

**The Cooper Health System
Institutional Review Board
FWA #: 00000211**

Notification of Expedited New Protocol Approval

Date: August 31, 2015

To: Principal Investigator
Brown, Spencer, PhD

Co-investigators/Coordinators

Ann Leilani Fahey, MD, Ashleigh Rapp, MD, Kiavash Koko, MD, Marc Fromer, MD, Martha Matthews, MD, Ping Zhang, PhD, Ryan Nolan, MD, Shaohua Chang, PhD

IRB#: 15-107EX

This number is a CHS IRB number which should be used on all correspondence.

Study Title: Examining the potential impact of chemotherapy and radiation on mesenchymal stem cells in cancer patients

Study Number: Cooper Foundation

Sponsor: Cooper Foundation

Approval Date: 08/25/2015

Study Application Version: 1.1

This approval is for a period of 12 Months

Expiration Date: 08/24/2016

(based upon date recommended for approval)

Specific Items and Information Pertaining to this Approval:

The IRB approved this study for subjects who are capable of giving consent on their own behalf.

This protocol and supporting materials have been reviewed and approved by an IRB member designated by the Chair using the expedited procedures set forth in 45 CFR 46.110(b)(2) and 21 CFR 56.110(b)(2) and the expedited review categories specified in the Federal Register/Vol. 63, No. 216 dated 11/9/98. The reviewer determined that the study qualifies for expedited review because it involves no greater than minimal risk and involves only procedures in the following category.

- ☐ (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - (a) Research on drugs for which an investigational new drug application is not required.
 - (b) Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- ☐ (2) Collection of blood samples by finger stick or venipuncture.
- ☐ (3) Prospective collection of biological specimen by non-invasive means.
- ☐ (4) Collection of data through non-invasive procedures.
- ☒ (5) Research involving materials collected solely for non-research purposes.
- ☐ (6) Collection of data from recordings made for research purposes.
- ☐ (7) Research employing surveys, interviews, etc.

Items reviewed and approved in this action:

- ☒ Investigator-initiated protocol in Study Application version: 1.1
- ☐ Sponsor's Protocol version: []
- ☒ Combined consent form and HIPAA authorization [date stamp/approved: 8/25/2015 expires 8/24/2016]
- ☐ Waiver of informed consent per the regulations at 45 CFR 46.116(d)
- ☐ Waiver of HIPAA authorization per the regulations at 45 CFR 164.512(i) (2)
- ☐ Waiver of documentation of informed consent per the regulations at 45 CFR 46.117(c)(1)
- ☐ Waiver of documentation of informed consent per the regulations at 45 CFR 46.117(c)(2)

- ☐ Tissue/specimen banking form
- ☐ Declaration of De-identification
- ☐ External investigator (specify IIA/FWA above)
- ☐ Cooper is Data Coordinating Center and/or FWA/IRB approval from other sites required (specify above)
- ☒ Other (specify: Data Sheet and Advertisement)

The research meets the criteria and approval is granted for:

- ☐ Children as subjects per Subpart D at 45 CFR 46.404 and of 21 CFR 50.51
- ☐ Pregnant women or fetuses prior to delivery per Subpart B at 45 CFR 46.204.
- ☐ Other:

Consent Form and HIPAA Authorization (if applicable): The approved and stamped consent form and HIPAA authorization must be used when enrolling subjects. You are responsible for maintaining signed consent forms for a period of at least three (3) years after study completion. **Print out and use the currently approved and stamped consent form and HIPAA authorization when enrolling subjects.** Please note that the expiration date is stamped on consent and HIPAA authorization forms as well as the approval date.

Other IRB-Stamped Approved Documents (if applicable); If any documents other than the consent form and HIPAA authorization were stamped with the IRB approval stamp, use only the stamped versions of the documents when conducting the research project.

Continuing Review: Federal regulations require that research involving human subjects be reviewed at least every 365 days although the IRB has the authority to set more frequent review requirements. You should receive electronic notification 60 days prior to the expiration of this project's approval. However, it is your responsibility to insure that an application for continuing review approval has been submitted by the required time. If the research study is not re-approved before the expiration date, accrual of new subjects must be suspended until approval has been renewed.

Amendments: It is the principal investigator's responsibility to inform the IRB of any and all changes to the approved study, including but not limited to changes in investigators and study staff and revisions to the protocol and/or consent form. You must have IRB approval before initiating any changes to the study except changes that are necessary to eliminate immediate hazards to the subjects.

Unanticipated Risk Reporting:

The principal investigator must immediately report to the CHS IRB any unanticipated problems involving risks to subjects or others and any serious harm to subjects.

Study Closure: You are required to submit a Study Closure Report summarizing the study's activity at the completion of the project.

Sincerely,

Judith Finkelstein
Senior IRB Coordinator