**APPLICATION FOR THE USE OF X-RAYS IN HUMAN RESEARCH**

General Remarks and Guidelines:

The VHA National Health Physics Program (NHPP) has tasked the Radiation Safety Committee (RSC) of the San Francisco VA Health Care System to oversee the use of x-rays. X-rays are traditionally used in diagnostic studies. However, the use of x-rays for proposed human research studies must also adhere to the ALARA (As Low as Reasonably Achievable) policy. The goal of this process is to review the use of x-rays outside of the traditional diagnostic arena and to monitor the appropriate use of x-rays from the radiation safety perspective. The RSC will work with the Principal Investigator(s) to ensure that they can comply with the ALARA policy for research involving the use of x-rays.

If the space allocated for your response is inadequate, use supplementary sheets, keying your answers to the corresponding numbers on this form; when completed, attach the sheets to the form.

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| **RSC USE ONLY** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **Approval #** | | | | | | | | | | | | | |  | | | | | | **Expiration Date** | | | | | | | | | | | | |
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| **Signature: Chairman, Radiation Safety Committee** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| NOTE: If granted by the RSC, approval is only for the personnel, procedures, equipment and the categories of patients or subjects described in this application. Any changes MUST be submitted to the RSC for approval PRIOR to their implementation. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. | a. | | | SERVICE NAME: | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | |
|  | b. | | | LOCATION(S) OF X-RAY UNIT (Room(s)/Building(s): | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | |
|  | c. | | | DESCRIPTION OF X-RAY UNIT: | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | |
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| 2. | a. | | | PRINCIPAL INVESTIGATOR(S): | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | |
|  | b. | | | PHONE EXT/EMAIL/MAIL SYMBOL: | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | |
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| 3. |  | | | TITLE OF STUDY: | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | |
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| 4. | **Briefly outline the relevant qualifications, training, experience of the Principal Investigator and other participating personnel, emphasizing their clinical, scientific, and technical backgrounds bearing on the proposal.** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | a. | | | PRINCIPAL INVESTIGATOR: | | | | | Provide a summary of Qualifications and Abbreviated C.V.  Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | b. | | | OTHER PARTICIPATING PERSONNEL INCLUDING TECHNOLOGIST(S): | | | | | Give their qualifications and Abbreviated C.V. (Append our short C.V. form and any additional information on supplementary sheets.)  Click or tap here to enter text.  Click or tap here to enter text.  Click or tap here to enter text.  Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | |
| 5. |  | | | **PROPOSED DURATION OF STUDY:** | | | | | From: Click or tap here to enter text. | | | | | | | | | | | | To: Click or tap here to enter text. | | | | | | | | | | | | |
|  |  | | | *I will notify the RSO by email if the research project is completed prior to the original duration of study.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 6. | **Please provide the following information:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | a. | | | The standard technique that will be used: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | b. | | | The standard name of the protocol to be used: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | c. | | | The type of dose reduction software or technique to reduce patient dose: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | d. | | | The type of shielding that will be used to reduce patient dose to the thyroid/gonads/lens of the eye: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | e. | | | State the maximum number of procedures for each patient: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | f. | | | State the policy for repeat studies: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | g. | | | X-ray technologists and/or operators are credentialed by the VA: | | | | | | | | | | | | | | | | | | YES | | |  | | NO | |  | |  |  | |
|  | h. | | | Non-radiologist physician training has been completed under the TMS system: | | | | | | | | | | | | | | | | | | YES | | |  | | NO | |  | | N/A |  | |
|  | i. | | | Non-radiologist proctored by approved physician: | | | | | | | | | | | | | | | | | | YES | | |  | | NO | |  | | N/A |  | |
|  | j. | | | Proctor statement reviewed and approved by designated individual: | | | | | | | | | | | | | | | | | | YES | | |  | | NO | |  | | N/A |  | |
|  | k. | | | Patient consent required. ICF copy enclosed: | | | | | | | | | | | | | | | | | | YES | | |  | | NO | |  | |  |  | |
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| 7. |  | | | **BRIEF RATIONALE AND SCIENTIFIC JUSTIFICATION FOR THE STUDY:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 8. |  | | | **PARTICIPATING EXPERIMENTAL POPULATION:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | a. | | | Total No. of Patients (Subjects): | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
|  | b. | | | Total No. of Controls: | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
|  | c. | | | Males: | | | | |  | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
|  | d. | | | Females: | | | | |  | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
|  | e. | | | Age Range: | | | | |  | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
|  | f. | | | Specific Physical Attributes and Conditions: | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
|  | g. | | | Other Selection Criteria: | | | | |  | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
|  | 9. List all expected procedures involving radiation and answer the questions for each:   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Name of procedure involving radiation** | **X-ray region of interest** | **Non- radiation alternative** | \***Maximum # of procedures per subject *in any 1 year*** | | \***Total # of procedures per subject *for entire study*** | | **RSC USE ONLY** | | **# for routine clinical care** | **# for research** | **# for routine clinical care** | **# for research** |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 10. | |  | **SPECIAL CONCERNS*:***  *(Indicate unusual or potential hazards presented by the proposed study not explained in item 7):* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 11. | |  | **DOSIMETRIC ESTIMATES:**  *On supplementary sheet, a) give estimates for the estimated doses received by the subjects (or patients) and controls; include the target and critical organs as well as the whole body. Estimates for CT procedures can be in CTDIvol and DLP and uGym2 or equivalent for fluoroscopic procedures.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| ***I hereby certify that all the information provided is correct to the best of my knowledge. I commit to working with the Radiation Safety Committee and the Radiation Safety Officer to ensure the safe use of x-rays and will***  ***advise him/her of any proposed changes prior to implementation. I understand that I can’t begin this proposed study until I am notified in writing by the Radiation Safety Committee and/or Radiation Safety Officer.*** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **Signature: Principal Investigator** | | | | | | | | | | | | | | | | |  | | | | | | **Date** | | | | | | | | | |
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| *If you have questions regarding the completion of this form, please communicate with the RSO at ext. 24944 and/or Victor.Goretsky@va.gov* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **APPLICATION FOR AMENDMENT TO EXISTING PROTOCOL** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Amendment being requested: (Attach supplementary sheets, if necessary) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **Signature: Principal Investigator** | | | | | | | | | | | | | | | | |  | | | | | | **Date** | | | | | | | | | |

[SUBMIT BY EMAIL](mailto:%20victor.goretsky@va.gov;?subject=RSC%20Application)  (Please save and attach this form to your email)