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Mock IRB

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Mock IRB

Washington University in St. Louis

October 30, 2013

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Live Stream

Click this link or copy link to your browser to view the Mock IRB.

http://stream.nts.wustl.edu/R131029001/

Slides for the Mock IRB follow.

CNE Disclosures

- Successful Completion: Participants must complete an evaluation form to receive a certificate of completion
- Contact Hours: 1 contact hour is available to those who meet the successful completion requirements
- Sponsorship & Commercial Support: This activity has received no sponsorship or commercial support
- Conflict of Interest: No conflicts of interest were identified
- Non-Endorsement: Accreditation approval refers only to MONAs continuing education activities and does not imply MONA or ANCC Commission on Accreditation endorsement of any commercial products
- Off Label Use: There will be no discussion of uses of products other than what is approved by the FDA.
- Expiration: Contact Hours expire on October 29, 2015

Titles in Human Subjects Research

- FDA: 21 CFR 50 and 56
- HHS: 45 CFR 46

Criteria for approval 45 CFR 46.111, 21 CFR 56.111

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Obtain informed consent
- Document informed consent
- Monitoring plan
- Protect privacy & maintain confidentiality
- Protect vulnerable populations

Actors and their Role

Principal Investigator (PI)	Suresh Vedantham
IRB Chair	Ed Casabar
IRB Administrative Rep.	Michael Leary
IRB Analyst	Linda VanZandt
IRB Coordinator	Charmin Montgomery
Physician Scientist (PS)	Mitchell Sommers
Other Scientist (OS1)	Michelle Jenkerson
Other Scientist (OS2)	Sarah Fowler-Dixon
Non-Scientist (NS)	Niki Bridges

Narrator, Martha Jones

Reviewers' Responsibilities

- All committee members are responsible for reviewing all agenda items prior to the meeting so they can discuss and vote on all items.

Study Documents sent for IRB Review and Approval Attachments

Study Materials

- Study Protocol
- Grant
- Investigator's Brochure
- FDA IND approval letter
- Adult consent form
- Minor assent form
- Spanish adult consent form
- Spanish minor assent form
- Translation certification
- Phone scripts
- Patient cost diary
- Questionnaires

Recruitment Materials

- Facebook advertisement
- Social media discussion boards used for recruitment
- Study website
- Physician poster
- Subject poster
- Patient brochure
- Physician to physician recruitment letter

The purpose of this study

- To determine if Pharmacomechanical CDT (PCDT) should be routinely used to treat proximal DVT. In order to do this, they are conducting a multicenter randomized clinical trial (the Acute Venous Thrombosis: Thrombus Removal with Adjunctive Catheter-Directed Thrombolysis [ATTRACT] Trial) to establish whether PCDT prevents Post-Thrombotic Syndrome (PTS) and improves health-related Quality of Life (QOL) with acceptable safety and costs.

The Primary Objective

- To determine if initial adjunctive use of PCDT (using rt-PA) with optimal standard DVT therapy reduces the occurrence of the Post-Thrombotic Syndrome during 24 months of follow-up compared with optimal standard DVT therapy alone.

Regulatory Criteria for Approval

- **(1) Risks to subjects are minimized**:
  - (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
  - (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

- **(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.**
  - In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).
  - The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility

Children: Research must fit into one of the following categories

- 45 CFR **404**; 21 CFR 50.**51**- **Research not involving greater than minimal risk.**
  - Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
  - Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians

- 45 CFR **405**; 21 CFR 50.**52**- **Research involving greater than minimal risk but presenting the prospect of direct benefit <u>to the individual subjects</u>.**
  - (a) The risk is justified by the anticipated benefit to the subjects;
  - (b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
  - (c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians

Children: Research must fit into one of the following categories

- 45 CFR **406**; 21 CFR 50.**53**- **Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.**
  - (a) The risk represents a minor increase over minimal risk;
  - (b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
  - (c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
  - (d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians

Children: Research must fit into one of the following categories

- 45 CFR **407**; 21 CFR 50.**54**- **Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children**
  - Research in this category must be reviewed by the IRB which determines that it does not fall into one of the previous categories
  - The study with the IRB findings is then submitted to the DHHS Secretary/FDA Commissioner for review by a panel of experts and sent out for public review and comment

Component analysis

Intervention	Risk (min, > min, minor increase over min)	If risk not minimal, is there PDB?	If PDB, identify benefit.	Approval category	Parent signs
Patient demographics	Minimal	N/A		404	1
Medical History	Minimal	N/A		404	1
Physical Exam	Minimal	N/A		404	1
Review of diagnosis of qualifying DVT episode	Minimal	N/A		404	1
Lab assessment	Minimal	N/A		404	1

Component analysis: Pre-Screen

Intervention	Risk (min, > min, minor increase over min)	If risk not minimal, is there PDB?	If PDB, identify benefit.	Approval category	Parent signs
Questionnaires	Minimal	N/A		404	1
Calf circumference	Minimal	N/A		404	1
Villalta PTS scale	Minimal	N/A		404	1
Venus duplex ultrasound	Minimal	N/A		404	1
Review of School or Employment history	Minimal	N/A		404	1

Component analysis: Study Procedures

Intervention	Risk (min, > min, minor increase over min)	If risk not minimal, is there PDB?	If PDB, identify benefit.	Approval category	Parent signs
Standard Care	> Minimal	Yes	Use of SOC drugs to dissolve clots	405	1
PCDT Procedure with investigational TPA	> Minimal	Yes	Delivery in to clot to dissolve it faster/better	405	1

Final Risks to Minors Based on Component Analysis

Risk Rating	Requirements
404; 51 **Minimal**	One parent's consent *(One or two may be required by IRB)*
405; 52 **> Minimal, Direct benefit**	■**One parent's consent** *(One or two may be required by IRB)* ■**Risk justified by anticipated direct benefit** ■**Benefit approximate to alternatives' benefit**
406; 53 **> Minimal, No direct benefit**	■Both parents' consent ■ Minor risk over minimal ■ Children must have disease/condition under study ■No direct benefit
407; 54 **Not otherwise approvable**	■Both parents' consent ■Generalizeable knowledge ■Additional approval from DHHS/FDA

Criteria for approval of Research

- (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

- (5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

Criteria for approval 45 CFR 46.111, 21 CFR 56.111

- (3) **Selection of subjects is equitable**. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

Criteria for approval of Research

- (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

Criteria for approval of Research

- (7) Adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data:

Privacy and Confidentiality Definitions

- Privacy: The freedom of the individual to pick and choose for him/herself the time and circumstances under which, and to the extent to which his/her attitudes, beliefs, behavior and opinions are to be shared with or withheld from others. (Levine, p 163)

- Confidentiality: Mode of management of private information. (Levine, p. 163)

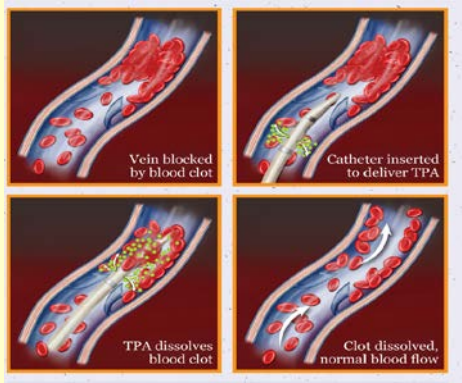
Criteria for approval of Research

- (7) (b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

the Attract STUDY

Do you have a blood clot in your leg (DVT)?

In this National Institutes of Health sponsored study, all patients will receive blood-thinning drugs, the standard treatment for blood clots. In addition, half of all study patients will be chosen to have their clot dissolved using a new treatment that a doctor will inject directly into the clotted vein through a specifically –designed drug delivery catheter. The other half of the patients will receive standard medical care.



Consider joining the ATTRACT study.

All patients will be followed for two years by a specialized team of doctors and nurses to determine if the new clot-busting treatment (TPA) helped prevent long-term complications such as pain, swelling, or skin ulcers (open sores) of the leg.

Eligible participants must be between the ages of 16 and 75.

Each person will be paid $1000.

Please call.

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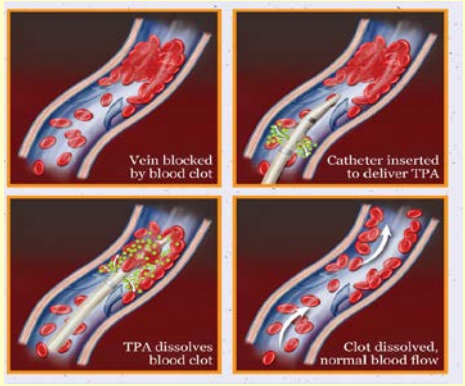

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Sponsor-Investigator Responsibility

- 21 CFR 312.50 Subpart D--Responsibilities of Sponsors and Investigators

- FDA IND Application
- http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm

- WU Investigational Drug/Device Accountability http://research.wustl.edu/PoliciesGuidelines/Pages/IDDA.aspx

- **WU IND Awareness Training for Sponsor-Investigators**
  - **Contact HRPO at 314-633-7400**

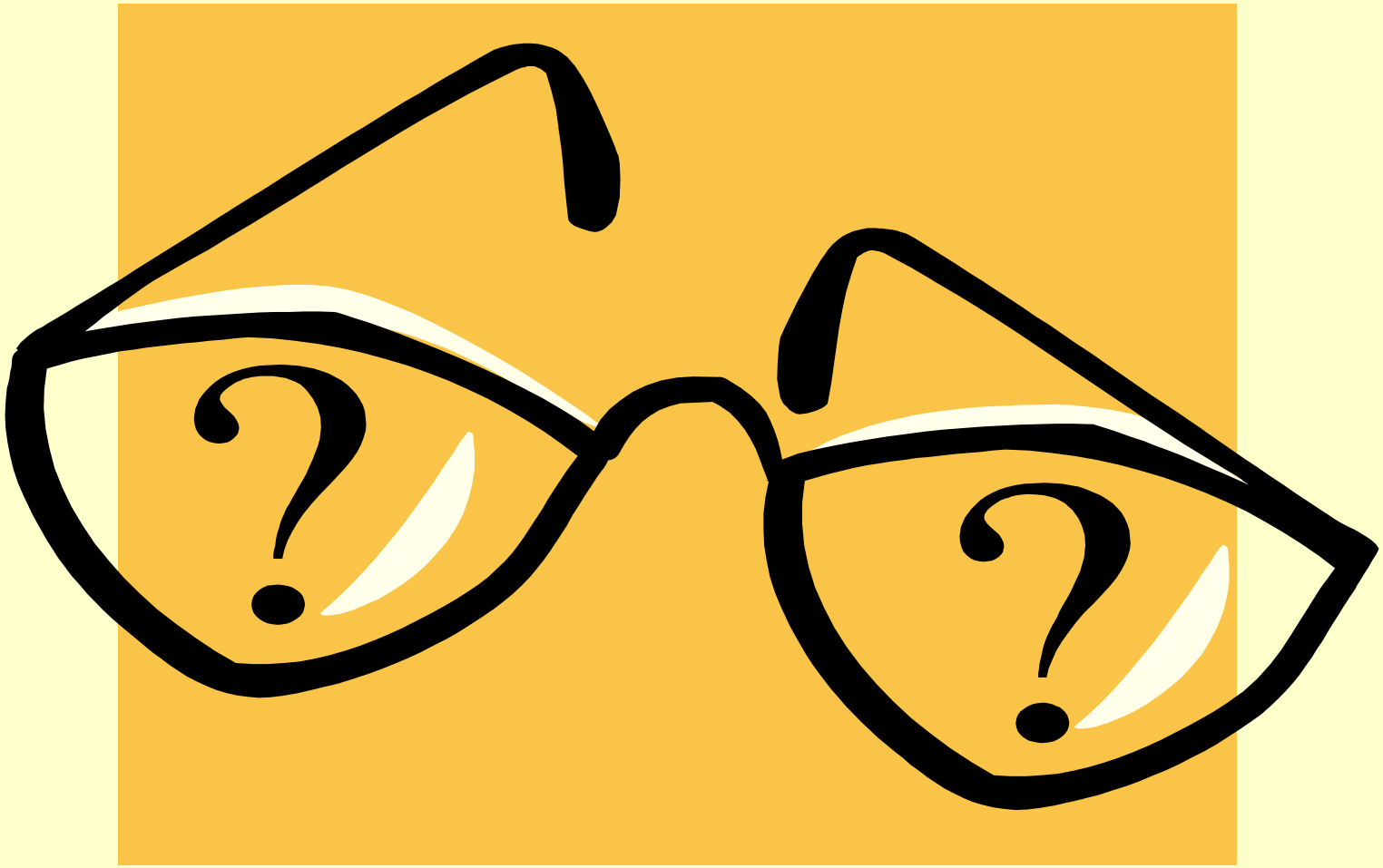
Coordinating Center or Lead Site should:

- Have written agreements with their sites
- Ensure IRB approvals are obtained at all sites
- Ensure proper training and qualifications
- Should develop standard operating procedures
- Ensure monitoring for all sites
- Collect all adverse events study-wide for data safety monitoring
- Have regular communications with all sites

Final Determinations

- Prescriptive Changes to the consent and myIRB application, and the recruitment advertisement
- Adults: Greater than Minimal Risk
- Minors: Both 45 CFR 404 and 405; 21 CFR 50.51 and 50.52
  - One parent signature
  - Assent process is appropriate with the prescriptive change to allow the child to discuss the study privately with the research team
- Continuing review in 1 year

Thank you



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