

v.1.0

## **HUS Review Procedures for Late Stage Cancer Studies**

Human Use Subcommittee (HUS) of the Radiation Safety Committee (RSC)  
“Standard Operating Procedure”  
(Version 1.0)

Approved by the HUS: August 18, 2015

### Purpose:

The purpose of this procedure is to provide an abbreviated application and more efficient review of late-stage cancer studies in adults. Subjects will continue to be informed of general radiation-related risks for research procedures.

### Summary

The application and review process for late-stage cancer studies will no longer include diagnostic radiation dosimetry and dose-related life-time cancer risk estimates (risk language). Diagnostic research procedures will be indicated for the first year and the expected frequency of the procedures after the first year for more open-ended studies. The review process by the HUS will be abbreviated. All other application procedures and processes will remain the same as currently done.

### Inclusion criteria

1. Late stage cancer subjects.
2. Median survival equal to or less than 24 months (to be determined by the PI).
3. Diagnostic radiation only.
4. Adult studies only.
5. Responsibility accepted by a Responsible User (RU)

### Exclusion criteria

1. “Umbrella” protocols that might include a range of different kinds of cancers or diagnoses.
2. Pediatric studies (less than 18 years of age upon entry into the study).
3. Pregnant or breast-feeding.
4. Studies proposed under RDRC authority (21CFR361.1).

### Application procedure for Late-Stage Cancer Studies

1. Complete the “**Protocol Radiation Use Review Sheet**” from the Huntsman Cancer Center (attached).
2. If **all** of the procedures that involve exposures to radiation (i.e. X-rays, CT, PET, MUGA, SPECT, Fluoroscopy) in the application are indicated as “standard of care” for subjects even if not in the study, then submit the forms to Radiological Health for pre-review as “Exempt”.

3. If the median life expectancy is indicated as  $\leq 2$  years and radiation exposures outside of standard of care are indicated, proceed with the “Late-Stage Cancer” application. The Principal Investigator (PI) will be responsible for determining the median life expectancy for the study cohort.
4. Indicate in the application the “research” radiation procedures to be done during the first year of the study and then the frequency of exposures if the study is expected to continue beyond the first year.
5. Insert informed consent language appropriate for the study (see below for an example\*).
6. Submit the application to the appropriate Responsible User(s) (RU) for review (list of RUs attached). **NO DOSIMETRY WILL BE REQUIRED FOR HUS REVIEW.**
7. Upload all required documents into ERICA and contact Radiological Health for a pre-review.
8. The review process will include the approval of the RU(s), review by Radiological Health, review by one or more members of the HUS to include at least one physician, and the Chair.

#### Guidance on Informed Consent Language for Late Stage Cancer Protocols.

All procedures, even standard of care, may be included in the consent if it will help the subject put their total treatment into “context”. However, “research” procedures that involve radiation must be clearly indicated and distinguished from standard of care procedures. Dose-specific risk estimates will not be required unless requested.

\*An example of consent language to be modified, as needed, for the specific study.

“This research study involves exposure to radiation (*indicate types of procedures and how many for the first year and frequency if study will continue beyond one year*). This radiation exposure is not necessary for your medical care and is for research purposes only. This radiation may involve a low risk of a later cancer, however, we believe that this risk is not clinically relevant. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting this study.”

Attachments (available from Radiological Health)

1. Protocol Radiation Use Review Sheet.
2. Table of Responsible Users and the facilities or equipment under their authorization.