

# NETT NewsFlash

January 2010



## IRB Study Modification Notifications

All IRB reviews/approvals of study modifications must be uploaded into WebDCU. A new entry named: 'IRB Study Modification Notifications' has been created to capture IRB reviews/approvals *OTHER THAN* initial applications, continuing renewals and consent forms.

Examples of these other reviews/approvals include: documentation of IRB stipulations to traditional IRB study submissions and your response; changes in study team members; new study materials; new study locations, etc.

Appropriate documentation for this entry would include:

1. The letter provided to you by your IRB upon their review/approval of the new material, and
2. The material that was provided for their (IRB) review.

See the examples below for clarification:

- IRB review/approval of: Change in Study Team Members  
WebDCU entry to upload: IRB Study Modification Notifications
- IRB review/approval of: Change in Informed Consent Form  
WebDCU entry to upload: IRB Approved Informed Consent Form

## RAMPART REMINDERS

- When the seizure stops, *declare it* and then you are *done* with the study meds.
- No study meds given for recurrent seizures - use rescue meds per your local protocol
- Declare seizure termination
- Declare ED arrival
- Declare seizure status upon ED arrival

## point

Enrollment begins in April.

If you have questions re: this study please contact Andrace Deyampert  
[andraced@umich.edu](mailto:andraced@umich.edu)

## Enrollment Update: ALIAS

As of 1/29/10 at 1pm EST



## RAMPART

<b>Arizona</b>	<b>4</b>	<b>25</b>
<b>Cincinnati</b>	<b>10</b>	<b>52</b>
<b>Emory</b>	<b>12</b>	<b>26</b>
<b>HFH</b>	<b>4</b>	<b>25</b>
<b>Kentucky</b>	<b>8</b>	<b>13</b>
<b>Maryland</b>	<b>0</b>	<b>Not Active</b>
<b>Minnesota</b>	<b>6</b>	<b>25</b>
<b>NYP</b>	<b>5</b>	<b>Not Active</b>
<b>Oregon</b>	<b>Legacy</b>	<b>9</b>
<b>Stanford</b>	<b>4</b>	<b>21</b>
<b>Temple</b>	<b>3</b>	<b>Not Active</b>
<b>Texas</b>	<b>13</b>	<b>2</b>
<b>UCSF</b>	<b>3</b>	<b>53</b>
<b>UPenn</b>	<b>9</b>	<b>7</b>
<b>VCU</b>	<b>2</b>	<b>36</b>
<b>Wayne State</b>	<b>3</b>	<b>57</b>
<b>Wisconsin</b>	<b>4</b>	<b>Not Active</b>
<b>TOTAL</b>	<b>90</b>	<b>351</b>



◆ **ProTECT Site Visits:** If your site expects to be ready to enroll before 3-25-10, please contact Harriet Howlett-Smith ([hhowlet@emory.edu](mailto:hhowlet@emory.edu)) at least one month in advance so that she can schedule necessary site visits and individual training

◆ **1st Annual ProTECT III Investigator Meeting March 25-26:** Expenses will be paid for up to 3 team members (PI, Coordinator, and one neuro-surgeon, trauma surgeon, or neuro-investigator). Please register for the meeting by completing the meeting travel form at: [http://sitemaker.umich.edu/protect/investigator\\_travel\\_form](http://sitemaker.umich.edu/protect/investigator_travel_form)

H A P P Y  
N E W Y E A R

## NETT Network

Contact Us: [nett-contact@umich.edu](mailto:nett-contact@umich.edu) (734) 232-2142 Website: <http://nett.umich.edu>