Guidance for X-Ray Radiation Use in Research Studies for Non-Healing Arts Purposes

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Under Wisconsin law, the Department of Health Services (DHS) is charged with regulating the receipt, use, transfer, possession, ownership or acquisition of sources of radiation. Currently, under DHS regulations pertaining to Radiation Protection, no persons may be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts.\(^1\) “Healing arts” means a profession concerned with diagnosis and treatment of human maladies, including the practice of medicine, dentistry, osteopathy chiropractic and podiatry.\(^2\) The deliberate exposure of an individual to useful beam radiation without prior examination disclosing a need for an x-ray procedure and prescription for such a study by a practitioner of the healing arts is prohibited absent a variance from DHS.\(^3\)

Research studies which expose subjects to x-ray radiation as part of standard clinical imaging or which are therapeutic in nature (i.e. those which present the prospect of direct benefit to subjects), do not presently require a variance from DHS. Additionally, no variance is required if the exposure to radiation is for the purpose of subject safety (e.g. x-ray to rule out metal in the body prior to a research MRI). However, if the research study is non-therapeutic in nature or enrolls healthy volunteers, a variance must be requested. The information to be submitted by investigators proposing to conduct a non-therapeutic research study or using healthy volunteers wherein such subjects will be exposed to x-ray radiation is set forth in Appendix M to Chapter DHS.

This guidance applies to research studies conducted by University of Wisconsin researchers. VA radiation facilities are not subject to WI state inspections, with all radiation safety related issues at the Madison VA Hospital being handled by federal inspectors and oversight groups. Therefore state radiation safety requirements, and related state DHS variances, do not apply at the Madison VA Hospital. Such studies must comply with VA regulations and undergo radiation safety review as part of the Research and Development Committee review process.

Process for obtaining a variance

For new studies
Before a variance request may be submitted to DHS, you must have IRB approval in place for your study. Note that IRB approval conditioned upon DHS’s issuance of a variance is acceptable. Upload a request for a variance (providing the information requested in Appendix M) on the Supplemental Information page of the ARROW application. The IRB Office staff have the variance reviewed by a radiology expert familiar with State Law to ensure the accuracy and consistency of the submission. IRB staff will then forward the request for variance and

\(^1\) DHS 157.74(2)(f).
\(^2\) DHS 157.03(155).
\(^3\) DHS 157.03(156).
supporting documentation on the study team’s behalf to the appropriate entities. When the variance is issued, the study team should submit a copy of the approved variance to the IRB in ARROW by responding to an administrative hold.

For studies previously approved by the IRB that involve x-ray radiation use for non-healing arts purposes but do not have a variance in place
Submit a copy of the variance request to the IRB via ARROW through an expedited change and select the “Supplemental Approval Only” option on the Change Type Continued page in the change form. A copy of the Appendix M document should be uploaded on the Supplemental Information page of the IRB application. The IRB Office staff will forward the request for variance and supporting documentation on the investigator’s behalf to the appropriate entities. When the variance is issued, the study team will be asked to review it and upload the variance in the IRB application before the IRB approves the change of protocol.

OR
Include the variance request when submitting another change of protocol. The IRB Office staff will forward the request for variance and supporting documentation on the investigator’s behalf to the appropriate entities once the change of protocol has been approved with an administrative hold. When the variance is issued, the study team should submit a copy of the approved variance to the IRB in ARROW by responding to an administrative hold.

For studies previously approved by the IRB that will add or revise procedures requiring a variance
Before a variance request can be submitted to DHS, you must have IRB approval in place for the change of protocol that will add or revise procedures requiring a variance. A copy of the Appendix M document should be uploaded on the Supplemental Information page of the IRB application. If a variance for the study was approved previously, revise the Appendix M document to reflect changes being made to the procedures that require a variance. As described above, the change will be approved with an administrative hold pending approval of the variance. The IRB Office staff will forward the request for variance and supporting documentation on the investigator’s behalf to the appropriate entities once the change of protocol has been approved with an administrative hold. When the variance is issued, the study team should submit a copy of the approved variance to the IRB in ARROW by responding to an administrative hold.

Note: For studies that use a non-UW IRB (e.g. WIRB or NCI CIRB) as the IRB of record, consult UW HS IRB staff for additional instructions.

After the variance has been granted
The study team is responsible for maintaining IRB approval for the duration of the study. DHS requires additional submissions only if study procedures are revised in a way that affects the study’s use of x-ray radiation.