**Protocol: Click here to enter text.**

**INDUSTRY SPONSORED CLINICAL TRIALS: STARTING**

NDA signed: Click here to enter text. Study Contract signed: Click here to enter text.

HSPPO #: Click here to enter text Approval date: Click here to enter text.

Hospital approval: Click here to enter text. HSPPO# Click here to enter text.=

OIC sends MIRA to ULH for review, approval letter sent to PI

Approval letter will be sent to PI

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*Material transfer agreement may be necessary. See: [Materials Transfer](http://louisville.edu/thinker/materials-transfer.html)

Do you need to register your trial? See: [Trial Registration](http://prsinfo.clinicaltrials.gov/)

Click here to enter text.

Create Informed Consent, Research Authorization and Complete or Partial waiver using templates at: [IRB forms](http://louisville.edu/research/humansubjects/applying-to-the-irb)

(note, sponsor usually wants to review ICF prior to IRB submission)

Submit protocol, investigators brochure, ICF, waivers, advertisements, subject materials and crf’s (if available) with electronic submission. Anyone listed as study staff must have appropriate training and complete UL financial disclosure form and COI checkbox in section 2 ‘study personnel’ of electronic submission. Complete new protocol on [BRAAN 2](https://braanprod.louisville.edu/)

(Contract and budget negotiations are completed simultaneiously with IRB approval)

Resources:[IRB Submission help](http://louisville.edu/research/humansubjects/investigator-research-team-information)

Click here to enter text.

All clinical trials must have a MIRA form completed and submitted. [MIRA form and instructions](http://louisville.edu/research/offices/industry-contracts/common/offices/industry-contracts/common/mira-multi-institutional-research-application-information.html)

Submit electronically to:i[ndcontr@gwise.louisville.edu](mailto:ndcontr@gwise.louisville.edu)

[NHC MIRA](http://louisville.edu/research/offices/industry-contracts/common/offices/industry-contracts/common/mira-multi-institutional-research-application-information.html) (use this if no UL employees, students, facilities, or ULH facilities will be used)

If your study includes any biological specimens, exotic plants or microbes, carcinogens, drugs,or toxins, you need to complete an Institutional Biosafety Committee application: [IBC application](https://louisville.edu/dehs/forms/forms.html)

Click here to enter text.

For initial review by OIC of projects that are clinical trials or projects that will involve NHC, JHSMH, ULH, OMHS

[TRIA form and instructions](http://louisville.edu/research/offices/industry-contracts/common/offices/industry-contracts/common/mira-multi-institutional-research-application-information.html)

Submit TRIA, protocol and contract, submit electronically to indcontr@gwise.louisville.edu

PI: assess feasibility

Start on budget. ULH research prices: Adriane@ulh.org

Complete [Form 1572](http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm)

Click here to enter text.

Receive NDA from sponsor

Complete review form:

<http://louisville.edu/research/offices/industry-contracts/common/oicnda-form.doc>

email review form and nda to indcontr@gwise.louisville.edu

negotiations and signatures

PI receives Protocol

\*All required training must be completed prior to study submission to IRB. (see training module)

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|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| NDA | TRIA | MIRA | HSPPO submission | Hosptial approvals, Misc |

Date completed:

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