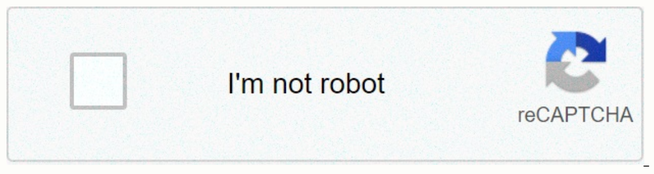


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# Informed consent document template

Using one of these templates will help ensure that all consent factors required by the regulations are included in your document. This template is just a guide and you can modify the document to meet your research needs. However, it is very important that you include all the agreed elements in your document unless your research falls into one of the types of research exemptions. The approval document should use an 11pt. or larger font. Please do not include headlines such as Attachments or Annexes on the consent form, as the approved document will be stamped with IRB approval. Please leave a 1 1/2 inch margin at the top of the document to accommodate stamps. The stamped document will then be copied for use in your research to ensure that the document approved by the IRB is currently in use. The IRB stamp will also serve as a reminder of the date of approval of the approval document and will assure participants that the study has been reviewed by the IRB. Note: For student submissions, the primary Supervisor's contact information must be included in the consent form. In some cases, the IRB may res noted requests for informed consent. View information about the abandon or change of notification consent. Researchers will be prompted to provide justification for consent-related exemptions in IRB applications. The IRB must ensure that the materials and processes to get research consent meet the full standards to protect the participants. The use of samples can assist investigators in preparing consent documents for the study by including the requirements outlined in the General Rule to protect study participants and requirements in WSU policy. The following templates are instructions. Instructions are integrated into the templates to show which elements are required and which can be modified to fit individual protocols. In general, language should make sense for specific research projects while meeting the regulatory requirements for informed consent. Notice Approval Guidelines and Notification Approval Process Tools: WSU IRB Roadmap for Approved Options notified for Research (PDF) Mandatory Elements of Consent Notified (updated 10/10/10) 2019) (PDF) Main Information Guide (RCR) How to check the reading level of an consent (.doc) Sample Lay Language for Risk (.doc) Exemption from consent or change to the consent form will used to draft specific forms of consent studies (Word Docs): Consent Notification Studies for Adults - Behavior Studies (revised 3/2019)Consent notification studies for adults Major - Medical Research (revised 3/2019)DMC /Tenet Research Informed Consent - All Research Using DMC Services (amended 3/2019)Mc Consent to announce Slaren's research ( amended 08/2019) VA approval form with hipaa & VA combined consent and hipaa guide pregnancy partner consent form (NEW) (04/2019) saving table information for adults - - Optional Signature (amended 3/2019) COVID-19 Phone Script (NEW) COVID-19 Participant Information Panel (NEW) Parental Permission/Informed Research Consent - Behavior or Medical Research (amendment 3/2019) Additional information letter from parents of students - Request to give up parental permission (amended 3/2019) Permission of school parents / Consent to study notice (amended 3/2019) Adolescents (ages 13-17) Ass sampleent - Medical research (revised 3/2019)Adolescents (ages 13-17) Consent form - Behavior study (revised 3/2019) Sample agreed to use the device humanitarian (04/04) 2015) Oral children (aged 7-12) Consent scenario (New) (3/2019)- The person who has oral consent must sign a parental license / Consent notification study on the appropriate signature line. For non-English speaking People Request translation consent for non-English speaking person (PDF) Short sample consent A short sample consent and oral translation of consent in English is required if an individual's access to consent is not fluent in English, a written translation of full consent is not available, and this is unforeseen. Short sample versions are available: Albania, Arabic, Bengali, Chinese-Simplified, Chinese-Traditional, Farsi, France-Canada, France-Europe, Germany, Greece, Hindi, Italy, Poland, Russia, Serbia, Spain-Mexico, Swahili, Tamil, Thailand, and Ukraine If short form is needed in a language other than these 18, the English version of the sample consent is short (PDF) must be translated into that language and the IRB approves the Clinical Trial Registration Requirement For all research initiated by investigators and sponsored research Clinical trial research required by law must be registered on the clinicaltrials.gov website [U.S. Public Law 110-85 (FDAAA)] and a statement must appear in the approved document notified saying it is registered. For more information about this law and requirements for donors and/or investigators, visit the Protocol Registration System (PRS) and the U.S. Public Law Information Page 110-85. The information here should be a clear and concise description of the bottom line of the study. Keep details of the study until later in the document. Briefly give the subjects some basic information about why this study is being done, which may include information about what is already known and what you hope to learn. WHAT IS RELEVANT TO THE STUDY? If you decide to participate, here is a basic outline of what happens during your participation ___ We think this will take you _____ Call the objects friends. Let the audience know exactly what to expect. Explain in detail what will happen during the research process and how the study will work. Include everything the audience will be asked to do step by step. Describe all the and data collection tools that objects will experience. Said where the research will take place, how often they will be asked to perform tasks, how long each survey or procedure will take, and specify the time (e.g. minutes, hours, days, months, until a certain event or end point) the subjects will be part of the study. If multiple visits will be organized provide a timeline and detailed description of each visit. If audio or video recording will be used, the subject must be notified. If recording is necessary to participate this must be clearly stated. If research takes place in a classroom it must be clear what effort is needed for classes and classification and what is research. Investigators can stop researching or take you out of research anytime they judge it to be in your best interest. They can also remove you from research for a variety of reasons. They can do this without your consent. If appropriate, list any additional reasons why the subjects could be taken out of the study. You can stop participating at any time. If you stop, you will not lose any benefits. RISKS This study relates to the following risks __ There may also be other risks that we cannot predict. List the physical and psychological risks associated with the study above. Risks may include side effects, stress, discomfort, security breaches, invasions of privacy, social, psychological or economic harm; risk of criminal or civil liability; damage to your financial situation, employment, or reputation. If no known risks then indicated We believe that there are no known risks associated with taking but there may be some we are not aware of. DO NOT SAY THAT NO RISK OR RISK SHOULD BE NORMAL. WHAT ARE THE BENEFITS OF PARTICIPATING IN RESEARCH? It is reasonable to expect the following benefits from this study: _____. However, we cannot guarantee that you will personally experience the benefits of participating in this study. Others may benefit in the future from the information we found in this study. List all the benefits that can be reasonablely expected from participating in the study. First describe the benefits to the subjects, then describe the benefits to others. Without benefiting from participating in research, that fact state. SECURITY We will take the following steps to keep information about you confidential and to protect it from unauthorized disclosure, tampering, or damage: ___ In some cases, it may be necessary, for your safety or for the integrity of research, for individuals from HSRO or appointed by HSRO, organizational staff, IRB or sponsors to access your data. List all individuals and agencies that will have access to data and records and how it will be described if published or shared with others. Will you be using direct discounts that can be traced to an individual? Will you be a combination of data? Specify data will be associated with an identified or unsymed number. The team did not report on the effectiveness of the data. Description: protect the secret here. Explain how you're protecting Information. Provide details where appropriate: for example, are data files stored in lockers, which are data stored on the computer, which are passwords necessary to access the system; person has access to data, etc. USING INFORMATION OR SPECIMENS One of the following statements about any research related to the collection of i identifieable information or i.e., biospecimens. The purpose of this is to increase transparency by let participants know that it can happen. If potential participants find it offensive, they may not want to participate in the study. Consent forms will need to say that the information or biospecimens collected for the study may be stripped of the identification code and used in other studies in the future, or this will not happen. Note that this is just about the future research use of information and biospecimens will be stripped of identification. A. If you or others will never use information/specimens from this study for future research inserted as follows: Your information or biospecimens, even if the identifying information is removed, will not be used or distributed for future studies or B. If possible information/specimens from this study will be used for future research, insert the following: The information or biospecimens collected from you in this study may be deprived of identifying information and used for other future studies. If we use information/specimens in future studies, or share information/specimens with other researchers so that they can use it, we will first remove anything that may identify you. We will use or share identified information/specimens without additional permission (consent) from you. ALTERNATIVES TO PARTICIPATE IN THIS STUDY (if any) For intervention-related studies (education, social, medical, behavior) include descriptions of alternative procedures or standard care available if the subject opts out of the study. OFFER Specify if the subject will receive anything to participate in. If there is a part of the offer or if the offer is evaluated at the rate describing the payment schedule and requesting payment. If you are using lotteries of any kind are notified that New York State gaming laws require you to allow anyone who wants to put their name in an opportunity regardless of whether they participate in the study. Questions about this policy should be forwarded to the Legal Office of RIT. Your rights as a research participant participating in this study are voluntary. You have the right not to participate at any time or leave the study at any time. The decision not to participate in or choose to leave the study will not result in any penalty or loss of interest that you have the right to, and it will not harm your relationship with Describe the withdrawal procedures and any follow-up that you will require the subject to withdraw early. Follow as as part of the study can not be forced on subjects who want to withdraw. CONTACT FOR QUESTIONS OR PROBLEMS? Call _____ at _____if email_____ Contact Heather Foti, Deputy Director of HSRO at (585) 475-7673 or hmfsrs@rit.edu if you have any questions or concerns about your rights as a research participant. Provide the name of one or more researchers who can be reached for support. If you are a student provide the contact information of your adviser too. The consent of the Subject (or Legally Authorized Representative)The signature of the Subject or representative Date_____ Upon signing, the subject or legally authorized representative will receive a copy of this form and the original will be kept in the subject's research record. Unless HSRO has other requirements, the waiver study does not require signatures. For all other studies, in some cases it may be in the best interest of the subject not to collect signatures and HSRO will advise you if that is the case. Situations.