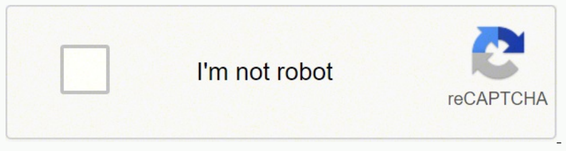
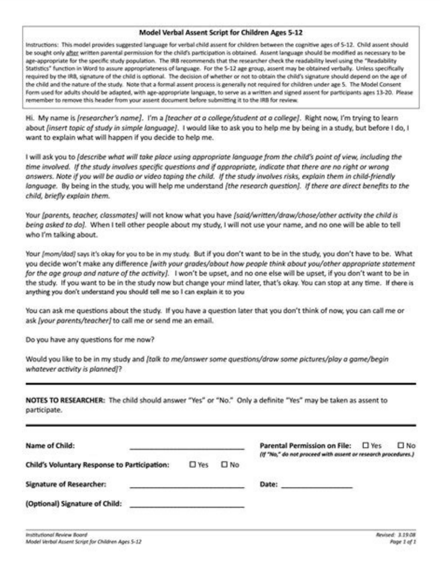
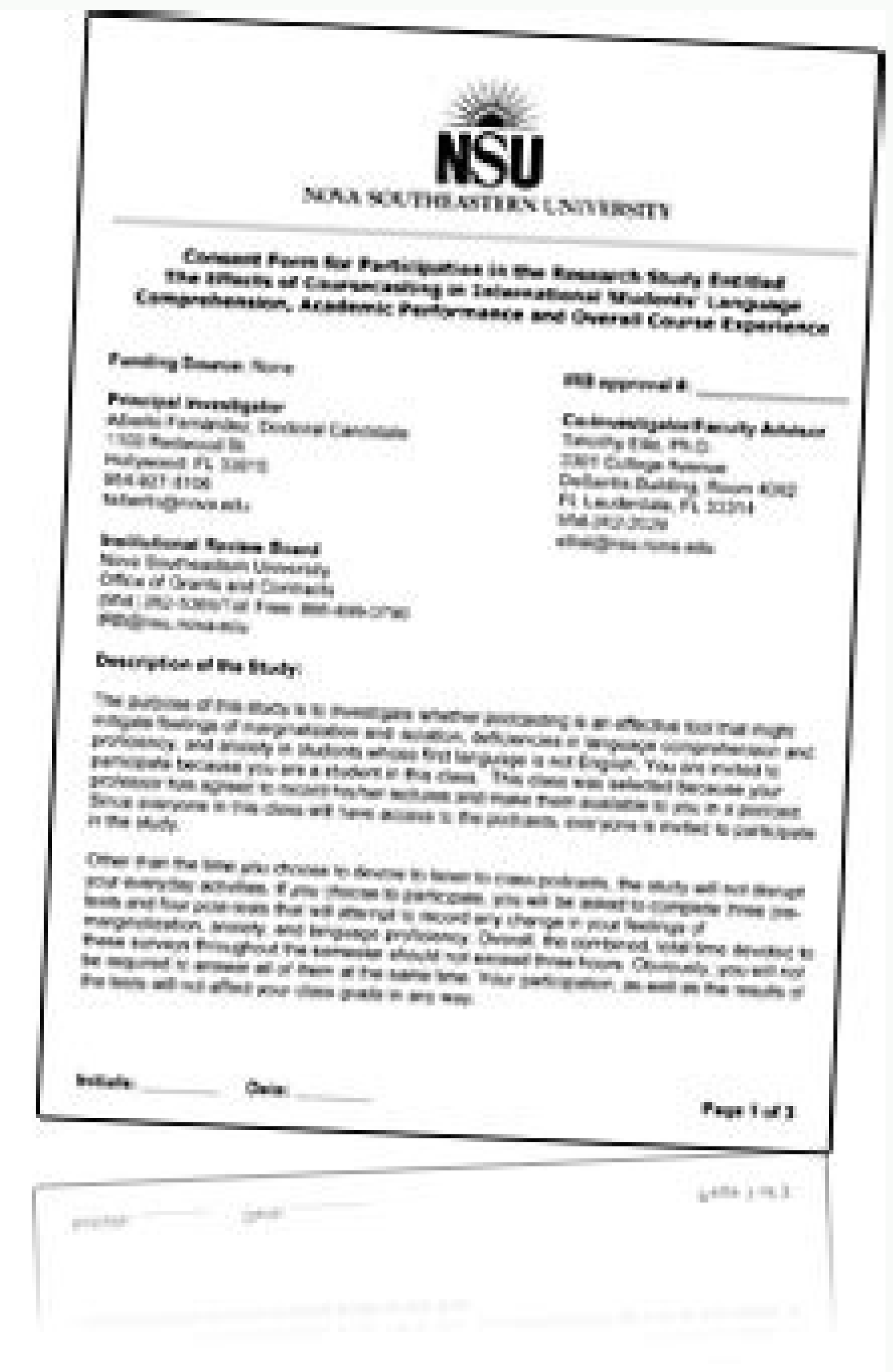


Open

Stanford irb consent form template



Model Verbal Assent Script for Children Ages 5-12



NSU

NOVA SOUTHEASTERN UNIVERSITY

Consent Form for Participation in the Research Study Entitled
The Effects of Coursecasting in International Students' Language Comprehension, Academic Performance and Overall Course Experience

Funding Source: None

IRB approval #: ____________

Principal Investigator
Alberto Fernandez, Doctoral Candidate

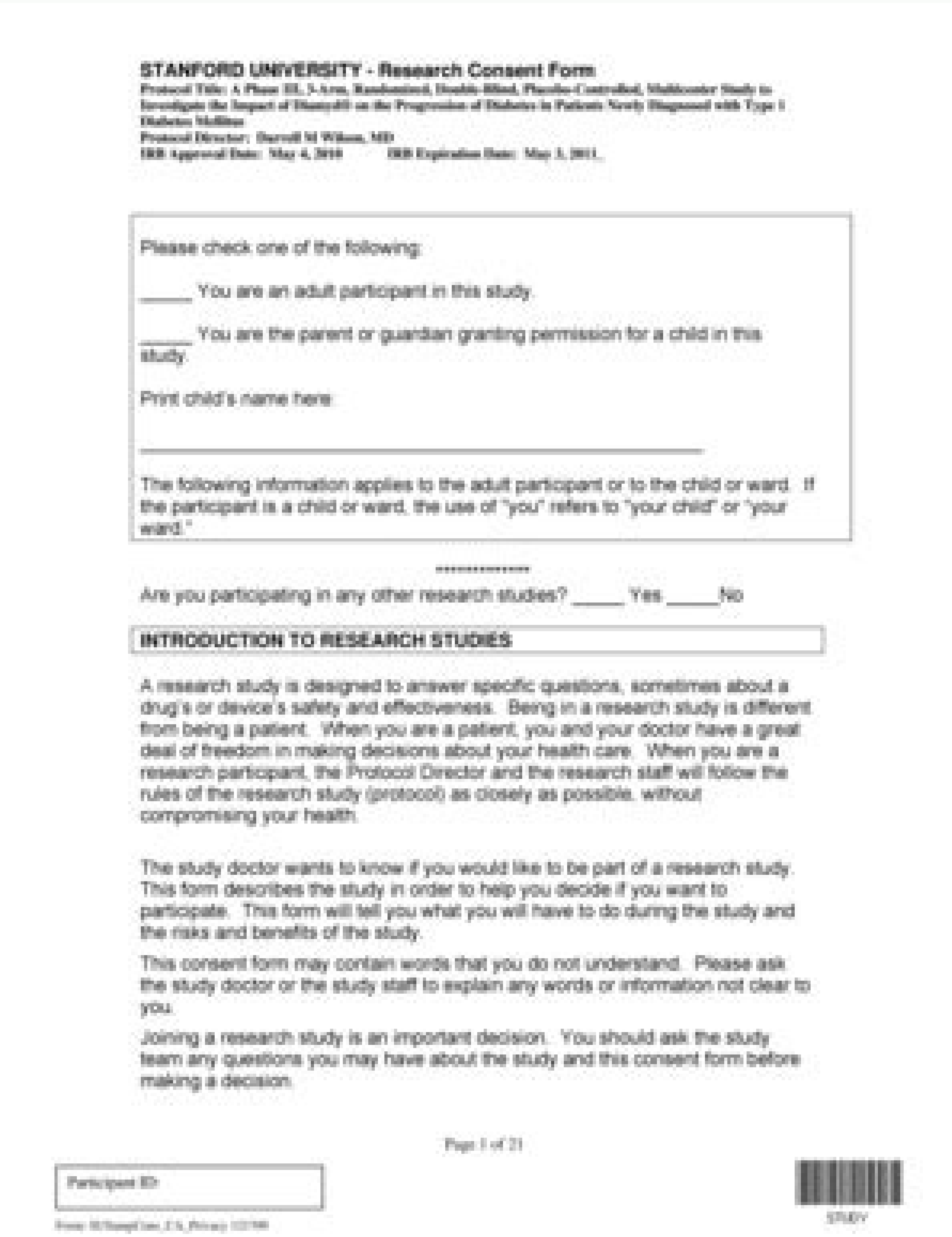
Co-investigator/Faculty Advisor

Institutional Review Board
Nova Southeastern University
Office of Grants and Contracts

Description of the Study:

Initials: ________ Date: ________

Page 1 of 3



STANFORD UNIVERSITY - Research Consent Form
Protocol Title: A Phase III, 3-Arm, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Investigate the Impact of Diamyd® on the Progression of Diabetes in Patients Newly Diagnosed with Type 1 Diabetes Mellitus
Protocol Director: Darrell M Wilson, MD
IRB Approval Date: May 4, 2010 IRB Expiration Date: May 3, 2011

Please check one of the following:

_____ You are an adult participant in this study.

_____ You are the parent or guardian granting permission for a child in this study.

Print child's name here:

____

The following information applies to the adult participant or to the child or ward. If the participant is a child or ward, the use of "you" refers to "your child" or "your ward."

****

Are you participating in any other research studies? _____ Yes _____No

INTRODUCTION TO RESEARCH STUDIES

A research study is designed to answer specific questions, sometimes about a drug's or device's safety and effectiveness. Being in a research study is different from being a patient. When you are a patient, you and your doctor have a great deal of freedom in making decisions about your health care. When you are a research participant, the Protocol Director and the research staff will follow the rules of the research study (protocol) as closely as possible, without compromising your health.

The study doctor wants to know if you would like to be part of a research study. This form describes the study in order to help you decide if you want to participate. This form will tell you what you will have to do during the study and the risks and benefits of the study.

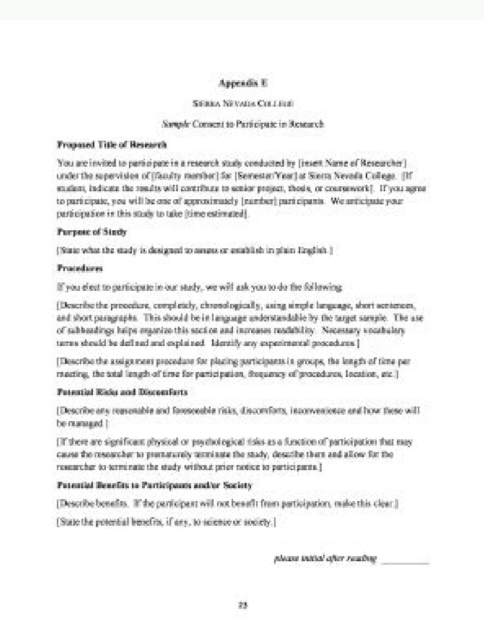
This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information not clear to you.

Joining a research study is an important decision. You should ask the study team any questions you may have about the study and this consent form before making a decision.

Page 1 of 21

Participant ID:

STUDY



Appendix E

Sierra Nevada College

Sample Consent to Participate in Research

Proposed Title of Research

Purpose of Study

Procedures

Potential Risks and Discomforts

Potential Benefits to Participants and/or Society

please initial after reading ________

IRB FORM 6

Consent Form Template

Consent To Take Part In a Research Study

[All items not bracketed must be included in consent]

1.**Subject Name**: _____

2. **Title of Research**: [Must be identical to protocol]

3. **Purpose of Research**:

You are being asked to take part in a research study. The purpose of this study is to find out if---------

[Remember to use lay language and explain unavoidable technical language. Make sure this tracks throughout the protocol. Be sure to avoid any implied pressures or coercive statement.]

[Indicate why participant has been asked to take part. Include the approximate number of subjects expected to be enrolled in this study.]

[It is important for the participant to know why they are in the study (even if only as a control) and why their participation may end. Also important is a listing of the exclusion criteria about which the patient would have knowledge from the study. This should be clearly indicated. You should also discuss possible prior treatment or medication which may affect the participant's risks or benefits of taking part in the study. They must know that they may choose not to be part of the study or may withdraw when they wish. They should also know what conduct or circumstances may end their participation in the study and any resulting loss or changes in treatment.]

4. **Procedures and Duration:**

You understand that the following things will be done to you. (Experimental procedures are underlined) [OR] You understand that all of the following things that will be done to you are experimental. (Don't underline)

[The subject's participation should be described in detail, underline any experimental procedures (unless all are experimental) and include at least the following:

- types of procedures, the number of each procedure, individual and cumulative durations, up to years of treatment, if appropriate; time and effort requirements for the patients, in terms of visits, their duration and frequency [a chart or graph may be helpful if the treatment protocol is particularly difficult to describe in words only. This chart may be an appendix to the consent form];
- whether hospitalization will be involved, or if an extension of hospitalization will be caused by participation in this study;
- What the participant will experience during the study, particularly indicating whether more invasive procedures (such as biopsies, endoscopies, intra arterial placements or the like) are principally research procedures or whether these procedures are clinically indicated, complemented by research procedures. Include number of blood draws and how much in tsp.]

5. Risks and Discomforts/Constraints

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This abbreviated translation or ¢ÂÂÂshort form¢ÃÂÂ (which attests that the elements of consent have been presented orally) may be used to document informed consent in writing for individuals who do not speak English in limited situations.Ã Â There are specific regulatory requirements that need to be met in order to use this form. The language and information in the template should be modified as appropriate for each protocol depending on the age and cognitive level of the subject population. Please feel free to use this sample in the development of assent documents. Use of the Short Form Consent The IRB provides short consent document translations in several commonly understood languages. Please feel free to use this sample in the development of information sheet documents. Some key information examples are provided below English Informed Consent Template (new data sharing information version dated October 2021) Concise Summary Example ¢ÂÂÂ Greater Than Minimal Risk Study Concise Summary Example ¢ÃÂÂ Minimal Risk Study Concise Summary Example ¢ÃÂÂ Repository Individual Patient Expanded Access Consent Template (only for use with protocols using the ¢ÃÂÂIndividual Patient Expanded Access¢ÃÂÂ submission type in CHeRP). Short FormÃ ÂChecklist for use with In-Person Interpreter Due to the increasing numbers of non-English speaking patients, interpreter services have contracted with remote interpreters to provide assistance as needed. This process is facilitated through the use of iPads dedicated for this purpose. Stanford University Glossary of Lay Terms University of Michigan plain Medical dictionary The fact sheets will not be uploaded to the ICLibrary website. Individual Patient Expanded Access Consent Template Informed Consent Library The BCH Informed Consent Library (ICLibrary) provides investigators and their staff with access to currently approved versions of their informed consent. When using a short form and the interpreter is present in the room with the topic, we have provided a checklist to help you with this process. Overall time commitment can also be an important factor. These examples would be included at the beginning of the consensus document. The following consent template has been developed to provide investigators with guidance on the information to be included in the consent form. There are currently no federal guidelines defining exactly what “key information” is required in the concise and targeted introduction. All documents in the information document must be examined by the IRB. Please refer to the links below for descriptions of common medical terms. Template for Informed Consent Information Sheet This template only applies to investigators who indicate that informed consent/consent/authorisation will be obtained by a method other than a written document referred to in Part C and who wish to prepare an information sheet. Short Form Translations Albanian Arabic Amaric Bosnian Bulgarian Cape Verdean Creole Chinese Czech Danish Dutch English Version (for reference) Farsi French German Greek Haitian Creole Hebrew Hindi Italian Japanese Khmer Korean Laotian Maay Nepali Polish Portuguese Russian Spanish Tamil Thai Telugu Turkish Urdu Vietnamese Assent Consent Model Informed documents must be reviewed and approved by the IRB. The following information sheet template has been developed to provide investigators with the information to be included in an information document. information.

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