Lurie Children's IRB: General Suggestions and Guidance for Writing Consent and Assent Forms

General Suggestions

1. **Use simple language.**
   We want you to write consent/assent forms at the 7th-grade reading level. In order to assist you in this, please see the section below called "Tips for Suggested Language."

   It also may be helpful to have a lay person proofread your consent form to assess readability. In addition, Microsoft Word allows you to test the reading ease and reading level of your document. If you do not know how to use this function, please consult Word Help.

2. **Follow S-A-D**
   Following S-A-D, Simple – Active – Declarative, whenever possible helps increase readability, increases clarity in the writing, and most adults process S-A-D statements more effectively than passive sentences.

   Examples:

   "Steve likes Amy." (active)
   "Amy is liked by Steve." (passive)

   "I heard it through the grapevine." (active)
   "It was heard by me through the grapevine." (passive)

   "I am holding the pen." (active)
   "The pen is being held by me." (passive)

   "The doctor will explain all study procedures to you on the day of your study visit." (active)
   "The study procedures will be explained to you by the doctor on the day of your visit." (passive)

3. **Avoid sentences longer than 20 words and paragraphs with more than 5 or 6 sentences.**
   Limit sentences to a single thought or idea. Avoid run-on sentences that have too many commas or conjunctions (e.g. and, or, but). Long paragraphs increase the reading (grade) level and decrease overall readability.

4. **Avoid medical terminology, jargon, and abbreviations, unless explained.**
   For instance, use "doctor" instead of "physician" and "give" instead of "administer." You can use a medical term if you define it in an easy-to-understand way and then use the medical term in the rest of the consent document. For instance, you could write, "You may have an anaphylactic reaction (a severe allergic reaction) after receiving the study drug. Signs of an anaphylactic reaction include. …"

5. **Do not include excessive detail.**
   While some detail is important, try to achieve a balance between all-inclusive information and minimal information. However, do not minimize significant risks and procedures by

having them "diluted" in a mass of insignificant material. Use concise language and description and avoid repetition.

6. **Clearly note which parts of the proposed project are experimental, including procedures, tests, drugs, and/or devices.**

7. **Pay attention to style issues.**
   - Use a font and font size that are easy to read.
   - Use bullets, bolding, and underlining to make things clear, but don't over-use them.
   - Use spacing between sub-sections.
   - Use active voice.
   - Check that the parental consent form is written for parents about their child, the adult consent form is written for the adult subject, and the assent form is written for the child subject.
   - Individuals referred to in the study should be called "patients" or "participants."
   - Use the spell-checker and carefully proofread to ensure correct spelling, sentence construction, information flow, readability, and formatting.

Standard Templates and Required Language

1. **Do not deviate from the order of the template.**

2. **Use the standard wording when appropriate and as required.** You must use the exact wording found in the required template.

3. **Remove the instructions from the final consent form.** They are provided throughout the template in italics.

4. **The consent/assent form must have a footer on each page with the following information:**

   - Left side: consent type (e.g. Adult Control Consent/ Adolescent Drug Assent) and version date (8/31/08). Note: Do not use automatic date stamp.
   - Center: page number of number of pages (1 of 4)
   - Right side: at least a 2 x 2 inch area for the IRB stamp

NOTE: *Once the consent form is approved it will be stamped electronically by the IRB. This stamp includes: approval date and expiration date. The IRB will e-mail a copy of each stamped consent document to the PI along with the approval letter.*

Additional Instructions for Investigators

1. **Recordkeeping of consent/assent forms:**
   - Federal regulations require that the investigator give one copy of the consent form to the parent, or guardian, or subject (if the subject is 18 years of age or older).

- IRB regulations require that the investigator give a copy of the adolescent assent form to the adolescent subject (12 to less than 18 years of age).

- The original signed form must be kept in the investigator's files and a copy should be placed in the medical record. This is HIM policy. Subjects must be informed that a copy of the signed consent form will be placed in their patient medical record (see the consent form template).

- One copy of the signed consent form should be kept by the PI in the Study Binder and Research Record.

NOTE: *Any changes to the approved consent/assent form require further review by the IRB prior to implementation.*

2. Procedures section:

- The consent form and study protocol must be consistent.

- Clearly note the time frame for the whole study, as well as the amount of time and location where each visit will occur.

- Clearly describe each procedure or test in the order in which they will happen. Describe each procedure in its own paragraph or bullet point. You may use sub- headings to organize the section increase readability. List how long each procedure takes and where and how often it will be done.

- Procedures that are part of clinical care and not related to the research need not be included. If a procedure is part of the study, it must appear in the procedure section and you should not refer to it as "standard" or "routine," or in any way imply it would be done anyway for clinical reasons. Rather, you should convey it is an extra lab test or procedure commonly done for clinical purposes but here done here for research purposes.

- If the study involves the use of randomization explain this concept in an easy-to-understand way. Insert sentences that define randomization and how it will be implemented in the study. For example; "Randomization means that you / your child will be put into one of the two groups by chance (like flipping a coin), so that you/your child will have a 50/50 chance of being put into one of the two groups. You and your/ your child's doctor cannot choose the group that you/your child will be in."

- If the study requires taking blood or other specimens from the subject, describe how often someone will draw blood (or take specimens) and how much blood or tissue will be taken each time. In the case of blood draws, list the total amount of blood you expect to draw over the whole study. Describe this amount using both ml or cc and teaspoons.

- A chart or calendar of the visits and procedures may be helpful.

Tips for Suggested Language

1. **General rules for choosing words for the consent/assent forms:**
   - Avoid words with more than 3 syllables
   - Avoid using fancy words when short, simpler, and colloquial words will work. For instance, "administer the drug" vs. give the drug," "undergo a test" vs. "have a test," "utilize" vs. "use."
   - Avoid abbreviations when possible.
   - Avoid complicated medical terms and jargon. If you must use them, define the term in a way that is easily understandable when you first use it. Then continue to use the medical term.
   - Please also see the following websites for additional lay language terms, including suggested lay language descriptions of common side effects or diseases:
     - ***Simplification Guide to Medical Terms*** –The University of Michigan Medical School Institutional Review Board (IRBMED)
     - ***Glossary of Lay Terms for Use in Preparing Consent Forms for Human Subjects*** – UC Davis, Office of Human

2. **Chart of Suggested Terms**

Medical Term	**Suggested Alternative**
Abdomen	belly
Accompany	go with
Additional	extra
Administer	give
Administer questionnaire	give a questionnaire *or* ask a series of questions
Administer test	a) take blood, urine b) have a test
Aggressive behavior	violent behavior
Allergic reaction	a) itching, rash, fever, shortness of breath, quick drop in blood pressure b) itching, rash, fever, etc. that could result in death
Alter	change
Analyze	study *or* look at the results
Annually	every year/yearly

(Un-)Anticipated	(un-)expected
Approximately	about
Assess	look at
Assign to a group	place in a group
Assist in making decision	help you make a decision
At the discretion of your physician	decided by *or* determined by your doctor
Baseline	first
Cardiomyopathy	damage to the muscles of the heart
Child-bearing potential	able to have a baby
Chronic	long-term *or* lasts a long time
Circulate in	move in
Claustrophobic	fear of closed places
Commonly accompanies	often goes along with
Complication	side effect *or* problem
Comprehend	understand
Comprehensive exam	full exam
Conduct	do
Correlates	relates *or* links
Currently	now
Deficit	loss
Depression	feeling very sad
Detect	find

Determine	decide/find out
Dietary record	record of everything you eat and drink
Discloses	shows
Discontinued	stopped
Dissipate	go away
Dose	amount (of medicine)
Draw	take (blood draw is a very medical phrase)
Duration of	throughout
Efficacy	how well it works
Eligible	if you qualify for the study
Ensure	make sure
Established	found
Evaluate	see *or* check for
Evidence	sign of
Exacerbation	worsening
Examine	look at
Exceed	be more than
Excretion	comes out -- *might come out in urine or stool*
Experience	feel *or* have
Extended use	if used for a long time
Extract	take
Extremities	arms or legs
Fast (referring to food & drink)	a) not eat b) not eat or drink anything c) not eat or drink anything except_____
Fatigue	tiredness or feeling tired

Frequent functioning	often working (liver function: how liver works)
Generate	make
Homicidal	thoughts of hurting someone else
Indicate	point out
Individually	each *or* by yourself
Individual(s)	person, people
Inflammation	a) *for blood draw*: gets red and swollen b) *for other*: describe symptoms
Inform you	tell you
Infusion	goes into
Insert in	put in
Insomnia	trouble sleeping
Initial	first
Initiate	start
Investigational drug/device	explain that the term "investigational," means that the drug or device being studied and is not approved by the Food and Drug Administration (FDA)
Investigator	doctor *or* researcher
Lethargy	tiredness
Mania	having too much energy and being overexcited
Markedly	greatly
Maximum of xx	no more than xx (*list amount)*
Maximum dose	highest amount

Minimize	reduce *or* decrease
Monitor	check
Notify	tell
Notified	told
Obtain	get
Occasionally	sometimes
Occupation	job
Occur	happen
Orally	by mouth
Participate in	take part in *or* be in
Perform a test	have a test *or* get a test
Performed	done
Physician	doctor
Placebo	a pretend medicine that does not contain any active drug, but is made to look and taste like the real medicine (like a sugar pill)
Potential	possible
Potential Adverse event	possible side effect
Prevent us	keep us
Prior to	before
Proceed	continue
Progress to	lead to
Promptly	quickly
Provide	give us

Psychosis	lose touch with reality
Receive	get
Recurrent	repeated
Regarding	about
Remain	stay
Resolve	go away
Respirations	breathing
Result in	cause
Scheduled intervals	set times
Sequentially	in a row
Simultaneously	at the same time
Skin Irritation	red or itchy skin
Specified	exact one
Stimulates	causes
Stool collection	collect bowel movement
Submit to	allow
Subsequent	remaining
Sufficient quantity	enough
Supply	give
Strenuous	hard
Tolerate	receive without problems
Transient	temporary
Unanticipated	unexpected
Undergo	have
Unforeseeable	not yet known

Unpredictable	without warning
Urinate	pee (or have urine)

Well tolerated	not bothering you
Will consist of	will have