

Model Consent Revisions with Instructions for Studies Affected by Research Care Plan Documentation Requirement (revised December 12, 2008)

SCOPE OF UW MEDICINE RESEARCH CARE PLAN DOCUMENTATION REQUIREMENT

If your research involves any clinical service, items, or tests provided by UW Medicine hospitals or clinics (Includes UW Medical Center, Harborview Medical Center, Eastside Specialty Center, Hall Health Primary Care Center, and Sports Medicine Clinic.), UW Physicians (UWP), or at the Seattle Cancer Care Alliance and active consent by research subject, you may be affected by a new UW Medicine policy requiring that the UW Medicine/SCCA medical records for research participants contain a “research care plan” note to facilitate research billing compliance and enhance patient safety. The research care plan documentation will require the entry of basic information about the research study (described more fully below) into the medical record for each research subject. For research studies supported by funding administered by the University of Washington, the UW Clinical Research Budget and Billing (CRBB) office can tell you whether this policy applies to your research or whether your research study may be eligible for an exemption from the research care plan requirement. Email CRBB at crbb@u.washington.edu or call (206) 543-7774¹. For research studies supported by funding administered by Fred Hutchinson Cancer Research Center (“FHCRC”), the Institutional Review Office (IRO) at FHCRC will assist you in determining whether this policy applies to your research and what steps you need to take, if any, to revise your study consent forms..

If it does, the language in your consent form may need to be revised NOW or at the time of your continuation review or other consent modification.

TIMING OF CONSENT REVISIONS (see also IRB Approved Guidelines [create hyperlink])

A. NON-THERAPEUTIC STUDIES [SUBMISSIONS REQUIRED NO LATER THAN February 13, 2009]

The IRB Guidelines recommend that consent revisions be submitted on an expedited basis for those studies in which the research subject would not necessarily expect that information about the research study would be included in a medical record or where including a reference to the study title in the medical record might impact negatively on the research subjects. Examples include studies involving individuals who agree to provide data and or specimens for cancer research but whose medical record contains no indication that the research subject has been diagnosed as having cancer or a heightened cancer risk. Other examples include studies involving healthy volunteers who agree to participate in a HIV-AIDS research study but who do not have HIV-AIDS. Including a study title with the terms HIV or AIDS in an individual’s medical record could negatively impact on the individual.

B. THERAPEUTIC STUDIES [SUBMISSIONS RECOMMENDATION AT CONTINUATION REVIEW OR NEXT CONSENT MODIFICATION]

The IRB Guidelines ask you to consider whether the medical records for individuals participating as research subjects in each study already contain information about the disease or health condition referenced in the title of the study. If that is the case, then there is little to no risk that the research care plan note would pose any new or enhanced risk that research subjects will be negatively impacted by the research care plan note being added to the medical record. Consequently, a consent revision at the time of continuation review or other consent modification would be acceptable. Another example of a case in which a consent modification might not be required on an expedited basis is the case in which

¹ With respect to studies performed only at UW Medicine facilities (and not SCCA) UW CRBB may grant an exemption from the research care plan note requirement for studies that meet all three criteria (1) heightened sensitivity; (2) minimal clinical risk; and (3) minimal billing compliance risk. For more information, contact crbudget@u.washington.edu.

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the informed consent form is already made part of the medical record (e.g., research studies performed at SCCA), In these cases, the consent revision need not be submitted on an expedited basis.

MODEL CONSENT LANGUAGE REVISIONS

Consent forms used for the enrollment of research subjects to be conducted at UW Medicine facilities or SCCA, or by UW Medicine Personnel are the only consent forms for your study that need to be revised. If you also enroll research subjects at other sites, you may elect to propose a consent supplement or addendum to attach to only those consents to be presented to individuals who will receive services, tests or procedures at UW Medicine or SCCA.

Select the appropriate language from the model consent revisions set forth below. It is recommended that you insert this language before the “Other Information” section of the consent if you used the FHCRC IRB consent form template. In the alternative, you may also consider inserting the new language in a section of the consent that covers topics such as “confidentiality” or “release of information to others.”

Remember that the IRB must review and approve your revised consent form before you can begin using it.

The IRB recognizes that risks will vary depending on the type of study. Not all of the language provided here will be appropriate for all studies. Do not include language that does not apply to your research.

MODEL CONSENT REVISION FOR NON-THERAPEUTIC STUDIES REQUIRED NO LATER THAN February 13, 2009]

Federal regulations and the policies of the University of Washington (UW Medicine) and the Seattle Cancer Care Alliance (SCCA) require that certain information about your participation in this research be made a part of your permanent medical record. If you do not already have a medical record at UW Medicine or SCCA, one will be created for you even if your only connection with them is as a research subject.

The information in your permanent medical record will include:

- *Name of the study [researcher to insert AAA account name]*
- *Name of the group or company that is paying for the research*
- *The number the group or company assigned to this study*
- *The name of the researcher*
- *The name of the study coordinator*
- *Contact phone number for the study*
- *Contact email address for the study*
- *Emergency phone number for the study*
- *Expected start and end dates for your time in the study*
- *Whether this study includes healthy volunteers*

Information about your research procedures and test results may also be put in your medical record. This will include: [researcher to insert list]

In the future, if you give permission to any person or group to look at your medical record (such as an insurance company or employer), they could receive this research information. If you have already given permission to anyone (such as your life or health insurance company) to look at your medical record, they may receive this information if they ask for a copy of your medical record.

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This disclosure to others may have a negative effect on you. For example, a life or health insurance company (but not Medicaid or Medicare) might consider this in deciding whether to insure you or to provide coverage for you.

MODEL CONSENT REVISION FOR THERAPEUTIC STUDIES [SUBMISSIONS RECOMMENDATION AT CONTINUATION REVIEW OR NEXT CONSENT MODIFICATION]

[Information about your participation in this study such as the title of the study and the names of the researchers involved in the study will be made a part of your permanent medical record. If you authorize others to see your medical record, they will find out about your participation in this study.]

Or

[Information about your participation in this study (including a copy of this consent form) will be made part of your permanent medical record. If you authorize others to see your medical record, they will see a copy of this consent form.]