

# IRB REGULATORY REMINDER

December 8, 1999

- In November of 1998, Expedited Review Research Categories were expanded.
- An example of the expanded categories is clinical studies of drugs and medical devices when certain conditions are met.

## STAY ON THE RIGHT TRACK

Help the IRB stay on the right track by ensuring that proposals submitted for Expedited Review FIT THE RESEARCH CATEGORIES.

Attached are the specific conditions which must be met before an Expedited proposal involving drugs and medical devices (Research Category 1) can be approved. These conditions are summarized below:

- The study must be minimal risk;
- An Investigational New Drug (IND) application is not required;
- An Investigational Device Exemption (IDE) is not required OR the device is marketed and being used as labeled.

PLEASE NOTE: The above information applies to **Expedited Reviews**.

If you are the Expedited reviewer it is critical that you determine the research fits within the Expedited Research Categories. If you have questions call the Office of Research Integrity:

257-8315

257-3138

Ride the Regulatory Reminder Railroad

Stay on track by ensuring  
Expedited proposals  
FIT THE RESEARCH CATEGORIES