HREB CONSENT FORM CHECKLIST

Please note that there is an informed consent template available on the Sponsored Programs Human Subjects web page. Please refer to this document. It will help clarify the comments below:
http://www.newpaltz.edu/sponsored_programs/informedconsent.pdf

Language

_____ Appropriate for intended population

Heading

_____ Title
_____ Principal Investigator
_____ Phone
_____ Department
_____ Position
_____ Subject Names
_____ Parent/ Guardian (if participants are under 18 or of diminished capacity to consent)
_____ Sponsor of project (if applicable)

Why is this study being done?

_____ Explanation of purpose
_____ Topic sentence using “research”

How many people will take part in this study?

_____ Approximate number of people involved

What is involved in the study?

_____ All procedures described
_____ Schema/calendar of events
_____ Experimental procedures described as such (if applicable)
_____ Procedures that are part of regular care (if applicable)
_____ Research design
_____ Procedures/activities that would occur irrespective of participation in the study
_____ Randomization description
_____ Treatment/control groups (if any) described
_____ Possibility of being in control group (if applicable)

How long will I be in the study?

_____ Approximate maximum length of study
_____ Number, duration and description of sessions

Revised April 30, 2014
Termination of Participation (if applicable)

Statement of circumstances under which research participation would be terminated
Statement for terminating participant
Statement that subject may terminate at any time

What are the risks of the study?

Nature, likelihood and severity of foreseeable risks or discomforts
Procedures for handling risk-associated events
“The risks discussed do not include those encountered in normal daily living” present (if applicable)

Are there benefits to taking part in the study?

Foreseeable benefits to subject
Foreseeable benefits to class of participants
Foreseeable benefits to society and others
Please note: Payments for participation are considered incentives and not benefits. Incentives fall under costs/incentives below.

What other options are there?

Alternative treatments, procedures available, if any, that might be advantageous
Availability of other items related to study procedures
Other options

What about confidentiality?

Description of how confidentiality will be maintained
Description of any limits to confidentiality inherent in the design
Organizations that may have access to data

What are the costs/incentives for participating?

Cost for participation
Payment/credit for participation
Emergency medical statement, if applicable

What are my rights as a participant?

Participation is voluntary
Ok to refuse and withdraw without penalty or loss
Referral to PI with questions (by phone)
Referral to Chair, HREB with questions (by phone)
New information clause (if applicable)

Revised September 23, 2013
Whom do I call if I have questions or problems?

_____ Researcher clause
_____ HREB clause

Other Information

_____ HREB Criteria met

Consent/Permission

_____ Space and lines for printed name and signature of participant and date
_____ Receipt of consent form statement
_____ Space and lines for alternative consent (if applicable)
_____ Informed consent will be appropriately documented OR justify waiver decision citing 117c
_____ Informed consent will be obtained OR justify waiver decision citing 116d
_____ Assent procedures/documents (if applicable)