CONSENT FORM GUIDELINES

Attached please find a sample consent form with items required by federal and state regulations, as well as the Institutional Review Committee (IRC) of the Greenville Hospital System. Specific instructions within the body of the sample consent form are in italics. All other wording has been approved by the IRC and should be used in your consent form, where applicable.

You will also find attached a list of word preferences the IRC has approved for use in consent forms. This list is not conclusive, but will help you in writing your consent form. If you have any questions, please call the IRC Office at 455-4984 (IRC-A) or 455-4360 (IRC-B).

General Guidelines

1. Consent forms should be written in second person (such as, "You are being asked to participate in a research study.").
2. Consent forms should be written in lay language. It is required that consent forms be written on a sixth grade reading level. It is suggested that after you have written your consent form, you should have a non-medical person read it for comprehension.
3. Consent forms should be written in a font type size 12 or higher and should not be in uppercase.
4. If applicable, list sponsor name on the first page of the consent; all other references throughout the remainder of the consent form must be 'sponsor' or 'study sponsor'.
5. Template HIPAA language [Authorization to Use and Disclose (Release) Medical Information] is non-negotiable. This language has been approved by GHS legal counsel and the IRC.
6. If you use a word that needs to be defined, define it the first time you use it. You will not need to define it again.
7. Several drugs have more than one name. Use only one drug name throughout the consent form. Also, if drug is in uppercase, make sure it is throughout consent.
8. Brand names of drugs may only be used once at the beginning of the consent form followed by the generic name or 'study drug' in parentheses. After this, use only the generic name or 'study drug'.
9. Brand names of devices may only be used once at the beginning of the consent form followed by a generic term or 'study device' in parentheses. After this, use only the generic term or 'study device'.
10. Define abbreviations when first used; after this, the abbreviation alone may be used [i.e. FDA (Food and Drug Administration), NCI (National Cancer Institute), AIDS (acquired immune deficiency syndrome), or HIV (human immunodeficiency virus)].
11. Use the same words throughout. Example: if radiation therapy is used, do not change to irradiation or radiotherapy; if treatment cycle is used, do not change to treatment course.
12. If courses or cycles are used, please define. Example: You will receive four courses of treatment. A course of treatment is once every four weeks.
13. If your study involves drawing blood, identify how much blood will be taken from the participant (in tablespoonsful or teaspoonsful). Include amount to be taken at each blood draw and also the total amount for the duration of the study.

IRC WORD PREFERENCES

WORD	*IRC PREFERENCE*
%	percent
<	less than
>	greater than
abdominal	stomach
absolute	total
access	make available
accessible	available
accrue	enroll
accurately	correctly
administration	giving the drug **or** record keeping
agent	drug **or** medication
alter	change
analysis	careful study
anemia	low red blood cell count
angina	chest pain
antibody	protein made by the body against another substance
anticipated	expected
antigen	any substance from outside the body that activates the body's immune system
anxiety	anxiousness
approached	asked about
appropriate	needed **or** proper
approximate	about
aspects	areas
assess/assessment	evaluate **or** examine
associated	related
atrophy	wasting away
attributed	related
bacteria	germ
beneficial	helpful
capacity	ability
cardiac	heart
catheter	flexible tube inserted in a vein
commencement	beginning
compensation	payment
compliant	follow
confirm	positively identify
conjunction	combined/joined with
continuous infusion	giving the drug in liquid form through a needle in your vein over a long period of time

counteract	oppose **or** cancel
criteria	requirements
data	information **or** results
depression	feeling sad
derived	gained
designated	selected **or** assigned
designed	made
despite	in spite of
deteriorate	break down
determine	find out
disclosed	made known, given out or released
discretion	decision
document, documenting	record, recording
duration	length of time
echocardiogram	sound wave test of the heart
e.g.	for example
electrocardiogram	electrical recording of heart rhythm
eligible	qualify **or** able
eliminate	remove **or** stop
embryo	newly conceived unborn child
etc.	and so on
extracted	drawn out
fatal	lead to death
fatigue	extreme tiredness
fetus	unborn child
frequently	often
foreseeable	known
gastrointestinal	stomach and intestines
heart beat	heartbeat
hemoglobin	red blood cells
i.e.	that is **or** such as
IM	in your muscle
implied	suggested
induced	produce
inflammation	swelling **or** redness
infusion	giving the drug in liquid form through a needle in your vein
initial	first **or** beginning
insure	make sure
interfere	hinder
involve	include
intravenous	in your vein
IV	intravenous (in your vein)
kill	destroy
life-threatening	leading to death

local	in one particular area **or** limited to one place
longer survival	living longer
maintain	keep
monitored	watched **or** checked
necessitate	require
neurologic	nervous system
objective	goal
obstruction	blockage
obtained	received, taken **or** gained
occur	found **or** happen
offspring	child **or** children
ongoing	continuing
optimal	best
options	plans **or** choices
orally	verbally **or** by mouth
patient	participant
pathology	the scientific and medical study of the nature of disease
performed	done
pertaining to	about **or** relating to
pertinent	related
physician	doctor
placebo	sugar pill **or** substance that does not contain any drug
PO	taken by mouth
primarily	mainly
project	study
post	after
potential	possible
pre	before
precise	exact
preclude	prevent
predispose	lead
pre-existing	prior
prejudice to future medical care	penalty or loss of any future medical care
prior	before
prognosis	expected outcome
progression	worsening
prolonged	extended **or** lengthened
protocol	study **or** plan
puncture	sticks
recurrence	return of your disease
regimen	plan
reimburse	refund
reimbursement	refund

relatively	usually
remission	no symptoms of your disease
renal	kidney
scaffold	support
significant	important **or** major
simultaneously	at the same time
site	area **or** place
specimen	sample
SQ	subcutaneous (under your skin)
standard	usual
stent	metal tube used for support
subject	participant
subsequent	future
tablespoons	tablespoonsful or tablespoonfuls
teaspoons	teaspoonsful or teaspoonfuls
terminate	stop
therapeutic measures	treatment options
therapy	treatment
tolerate	manage
toxic	harmful
toxicity	side effects
transiently	temporarily
trial	study
ultrasound	sound wave echo test
unforeseen	unknown
via	by
venipuncture	needle stick
vital signs	temperature, respiration, pulse and blood pressure
waived	given up