



COMMERCIAL INSTITUTIONAL REVIEW BOARD, LTD.

133 South Fourth St. • Suite 202 • Springfield, IL 62701
217/492-1369 • 217/492-9369 (fax)

APPLICATION COVER FORM

Attach one of these as a cover for each of the protocol copies

Protocol Number: _____

Protocol Date: _____

Title: _____

PRINCIPAL INVESTIGATOR:

(For several investigators, attach a list indicating Co- or Sub-)

Name: _____

Street: _____

City: _____ State: _____ ZIP: _____

Phone: _____ Fax: _____

Who is the research coordinator (i.e. chief study nurse):

Name: _____

Phone: _____ Fax: _____

In the PI's absence, who will assume responsibility for continued care of the subjects?

STUDY SITE(S): Name and address (For several sites, attach a list.)

SPONSOR:

Name: _____

Address: _____

Contact Person: _____

Phone: _____ Fax _____

TEST ARTICLE - DRUG:

Name _____

Name 2 _____

IND # _____

STUDY PHASE:

Phase I _____ II _____ III _____ IIIB _____ IV _____

TEST ARTICLE - DEVICE:

Name _____

Has FDA determined this class of devices to be SR? YES NO

Has any IRB found this device to be SR? YES NO

Is a non-significant risk decision being requested? YES NO

IDE# _____

Date FDA approval is expected _____ PMA 510(k)

STUDY SUBJECTS:

Total number at your site? _____ Total number in the study? _____

Age: Minimum _____ Maximum _____

Check which target groups are involved:

- Males Females
 Minors Non-English Speaking
 Prisoners Economically Disadvantaged
 Pregnant Women Educationally Disadvantaged
 Mentally Disabled Life-Threatening Condition
 Physically Disabled Seriously Debilitating Illness or Disease
 Healthy Volunteers Placebo Controls

Recruitment

- Will subjects be drawn from your own patient base? YES NO
If no, will you contact the subject's personal physician? YES NO
Will advertisement using any media be necessary? YES NO
Are any finder's fees involved in recruitment? YES NO
How much? _____

Gender Issues

- Are there any exclusion criteria for women due to child-bearing potential? YES NO
Are there any exclusion criteria for men due to risk to sperm? YES NO

FINANCIAL CONSIDERATIONS:

Subject payment

- Are subjects being paid for participation/travel? YES NO
How much? _____
Is there a completion bonus? YES NO
How much? _____

Subject Charges (Will subjects pay for any part of participation?)

- Qualifying examinations Follow-up office visits
 Investigational drug Investigational device
 Concomitant drugs Laboratory tests
 Prolonged hospitalization Research related injury

Are any of these procedures standard of care? YES NO

Will the subject's third party carrier be charged for any research-related procedures? YES NO

\$ _____ Estimate of total amount subject (or insurer) might be asked to pay of study-related costs?

RELATIONSHIP TO OTHER IRBS:

Has the P.I. submitted this study to another IRB? YES NO
If yes, was this study rejected by the IRB? YES NO
(If yes, please provide the IRB's letter explaining the reason.)

Is there an institutionally-based IRB available to the P.I.? YES NO