, this website analyzes related issues that may be involved in PIS, explains terms that researchers may be confused about, provides explanations of questions in PIS, guidance and tips on how to answer corresponding questions, and tons of correct examples. This helps such researchers to figure out how to present relevant information about their projects in PIS. At the same time, this website also provides several text area that researchers can input their ideas in time and complete part of the PIS writing directly on this page. After the researcher completes the relevant text area through the guidance and prompts of the website, the website will also provide a tex file of the latex code of the PIS that can be modified, so that the researcher can download it easily. Also, they can make further revise in this PIS tex file according to the specific circumstances of their own project.

1.3 Research Question

The research question of this project is what are the frustrations encountered by researchers in writing PIS and what are the common mistakes they make? What kind of website can be provided to help researchers be more confident to write high-quality PIS?

It should be noted the limitation of this project is that this project is completed in response to the ethical requirements and regulations of PIS of the School of Informatics of the University of Edinburgh, which may not meet the relevant rules of colleges and other schools.

1.4 Related Work and Innovation

“Ethics and Integrity” website [3] provided by the School of Informatics of the University of Edinburgh provides a summary of the School ethics pages, including the School’s ethics and integrity guiding principles, ethics procedure which contains a simple introduction of PIS and downloadable templates. Similarly, the “Consent and Participant Information Guidance” [4] website provided by the NHS combines the writing templates of PIS and consent informed forms and the reference webpages of the ethics they involve, such as the General Data Protection Regulation (GDPR) related requirements, etc. Although these two websites have different forms of expression, they are both websites with a large amount of information collection. They all require users to explore and learn all the content needed in the process of writing PIS.

Compared with the above two websites [3] [4], the innovation of the website established by this project is that it enumerates the content that researchers need to learn for each problem in PIS, eliminating the need for researchers to find relevant content by themselves. In addition, this website allows researchers to enter PIS content through text area on the website, and finally provides a personalized template file containing the input text, instead of only providing structured templates like the two websites above.

1.5 Goal and Results Achieved

The purpose of this project is to help researchers write high-quality PIS confidently and efficiently. To this end, I analyzed the problems encountered by researchers in the process of writing PIS and what frustrated them, as well as the source of mistakes that researchers often make in PIS. According to the analysis results, the website, which helps researchers create participant information sheets for studies with humans, has been built.

The results obtained by the project include the collection and analysis of the problems in the current PIS writing and the design and construction of the website. The website named "Help Your PIS" is available from https://sweb.inf.ed.ac.uk/s1927736/. After the establishment of the website, it also has been evaluated. Think-aloud method [40] is used between 8 participants to qualitatively analyze the functions and content of this website. Through the evaluation of the website, it was found that nearly 6 participants were very interested in the PIS-related writing guidance provided, and 7 participants stated that the link to the PIS-related ethical regulations provided in the navigation bar of the website released the confusion that they did not know where to find PIS related requirements. 8 participants said that by using the website, they felt more confident in writing PIS by themselves and it took less time to write it than before.

1.6 Dissertation Outline

The entire paper will be decomposed in detail according to the following structure:

- Chapter 2 analyzes the existing research and achievements of PIS field, discusses the literature related to ethics, and explains the meaning and essence of PIS in detail.

- Chapter 3 specifically describes the research methods adopted by the project in the early analysis process of potential user needs.
- Chapter 4 describes the detailed implementation of the website, including the prototype design and code development. In detail, it includes research on interface visual design, website construction methods, and website development methods.
- Chapter 5 evaluates the design and content of the entire web page, and after the web page optimization, discusses this project fully.
- Chapter 6 summarizes the process and results of the entire project.

Chapter 2

Background

According to the requirements of the School of Informatics, the University of Edinburgh [3], PIS is a document that researchers must submit before conducting research that involves human participation. Because some researchers may not know the ethics regulations of the school very well, when writing PIS, they are likely to copy some the text in the PIS template provided by the school, without thinking whether these contents match their own projects. For potential participants, such a PIS is not enough for them to fully understand the research content, and their own rights are also difficult to be guaranteed. This is clearly contrary to the basic ethics rules. It is not complicated to write a PIS at will, but it is difficult to write a PIS that fully describes the project contents and meets the ethical requirements. To write such a PIS, it is necessary to emphasize the importance of PIS, understand the relevant ethical requirements, and explore how to improve the quality of PIS.

The main purpose of this chapter is to explain the content and importance of PIS, summarize the relevant ethical regulations to be followed, and analyze the history of methods to improve the quality of PIS writing. The research on the background provides ideas for the research questions and methodology selection.

2.1 Understanding participant information sheet

2.1.1 What is Participant Information Sheet

Researchers need to obtain potential participants' informed consent before they participating in the study. The purpose of obtaining informed consent is to allow participants to freely understand the relevant information of the project, including experimental

procedures and potential risks, and can freely decide whether to participate in without pressure [8]. So when researchers' experiments require human participation, what they need to consider carefully is how to express the project information to the participants in a concise and easy-to-understand language, and so that the potential participants can understand in detail what they will do , as well as the risks and benefits that may be encountered when participating in project research. In this case, they can independently decide whether to participate in this project research.

The process of obtaining participants' informed consent can be roughly divided into two steps: providing information and obtaining consent [6]. In detail,

- Step 1: Researchers provide participants with all the project information they need to know. In the stage of providing information, potential participants should read and understand the information. In this process, potential participants should not be forced to make a decision whether to participate.

- Step 2: The researcher needs to reiterate the main points of the project, usually in the form of listing main points. Potential participants will read this document again carefully. If they agree to each of the main points and determine that they are willing to participate in the study, they can sign the document or make a verbal consent. The specific method of consent depends on the project requirement.

According to the requirements of the School of Informatics of the University of Edinburgh, in Step 1, in order to provide clear information, the researchers need to write PIS and to express all the required content. PIS is an important aspect of organizing and conducting research, because the PIS provides the necessary understanding of the motivation and procedures of the research to potential participants, so that they can obtain informed consent.

In conclusion, before conducting any research that requires human participation, researchers must obtain consent before collecting data from the participants. The potential participant's consent must be voluntary, informed, and made by someone who can make such a decision by themselves (for example, not a child) [4].

In Step 2, the researchers need to provide a consent form for participants. All participants who agree to participate in the project should fill out the consent informed form. The form should only be filled out by the participant after reading the relevant PIS provided in Step 1.

2.1.2 Importance of Participant Information Sheet

On March 13, 2006, the first human experiment of TGN1412 began [36]. Six healthy human volunteers received a CD28 which threatened their lives as a result [18]. In conducting human-related experiments, human life safety and other rights must be guaranteed. In addition to the reasons of the research itself, after analyzing the consent form of this research, the Royal Statistical Association [32] pointed out that in describing the treatment timetable and the process of the project, too many complicated professional terms were used, which caused serious consequences for personal safety.

Informed consent should not be regarded as a single act of "signature with participant's consent", it should be a process [4]. Before conducting the experiment, the researcher must ensure that the potential participant has been provided with all the information necessary for him to decide whether to participate in the research, otherwise the researcher's consent will not be accepted even if the participant's signed consent is obtained [33]. Simply put, it is necessary to provide PIS before obtaining informed consent. As an important part of informed consent, PIS plays the role in transmitting and explaining relevant information. In this case, PIS should express the content of the project in a concise language without losing clarity [29].

2.1.3 Content of Participant Information Sheet

There is no mandatory fixed format for PIS document writing, but according to the relevant information provided by the School of Informatics, the University of Edinburgh, PIS needs to include but not limited to the following [3]:

- Basic information of the research team: such as the names and contact information of the researchers and mentors
- The motivation and purpose of the project
- If potential participants decide to participate in the study, what will happen to them
- All risks that participants may face
- Benefits of participating in the project
- Confidentiality of participants' private information

In order to write a PIS that contains the above content and meets the school's ethics rules, it is necessary to learn and analyze relevant ethical content and understand how to improve the quality of PIS. In the next two parts, these two parts will be described in detail.

2.2 Ethics

In the process of writing PIS, the ethics issues encountered by researchers can be divided into two categories. One is to protect human participants, and the other is to protect human participants' private information. The Belmont Report [27] summarized the ethical guidelines for research involving human participants. The General Data Protection Regulation (GDPR) [41] summarizes the regulations on data protection and privacy for all EU individuals in EU law, and involves the export of personal data outside Europe. Due to Brexit in 2019, the United Kingdom approved the Data Protection Act 2018 [1] on May 23, 2018, which contains the corresponding regulations and protection measures in the GDPR.

2.2.1 Balmont Report

The Belmont Report explains unified moral principles. When using human beings to participate in research, the three basic ethical principles that researchers need to follow are "Respect people, Benefits and Justice" [12].

Specifically, first of all, in this type of research, researchers need to give the participants the greatest respect and protect the autonomy of all. Before conducting the experiment, they need to obtain the participants' informed consent. For all steps in the experiment and potential risks, the researcher must inform the subjects honestly and completely. Secondly, in the course of the experiment, the researchers need to uphold the concept of "no harm", and do their best to improve the project's profit and reduce the potential risks faced by the subjects. Finally, what needs to be paid attention to in the course of conducting the research is that the researchers need to conduct the experiment fairly and non-explosively and without pressure, and distribute the benefits to all participants fairly [17].

Adhering to the respect for human participants, after considering the above issues, researchers need to think how to store research data and how to store personal information reasonably and confidentially. For data ethics, the School of Informatics of the

University of Edinburgh refers to and follows the GDPR.

2.2.2 GDPR and Data Protection Act 2018

The General Data Protection Regulation (GDPR) is a EU-wide data privacy regulation [41]. The GDPR contains provisions and requirements of the regulations concerning the handling of personally identifiable information of data subjects within the EU [5]. When researchers conduct project experiments that require human participants, the collected personal data of the subjects must be strictly protected. First of all, these personal data must be stored by anonymization or pseudonymization. Secondly, when using these data, do their best to set the privacy of these data. Without the permission of the participants, these data must not be made public.

The Data Protection Act 2018, as a law of the UK Parliamentary Act on data protection updates in the UK, supplements and improves the contents of the GDPR and Data Protection Act 1998 [1]. The Data Protection Act 2018 controls how personal information is used by organisations, businesses or the government. The regulations on the use of personal data by the School of Informatics of the University of Edinburgh are consistent with the GDPR and Data Protection Act 2018.

When researchers consider personal data issues, they first need to think about their own projects to confirm whether this project involves the use of personal data. Personal data that may be involved in the research include basic information such as name and contact information, answers to the researchers' questions during the experiment, media information such as personal audio and video interview records, and information related to identification symbols and general categories of personal data such as human biological materials, etc.

If the researchers confirm that their project involves the personal data mentioned above, then they need to follow the GDPR and the Data Protection Act 2018 to properly store these data according to the requirements of the college.

2.3 Previous Work to Improve Quality

After understanding the relevant regulations of ethics that need to be followed, the researchers need to consider how to express the research content to potential participants in concise and clear language on the premise of meeting the ethics regulations. Reading the literature before the analysis, I found that there are many ways to improve PIS.

Analyzing and comparing various methods of quality improvement is very helpful for the project to determine how to help researchers who have not experienced PIS writing to write PIS. It also has great inspiration for determining the methodology of this project.

In 1969, LC Epstein and L Lasagna [14] asked 66 subjects (64 of whom were female hospital or medical school staff) who had learned the relevant information and risks of the experiment through the informed information sheet, whether they would be willing to take two tablets of "acetylhydroxybenzoate" or placebo drugs in the next headache. Through the feedback of the subjects, they found that nearly one-third of the subjects said that they refused to take "acetylhydroxybenzoate", but when they were told that "acetylhydroxybenzoate" was aspirin, 20/21 participants indicated that they can accept taking this medicine. In short, in addition to the length of the information sheet, the professionalism, comprehensibility, or readability of the content also have a great influence on the volunteers' understanding. Using more understandable expressions can help subjects better understand the content of the project and make a clearer decision about whether to participate in the study.

In order to study the impact of the length of information documents on the understanding of potential participants, L Malik and J Cooper [26] reviewed the past 30 years of informed consent forms for phase I oncology trials in 2018. In this field, the length of informed consent forms was increasing from 1986 to 1999 and 2000 to 2015, and only 21% (1986-1999) of the informed consent forms analyzed and 12% (2000-2015) reading level less than 8th grade. This means that for most people, these information sheets are too difficult to read. According to the research results, the authors found that these informed consent forms became longer and more difficult to read, but still lacked some important information.

On the other hand, with regard to the comprehensibility and readability of the content of the information table, in 2004, L Franck and I Winter [16] pointed out that the reading requirements of many participating information tables are higher than the recommended level. The solution authors raised is before the researchers provide the information sheet, they should calculate the readability of the content by themselves, modify and optimize this document according to the calculation results, and then provide it to potential participants. In 2008, M Jefford, et al. [21] made a similar point, but for improving the quality of this document, they gave more detailed suggestions. Authors believed that the use of understandable language rather than professional and complicated terms when writing relevant content can improve participants'

understanding and satisfaction of the informed consent process. I n 2015, L Ennis, T Wykes published an article [13] about PIS sense and readability in research. They proposed to use shorter words, sentences and paragraphs, and to replace complex medical and research terminology with simple ones. It can help reduce the reading time of the information sheets, thereby improving the understanding of participants. The University of Michigan has provided guidelines for simplifying medical terminology Plain Language Medical Dictionary [24] that can produce a similar vocabulary to research terms.

From the readability of the text itself, the participants' education level also has a certain influence on the understanding of the informed consent process. In 2017, L Ennis and T Wykes [22] analyzed the information sheet of informed consent for surgery in Iran and found that young Iranian patients have a better understanding of informed information than older patients. The author believed that this was likely due to the current the level of education of Iranian young was generally higher than that of the elderly (much help to understand the content). Similarly, E Beardsley, M Jefford, et al. [10] explored the impact of the length of the informed consent information sheet on the understanding of potential participants and found that when providing the English information form, participants whose second language was English had a lower level of information understanding than native speakers. Providing an information sheet in the more simple language would effectively improve this problem.

In 2014, W Montalvo, E Larson, et al. [28] concluded that ways to improve the quality of informed consent can be divided into 1. Enhanced consent procedures or formats 2. Multimedia methods 3. Participant education. In 2004, J Flory and E Emanuel [15] found that although enhanced consent procedures or formats and the adoption of multimedia methods had limited success if researchers spent time in face-to-face communication with potential participants to express project-related information. A class of methods can significantly improve their understanding. With the development of science and technology, the way of multimedia has been further improved and popularized. In 2019, KA Lindsley [25] proposed that a touch screen computer can be used to sequentially display various types of information related to informed consent. This method has been widely recognized by volunteers.

In 2016, L Stunkel, M Benson, et al. [35] put forward different views on the above-mentioned influencing factors and methods for improving quality. The authors found that neither the understanding of the research information nor the satisfaction of the consent process will be affected by the length or complexity of the consent form.

When interviewees found that they would receive higher compensation, they would be more inclined to cooperate with the requirements of the main research. But despite this, the author recommended writing a concise and clear PIS in an easy-to-understand way. Also, in addition to the quality problems of PIS itself, researchers also need to make targeted adjustments and modifications to PIS according to the target participants' age [38], mental state [34] and other aspects.

In short, there are many ways to improve the quality of informed consent information. By analyzing and comparing the previous literature, as far as this project is concerned, what it can do is to guide potential users to a certain extent by simplifying the language, shortening the length of the article, and improving the readability of PIS.

2.4 Related Work

The goal of this project is to establish a website to give researchers who need to write PIS reasonable guidance and help them complete PIS writing. The main purpose of the information website provided by NHS[1] is similar to this project. In addition to providing practical PIS examples and templates, this page explains how to implement specific elements to help improve the consent document. As mentioned earlier, in order to improve the quality of PIS, we can write in concise language. The page also gives suggestions for concise presentation. At the same time, the web page also make relevant explanations on the content that will be involved in the process of informed consent, such as GDPR related requirements and risk declarations. Consistent with the suggestion of "calculating the readability of this content" mentioned above [16], the website provides a calculation method and relevant examples of readability scores.

Compared with the way the NHS website provides integrated information, the biggest difference is that the "Help Your PIS" website explains the details of the problems encountered in the PIS, and provides the content that users need to learn during the guidance process, saving the time for users to learn and search independently. In addition, it also provides a text input box so that users can record their thoughts in time during the learning process. These contents will also be automatically integrated into the Latex Code template. The website will provide download links of modifiable tex files to help researchers solve the problem of the PIS format and help them complete writing more effectively.

[1]The NHS website URL is http://www.hra-decisiontools.org.uk/consent/examples.html

Chapter 3

Methodology

Introduction in Chapter 1 and Background in Chapter 2 specifically explain the motivation and purpose of the project, make an analysis and summary of different ways to improve the quality of PIS, and compare the related work to clarify the innovation and significance of this project.

As mentioned in Chapter 1, the first research question is "What the frustrations encountered by researchers in writing PIS and what are the common mistakes they make?", in order to understand the pain points of researchers, who are the potential users of the Help Your PIS website, that is, the frustration and the source of errors in their writing PIS, the essential step is to analysis the users' requirement. After understanding the needs of users, what can be determined is the content that needs to be presented on the website, and then the second research question can be clarified "What kind of website can be provided to help researchers be more confident to write high-quality PIS?".

This chapter will elaborate on the methodology for users' requirement analysis. This section specifically includes investigate design, data collection methods, data content analysis, investigate limitations, and ethics issues. Subsequent chapters will focus on the second research problem.

3.1 Investigate Design

In order to explore the research question of the project "What the frustrations encountered by researchers in writing PIS and what are the common mistakes they make?", potential user requirement research was completed. The purpose of potential user needs research is to understand the user's pain points, so as to figure out what kind

of assistance help the user really needs. This part determines the content selection and website construction. At the same time, the research question of this project determines that the data that needs to be collected at this stage is the problem-oriented description of the target participants.

What needs to be understood is the frustration of researchers in the process of writing PIS and the problems they often make. Understanding frustrations means that I need to communicate with the researchers, while the researchers may not be very clear about the mistakes they made in PIS writing, in addition to communicating with them, I also communicated with the ethics panel members to understand what are the common problems in the PIS submitted to the school. Of course, because the ethics panel members are also researchers, who has a lot of experience in writing PIS, so in the process of communicating with them, I collected their frustrations with writing PIS.

The investigation of this project chooses the method of exploratory research, specifically using interviews and focus groups discussions to collect first-hand data. Because each researcher has different views on frustrations, and many of them may still be unfamiliar with PIS and need more guidance in the dialogue process, so one-to-one interview is used to obtain relevant information from the researchers. The members of the ethics panel are very familiar with PIS, and the focus group method is convenient for in-depth discussion of the problem, so more information can be obtained through interaction and discussion efficiently. After collecting this part of information, I analyzed and summarized the research question "What the frustrations encountered by researchers in writing PIS and what are the common mistakes they make?". The data collected in this part is the basis for exploring the second research question.

3.2 Participants and Data Collection Methods

The data collection methods adopted by the project are divided into interviews and focus groups.

3.2.1 Interview

In order to understand the various confusions encountered by different researchers in writing PIS, interviews were conducted with participants who had PIS writing experience and felt frustrated during the writing process. Due to the epidemic, the interview

was conducted remotely through the audio call function of Microsoft Team. Volunteers involved in the interview included 7 MSc students and 1 PhD student at the School of Informatics of the University of Edinburgh. Each interview lasted approximately 20 minutes. After obtaining the verbal consent of the participants, I recorded the content of the interview through audio recording.

3.2.2 Focus Group

To better understand the common mistakes researchers made in PIS, writing a structured focus group meeting was held with some members of the ethics panel from the School of Informatics at the University of Edinburgh. Due to the epidemic, the focus group meetings were conducted remotely through the video call function of Microsoft Team. A total of 8 people, including the moderator, participated in the focus group meeting, and the discussion lasted for an hour. After obtaining the verbal consent of all participants in the discussion, I recorded the content of the meeting through video recording.

3.3 Interview and Focus Group Results

The content collected through interviews is what made researchers feel confused or difficult in writing PIS. In addition to the frustrations in PIS. Common mistakes made in the PIS submitted to the school were collected from the perspective of ethics panel members via focus group meeting. In this section, the collected content is classified and summarized according to themes.

3.3.1 Frustrations in PIS Writing

The frustration content in PIS writing comes from two types of participants, one is student researchers, mostly MSc students from the School of Informatics, the University of Edinburgh, and the other are a members of the ethics panel of the School of Informatics. The difference between the two groups is that the first type of student researcher has less experience with PIS than the second type. The content of frustrations obtained from these two types of participants are also be somewhat different.

Open Coding was used to analyse the data from the interview and focus group meeting. Open Coding includes labelling concepts, defining and developing categories based on the properties and dimensions of the data [20]. The content of frustration

gained through interviews and focus groups is summarized in the following table 3.1.

Open Codes	**Theme**
Don't know where the relevant ethics regulations are	Confusion about searching relevant information
Don't know where to download the relevant template	
Risk's boundary is not clear	Unclear understanding of terms in PIS
The definition of Compensation is not clear	
The definition of Benefits is not clear	
Explanation of target participants is not clear	Other issues
It is confusing to complete many questions that are not in the PIS when applying for the Ethics form.	
The method of data collection is uncertain	Data collection and storage methods
Don't understand the requirements of data storage	

Table 3.1: Frustrations themes derived from open codes

Based on the content in the above table, the content that needs to be solved by potential users is divided into three aspects:

- Access to related resources
- Keyword definition
- Data collection and storage methods

In the follow-up website content design, this project will provide targeted help information for these three aspects and provide external websites links with reference significance. How to build website content based on the data analysis will be elaborated in the implementation part of Chapter 4.

3.3.2 Common Mistakes in PIS

Through the focus group meeting, after communicating with the members of the ethics group, the common mistakes in PIS include the following points:

- The description of the project is too long and provides many details of the project that participants do not need to know

- In the task description, too many technical and completed terms are used, which affects the reading comprehension of potential participants
- As the content of the template is simply copied without combining the needs of the project itself, there are contradictions and inconsistencies in the context
- The combination of collected personal information makes it possible for participants to be identified

In the follow-up website content design, in order to minimize the occurrence of the above problems, this project will give hints and guidance based on different points. The content of specific website construction will be elaborated in the implementation part of Chapter 4.

3.4 Ethics Issue

Prior to the interview, this project received ethical approval from the School of Informatics of the University of Edinburgh. I recruited interviewees by email, providing PIS and informed consent forms for each interviewee. The documents can be seen in Appendix E. All interviews were conducted after obtaining the informed consent of them. Due to the epidemic situation, the signing of informed consent is no longer used, as an alternative to the method of obtaining verbal consent. All audio and video recordings are made after obtaining verbal consent.

This experimental research is highly compatible with the ethical requirements of the School of Informatics, the University of Edinburgh, and the storage of all research data is compliant with the ethical standards of GDPR.

3.5 Investigate Limitation

During the implementation of interviews and focus groups, the collected content data has certain limitations. First of all, from the interviewee's point of view, the selected interviewees are all from the School of Informatics, and the collected content is more inclined to related problems encountered in the direction of the computer. Individual interviews are mostly conducted by MSc students, and the questions obtained from them are simpler and more general than those of more experienced researchers. Which means the content would not contain the completed problems that could be encountered

in deep research. The interviewees of the focus group are all PhD, and the content of the frustrations of PIS writing obtained from them has made up for the defects mentioned before to a certain extent. However, due to the form itself of the focus group discussion, it is inevitable that a respondent's response may be affected by others. In the process of moderating the focus group discussion, everyone has the opportunity to speak and the moderator encouraged them to express their thoughts and welcomed different opinions. Trying to reduce their afraid to express their opinions for holding different opinions.

3.6 Meaning

By analyzing the requirements and pain points of the potential users, it was convenient to indirectly analyze which kind of PIS writing guidance the potential users desire based on their frustration and errors, what kind of help does this website provide to truly meet the needs of potential users. In conclusion, the content of this section provides a guideline for the content of subsequent website implementation. Before completing the website development, through the content analysis of this part, what should be presented by the following website is determined.

Chapter 4

Implementation

In this chapter, I will explain the process I went through to implement the website. From a certain perspective, the construction of the website connects the two research questions of the project. Specifically, based on the analysis of the first research question in Chapter 3, I determined the content and presentation form of the website. According to these contents, this chapter completes the establishment of the website. The establishment and follow-up evaluation of the website will answer the second research question.

4.1 Preliminary Conceptual Design

According to the second research question "What kind of website can be provided to help researchers be more confident to write high-quality PIS?", it is clear that the goal of the website is to help write PIS that meets the requirements. From the analysis of the needs of potential users in Chapter 3, I learned that some researchers were not very clear about where to find relevant resources, the definition of keywords, and the methods of data collection and storage. In order to help them clarify these contents, the website will provide different solutions for each problem.

According to the above questions and the basic needs, the design requirements of the website are:

- **Beginner friendly**

  The target audience of this project is researchers who have difficulties in writing PIS, so the website should have a clear structure and provide easy-to-use functions. As shown in the Figure 4.1, I divided the page into a navigation bar on the left, a content area in the middle, and a hints column on the right. I divided

the content area into the “Title & Intro” and “Main Content” of the current page. One interview participant said that “The current websites provide a collection of various information, and the information is too complex, which makes me confused about what each part of the content is for.”. For this reason, I wrote a descriptive paragraph of the content and aim of each page in the “Title & Intro” section to help them clarify the function and purpose of the web page, and also make the website easy to understand and use.

- **Provide explanations and guidance information**
  Through the preliminary investigation and analysis, the researchers did not know much about the parts that need to be filled in the PIS template. One of the main problems they encountered was the vague definition of the terms in the problem. For example, an interview participant said “I don’t know what compensation means in PIS.”, so I gave a prompt statement on the website: “Compensation includes any form economic benefit, including money, material goods, even soft dollar compensation(research services, software, clearing services, etc.).”. Similarly, another participant said “I don’t know what a risk is and how to define the board of risk”, so I added an explanation like “Risks include information about physical and mental health, race, ethnicity, political opinions, religious beliefs...”.

  In this way, I provide explanations for any terms or problems that users are not sure about. In addition, according to the interview and focus group discussion, researchers often felt frustrated and made mistakes in the question “What will happen if people decide to take part?”. For example, a focus group participant said, “Some researchers don’t know what kind of personal information they need to collect... Sometimes they collect too much personal information so that participants can be recognized by the combination of this information... Some researchers don’t clearly state that they will collect What kind of personal information is there.”. So, first of all, I set a question to ask users whether they would collect personal information. By asking, I would draw users’ attention to this aspect. Second, I provided a specific definition of “personal information” to help users figure out what they need for their projects. One interview participants said “I don’t know how detailed my project description should be. Do I need to write all the information about my project in PIS?”. In response to this confusion, I added an explanative sentence like “This section details what will be involved

in your research study from a participant's point of view, and in the order, they will experience it. If there are multiple study visits, describe them in turn..." At the same time, I also provided some examples. Researchers can learn about the general answering method and the level of detail of this part of the content by studying those provided examples.

- **Provide links to external websites that are of reference significance in the process of writing PIS**
  According to the analysis of potential user requirements in Chapter 3, some researchers had no idea how to find PIS related content or the relevant regulations of the college. For example, one interview participant said, "I don't know where to obtain information similar to the ethics procedure, GDPR or the template provided by the school.". So I integrated some reference pages necessary in the process of writing PIS, such as the college's introduction to the ethics procedure, PIS templates download page. I provide these pages to users through the navigation bar. In this way, users can find the content they need more conveniently and quickly.

- **Provide a unified format downloadable PIS template**
  One focus group participant said, "Some researchers were not very clear about the use of template files. The PIS they uploaded did not have a reasonable format.". So I provided a downloadable and modifiable PIS tex file. The tex file contains compilable LaTeX codes. These codes specify the format of the text and include the preset text that is not recommended to be changed and the user-defined text content provided by the user. The tex file can be compiled into a uniform format PDF file.

Because these explanations and design are responses to feedback from my interviews and focus group discussion, these content can meet user expectations. This was confirmed in the next prototype evaluation.

4.2 Prototyping the Design

The main objectives of prototyping were:

- Respond to user needs
- Determine the stylized design of the page

Figure 4.1: Draft sketch of function page

- Determine interaction design

As Chapter 4.1 mentioned, I have transformed the user needs from interviews into the guidance that the website needs to provide. The task that the prototype design needs to complete is how to present this content. Next, I will elaborate on how to choose prototype tools and how to present PIS guidance through stylization and interaction design.

The significance of prototyping is to visually present the basic concepts and ideas of the website to be developed in the future so that everyone involved can view and use it and then give feedback. Based on their feedback, I made necessary adjustments before the final version was finalized. After determining all the elements and functions that need to be implemented through the prototype design, I recruited two interview participants to evaluate the prototype design. They believed that the prototype basically met their needs. The specific feedback content will be detailed in Chapter 4.3 description.

4.2.1 Prototyping Tools

This project uses Axure to complete all the content of the prototype design. There are many kinds of prototyping tools that can be used at present. In addition to Axure,

Figma and Sketch are both commonly used tools. In this project, the tasks that need to be completed with prototyping tool mainly include the creation of low-fidelity and high-fidelity design drawings, and the realization of interactive functions. Since Axure is more conducive to the efficient completion of the project in terms of low-fidelity design drawings and the realization and sharing of interactive functions. Although it is not as good as Figma in constructing high-fidelity design drawings, it is only a preliminary determination of the style of the web page, which means, in the future, I can complete the defects in this term through website construction. Therefore, in terms of prototyping, we choose Axure as the main tool to complete this part of the content.

4.2.2 Prototype Design and Implementation

The overall website design includes three types of pages: introduction page, function page and resource page. Each type of page design adopts a unified layout. The introduction page is the homepage of the website, which provides a brief introduction to the website's functions and usage. The resource page includes various pages that provide PIS-related resources, including the template download page provided by the school, and the complete PIS sample page. The introduction page and the resource page use the same layout, as shown in Figure 4.2, which mainly includes the navigation bar on the left, the logo of the School of Informatics, the University of Edinburgh above, the page introduction in the middle part and the text content of the page. The function page contains two pages, custom information and data information, with the same page layout, as shown in Figure 4.3. The page layout of the function page is very similar to that in Figure 4.2. In the function page, the question and input area on the left and the hints area on the right replace the page text content in Figure 4.2.

In addition to the basic "previous page" and "next page" interactive functions in the web page, the more important functions include: tooltips of terms, the corresponding alert box displayed after the radio button selected, the button to obtain the latex code, the button to download code file. Each function is repeated multiple times on the page and uses the same interactive actions.

- **Tooltips**: When users' mouse enters the area where the term is located, they will see a detailed explanation of "confusing" terms through tooltips. This method can be used to reduce potential users' confusion and strengthen their understanding of the problem. Take one question on the page as an example. As shown on the left side of Figure 4.4, in the interface of the Axure prototype design, Fig-

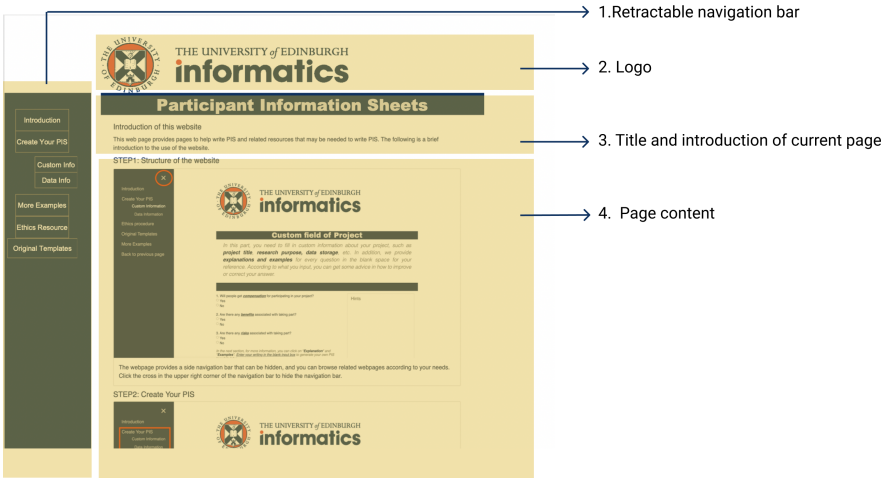

Figure 4.2: Layout diagram of introduction page.(same as the resource page)

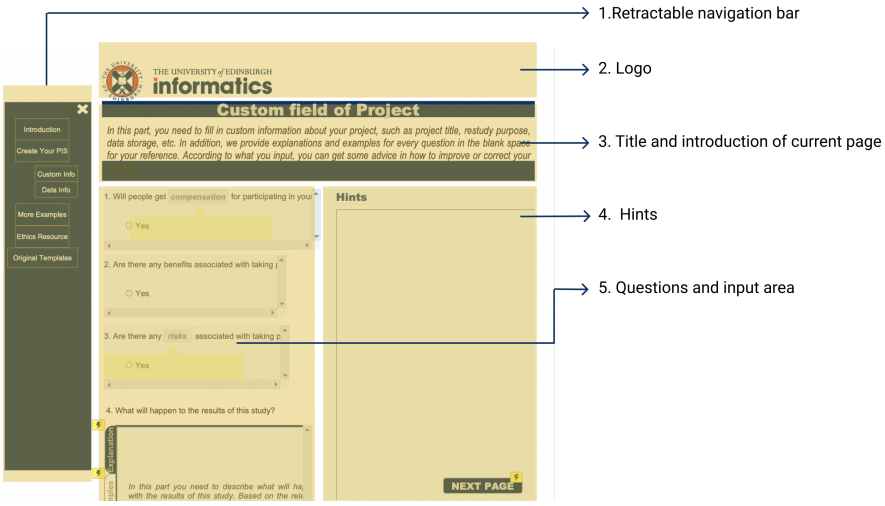

Figure 4.3: Layout diagram of function page

ure 4.5 is a preview of the design. On the right is the page status when the keywords in the question are not clicked or entered. There is no prompt at this time. As shown in Figure 4.5, when the mouse is moved to the keyword, the relevant text prompt will be displayed below the it.

- **Hints and alert**: The web page gets the user's answer by asking questions, such as the question "Will people get compensation for participating in your project?". The user chooses "Yes" or "No" according to their actual situation. Based on the user's choice, the website will provide the corresponding hints and examples in the Hints column. As shown in Figure 4.6, when the user selects "Yes", the website gives an example like "Examples: Paid by money: You will

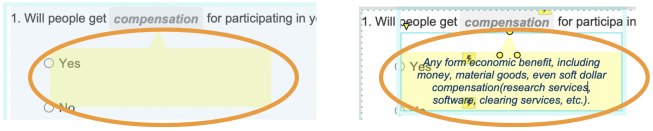

Figure 4.4: Tooltips prototype design in Axure.

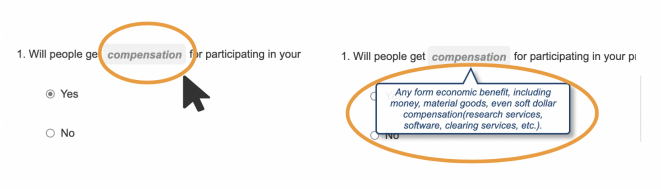

Figure 4.5: Preview of tooltips prototype design in Axure.

receive 9 pounds as compensation for completing this survey, along with the knowledge that you have helped science and software engineering research." The user selects "No" and the website provides an example "Examples: Subjects will not be compensated for participation in this study." In this way, targeted help can be given to the user.

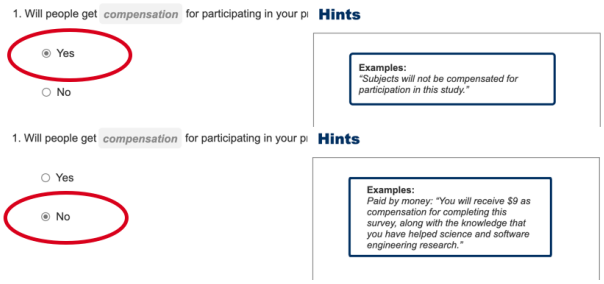

Figure 4.6: Preview of Hints column under different choices

- **"Get Latex Code" and "Download" buttons**: The "Get Latex Code" and "Download" buttons appear at the end of the function page. As shown in the preview image in Figure 4.7, after the user enters the relevant text in the input field behind "Starting your writing here" above, when clicking the "Get Latex Code" button, the blank box above needs to display the Latex code with previous input in the corresponding place. Click the "Download" button, the browser needs to save the above code as a tex file and automatically download it locally. The real-time update of the code is achieved through the splicing of global vari-

ables and text in Axure. First, set the user's input in the text box as a global variable to ensure the transmission of the text box page. At the same time, the combined text of the pre-written text content and the global variable is also set to the global variable "tex". After that, set the properties of the code box to display the content of the variable "tex" after clicking the "Get Latex Code" button, so as to realize the function of real-time code update.

Due to the limitations of Axure, the "Download" function is more difficult to implement, so this project did not implement this function in the prototype design stage. Instead, implement this function in the subsequent web page implementation.

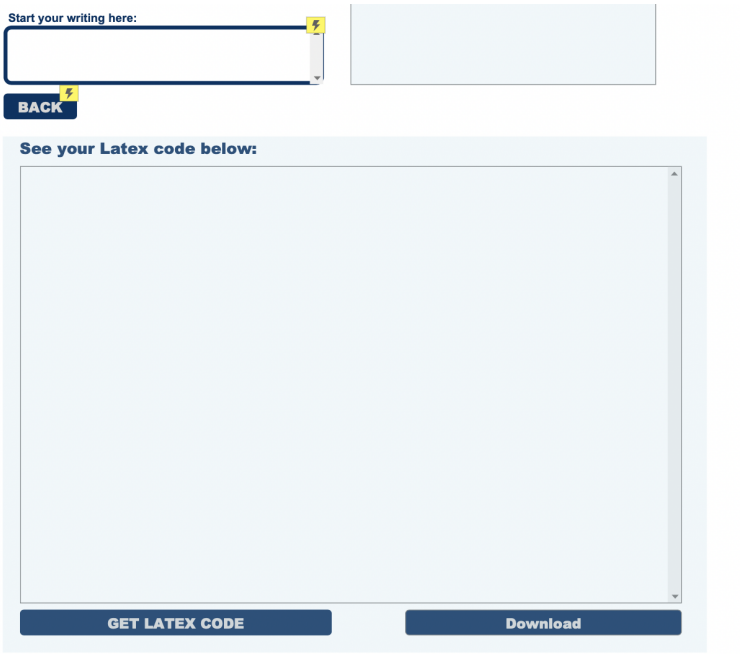

Figure 4.7: The interface preview of the part of download module in Axure

4.3 Feedback on Prototype Design

All the content of the prototype design was based on the results of my interview and focus group discussion. After I completed the prototype, in order to test whether the content of the web design could really help potential users write PIS, I selected two participants to evaluate this design. Through unstructured interviews, I asked them to talk about whether they think such a design is sufficient to meet their needs, also asked them to make some suggestions for the style of page design.

Through Interviews, I learned that both participants believed that the current form of assistance and content design basically met their expectations. At the same time, one of the participants said, “Because the explanation of the terms can actually represent the explanation of the entire topic, perhaps this part of the content can be unified in the Hints column.” In addition, both participants believe that the overall design direction was valuable, but the text needed to be richer.

In general, through the evaluation of the prototype design, I learned that the design direction and ideas of the entire project were correct. In the later process of website code development, what needed to be done was to enrich the text content, complete the unfinished download code modules in the prototype design, and improve the interactive experience.

4.4 Website Development

4.4.1 Development Tools and Languages

For website development this project uses HTML as the main language for the web pages, uses CSS to design the web page style, and uses JavaScript to realize web page interactive functions. In this part, I used Visual Studio Code and Chrome together to complete code development.

4.4.2 Choice of Framework

In order to unify the style of all web pages in the website, the front end uses the Bootstrap framework [11]. Bootstrap is a front-end framework that integrates CSS and JavaScript packages. It provides many basic modules such as Grid, Typography, Tables, Forms, and Buttons, as well as Dropdowns, Navigation, Modals, Typehead and other components [19]. Through Bootstrap, the front-end construction can be completed efficiently by calling various classes provided by the framework. For example, according to the page layout design in the prototype, in Figures 4.2 and 4.3, the page needs to be divided into multiple areas. I used the class “col-md-4” in Bootstrap to divide the site layout efficiently.

In addition, Bootstrap requires jQuery [30] to run. jQuery [7] is a JavaScript library that not only simplifies JavaScript but also increases browser compatibility with JavaScript. So before using Bootstrap, I introduced jQuery library files in the HTML file.

4.4.3 Web technology

According to the early prototype design, in addition to the page layout, another important content that needed to be completed was to obtain the user's text input and integrate the text content into the LaTeX code of the preset PIS template.

4.4.3.1 Cross-page Transfer of Data

According to the analysis of the needs of potential users, it can be seen that users have more problems with the content of "data collection and storage methods". In order to explain this part of the content in more detail and provide more complete and specific guidance information, I create 2 pages for the "function page" mentioned before and named these 2 pages as one section called "Create Your PIS". The first page provides guidance and explanation of questions which contain confusing terms, and the second page provides detailed explanation of the content of the data collection and storage. At the same time, the website needs to implement the functions of code preview and tex file download in the "Create Your PIS", which means that the input data of the two pages in the "Create Your PIS" needs to be transferred across pages.

In order to pass the input value of the first page to the second one, the method adopted by the website is to add cookies on the front end. Because the HTTP protocol is stateless, the server does not know what the user did last time, which severely hinders the implementation of interactive web applications [31]. HTTP does not use additional means, and the server does not know what the user did. In order to do this, cookies and sessions are needed. The server can set or read the information contained in the cookie or session to maintain the state of the user in the conversation with the server [39].

In general, compared with sessions, the advantage of cookies is that they will not cause pressure on the server when the traffic is large, but the security is relatively poor compared to the session stored on the server [2].

The website of this project does not require users to fill in private information such as passwords, so there is no need to worry about security when using cookies to complete the page transfer function. At the same time, since the website may be accessed by multiple people at the same time, the use of cookies can greatly reduce the pressure on the server.

In the construction of the website, the cookie is embedded in the front-end code to complete the interactive tasks between web pages. The entire website eliminates the need for back-end construction and database establishment, and completes the interac-

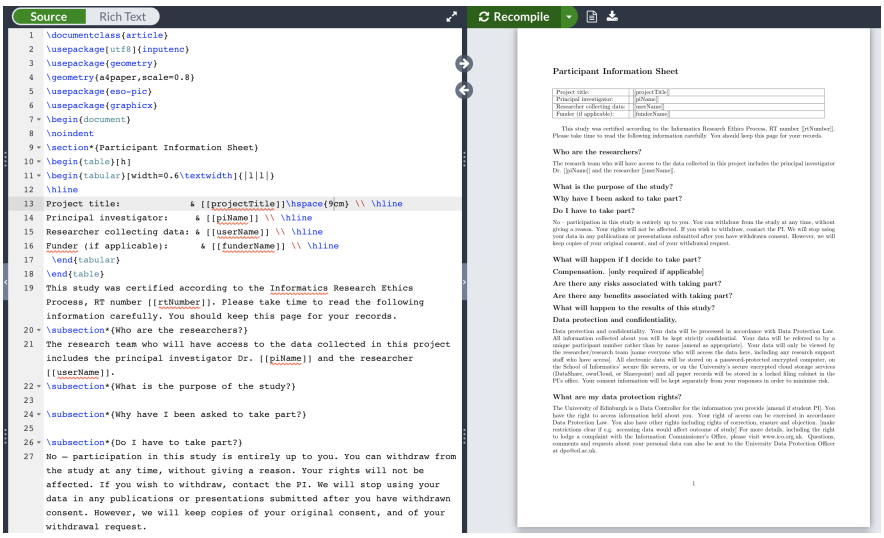

Figure 4.8: The converted part of LaTeX code and the compiled PDF preview.

tion of the entire website with minimal cost.

4.4.3.2 Generate and Download the Latex Code

After the data is transferred across pages, in the second page of "Create Your PIS", all user input can be called by the page. In this part, the main purpose is to embed user input into the corresponding position of the PIS template and display the LaTeX code.

First of all, because the PIS template is displayed in the form of a Word document. According to the project requirements, I converted the text content of PIS into LaTeX code. The converted part of LaTeX code and the compiled PDF preview are shown in Figure 4.8.

Secondly, I completed the format conversion by converting LaTeX code to HTML format, so that the text content can be normally displayed in the website.

Finally, as shown in Figure B.1, using jQuery, I obtained the data passed by the cookie in the previous step and used *console.log()* to obtain the input text content. After that, for example, if I want to call the corresponding text content named "reason_content", I can call it by embedding code in the format of $reason_content in the appropriate position of the LaTeX code.

After finishing the integration of Latex code, I used JavaScript to implement the code download function. The main idea of this function is to use the Blob object to create the specified file and download it. The Blob object represents an immutable, original data file-like object. First, I created a new Blob object and specified its data as the content of the text area that displays LaTeX code. After that, I named the download

link *"save_link"* and used *document.createElementN()* to generate <a> tag. Therefore, I create a new URL object through *URL.createObjectURL()* to specify the download link of the previous Blob object and specify the href attribute of *"save_link"* as this download link. Also, I use the download attribute to name the file name during downloading *"PIS_latex_code.tex"*. The entire download task will be triggered by the *click()* event.

4.5 Website result

The appearance of the created web page is shown in the Appendix A.1. The user can directly enter the introduction page after logging into the website. The introduction page briefly explains how to use the website. Click "Start My PIS" button in the lower right corner of the introduction page or click "Create Your PIS" in the navigation bar to enter the "function page" of the website, which is the "Create Your PIS" section. The first page contains the questions that need keyword explanation in the PIS. This part shows these questions with the single-choice area or the text input area. Click the bold keyword in the question, and users can get the text explanation in the "Hints" column on the right. Similarly, when users make a selection in the single-choice area, the relevant guidance information corresponding to the different choices will also appear in the Hints column. Then the users can fill in the text area according to the explanations and examples provided under certain questions. After filling in, click "Next Page". The second page focuses on the question "What will happen if people decide to take part". Through the explanation of the first three questions, help users understand the preliminary preparations needed to answer "What will happen if people decide to take part" so that they can better answer the last question. Similarly, the last question also provides explanations and examples. After the user fills in, click "Get Latex Code" to convert the previously filled content into LaTeX code and display it in the text area below. As shown in Figure A.5, clicks "Download " button, users can download the tex file of the latex code of PIS.

In addition to the "function page", users can click on relevant internal and external links as needed through the navigation bar, which is the "resource page" mentioned earlier. The "resource page" includes PIS templates and PIS examples. The interface of the website in this part can be seen in Appendix A.1.

Chapter 5

Evaluation and Result

In Chapter 3 Methodology, I collected and analyzed data through interview and focus group discussion, and finally solved the two research questions raised in Chapter 1. In Chapter 4, based on the results of the data analysis in Chapter 3, I determined the website implementation plan and completed code development. Chapter 5 will elaborate on the evaluation process and results. I conducted two evaluations on the initially completed website, namely the interface evaluation and the usability evaluation. After the first evaluation, according to the results, I modified and optimized the initial website. After that, a second iterative evaluation was performed. Through think-aloud method, I conducted a usability analysis on the final result of the project.

5.1 Evaluation

5.1.1 Interface Evaluation

After completing the establishment of the entire website, I selected two participants from the interview and focus group discussion during user requirement analysis to help me complete the interface evaluation. The interface evaluation was done through an unstructured interview. The two participants were asked to browse and try to use the website freely. During the process of using it, they also recorded the areas they felt confused or had a bad sense of use. During the interview, we discussed this information. The interface of the website which participants used when evaluating as shown in Appendix A.1. After the interview was completed, similar to Chapter 4, using open coding, I organized the results of the discussion into a Table 5.1.

According to the Table 5.1, the main content to be modified includes 3 aspects:

Open Codes	**Theme**	
Enjoyed the color scheme of the website	The appearance style of the website page that participants liked	Website positive
Enjoyed website font		
Enjoyed the consistence overall style of the website		
Enjoyed the way the information displayed (alert)	Interactive features that participants liked	
The information provided in the navigation bar is very helpful		
The download function is very convenient		
The two page titles and introductions under Create Your PIS are a bit confusing	The title and explanation of the page need to be revised	Website improvements
Alert information displayed on the right side Hints column does not conform to inertial thinking	Guidance display method and content need to be improved	
Some tips are too long to read		
Hope there are more examples		
The animation of the navigation bar when entering the website is a bit redundant	The logic and animation of the navigation bar need to be improved	
The navigation bar does not need to be folded		
The order of the information provided in the navigation bar is a bit messy		

Table 5.1: Interview themes derived from open codes

- Each web page needs a clearer and more understandable title.
- The way to provide guidance needs to be improved. Too long guidance information needs to be expressed in a more concise manner.
- The logic of the external links and animation of the navigation bar.

After clarifying the content that needs to be modified, I revised the interface of the website. For the first point, I changed the original title "Custom Field of Project" to "Risk, Benefits, and Results", and changed "Data Information" to "Data Storage & PIS Download". In addition to changing the page title to more direct and clear text, I also made some changes to the text description of each page. For the second point, I modified the layout of the entire web page. As shown in Figure 5.1 I deleted the "Hints" column and replaced it with prompt messages corresponding to different operations directly below each question. At the same time, as shown in the Figure 5.2, after each question, I added a unified text prompt trigger button "NEED HELP?", which replaced the previous method of triggering prompt information through keywords. What's more, I changed the presentation of the long text prompt information from pop-up all text to the Tab. I categorized the information into different tabs. Under each tab, the information was reasonably folded. In this way, the length of the overall information could be shorter, and users could expand and view the information according to their needs. The final interface of the page is shown in Appendix A.2. Finally, for the third point, I deleted the animation effect of the navigation bar, modified the logical sequence of external links provided by the website, and added small icons to external links to help users distinguish between internal links and external links.

5.1.2 Usability Evaluation

Think-aloud [40] is a method used to collect data in usability testing. Think-aloud requires participants to speak out their thoughts aloud when completing assigned tasks. In this way, researchers can analyze the data by recording their words, and finally get the results of the usability test [37].

System Usability Scale (SUS) was originally compiled by Brooke in 1986 [9]. The scale consists of 10 items, including positive statements for odd items and negative statements for even items. Participants are required to give 5 points for each item after using the website. The original purpose of SUS was to measure availability quickly and roughly, and it is now widely used in usability evaluation [23].

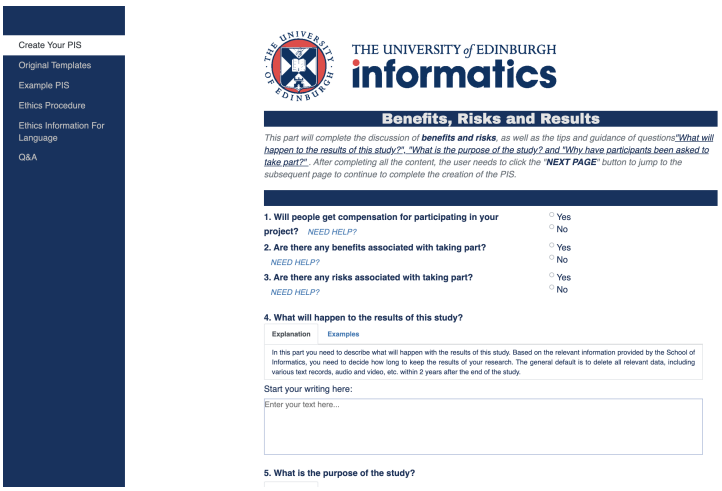

Figure 5.1: Interface of the web page after deleting the Hints column.

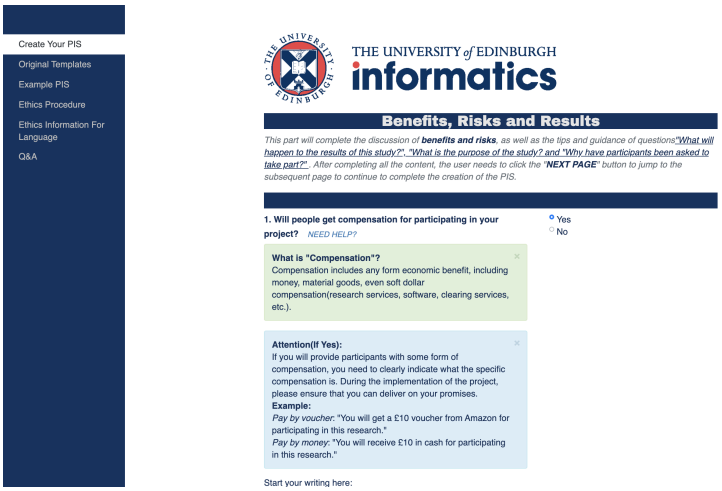

Figure 5.2: Interface of the web page after clicking the “NEED HELP” and “Yes” radio button.

According to the think-aloud method, participants were asked to complete tasks and the SUS questionnaire. I collected relevant feedback and the results of the questionnaire, completing the usability evaluation of the revised website. In the usability evaluation of this project, I recruited 8 participants to think-aloud. The script of think-aloud can be seen in Appendix B. All think-aloud is completed through the screen sharing and voice calls via Microsoft Team. Participants shared their computer screens with me and spoke their thoughts when completing the task. I recorded their words for later data analysis.

Think-aloud includes three tasks: Explore the website, Create your PIS and Get your PIS template. The general content and purpose of these tasks are as follows:

- Explore the website: This task required participants to browse the entire website and use the relevant links provided in the navigation bar to obtain the information they need when writing PIS, such as ethics regulations, PIS templates, etc. The purpose of this task is to find out whether the reference links provided by the website alleviate the anxiety of not being able to find the relevant regulations of PIS, as mentioned in Chapter 2.

- Create your PIS: This task required participants to answer all questions on the web page. In the process of answering the questions, they got some explanations and examples. The purpose of this task is to understand whether the guidance provided by the website can help them understand the content of the question better and feel more confident in how to fill in certain parts of the PIS.

- Get your PIS template: This task required participants to try to obtain and download the Latex code file according to their own understanding of the website. After the download is complete, they need to confirm whether it can be compiled into PDF files normally. The purpose of this task is to confirm whether the design of the website is easy to understand and whether the download function is working properly.

I used open coding to analyze the data collected during the think-aloud process. I organized this part of the data analysis into the following Table 5.2.

Through think-aloud, I found that 6 participants said they were happy to click "NEED HELP" to view the explanation of the question when answering it, and said that these explanations gave them a clearer understanding of the meaning of the question. 7 participants expressed that they are very satisfied with the external links provided in the navigation bar because these links provide almost all the content they want to see in the process of writing PIS. All 8 participants said that when they used this website to write PIS, they were more certain and more confident about what the questions meant and what they wanted to write. Compared with writing PIS by themselves before, they believed that this approach improved efficiency to a certain extent. But at the same time, some participants also put forward the defects of the website and optimization suggestions. 2 participants said that they think the examples provided under each question are not comprehensive enough. One of them said like "If its target users are researchers from the School of Informatics, you can add more examples of related projects, which will be more valuable." One participant thought the whole page was

a bit boring, and the way he answered the questions made him feel like he was filling out a questionnaire. These problems are the direction that this website needs to be optimized in the future. The final interface of the website can be seen in Appendix A.2.

5.2 SUS Result

After think-aloud, 8 participants completed the SUS questionnaire, which can be seen. I compiled the results of the questionnaire as a table which can be seen in Figure D.1 Appendix. Based on the SUS calculation formula, the SUS score of this project is 87.8125. The learnability score is 98.4375 and the usability score is 85.1563. The result means this project is usable and learnable.

Open Codes	**Theme**	
Don't know what should learn before the writing, the website provides ideas	External links solve users confusion in learning PIS-related information	Website positives
Don't know where to get the PIS template, the website solves it		
Don't know what regulations PIS needs to follow, the website solves it		
The website provides examples which help to know how to write	Guidance given by the website provides assistance	
The explanation of the problem is simple and easy to understand		
Each question has reasonable hints and examples		
Getting code very smoothly	Download function works well	
The website logic is clear, and the download function is simple and easy to understand		
The provided code file compiles smoothly		
The code file compiled in PDF format is fine		
Examples are not comprehensive enough	Website defects	Website improvements
The page is a bit boring, it feels like filling out a questionnaire		

Table 5.2: Think-aloud themes derived from open codes

Chapter 6

Conclusions

6.1 Overview

The purpose of this project is to help researchers whose studies involving human participants to write a participant information sheet. I planned to assist such researchers by providing an instructional website. In order to understand the problems or frustrations encountered by researchers in the process of writing PIS, and what are the mistakes that often occur in the PIS written by themselves, I used interviews and focus group discussions to explore user needs and pain points for data collection and analysis. A total of 15 participants included MSc and Ph.D. students and members of the ethics panel of the School of Informatics of the University of Edinburgh. From the descriptions of the participants, I determined what kind of help they would like to get when writing the PIS and what mistakes I needed to help them avoid. Based on this, I determined and completed the prototype design of website using Axure. Through two participants' feedback on it, I modified and improved the design. After prototyping the design, I used HTML, CSS and Javascript to complete the code implementation of the entire website.

I iteratively evaluated the interface and usability of the website. First, I randomly selected two pervious interview participants, and asked them to help complete the interface evaluation through the interview. They put forward suggestions for modification including webpages logic, component animation, text content, etc. Based on the content of this interview, I optimized the website iteratively. After this, I conducted the evaluation of the website usability. A total of 8 participants participated in the evaluation of this project through think-aloud. After completing the think-aloud process, in order to quantitatively analyze the usability of the website, they were also asked to fill

in the System Usability Scale questionnaire.

6.2 Results Achieved

This project summarized the frustrations encountered by researchers in the process of writing PIS and the mistakes they often make, mainly including the inability to obtain relevant resources, the vague definition of keywords, and the lack of understanding of data collection and storage methods. I concluded that the website established based on results analysis did help users to write PIS. Because most of the participants said that this project alleviated their anxiety about not knowing how to find PIS-related information, and provided comprehensive and practical help to make them more confident about what PIS is and how to write PIS. In general, providing a leading website like "Help Your PIS" can help researchers to write high-quality PIS with greater confidence.

6.3 Contribution and Limitation

By providing leading websites, this project saves potential users the time to independently search for materials, learn relevant ethics regulations, and PIS writing methods. Also, this project fills the gap that most websites currently only provide information collections and do not provide guided help step by step. The establishment of this website makes it easier for researchers who lack PIS experience to write PIS more confidently and efficiently. On the other hand, because researchers have a better understanding of PIS, the PIS they write with the help of the website can be more reasonable. This also reduces the workload of the members of the ethics panel who need to review the PIS.

Through the project evaluation, this project still has some limitations. For example, one participant thought the page design was a bit boring, and another participant wanted more comprehensive examples. Also, there is some content on the website that do not necessarily appear in the PIS, such as the question, "Will people get compensation for participating in your project?". If the user does not provide any compensation, then this part can be deleted from the template. However, due to time constraints, I did not realize the function which can automatically delete content based on user selections. I only marked that this part of the content can be manually deleted as needed in the template provided. These problems will be resolved in the future.

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Appendix A

Interface of the Website

A.1 Website Interface after the Initial Implementation

A.2 Website Interface after the Evaluation(final interface)

Figure A.1: Interface of the first page in “Create Your PIS” section.

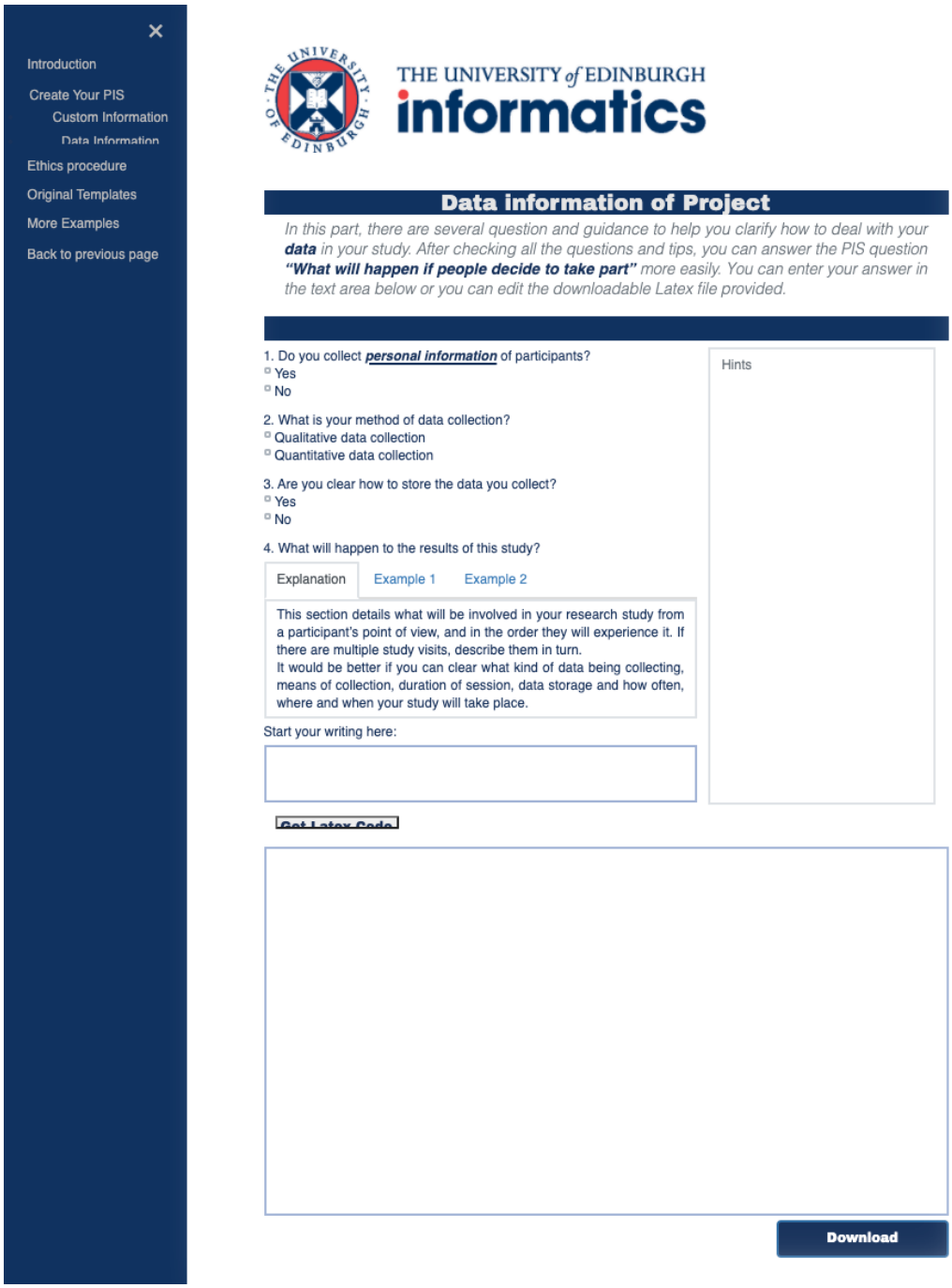

Figure A.2: Interface of the second page in “Create Your PIS” section.

Figure A.3: Interface of the first page in “Create Your PIS” section.

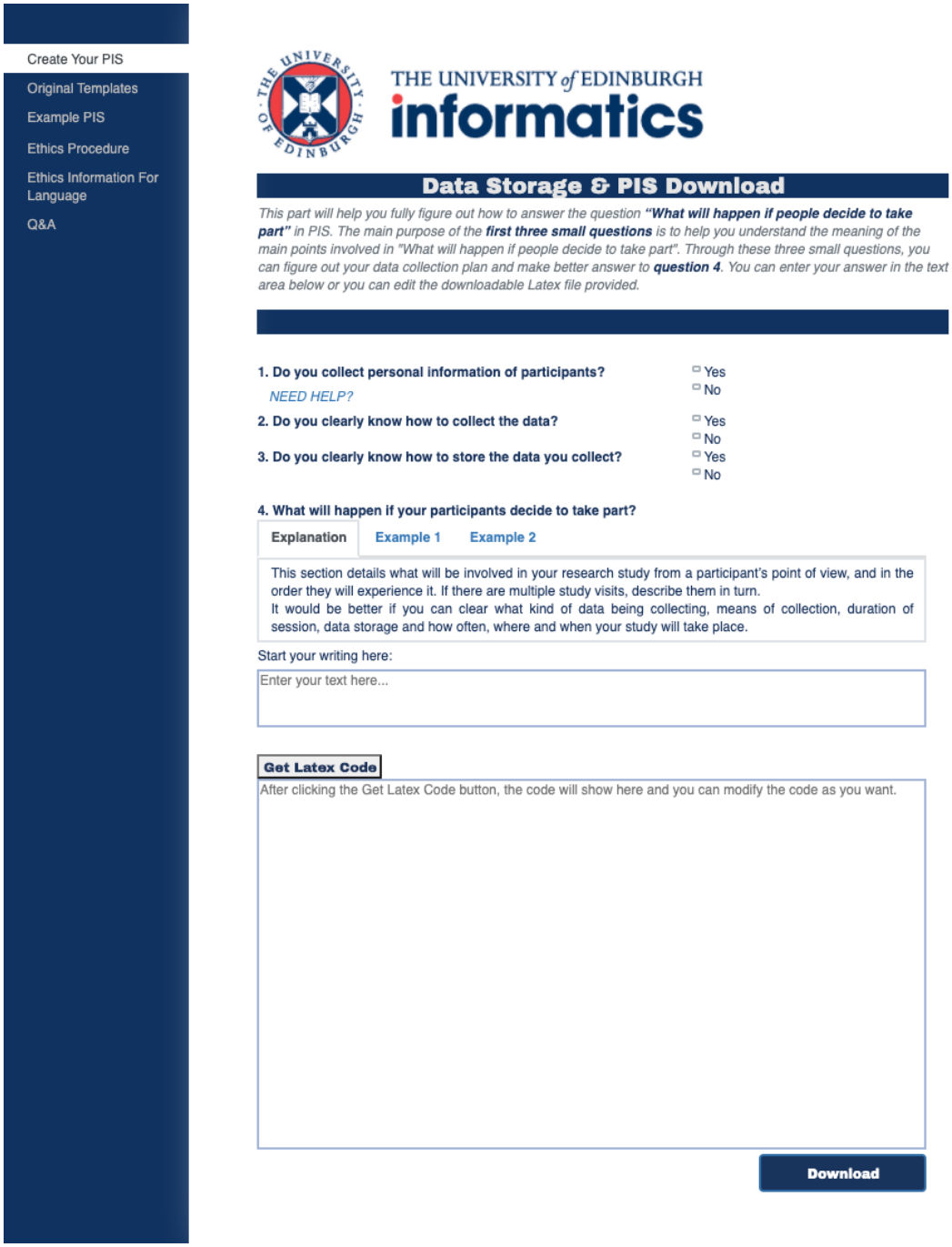

Figure A.4: Interface of the second page in “Create Your PIS” section.

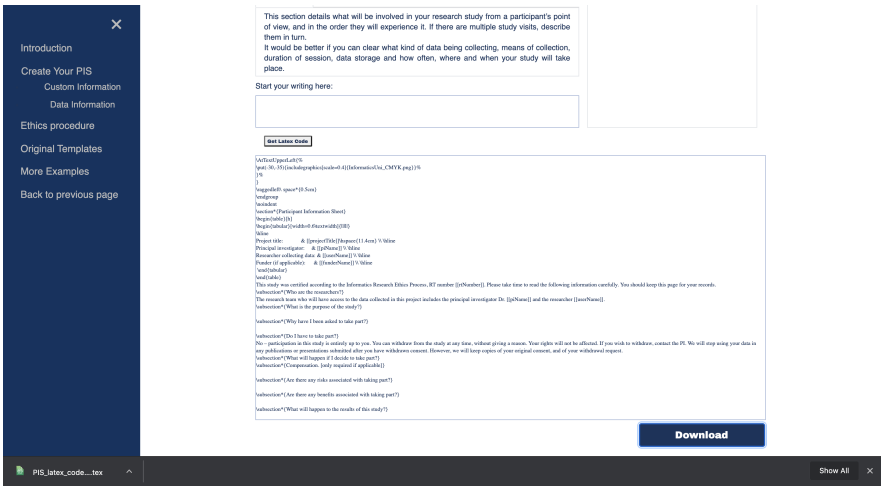

Figure A.5: The interface of the web page after click “Download” button.

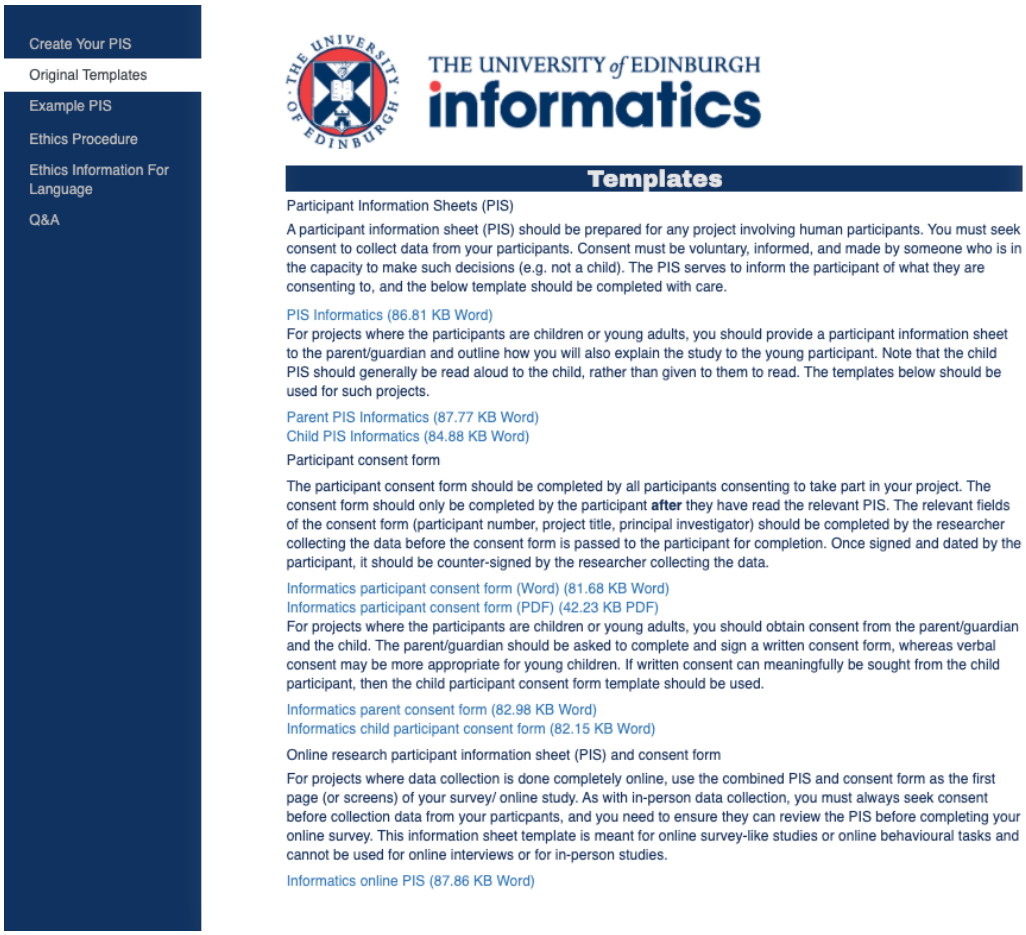

Figure A.6: Interface of the “Original Templates”.

Figure A.7: Interface of the "Example PIS".

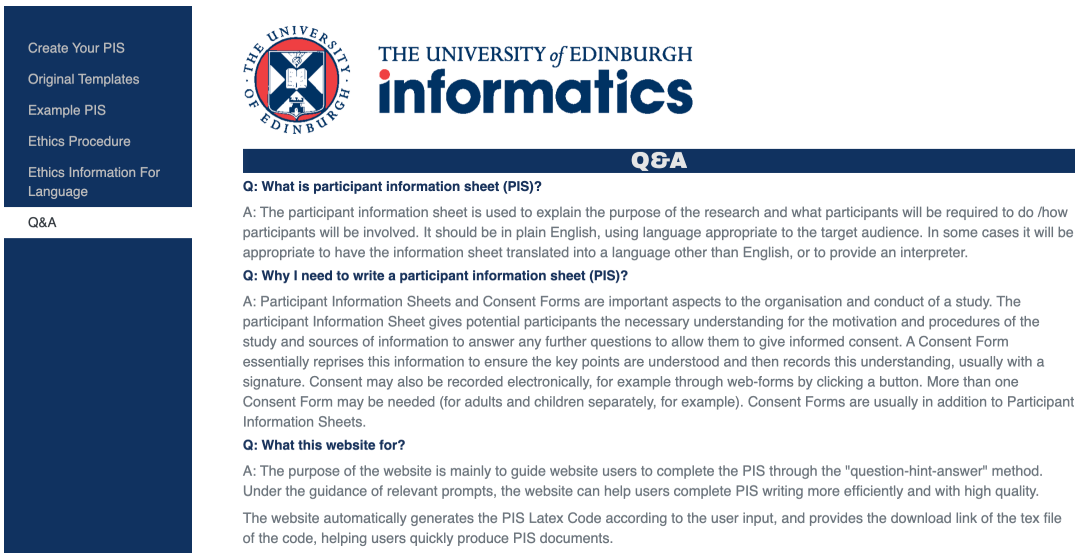

Figure A.8: Interface of the “Q&A”.

Appendix B

Important Code Screenshots

```
<script>
    var compensation_content_yes = $.cookie("compensation_cookie_yes"),
        benefit_content_yes = $.cookie("benefit_cookie_yes"),
        risk_content_yes = $.cookie("risk_cookie_yes"),
        compensation_content_no = $.cookie("compensation_cookie_no"),
        benefit_content_no = $.cookie("benefit_cookie_no"),
        risk_content_no = $.cookie("risk_cookie_no"),

        purpose_content = $.cookie("purpose_cookie"),
        reason_content = $.cookie("reason_cookie"),
        result_content = $.cookie("result_cookie");

    console.log(compensation_content_no);
    console.log(benefit_content_no);
    console.log(risk_content_no);
    console.log(compensation_content_yes);
    console.log(benefit_content_yes);
    console.log(risk_content_yes);
    console.log(purpose_content);
    console.log(reason_content);
    console.log(result_content);
</script>
```

Figure B.1: Screenshot of code used to obtain the input content by cookie.

Appendix C

Think Aloud Script

1 Researcher Script

Hello my name is: Souven Chen

Today we will be using the Help Your PIS website to do typical tasks like explore the links in navigation bar, check the guidance the website provides and create your PIS under the guidance of this website. You will not be entering any financial information and your participation today is purely voluntary, you may stop at any time.

The purpose of this exercise is identify issues with the Help Your PIS website. Please remember we are testing the website, we are not testing you.

1.1 Think aloud training

In this observation, we are interested in what you think about as you perform the tasks we are asking you to do. In order to do this, I am going to ask you to talk aloud as you work on the task. What I mean by "talk aloud" is that I want you to tell me everything you are thinking from the first time you see the statement of the task till you finish the task. I would like you to talk aloud constantly from the time I give you the task till you have completed it. I do not want you to try and plan out what you say or try to explain to me what you are saying. Just act as if you were alone, speaking to yourself. It is most important that you keep talking. If you are silent for a long period of time, I will ask you to talk. Do you understand what I want you to do?

Good. Now we will begin with some practice problems. First, I will demonstrate by thinking aloud while I solve a simple problem: "How many windows are there in my mother's house?"

[Demonstrate thinking aloud.]

Now it is your turn. Please think aloud as you multiply 120 * 8.
[Let them finish]
Good. Now, those problems were solved all in our heads. However, when you are working on the computer you will also be looking for things, and seeing things that catch your attention. These things that you are searching for and things that you see are as important for our observation as thoughts you are thinking from memory. So please verbalize these too.

As you are doing the tasks, I won't be able to answer any questions. But if you do have questions, go ahead and ask them anyway so I can learn more about what kinds of questions the Help Your PIS website brings up. I will answer any questions after the session. Also, if you forget to think aloud, I'll say, "Please keep talking."

Do you have any questions about the think aloud?

Now I have some tasks printed out for you. I am going to go over them with you and see if you have any questions before we start.

[Hand them the tasks.]

Here is the task you will be working on. Please read it aloud so you can get comfortable with speaking your thoughts.

Do you have any questions about the tasks? You may begin.

2 Tasks

It should be noted that you need to share your screen and have a voice call with me. I will observe the entire process of completing the task.

The link of the Help Your PIS website is: https://sweb.inf.ed.ac.uk/s1927736/

Task 1 Explore the website

Enter the website, find the navigation bar on the left, browse the links provided in the navigation bar except "Create Your PIS", and select the ones you are interested in or you think may be useful to view.

进入网站，找到位于左侧的导航栏，浏览导航栏中提供的除“Create Your PIS”之外的其他链接，选择你感兴趣的或者你认为可能有用的进行查看。

Task 2 Create your PIS

Go to the "Create Your PIS" section and answer all the questions in this section. This section contains two pages. After completing all the content of the first page, enter the next page through the "Next Page" in the lower right corner. You can try to obtain the help information given in the question according to your understanding of the content of the website, and complete the text of the corresponding questions. Stop operation when all questions have been answered.

For this part of the task, in order to improve efficiency, you can prepare the PIS you wrote before as a reference. When filling in the question, you can choose to rewrite or revise your previous PIS.

进入“Create Your PIS”部分，回答这个部分的所有问题。这个部分包含两个页面，完成第一个页面的 所有内容后通过右下角的“Next Page”进入下一页。你可以根据你对网站内容的理解，尝试获取问题中所给出的帮助信息，并完成相应问题的文字填写。当所有问题均被回答后停止操作。对于这部分task，为了提高效率，你可以准备好你之前写过的PIS作为参考，填写问题时，可以选择重写或者对你之前的PIS改写。

Task 3 Get your PIS template

After completing Task 2, you should now be on the second page of the Create Your PIS section. According to your understanding, try to obtain the Latex code of PIS, check whether the content you filled in before appears in the corresponding position of the code. If necessary, you can modify the code provided on the webpage. Download the code and compile the downloaded tex file according to your usual habits. Find out whether it can be compiled into a reasonable PDF file.

完成Task 2后，你现在应该在Create Your PIS这部分的第二个页面。根据你的理解，尝试获取PIS的Latex code，检查你之前填写的内容是否出现在了代码的相应位置，如有需要，你可以对网页提供的代码进行修改。下载该代码，并根据你平时的习惯，将下载的文件进行编译。搞清楚是否可以编译为合理的PDF文件。

Appendix D

SUS Questionnaire

D.1 SUS Questionnaire File

D.2 SUS Results

System Usability Scale

*Required

1. Please rate your level of agreement with each of the following statements: *

Mark only one oval per row.

	1 - Strongly Disagree	2	3	4	5 - Strongly Agree
I think that I would like to use this website frequently.					
I found this website unnecessarily complex.					
I thought this website was easy to use.					
I think that I would need assistance to be able to use this website.					
I found the various functions in this website were well integrated.					
I thought there was too much inconsistency in this website.					
I would imagine that most people would learn to use this website very quickly.					
I found this website very cumbersome/ awkward to use.					
I felt very confident using this website.					
I needed to learn a lot of things before I could get going with this website.					

Score	NO.1	NO.2	NO.3	NO.4	NO.5	NO.6
Q1	4	5	5	4	4	5
Q2	2	2	2	1	2	3
Q3	5	5	5	4	5	5
Q4	1	1	1	1	1	1
Q5	5	4	4	4	4	5
Q6	1	2	1	1	1	2
Q7	5	5	5	5	5	5
Q8	1	2	2	2	1	1
Q9	5	4	4	3	3	4
Q10	1	1	1	2	1	1

Figure D.1: The result of SUS questionnaire. The row means the score for each quesiton(Q1-Q10), and the column means each participant's number(NO.1-NO.8)

Appendix E

Ethics Procedure Documents

E.1 Participant Information Sheet

E.1.1 Focus Group

E.1.2 Interview

E.2 Consent Informed Form

Participant Information Sheet

Project title:	Help researchers write participant information sheets for studies with humans
Principal investigator:	Kami Vaniea
Researcher collecting data:	Souven Chen

This study was certified according to the Informatics Research Ethics Process, RT number 2019/50762. Please take time to read the following information carefully. You should keep this page for your records.

Who are the researchers?

The research team who will have access to the data collected in this project includes the principal investigator Dr. Kami Vaniea and the researcher Souven Chen.

What is the purpose of the study?

Writing a participant information sheet, such as the one you are reading now, can be challenging for researchers, especially students who are still learning about consent and research ethics. The aim of this study is to identify challenges researchers face when writing participant information sheets and build a website that will help them.

Why have I been asked to take part?

We are advertising the study to researchers with experience in writing participants information sheets and ethics panel members.

Do I have to take part?

No – participation in this study is entirely up to you. You can withdraw from the study at any time, without giving a reason. Your rights will not be affected. If you wish to withdraw, contact the PI. We will stop using your data in any publications or presentations submitted after you have withdrawn consent. However, we will keep copies of your original consent, and of your withdrawal request.

What will happen if I decide to take part?

You will be included as a member of the focus group. We will ask you to participate in a group discussion focus on your experience with writing participant information sheets. We will be asking several questions to guide the discussion which are aimed at understanding the process of writing a participant information sheet. Including what elements of the process were easy as well as those that were more challenging.

Due to the impact of the epidemic, we will hold these discussions using an online meeting platform like Microsoft Teams. With your consent, the video and audio of the interview will be preserved by recording. All recordings will be saved on a password-protected encrypted computer locally. Though they may also be stored on Teams itself temporarily as part of the recording process. If at any point you feel uncomfortable, you can ask me to stop the recording or state that you do not want something specific quoted.

Are there any risks associated with taking part?

There are no significant risks associated with participation.

Are there any benefits associated with taking part?

You will receive no compensation for participating in this study other than the knowledge that you have helped in the creation of a website which can provide helpful information.

What will happen to the results of this study?

The results of this study may be summarised in published articles, reports and presentations. Quotes or key findings will be anonymized: We will remove any information that could, in our assessment, allow anyone to identify you. With your consent, information can also be used for future research. Your data may be archived for a minimum of 2 years.

Data protection and confidentiality.

Your data will be processed in accordance with Data Protection Law. All information collected about you will be kept strictly confidential. Your data will be referred to by a unique participant number rather than by name. Your data will only be viewed by the lead researcher, Dr Kami Vaniea (kvaniea@inf.ed.ac.uk), and the researcher Souven Chen (s1927736@ed.ac.uk).

All electronic data will be stored on a password-protected encrypted computer, on the School of Informatics' secure file servers, or on the University's secure encrypted cloud storage services (DataShare, ownCloud, or Sharepoint) and all paper records will be stored in a locked filing cabinet in the PI's office. Your consent information will be kept separately from your responses in order to minimise risk.

What are my data protection rights?

The University of Edinburgh is a Data Controller for the information you provide. You have the right to access information held about you. Your right of access can be exercised in accordance Data Protection Law. You also have other rights including rights of correction, erasure and objection. For more details, including the right to lodge a complaint with the Information Commissioner's Office, please visit www.ico.org.uk. Questions, comments and requests about your personal data can also be sent to the University Data Protection Officer at dpo@ed.ac.uk.

Who can I contact?

If you have any further questions about the study, please contact the lead researcher, Dr Kami Vaniea (kvaniea@inf.ed.ac.uk), or the researcher Souven Chen (s1927736@ed.ac.uk). If you wish to make a complaint about the study, please contact inf-ethics@inf.ed.ac.uk. When you contact us, please provide the study title and detail the nature of your complaint.

Updated information.

If the research project changes in any way, an updated Participant Information Sheet will be made available on https://web.inf.ed.ac.uk/infweb/research/study-updates.

Alternative formats.

To request this document in an alternative format, such as large print or on coloured paper, please contact the lead researcher, Dr Kami Vaniea (kvaniea@inf.ed.ac.uk), or the researcher Souven Chen (s1927736@ed.ac.uk).

General information.

For general information about how we use your data, please visit:
https://edin.ac/privacy-research

Participant Information Sheet

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No – participation in this study is entirely up to you. You can withdraw from the study at any time, without giving a reason. Your rights will not be affected. If you wish to withdraw, contact the PI. We will stop using your data in any publications or presentations submitted after you have withdrawn consent. However, we will keep copies of your original consent, and of your withdrawal request.

What will happen if I decide to take part?

We will interview you with some questions about your experience with writing participant information sheets. The questions are aimed at understanding the process of writing a participant information sheet. Including what elements of the process were easy as well as those that were more challenging. For ethics panel members and supervisors, we will also be asking about common errors that they often see researchers and students make.

Due to the impact of the epidemic, you can choose to be interviewed by video conference, audio (telephone) or email. With your consent, the audio of the interview will be preserved by recording, and the text content of the email will also be saved. All of the audio record and the email will be saved in a password-protected encrypted computer locally. If at any point you feel uncomfortable, you can ask me to stop the recording, or state that you do not want something specific quoted.

Are there any risks associated with taking part?

There are no significant risks associated with participation.

Are there any benefits associated with taking part?

You will receive no compensation for participating in this study other than the knowledge that you have helped in the creation of a website which can provide helpful.

What will happen to the results of this study?

The results of this study may be summarised in published articles, reports and presentations. Quotes or key findings will be anonymized: we will remove any information that could, in our assessment, allow anyone to identify you. With your consent, information can also be used for future research. Your data may be archived for a minimum of 2 years.

Data protection and confidentiality.

Your data will be processed in accordance with Data Protection Law. All information collected about you will be kept strictly confidential.

All electronic data will be stored on a password-protected encrypted computer, on the School of Informatics' secure file servers, or on the University's secure encrypted cloud storage services (DataShare, ownCloud, or Sharepoint) and all paper records

will be stored in a locked filing cabinet in the PI's office. Your consent information will be kept separately from your responses in order to minimise risk.

What are my data protection rights?

The University of Edinburgh is a Data Controller for the information you provide. You have the right to access information held about you. Your right of access can be exercised in accordance Data Protection Law. You also have other rights including rights of correction, erasure and objection. For more details, including the right to lodge a complaint with the Information Commissioner's Office, please visit www.ico.org.uk. Questions, comments and requests about your personal data can also be sent to the University Data Protection Officer at dpo@ed.ac.uk.

Who can I contact?

If you have any further questions about the study, please contact the lead researcher, Dr Kami Vaniea (kvaniea@inf.ed.ac.uk), or the researcher Souven Chen (s1927736@ed.ac.uk). If you wish to make a complaint about the study, please contact inf-ethics@inf.ed.ac.uk. When you contact us, please provide the study title and detail the nature of your complaint.

Updated information.

If the research project changes in any way, an updated Participant Information Sheet will be made available on https://web.inf.ed.ac.uk/infweb/research/study-updates.

Alternative formats.

To request this document in an alternative format, such as large print or on coloured paper, please contact the lead researcher, Dr Kami Vaniea (kvaniea@inf.ed.ac.uk), or the researcher Souven Chen (s1927736@ed.ac.uk).

General information.

For general information about how we use your data, go to: edin.ac/privacy-research

Participant number:_____

Participant Consent Form

Project title:	Help researchers write participant information sheets for studies with humans
Principal investigator (PI):	Kami Vaniea
Researcher:	Souven Chen
PI contact details:	kvaniea@inf.ed.ac.uk

By participating in the study you agree that:

- I have read and understood the Participant Information Sheet for the above study, that I have had the opportunity to ask questions, and that any questions I had were answered to my satisfaction.
- My participation is voluntary, and that I can withdraw at any time without giving a reason. Withdrawing will not affect any of my rights.
- I consent to my anonymised data being used in academic publications and presentations.
- I understand that my anonymised data can be stored for a minimum of two years.

Optional study components

The following are parts of the study that would assist our research, but are not required. At the beginning of the interview or focus group, we will ask if you are comfortable with each of the points below. If you are not comfortable, it is ok to say so. You may also contact a researcher in advance or after the study to express your preferences.

- Audio and video recording
- Use of my data in future ethically approved research.