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APPROVAL NOTICE

New Study

DATE:	5/29/2015
TO:	EDWARD LEE RADIOLOGICAL SCIENCES
FROM:	FAIROOZ KABBINAVAR, MD Chair, MIRB2
RE:	IRB#15-000608 Retrospective Study Evaluating the Effectiveness of BRTO (balloon-occluded retrograde transvenous obliteration) in Patients with Liver Disease

The UCLA Institutional Review Board (UCLA IRB) has approved the above-referenced study. UCLA's Federalwide Assurance (FWA) with Department of Health and Human Services is FWA00004642.

Submission and Review Information

Type of Review	Expedited Review
Approval Date	5/28/2015
Expiration Date of the Study	5/27/2018
Funding Source(s)	

Specific Conditions for Approval

-- **3 Year Extended Approval** - the IRB has determined that this study meets the criteria for a 3 year extended approval. (For reference, please see the OHRPP guidance document "Extended Approval for Minimal Risk Research Not Subject to Federal Oversight" at http://ora.research.ucla.edu/OHRPP/Documents/Policy/4/Extended_Approval.pdf)

Regulatory Determinations

-- **Expedited Review Category(ies)** - The UCLA IRB determined that the research meets the requirements for expedited review per 45 CFR 46.110 category 5.

-- **Waiver of Informed Consent** - The UCLA IRB waived the requirement for informed consent under 45 CFR 46.116(d) for the entire study.

-- **HIPAA General Waiver** - The UCLA IRB waived the requirement for HIPAA Research Authorization for the research.

Documents Reviewed included, but were not limited to:

Document Name	Document Version #
Data Abstraction List.pdf.pdf	0.01

Important Note: Approval by the Institutional Review Board does not, in and of itself, constitute approval for the implementation of this research. Other UCLA clearances and approvals or other external agency or collaborating institutional approvals may be required before study activities are initiated. Research undertaken in conjunction with outside entities, such as drug or device companies, are typically contractual in nature and require an agreement between the University and the entity.

General Conditions of Approval

As indicated in the PI Assurances as part of the IRB requirements for approval, the PI has ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IRB.

The PI and study team will comply with all UCLA policies and procedures, as well as with all applicable Federal, State, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

- Ensuring that the personnel performing the project are qualified, appropriately trained, and will adhere to the provisions of the approved protocol,
- Implementing no changes in the approved protocol or consent process or documents without prior IRB approval (except in an emergency, if necessary to safeguard the well-being of human subjects and then notifying the IRB as soon as possible afterwards),
- Obtaining the legally effective informed consent from human subjects of their legally responsible representative, and using only the currently approved consent process and stamped consent documents, as appropriate, with human subjects,
- Reporting serious or unexpected adverse events as well as protocol violations or other incidents related to the protocol to the IRB according to the OHRPP reporting requirements.
- Assuring that adequate resources to protect research participants (i.e., personnel, funding, time, equipment and space) are in place before implementing the research project, and that the research will stop if adequate resources become unavailable.
- Arranging for a co-investigator to assume direct responsibility of the study if the PI will be unavailable to direct this research personally, for example, when on sabbatical leave or vacation or other absences. Either this person is named as co-investigator in this application, or advising IRB via webIRB in advance of such arrangements.