Stony Brook University Institutional Review Board (IRB)

DATE:	June 29, 2018
TO:	Elaine Gould, MD
FROM:	Stony Brook University IRB (CORIHS B)
SUBMISSION TYPE:	Continuing Review/Progress Report
STUDY TITLE:	[789345-7] Evaluation of Incidental Adhesive Capsulitis in Oncology Patients Undergoing PET/MR and PET/CT Imaging
CORIHS#:	2015-3396-R2
ACTION:	APPROVED
SUBMISSION APPROVAL DATE:	June 29, 2018
PROJECT EXPIRATION DATE:	June 28, 2019
REVIEW TYPE:	Expedited Review
EXPEDITED REVIEW CATEGORY:	*5, 7*

Thank you for your submission of Continuing Review/Progress Report materials for this research study. Stony Brook University IRB (CORIHS B) (FWA #00000125) has deemed that your study can proceed.

Before you begin your research, you need to:

1) Download the stamped consent(s) / assent form(s) located in IRBNet. Go to your project. Immediately under the first heading is a link called "Designer". Click on "Designer", which will bring you to the next screen. To get stamped documents and approval letters, click on "Review details".

- Consent is an on-going process. You should continue to assess the subject's capacity to consent and the subject's willingness to continue to be in the study. Use only the current CORIHS-stamped forms in the consent process and ensure that each subject receives a copy of his/her signed consent/permission/assent document.

2) Obtain additional signatures in IRBNet BEFORE you start. If the study:

- involves University Hospital facilities, Rhona Vainder (Chernoff) or Regina Rigoroso or John Shen must sign.
- involves medical devices, Martin Griffel must sign.
- involves surgical pathology or cytology specimens, James Davis and Jingxuan Liu must sign.
- involves Pathology/Laboratory Services, Eric Spitzer must sign.
- involves research-related radiation, Sean Harling must sign.
- involves study drugs, the Research Pharmacy must sign.
- involves Radiology services, Mark Schweitzer must sign.
- involves identifiable subject health information being electronically transmitted outside of SBU, Stephanie Musso Mantione must sign.

3) Obtain other committee approvals as needed; for example, the Institutional Biosafety Committee, the Stem Cell Research Oversight Committee and the Radioactive Drug Research Committee.

4) When you are ready to schedule and undergo the consent process with your first post-approval subject, please contact Mary O'Neill at Mary.oneill@stonybrook.edu to coordinate having her present to witness your consent process. This process is part of our ongoing effort to ensure maintained quality in our human research protection program.

You are reminded that:

1. Approval includes the protocol uploaded on 5/21/2018 as well as continued use of the questionnaire uploaded on 8/29/2015.
2. Your approval to conduct this research will expire on the date above. You must apply for and be granted continued approval for this study before that date in order to be able to conduct your study in an uninterrupted manner. If you do not receive approval before this date, you must cease and desist all research involving human subjects, their tissue and their data until such time as approval is granted.
3. All research must be conducted in accordance with this approved submission. Any modifications to the study as approved must be reviewed and approved by CORIHS prior to initiation.
4. Unanticipated problems (including serious adverse events) must be reported to the Office of Research Compliance in accordance with SBU Policy at http://research.stonybrook.edu/human-subjects-standard-operating-procedures/unanticipated-problems-involving-risks-subjects-or.
5. Any complaints from subjects or issues of non-compliance must be immediately reported to the Office of Research Compliance.
6. Consent forms signed by subjects in this study must be kept by the investigator for 7 (seven) years from study termination, or indefinitely (if so indicated in the consent form).

Transfer of identifiable health information
If your study involves the transfer of identifiable health information (as a limited data set) to someone outside SBUH (such as a sponsor or collaborator) or from someone outside SBUH to you, you may need a Data Use Agreement. Please contact the Privacy Officer, Stephanie Musso Mantione, for details on how to do that.

If you have any questions or comments about this correspondence, please contact (include your study title and CORIHS number):

Office of Research Compliance
Division of Human Subject Protections
Stony Brook University
Stony Brook, NY 11794-3368.
Phone: 631-632-9036
Fax: 631-632-9839

We are interested in receiving feedback regarding your experience with the Office of Research Compliance, SBU's IRBs (CORIHS), or any other aspect of our Human Research Protection Program. Please feel free to e-mail Margaret McNurlan, Interim Assistant Vice President for Research Compliance, at Margaret.McNurlan@stonybrook.edu.