

IRB 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

Comment:

Heading

Title Principal Investigator Phone Department Position Subject Names

Parent/ Guardian Sponsor of project, if applicable

Comment:

Why is this study being done?

Explanation of purpose Topic sentence using "research"

Comment:

How many people will take part in this study?

approximate number of people involved (maximum)

Comment:

What is involved in the study?

schema/calendar of events research design randomization description treatment/control groups (if any) described possibility of being in control group (if applicable) experimental procedures identified as such all procedures described procedures that are part of regular care standard procedures that are being done because of being in the study

Comment:

How long will I be in the study?

approximate maximum length of study number, duration and description of sessions

circumstances under which research participation would be terminated statement for terminating participant

statement that subject may terminate at any time

Comment:

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

Comment:

Are there benefits to taking part in the study?

foreseeable benefits to subject foreseeable benefits to others

Comment:

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

Comment:

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

Comment:

What are the costs?

cost for participation payment/credit for participation emergency medical statement, if applicable

Comment:

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, IRB with questions (by phone) new

information clause, if applicable

Comment:

Whom do I call if I have questions or problems?

researcher clause

IRB clause

Comment:

Other Information

IRB Criteria met

Comment:

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

Comment:

revised 10/16/03

KEY: X = adequate
O = missing or not acceptable
NA = not applicable