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Lecture – 08 Institutional Review Board, Ethics committee, IRB documents / application, consent form

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Welcome back to week 3 for the course introduction to human computer interaction. What I am going to do now is to walk you through some of the documents and some of the information that you will have to prepare for actually doing user studies. So, there is a huge set of requirements or needs now which is coming up if you were to do any human subjects study where you are collecting data from end users, where you are collecting users to do use the systems it has become necessary for doing this IRB approval.

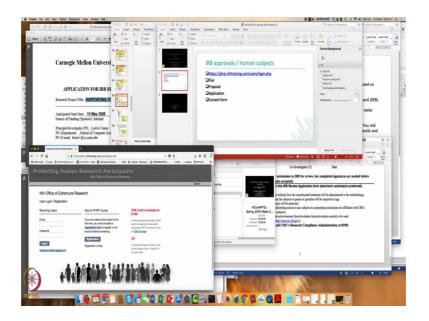
IRB stands for Institutional Review Board, but I think in India there is Ethics Committee, there is Ethics Review Committee, there are many different forms of the same entity called IRB. And the main purpose of this IRB is to actually look at the information that you are presenting to them about what study you want to do, what information you want to collect, how will you collect the information, who will be their end users all of that information.

What I am going to do now is I am going to first walk you through all the necessary information that you need to create the IRB application. And I will also show you a sample concern form, which you can probably use for the studies that you will end up doing. And remember this is not only necessary for academics or researchers, this is important for industry too, because if anything goes wrong, it will be necessary for somebody to protect you as the administrator of the study and the participant of the study. So, it is better to have some level of approvals for doing the human subjects study, users study, data collection from users all of that.

So, I have listed here five different topics. The first one is small training program that you should undergo to get the information about how to do these human subjects. It is a very short content you go through. And if you finish the content, they will ask you some questions; and if you answer it, the questions are also very very subjective. So, depending on your answer at the end of it they will give you a certificate which you will have to actually attach it when you are doing this IRB approval.

And whatever I am going to show you I did it personally myself during my grad school and these are the applications, these are the proposal application consent form fliers and the certificate that I had during my grad school. So, it will give you a real world application with real information on how you can actually write the IRB application and get it approved.

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So, let us go to the first one. So, this is the link that is in the slide which is on protecting human research participants and I as office of extramural research. So, it is basically a place where you can go sign up, go through the content and get your final certification. So, once you have the certificate, you can actually open you can actually submit the application with this certificate. I will show you an example of the certificate also.

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Here is an example of a certificate. When you are done with the content from the website from NIH website, you should be able to have this completion certificate like. The reason why you want to have this completion certificate is whenever you are applying for your IRB approvals, you should actually present saying that I am I am done with the content, I know the content about how to conduct human subjects research.

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Now, let me show you the second one, which is a flyer this is an actual flyer that I used during my data collection. Let us see what all this flyer has and how you can actually reproduce it in any of the studies and data collection that you are doing. 70 minutes interview get paid 20 dollars research group at Carnegie Mellon university is conducting a 70 minute user study, qualification for participation must have an email account, ability to travel to Carnegie Mellon's campus be at least 18 years old 20 dollar payment upon completion. And then there is a stub that is kept at the end where you will cut it in between the two stub which is 70 minute interview 20 dollars contact some email address right.

You cut it and keep it you kind of paste this flyer around wherever you were looking for collecting getting users. And when the users are interested in study, they will take the stub email at email the person mentioned in this stub, and coordinate for the user study. There are many mechanisms by which you can actually get participants one of the mechanism is like this which is a typical way of putting a flyer, but other than that there are campuses where you would campuses or portals where you can actually talk about ask for participants. And there is of course, mechanical turk now, and there are many portals like this where you can recruit participants.

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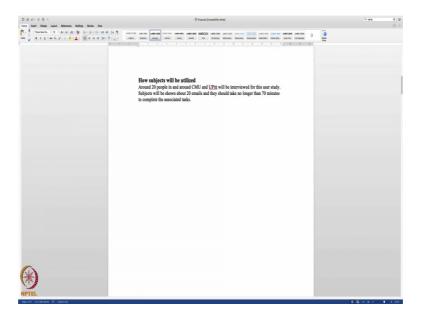


Now, let me walk you through the proposal which you have to prepare for getting the IRB approval. Again this is only an indicator this is not the only kind of document only a kind of proposal that you can write. This is the kind of proposal that I have written. So, I am just sharing with you how a proposal for IRB approval IRB approval is done. Essentially as I said what is the main goal for the IRB committee is to check whether this is the only way to collect data, and how are you collecting the data, who are the participants what kind of data is being collected.

So, in the proposal first you basically describe summary of the study so to say the study investigates why people fall for phishing scams that is my kind of work. We describe how we are going do what, what is this study all about right we want to test how effective standard email security notices are. We plan to conduct the study with people who are non-technical and novice in the area of security.

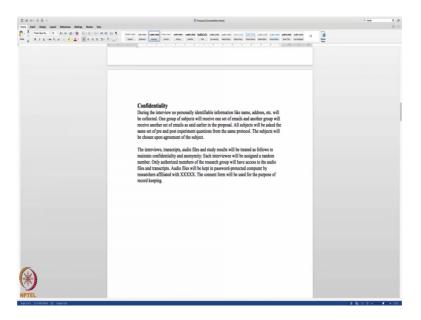
When these findings will help us understand how to make how people make online decisions we plan to show about any emails for subjects to make decisions you know personal information will be collected during this time. So, that is the kind of meaning I will I will make this document also publicly available for in inside the course mailing list, but the point I want to get across with showing the proposal is at least the first part is talking about a summary of the study, what is the study all about.

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So, then how subject will be utilized how many what kind of subjects are you planning to get. So, around 20 people in and around CMU and University Pittsburgh will be interviewed for the study subjects will be shown about 20 emails and they should take no longer than 70 minutes right. So, that is the kind of information that you are giving to the in the proposal.

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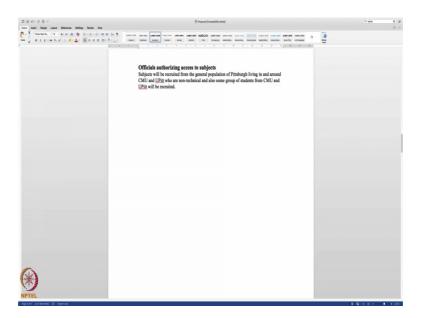
Here are some important pieces of information which is that how are you going to protect the confidentiality of the information that you collected. And I think it briefly

also mentioned in the last lecture that I would recommend when you are collecting data about the users to keep the username which is (Refer Time: 07:59) grow in this case away from the data that you are collecting. So, that there is some kind of a random number or some number that you have alphanumeric digits that you have which is reference to me and not necessarily my own name.

During the interview no personally identifiable information like name, address etcetera will be collected, one group of subjects will receive one set of emails and the other group. So, this I think we will I will cover this later which is a concept called how do you design a study which is within a design and between design studies will actually cover this later. But all subjects will be asked the same set of pre and post experimental questions from the same protocol.

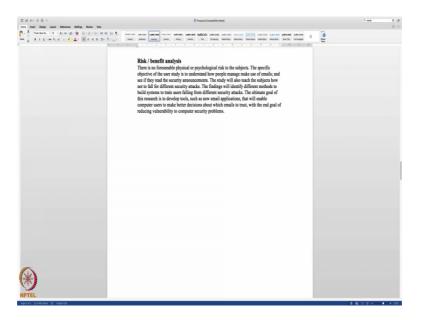
So, some new terms are coming in I will just briefly tell you what they are right. As a pre and post experiment which is before actually study actual experiment, you are going to ask them some questions; and the ex when the experiment is done you are going to ask them some questions that is the pre and the post. And the same protocol the word protocol is referred to basically about the question or questions that you are asking the participants. The subjects will be chosen upon agreement of the subject, the interviews transcript audio files and study results will be treated as follows to maintain confidentiality only authorized members of the research group are basically protecting the data. So, hopefully you get the point that.

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The information is not the data that you collected is not accessible to anybody and everyone. Subjects will be officials authorizing access to subjects, subjects will be recruited from general population of Pittsburgh living in and around CMU and University of Pittsburgh or non technical and also some group of students from CMU and it will be recruited.

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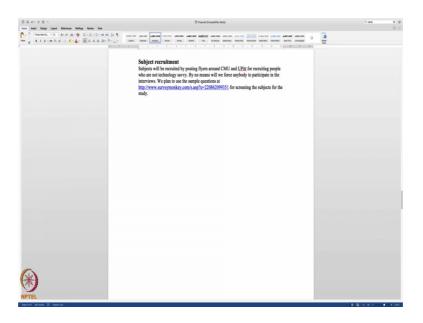


So, then we describe what kind of risks are for these kind of studies and particularly there are meaning when I show you the application, you will actually see that the three

kinds of broadly three kinds of studies where the one does minimal risk, medium risk, and very high risk. Majority of the studies that we do in this kind of thing in this kind of topic like security and computer science is going to be mostly minimal risk. There is no foreseeable physical or psychological risk to the subjects. the specific objective of the user study is to understand how people manage make use of emails and see if they read the security announcements so right so that is the goal of benefit for doing the study.

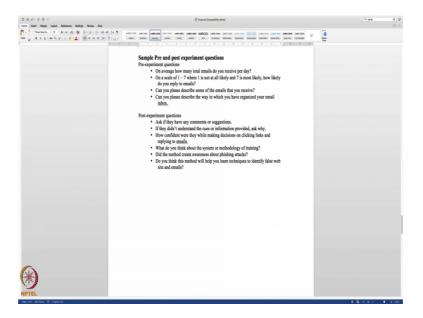
The study will also teach the subject are not to fall for different security attacks. The findings will identify methods to build systems to train users falling from different security attacks. The ultimate goal of this research is to develop tools such as new email applications right, so that is the kind of explanation that you are giving what the benefits are.

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Subject recruiting subjects will be recruited by posting flyers around CMU and University of Pittsburgh for recruiting people who are not technology savvy. So, the point that I showed you first the flier is this right when I mean flier here is the flyer that I showed you earlier with stubs and way to contact to be part of the study. And we plan to use the sample questions given here for screening the subjects for the study I will show you the survey questions in few minutes, but that is the information that we are presenting in the subject recruitment category.

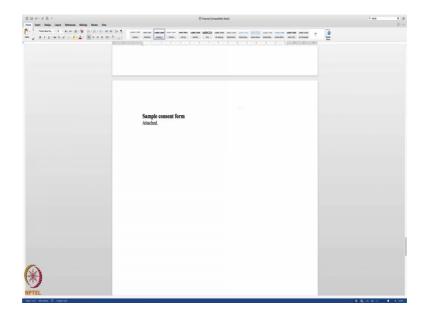
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So, here is the sample for pre and post experiment questions. There are many types of questions that you can ask in the pre and the post. One of the reasons why you definitely want to have a free experiment questions is to actually recruit people or design people who will participants who will participate in your study. This you could just use this as a screening questions, where you can say that I need participants who are this category which is male, age 20 to 25, studying engineering in engineering colleges, and doing this sort of thing or have this type of experience. On average how many total emails do you receive per day right these are the questions that I asked in my pre-questions.

And post questions is asked if they have any comments or suggestions if they did not understand the cues or information provided. So, basically one of the other thing that you will see later in the lectures also is this idea of debriefing. Debriefing is super important while doing the user studies. We will get into details of a debriefing error, but for now these are the kinds of questions or comments that you can make during the debriefing that we are doing.

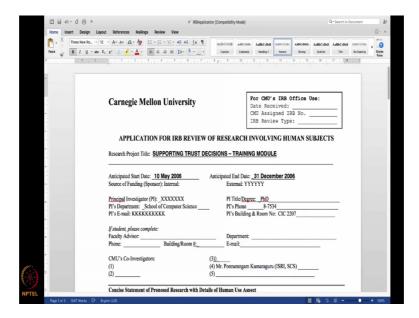
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Sample concern form, so we will come back to the sample consent form again so, what are the things that we will come back, we will come back to the server question or concern form. Human subject's clearance requests the one I just now showed you which is a set you have to go through the NIH training have the certificate and basically you put that certificate with the application, so that that gives you a sense of what the IRB application is. In general, I think having these kind of applications these kind of proposals written is very very sound because I think the ethics committee be IRB committee gets a very good insight on what the study is going to be, what kind of data you are going to collect, so they can actually make a judgment.

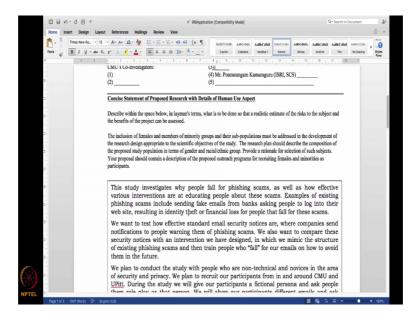
So, that is the main reason about why these kind of proposals applications processes being created is because there have been in the past studies that have been done where data has been collected and it has a hide effect on the users and negative effects on the users also. So, that is one of the reasons why such kind of processes and such kind of requirements have been imposed. Now, that when you do human subjects study you are supposed to be collecting such kind of you are supposed to be having these kind of proposals written consent form which actually describes what the study is. I will show you that consent form again, so that describes what the proposal is. I will show you later about the consent form, survey questionnaire application that we likes to develop for writing the proposal package.

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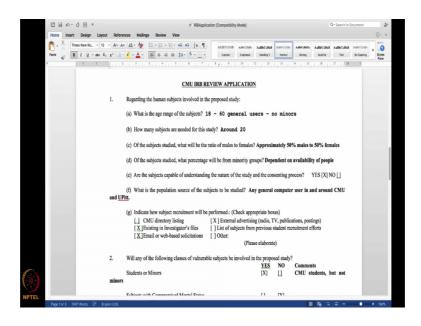
Now that we have seen the, IRB proposal document let me walk you through the IRB application form. Why is this application important as I said before the application is important because it describes the kind of data that you want to collect describes, how you plan to use the data and describes the kind of way that you will actually use this data for doing the analysis. But this is an application that I use during my data collection, so I am just walking you through the exact up application that I actually used. So, initially it is all more administrative purposes starting date end date, who is the investigator rule have access to the data.

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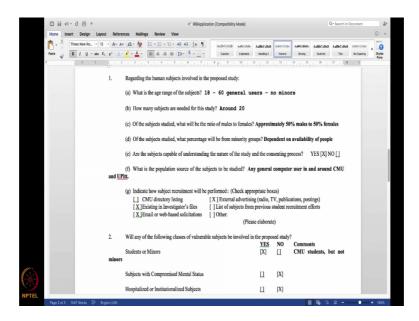


If you see this is the summary of the study that we will plan to do it is probably the same as the first few paragraphs that we had in the proposal.. So, here it says this, this study investigates why people fall for phishing scam as well as how effective where these interventions are at educating people about these scams. We want to test how effective standard email security notices are where companies send notifications to people, warn warning them of phishing scams. So, essentially it is building on the phishing study that I was doing. We plan to conduct the study with people who are non technical or novices in the area of security and privacy, so that is the kind of subjects. Again this is just a summary.

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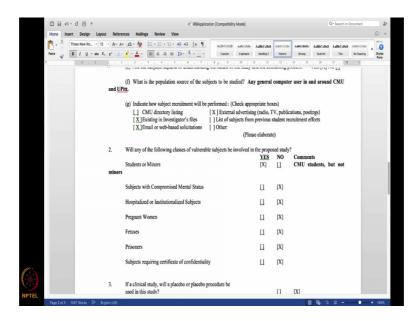
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Here are some important things that you want to actually keep in mind while applying or while actually creating these kind of forms in your own institutes or wherever you want to apply this kind of information. What is the age range of the subjects? So, I generally you want to actually mention that what is the age group that you want to collect the data from. How many subjects of the subject studied, what will be the ratio of male and female, one of the thing that the IRB or the ethics committee is looking for is the distribution of the gender data that you are collecting. Usually you want to mention that it is fifty-fifty and it is actually good for your even study that if you have male and female fifty-fifty distribution it is going to be hard. But if you keep it fifty-fifty the kind of conclusions can be more concrete.

Of the subjects study what percentage of them would be minority groups, so all this is basically trying to look at what kind of data you collecting, and what are the sample that you are studying. Are the subjects capable of understanding the nature of study and consenting process, what is the population source of subjects to be studied, indicate how subject recruitment will be performed. So, if you go back I if you remember I showed you about the flier. So, I have it here existing in investigators files email or web base, external advertising to TV publication, postings which is flier.

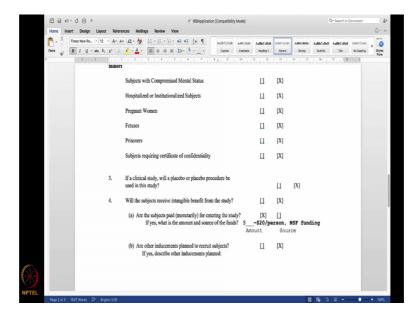
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And particularly the IRB and ethics empathy is looking for that the subjects that you are going to collect data from are not vulnerable so to say. So, here if you see the categories of questions or the options that is given are students or minor subjects with compromised mental status hospitalized or institutionalized subjects, pregnant women, fetuses, prisoners, subjects requiring certificate of confidentiality.

So, the idea is that if you are going to collect data from these kind of participants, the kind of evaluation for the application will be slightly different. What I what the application that I have is more like a minimal risk study and I was just collecting about emails. So, it probably does not have too many risk attached to it.

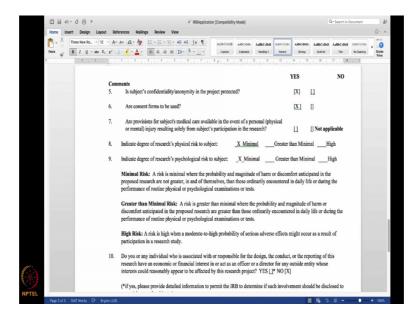
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Just imagine if you were to do a medical study that is if you were to let us take develop a new tablet for some disease. And you want to test it on human beings. You want to give them the medicine see them after a couple of days, take some tests and look at the results and things like that. In that case, the IRB is going to actually look at your application more seriously, and make sure that the kind of data that you are collecting the kind of participants that you are collecting data from are actually protected in somewhere.

Here are the other set of questions if a clinical study will a placebo or placebo procedure be used. Again these are all more details about the kind of subjects. Are the subjects paid for entering the study if s what is the amount or other inducements plan to recruit subjects.

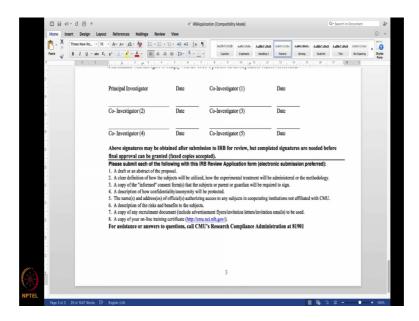
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And, so here is what if you remember I mentioned one thing about the kind of study or the kind of risk that is associated with it. Here it says indicate degree of research physical risk to subject indicate degree of research psychological risk to subject this is one critical piece of information that you want to keep in mind while doing these kind of human subjects studies what is the kind of risk level that you are putting the subjects into which is the subjects are going to have only minimal risks just by looking at emails. Whereas, they may have high risk if they if you are going to give them let us take a tablet, medicine and study something about how it is at what is happening inside the body.

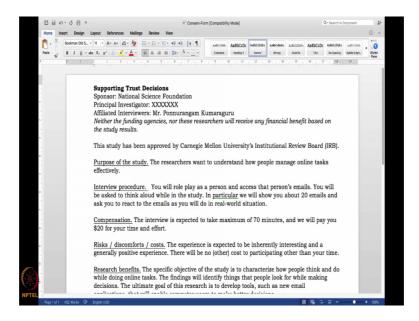
So, this is simple definition of minimal risk. And risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research or not greater in and of themselves then those ordinarily encountered in daily life. Risk is high when a moderate to high probability of serious adverse effects might occur as a result of participation in the research study right. And then it says about different people involved in the study and then the application and step.

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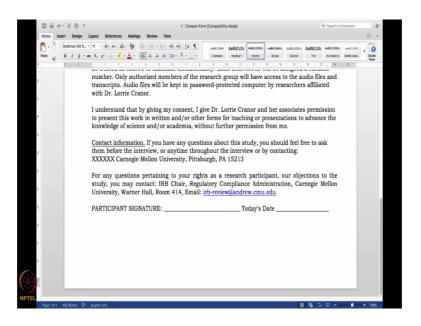
I really think that in India, when we do study, we should actually start looking at these kind of ethics board, IRB ethics committee to be more serious to make sure that at least there is some kind of sanity check in the kind of data that is being collected. And particularly in computer science particularly where technology is involved, it is probably nice to have these kind of protection. And if you are a researcher, the conferences and journals have started asking this regularly now that you have to present your IRB approval documents to the conference and journal for them to actually accept your paper. I hope that gives you a sense about what an IRB application is.

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Now, let us look at the last document that I wanted to share in this sequence of documents about IRB approvals. So, this is the consent form. What is the consent form consent form is something when you take part in a study you are basically provided information about the study, how the data will be used. And as a participant in the study you are signing up for saying that I am with participating in the study. This is like end users license agreement right. When you are downloading an app it shows you a bunch of text, and you are agreeing to download the app and use it. It is the same thing. You are agreeing to be part of the study is by signing on this consent form. The way that this consent form will be a presented is that this draft is presented to the IRB, IRB approves the consent form and they actually sign it at the end at the bottom right or bottom left.

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And then you take the photocopy of this particular signed copy of the IRB approval consent form. And you take the signature of the participant in the consent form. So, this does not have to be in the physical form it could be even in the online world, you could put the concern form and then have an agree button when they click on the agree button, it is assumed that the participant is agree into to be part of the study.

Let me tell you what are the important things that you want to actually keep in the consent form. I think consent form is a good idea. Even if you do not have a IRB requirement or an ethics approval requirement, it is always a good idea to have a consent form while you are talking to an user. So, you can actually use the data as you can

actually take a picture of the user, and use the picture in your let us take slides, report, other places and recordings that you do you can probably plate in other places and show it to people, video recording and everything like that. So, it is a good idea to have a consent form signed by the participant.

So, here it says about the project title principal investigator who are involved this study has been approved by so and so purpose of the study. See, if you look at it these lines are basically a condensed version of what is in the proposal an application the researchers want to understand how people manage online tasks. Interview procedure this is what will happen 20 emails will be shown to you, and you have to react to it compensation you will need approximately will take about 70 minutes and will pay it 20 dollars. Risks or discomforts the experience is expected to be inherently interesting and a generally positive experience, there will be no cost to participating other than your time.

Research benefits the specific objective of the study is to characterize how people think and do while doing online tasks. And benefits the findings will identify things that people look for while making decisions the ultimate goal of this research is to develop tools. Again it is a it is a text from the proposal right. By no means should you feel forced to participate in this interview, you can withdraw your consent and stop your participation in the interview now or at any time. Without affecting your relationship with it the university or the organization and without loss of any benefits to which you may otherwise be entitled.

Confidentiality I understand that the interviews transcript audio files and the studied results will be treated as follows same thing from the confidentiality section of the proposal I understand that by giving my consent I give now so and so under associates a permission to present this work in written and or other forms for teaching or presentations to advance the knowledge of science and or academia with it. So, basically this is the reason why you want to get the sign, because it is clearly stating that the data the pictures that you are taking the transcription that you will make from the interviews can actually be used for other reasons.

If you have any questions about the study you should feel free to ask them before the interview bla bla and some contact details that right. So, this helps to wrap up this part about IRB application. And I will actually later follow up on why these things are

more important now in terms of doing user studies. With that I will wrap the content for the first part of the week three, where I am just describing about different documents that are needed for IRB approvals basically for doing user studies.