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01. Amendment Cover Sheet

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This amendment is being submitted for the following application:

Study Title: ptreed - fda
PI ID: Lark-Aeryn Speyer
Expiration Date ID: 11/14/2025
eResearch ID: HUM00255685
MCRU ID:

1.1* Amendment Title *(limited to 256 characters)*:

speyer-Amendment 1

1.2* Provide up to six keyword descriptors for this Amendment.

ha ha there's a question gone!

1.3* Proposed changes:

	Description of change	Corresponding application section
☑	General study information changes (e.g. change in study team, administrative updates to study documents, etc.).	Section 1 General Study Information
☐	Change to research/application type (update from umbrella application to application for research with human subjects, exempt to standard, etc.)	Section 1-1 Application Type
☐	Change to sponsor/support of this study.	Section 2 Sponsor/Support Information
☐	Change to a performance site or provide IRB/site approval documentation.	Section 3-1 Performance Sites
☐	IRBMED ONLY Update to Cancer Center enrollment numbers.	Section 3-2 Cancer Center Subject Participation
☐	Change in research design, intervention, goals or specific objectives(e.g.study specific evaluations such as statistical analysis, blood tests, clinical visits, dosing schedule, etc.).	Section 5 Research Design
☐	Update to the risks or anticipated benefits to research subjects.	Section 6 Benefits and Risks
☐	Change in enrollment numbers.	Section 8 Subject Participation
☐	Change in recruitment procedures or documentation.	Section 8-1 Subject Recruitment
☐	Update to subject populations/vulnerable subjects.	Section 09-1 Subject Populations
☐	Change to the informed consent document or process.	Section 10 Informed Consent
☐	Study changes that could effect the clinical research billing calendar.	Section 14-1 Clinical Research Billing
☐	Update to Investigator Brochure or change to the study drugs or biologics.	Section 15 Drugs, Biologics, etc.
☐	Change to or addition of study devices	Section 16 Devices
☐	Changes to the biological specimens collected for research purposes.	Section 18 Biological Specimens
☐	Changes to any aspect of radiotracer administration (e.g. number of doses, dosimetry, change of protocol, consent form, side effects,	Section 21 Ionizing Radiation and

Description of change	Corresponding application section
mis-administrations)	RDRC/SHUR Information
☐ Change to or addition of survey instruments.	Section 29 Survey Research
☐ Other - Describe below.	

1.4* Provide a description and justification for each proposed change. Include a comprehensive summary of the changes where available (such as those included with protocol amendment). ***Proposed changes to uploaded supporting documention (e.g., research protocol, informed consent document, investigator's brochure, survey instrument, recruitment script, etc.) may not be readily apparent to reviewers and therefore should be described here in detail.***

grea

1.5 If the amendment includes a revision to the informed consent document or process, specify which subjects, if any, you intend to re-consent [*Required for clinical interventions for which subjects have already been consented and all IRBMED studies]. Provide the rationale if any (or all) subjects will not be re-consented ***(e.g. subjects have completed study intervention and follow-up).*** **Explain criteria if only some subjects will be re-consented** ***(e.g. subjects who are on active study treatment, or subjects who recieved the experimental drug).***

Select the one that applies:

- ● No previously enrolled subjects will be re-consented
- ○ All previously enrolled subjects will be re-consented
- ○ Only subjects meeting criteria specified below will be re-consented

Clear

no enrollment yet

1.6* Why is this amendment being requested?

Select all that apply:

- ☑ Initiated by principal investigator
- ☐ Initiated by study sponsor, coordinating center, etc.
- ☐ Response to an adverse event (AE) or other reportable information or occurrence (ORIO)
- ☐ Response to a regulatory requirement
- ☐ Other

1.7 Is this an amendment issued by a National Cancer Institute (NCI) sponsored Cooperative Group/Consortium requiring IRB approval in a designated time window (such as within 30 or 90 days of distribution)?

○ Yes ● No Clear

Sites that agree to partner with the National Cancer Institute to conduct Cooperative Group Clinical Trials are competitively ranked on the amount of IRB approved research conducted at each site and how quickly sites get up and running with enrollment. This also includes how quickly amendments get approved.

The Cooperative Group Program involves more than 3,100 institutions that enroll subjects to group-conducted clinical trials. Cooperative groups include researchers, cancer centers, and community physicians throughout the United States, Canada, and Europe. They work with NCI to identify important questions in cancer research and to design clinical trials to answer these questions.

appropriated funds for NCI to establish the Chemotherapy National Service Center. At that time, the main focus of the program was to test new anticancer agents from NCI's drug development program. The emphasis on chemotherapy has gradually shifted to studies of combined therapy approaches in cancer treatment.

1.8* Confirm that this amendment includes any necessary additions to and deletions from the study team.

- Newly added individuals may take part in study activities only after the amendment is finalized.
- Remove members who leave the project or become external collaborators (a reliance agreement may be necessary).

☑