# RADIATION PROCEDURE GRID

Study Title:

PI:

These grids must be completed and submitted to the CHW Radiation Safety Research Subcommittee (RSRS) for all research studies involving radiation use beyond uses and exposures that are a routine aspect of the patient's on-going care.

Submit this form along with a copy of the study protocol, informed consent, and assent (if applicable) via email to **Linda Strain** at **lstrain@childrenswi.org**

In the first "procedure" column below, list each radiation-related procedure (using beam or radioactive materials) that subjects/patients in this study will be expected to complete based on the overall study protocol. Include "standard of care" procedures here if they are specified in the overall study protocol. If (for example) an x-ray will be limited to one view at some study time-points, but calls for a different view or multiple views at other study time-points, list the different view-packages as separate procedures. Referring to the overall study protocol, describe how often each procedure will be repeated by specifying the relevant protocol time-point intervals in the first row, then entering an X in the appropriate procedure row to show repetitions.

For screening and baseline procedures, list every procedure specified in the overall study protocol. If the protocol allows the investigator to access a recently-completed procedure (within recent time limits) in place of a protocol-required one, put an asterisk (*) next to the appropriate time-point entry (generally, TP1 screening) for that procedure.

For each X, mark if the procedure is SOC (standard of care) or RES (research). By "standard of care" we mean that the investigator can demonstrate (with reference to clinical records) that similar patients with a similar disease/condition usually undergo that procedure, and undergo the same number of repetitions, and undergo repetitions at the same time intervals. It is important to code the first time-point (screening) correctly – here the question is: "if the patient does not choose to enroll in the study, would routine care require the procedure at this time-point?" If you aren't sure about how "SOC" applies to one of the time-points, do not mark it SOC.

| **Radiation Procedure** | **Timepoint 1: Specify _____** | **Timepoint 2: Specify _____** | **Timepoint 3: Specify _____** | **Timepoint 4: Specify _____** | **Timepoint 5: Specify _____** | **Total number per year** | **Total number per participant (over life of study, which may be more than one year)** |
|---|---|---|---|---|---|---|---|
| a. | | | | | | | |
| b. | | | | | | | |
| b. | | | | | | | |
| d. | | | | | | | |

For each procedure / timepoint marked as RES (not SOC) what is the justification for the procedure

| PROCEDURE | Timepoint (specify) | Justification |
|---|---|---|
| | | |
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For any procedure that is not consistently (i.e., across the entire row) marked as SOC, propose consent document language to describe the procedure and reasonably foreseeable risks.

| PROCEDURE | Timepoint (specify) | Consent document language about exposure/risk |
|---|---|---|
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For RSRS use only:

1. Does consent/assent document language about exposure/risk for non-routine care exposure; does language sound correct?
2. Does RSRS question whether any of the procedures or time-points noted as "SOC" are justifiable?
    a. If yes, which ones and why?
3. Which non-routine care activities raise safety questions because of dose, cumulative dose, or any other concern?
4. Does project requires variance to DHS 157 appendix M?