



## Protocol Submission Form\*

Harrison IRB thanks you for choosing us as the IRB for your study!

Sponsors or CROs, on behalf of the Sponsor, should complete the following information when submitting study materials for initial review. If you have any questions regarding your submission, please do not hesitate to contact Harrison IRB at 740 845 0814. We look forward to working with you!

Contact Person Submitting Study Materials for Initial Review: \_\_\_\_\_

Phone: \_\_\_\_\_

Fax: \_\_\_\_\_

Sponsor: \_\_\_\_\_

Protocol Number: \_\_\_\_\_

Study Title: \_\_\_\_\_  
\_\_\_\_\_

**Submission Documents:** Please indicate the study materials you are submitting by checking the appropriate boxes:

- Protocol
- Protocol Amendments, if applicable Number of Amendments: \_\_\_\_\_
- Investigator's Drug Brochure
- Template Consent Forms
- Additional Consent Forms (Provided as MS Word format only: email, diskette or CD)
  - Informed Consent Template
  - Genetic Consent
  - Assent
  - Other: \_\_\_\_\_
- Study –related materials, such as patient questionnaires, diaries, etc.
- Recruitment materials, if available Number of Materials: \_\_\_\_\_
- If applicable, results of any prior IRB reviews of this study
- Other supporting materials, such as package inserts, etc.
  1. \_\_\_\_\_
  2. \_\_\_\_\_
  3. \_\_\_\_\_

### For Device Studies Only:

Submit the above-mentioned documents in addition to the following:

- FDA Letter Granting IDE
- Report of Prior Investigations
- Letter from Sponsor stating study is non-significant risk, OR
- Letter explaining why device is exempt from IDE requirements

Date of Submission\*: \_\_\_\_\_

Date of Board Meeting: \_\_\_\_\_

**\*The deadline for protocol submissions is Thursday 6PM for next Wednesday's board meeting.**