RDRC PROTOCOL REVIEW CHECKLIST: Criteria for the Evaluation of the Appropriateness of Research Studies under a RDRC

To approve a proposed research study, the RDRC must consider the following:

	YES	NO	N/A
1. Is the pharmacologica1 dose within the following limits?			
A. The amount of active ingredient or combination of active ingredients shall be known to not cause any clinically detectable pharmacological effect in humans.			
* Sufficient documentation provided.			
B. If the same active ingredients (exclusive of the radionuclide) are to be administered simultaneously (e.g., under an IND or for a therapeutic use), the total amount of active ingredients including the radionuclide shall be known not to exceed the dose limitations applicable to the separate administration of the active ingredient excluding the radionuclide.			
*Sufficient documentation provided.			
2. Were pharmacological dose calculations based on data available from published literature or from other valid studies?			
3. Is the radiation dose within the following limits?			
A. Subject must receive the smallest radiation dose practical to perform the study.			
*Absorbed dose calculations based on biologic distribution data avaiIable from published literature or from other valid studies was provided.			
*An acceptable method of radioassay of the radioactive drug prior to its use was provided.			
*Adequate and appropriate instrumentation for the detection and measurement of the specific radionuclide will be utilized.			

	YES	NO	N/A
*The radioactive drug has the combination of half-life, type of radiation, radiation energy, metabolism, and chemical properties that results in the lowest dose to the whole body or specific orifices which is possible to obtain the necessary information.			
B. For adult subject: Under no circumstances may radiation dose from a single study or cumulatively from a number of studies conducted within 1 year exceed:			
*Whole body, active blood-forming organs, lens of eye, and gonads:			
Single dose 3 Rems			
Annual & total dose 5 Rems			
* Other organs:			
Single dose 5 Rems			
Annual & Total Dose 15 Rems			
C. For subject under 18 years of age: Radiation dose may not exceed 10 percent of dose set forth above.			
D. When determining total radiation doses and dose commitments must consider:			
*All radioactive material included in drug either as essential material or as significant contaminant or impurity.			
* X-ray procedures that are part of the research study.			
* Possibility of follow-up studies.			
E. Are the numerical definitions of dose based on absorbed fraction method of radiation absorbed dose calculation (e.g., system set forth by Medical Internal Radiation Dose Committee of the Society of Nuclear Medicine or by the International Commission on Radiological Protection)?			
*Sufficient documentation provided.			
4. Is the radiation exposure justified by the quality of the study being undertaken and the importance of the information it seeks to obtain?			

	YES	NO	N/A
5. Is each investigator qualified by training and experience to conduct the proposed research studies?			
6. Is the investigator's or institution's license to handle radioactive materials appropriate? Does the investigator meet the following requirements?			
A. For reactor-produced isotopes: The investigator or institution shall be licensed by the Nuclear Regulatory Commission or Agreement State to possess and use the specific radionuclides for research use or be a listed investigator under a broad license.			
B. For non-reactor-produced isotopes: The investigator or institution shall be licensed by other appropriate State or local authorities, when required by state or local law.			
7. Is the use of human subjects appropriate and does it meet the following requirements?			
A. Number of subjects should not exceed 30.			
B. Research must be reviewed and approved by an institutional review board and consent must be obtained from the subjects or legal representatives.			
C. Research subjects must be at least 18 years of age and legally competent.			
D. Exceptions to preceding requirement only permitted if:			
*Investigator can demonstrate that: 1) the study presents a unique opportunity to gain information not currently available; 2) requires use of subjects less than 18 years of age; 3) is without significant risk to subjects.			
*RDRC review is supported with review by qualified pediatric consultant.			
E. Female subjects of childbearing potential must: 1) state in writing that they are not pregnant or 2) on basis of pregnancy test be confirmed as not pregnant.			

	YES	NO	N/A
8. Does the radioactive drug meet appropriate chemical, pharmaceutical, radiochemical, and radionuclidic standards of identity, strength, quality and purity?			
Were the radioactive materials for parenteral use prepared in sterile and pyrogen-free form?			
9. Is the research design appropriate in that:			
A. Scientific knowledge and benefit is likely to result from the study and the research shall be based upon sound rationale derived from appropriate animal studies or published literature;			
B. Scientific knowledge and benefit should be of sound design such that information of scientific value may result.			
C. Will the radiation dose be sufficient and no greater than necessary for purpose of the study?			
D. The projected number of subjects shall be sufficient and no greater than necessary and should reflect the fact that the study is intended to obtain basic research information and not intended for other purposes.			
10. Is the packaging, label, and labeling of the radioactive drug in compliance with Federal, State, and local law regarding radioactive materials?			
Is the label of the immediate container and shielded container, if any, in compliance with RDRC requirements?			

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