Informed Consent Checklist - **Use the following checklist and submit it with your application. There is also a consent template available on the g: drive (sample consent - g: drive – Research Directory (consent.doc). The 1st page of the consent is an instruction sheet. If you need further assistance in the preparation of the informed consent form, call the IRB Office, 545-9980.**

1. Use wording **understandable to the subject population**, and exclude any statements that may be considered coercive (unduly encourage subject to participate).
2. At the beginning of the consent form give an explanation that **the study involves research** and describe the procedures to be followed including: a) **purpose** of the research; b) **procedures which are experimental**; c) **expected duration** of the subjects' participation.
3. Description of the **risk, discomforts, and side effects**.
4. Description of the **safeguards to be used to protect the subject**.
5. Discuss **alternatives** to participate in this study, including alternative forms of therapy available (i.e. the subject has to know what is available to him/her if the choice is made not to participate).
6. Description of any **benefits t**hat may be expected
7. An **offer to answer any inquiries** concerning the procedures.
8. Tell subjects that **participation is voluntary and they may refuse**.
9. State that the **subjects may withdraw**, or be withdrawn from the study at any time **without jeopardizing present or future care.** Describe anticipated **circumstances under which the subjects' participation may be terminated by the investigator** without regard to the subject's consent.
10. State the **terms of subject compensation** for participation, if any.
11. State clearly what costs the subject will incur by participating in the study, and what will be paid for as part of the study.
12. State that every effort will be made to **maintain confidentiality**. In research involving FDA regulated products, the consent form must contain a statement that the FDA and the drug company may inspect the subject's medical record. Also **disclose any other infringements upon privacy or confidentiality that may result** from participation in the research.
13. **Contact information** (name and telephone number) of the principal investigator or other responsible individual who can be contacted if the subject experiences problems or an adverse effect during the research study. Also include contact information (name and telephone number) of **whom to contact for answers to questions or complaints** about the research, and about the research subject's rights (e.g., the IRB Office).

Include #14-17, if appropriate:

14. A statement that the particular treatment or procedure **may involve currently unforeseeable risks** to the subject.
15. The consequences of a subject's decision to withdraw from the research procedures for **orderly termination** of participation by the subject (i.e. removal of a device or discontinuation of study drug).
16. A statement that **significant findings** that arise during the course of research, and which may relate to the subject's willingness to continue participation, will be provided to the subject.
17. The approximate **number of subjects** involved in the study at this facility compared to overall subject population.
18. GINA information regarding genetic information (if collecting genetic information)

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19. Include a statement of consent to participate in the study.
20. Include a statement that the subject has received a copy of the consent form.
21. Inclusion of the appropriate policy statement regarding compensation in the event of a research-related injury for projects involving more than minimal risk.

FOR PROJECTS AT CCMC THE FOLLOWING:

If I am injured/my child is injured as a direct result of participating in this study, I understand that any immediate, short-term medical treatment related to this injury is available at Connecticut Children's Medical Center, but such treatment will not be free of charge. I understand that while medical insurance may pay for such treatment, I will ultimately be responsible for payment. I also understand that any additional, non-emergency medical treatment related to this injury is available at Connecticut Children's Medical Center, but such treatment will not be free of charge.

21. Include a signature and date line for each of the following: a) subject (if 18 and older); b) investigator or person obtaining consent, c) witness (must be someone other than b).
22. For projects involving subjects under the age of 18 years: See instructions Page 1 of consent g:ccmcdoc/research/irb/consent.doc) or application instructions (instruct.doc).

IF THIS STUDY INVOLVES DRUGS IN HUMAN SUBJECTS, MAKE SURE PHARMACY IS CONTACTED AND MADE AWARE OF THEIR INVOLVEMENT