UF | Institutional Review Board
UNIVERSITY of FLORIDA

E-MAILED
9-28-2012
Munoz, McGaha

Health Science Center / Jacksonville
College of Medicine
Institutional Review Board

FWA00005790

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MEMORANDUM

DATE: September 28, 2012

TO: Juan Carlos Munoz, MD
653-1 W. 8th Street
Jacksonville, FL 32209

FROM: Sheila M. Austin, CIP
Coordinator, Institutional Review Board for
Alan Halperin, MD
Chair, Institutional Review Board

SUBJECT: Expedited Review of UFJ 2012-120

TITLE: Self-expanding Stents for Benign and Malignant Lesions of the Esophagus. Metal Versus Plastic? A Retrospective Clinical Case Series

Your request for approval of the above study under the classification of expedited was reviewed in the IRB office and as IRB Chair I am pleased to inform you that your study was approved on 9/18/2012 under the following expedited category(s):

___1. Clinical studies of drugs and devices only when:
a. An investigational new drug application (IND) or investigational device exemption (IDE) is not required, and there is no significant increase in risk or decrease in acceptability of risk, or
b. The device is cleared or approved for marketing and is being used in accordance with its labeling.

___2. Collection of blood samples by finger, heel, or ear stick, or venipuncture no more than twice weekly as follows:
a. From healthy non-pregnant adults weighing at least 110 pounds, in amounts less than 550 ml per 8 weeks.
b. From other adults and children, considering the health and habitus of the subjects, in amounts less than 50 ml or 3 ml per kg (whichever is less) per 8 weeks.

___3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
a. Hair and nail clippings (non-disfiguring).
b. Deciduous teeth at exfoliation or indicated extraction
c. Permanent teeth excreta at indicated extraction
d. Excreta and external secretions including sweat
e. Uncannulated saliva
f. Placenta removed at delivery
g. Amniotic fluid at the time of rupture of the membrane prior to or during labor
h. Supra- and sub-gingival dental plaque during routine prophylactic scaling
i. Mucosal and skin cells by buccal scraping or swab, skin swab, or mouth washings.
j. Sputum after saline mist nebulization

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___ 4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Examples:
a. Physical sensors that do no involve input of significant amounts of energy or invasion of privacy.
b. Weighing or testing sensory acuity.
c. Electro-cardiography, electro-encephalography, thermography, detection of naturally- occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography.
d. Moderate exercise, muscular strength testing, body composition assessment and flexibility testing where appropriate for age, weight and health.

☑ 5. Research involving materials (data, documents, records, specimens) that have been or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

___ 6. Collection of data from voice, video, digital, or image recordings made for research purposes.

___ 7. Research on individual or group characteristics or behavior (such as studies of perception, cognition, motivation, identity, language, communication, cultural beliefs and practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Research records (data collection sheets, records of clinical, educational, behavioral intervention, signed Informed Consent forms, and IRB correspondence) must be kept for at least 3 years following the completion of the research. Holding onto these documents for three (3) years allows for authentication of research activities and findings. In addition, investigators may need to make these records available for review by various agencies that oversee human subject protections.

The new HIPAA rule mandates that all Authorizations given by research participants to use their protected health information for research purposes be maintained by six (6) years following completion of the research project. That means that all separate HIPAA Authorizations and all Informed Consent forms that include HIPAA Authorization must be kept for an additional 3 years over the other research records.

You must inform the Board of any modifications or changes to this research (protocol or consent changes) since they could affect its expedited status.

Please note the category of informed consent listed below that has been approved for this study.

_____ You have been granted approval to conduct this study using the enclosed stamped, IRB-approved consent form. This consent must be photocopied and used when enrolling subjects into this project.

OR

_____ You have been granted a waiver of documentation of informed consent, in lieu of a verbal consent.

OR

☑ You have been granted a waiver of informed consent.

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Your protocol is approved until 9/18/2013 at which time you will need to submit a regular continuing review report in order to continue the study. This study has been approved for enrollment of 50 subjects. If you find the need to increase this number, please submit a Revision to the IRB office immediately.

Thank you for informing the Board of your proposal.