MEMORANDUM

DATE: July 1, 2015

TO: Kimberly Summers, Pharm.D.
Institutional Review Board

FROM: Carlos A. Rosende, M.D.
Executive Director, UT Medicine

RE: UT Medicine Patient Recruitment for Research Studies

At your request, the MSRDP Board of Directors reviewed the HSC IRB policy on recruitment of research participants from UT Medicine’s patient population. The policy limits recruiting of UT Medicine patients to only those researchers who have an “established relationship (either treatment or research)” with the patient.

The IRB policy does not allow the practice of “cold calling” of potential research subjects who receive medical care within UT Medicine. A “cold call” is defined as a planned communication with a potential research subject by an investigator or a member of the investigator’s team when neither the investigator nor the contacting person is known to the potential subject or would be expected to have access to his/her protected health information (PHI).

The MSRDP Board of Directors considers UT Medicine to be one clinical practice and this applies to the recruitment of research participants. Therefore, UT Medicine providers who are recruiting patients for treatment studies using UT Medicine records under an IRB approved protocol would not be considered “cold calling”.

It is expected that the IRB will continue to evaluate the recruitment plan for each human subjects research protocol and that it will implement appropriate safeguards. Preferably, prospective research participants should be contacted by persons known to them, such as persons directly involved in their care. However, if this approach is impractical, UTHSCSA researchers may directly contact subjects, if permitted by applicable regulations as determined by the IRB.

Investigators must be reminded that extreme caution should be exercised when potential participants are identified through chart reviews or through research data repositories under a Waiver of HIPAA Authorization for recruitment, as these avenues to PHI are less familiar to participants. Investigators should first send a letter to prospective participants, signed by a health care provider or clinical specialty department that would be recognizable to the potential participant, and provide a telephone number or other means by which the potential subject can verify that the study constitutes legitimate UTHSCSA research.