University of Kentucky ClinicalTrials.gov Registration Checklist

General guidance and recommendations for registering investigator-initiated clinical trials in clinicaltrials.gov.

Login

- ☐ If you do not have a clinicaltrials.gov account, request an account here.
- ☐ Once you have an account, login in at register.clinicaltrials.gov with your username and UKentucky as the organization. The assigned username is typically your last name with your first initial (ex. SmithJ). If you have forgotten your password, click here to request a reset.

Considerations For Registration

- ☐ **Notes** and **Warnings** are suggestions that are not always necessary to fix but **Errors** must be addressed.
- ☐ **Register your trial as soon as possible.** While the FDA and NIH allow for registration 21 days after the enrollment of the first participant, the ICJME requires registration **prior** to enrollment of the first participant. Changes can be made to the record after registration.
- ☐ PRS review may take **up to 10 business days or more** for a new trial. Be sure to budget this into your registration timeline as changes may be requested and **multiple rounds of PRS review** may be required.

Protocol Section

- ☐ Unique Protocol ID: If your trial will be entered into OnCore, list the OnCore ID. If not, list the E-IRB number.
- ☐ Brief Title and Official Title can be the same.
- ☐ Secondary IDs: Add federal grant information here, if applicable. For NIH trials, listing the grant number allows you to use the clinicaltrial.gov record to auto-populate information into NIH ASSIST/eRA commons for your research performance progress report (RPPR). If your Notice of Award says "Yes" to Clinical Trial Indicator, you must register your trial.

Study Status

- ☐ Record verification: This is the date you enter information into the record. **Any time you change information in the clinical trial record, update the record verification date.** You are required to review the record and update the record verification date *at least once per year* to maintain compliance.
- ☐ Overall Status: Choose the appropriate study status and **update the status promptly (within 30 days) throughout the lifetime of the trial.**
- ☐ Study Start Date: Initially, this will be the anticipated month/year when participants will first be enrolled. **Update to an actual date promptly after the first participant is enrolled.** Anticipated dates should be future dates (cannot be in the past).
- ☐ Primary Completion Date: The anticipated month/year of the last interaction with a participant for the primary outcome. **If this date changes, update promptly (within 30 days).**

- ☐ Study completion: The anticipated month/year of the last interaction with a participant for any outcome (secondary/other). **If this date changes, update promptly (within 30 days).**

Sponsor/Collaborators

- ☐ Responsibly party: For all PI-initiated records at the University of Kentucky**, the principal investigator (PI) is the sponsor-investigator.** Select "Sponsor-Investigator" from the drop-down. Select the PI's name for "Investigator Name" and enter the Investigator Official Title (e.g., professor, associate professor, assistant professor, etc.) The investigator affiliation will default to University of Kentucky.
- ☐ Sponsor: This will be auto-filled with the sponsor-investigator.
- ☐ Collaborators: List any collaborators. If NIH-funded, list the specific institute involved as a collaborator. Other collaborators may include drug/device companies that are not sponsoring the trial but are providing the investigational product.

Oversight

- ☐ U.S. FDA-regulated Drug: Select "yes" if the clinical trial is studying an FDA regulated drug and then complete dropdown.
- ☐ U.S. FDA-regulated Device: Select "yes" if the clinical trial is studying an FDA regulated device and then complete dropdown.
- ☐ U.S. FDA IND/IDE: Complete, if applicable.
- ☐ Human Subjects Review: List the status of IRB approval, E-IRB number, and the board name (Institutional Review Board 1, 2, 3, 6, or nonmedical) with the following address:
  Office of Research Integrity
  University of Kentucky
  316 Kinkead Hall
  Lexington, KY 40506-0057
  859-323-7399
  irbsubmission@uky.edu
- ☐ Data Monitoring: Select "yes" if there is an external data monitoring board for the trial; do not select "yes" if the trial only has a data safety monitoring plan.
- ☐ FDA Regulation Intervention: If drug, device, dietary supplement, or radiation, select "yes."
- ☐ Section 801 Clinical Trial: Select "yes" if FDA regulated intervention.

Study Description

- ☐ Brief Description: Include a brief description of the trial in lay language **without using personal pronouns** (you, we, I, etc.)
- ☐ Detailed Description: *Optional.* If not entered, clinicaltrials.gov will note "detailed description has not been entered."

Conditions

- ☐ Conditions: As you type, suggested conditions will appear. Add one or more condition being studied in the trial.
- ☐ Keywords: Add any other terms that may help an interested participant find your trial on the public clinicaltrials.gov website. List one term per line.

Study Design

- ☐ Study Type, Primary, Purpose, Interventional Study Model: Click "Definitions" near the top left of the record for guidance on what to select for each of these.
- ☐ Number of Arms: Enter the study of arms in the trial.
- ☐ Masking: Select option. Masking description is not required.
- ☐ Randomization: Select randomized or non-randomized or N/A (if trial is single arm)
- ☐ Enrollment: List the estimated number of participants. Once the trial is closed to enrollment, update to the actual number enrolled.

Arms and Interventions

- ☐ Arms and Interventions: Enter the arms and interventions for the trial.
- ☐ Cross-Reference: Checkmark the appropriate interventions for the arms in the table. This is not necessary for single-arm studies.

Outcomes Measures

- ☐ Outcomes measures will result in the most comments and required changes from the clinicaltrial.gov PRS review procedures. Each outcome measure should outline **one** outcome.
- ☐ Each outcome measure must have the following information:
    - The name of the instrument/tool/method used
    - How are you measuring the outcome?
    - The range of values the measure can have (e.g., 0-100)
    - Interpretation of the values (100 = high, a higher score means…)

Eligibility

- ☐ Respond to Sex and Gender Based dropdowns based on the trial.
- ☐ Age limit: First select unit (often "years") from dropdown for both minimum and maximum and then enter the range.
- ☐ Accepts Healthy Volunteers: Select "yes" if the trial includes participants who do not have a disease or condition being studied.
- ☐ Eligibility Criteria: This does **not** have to be a comprehensive list. List those criteria that will help the participant decide whether they qualify. **The criteria must be listed with bullet points.**

Contacts/Locations

- ☐ Central Contact Person and Study Official is usually the PI but may be the study coordinator or other key personnel. Add Central Contact Backup, if applicable. This information will be available on the public clinicaltrials.gov website.
- ☐ Location: Click add new and add the University of Kentucky and any other applicable locations. Each location's recruitment status must be updated individually.

IPD Sharing Statements

- ☐ Plan to Share IPD: You must respond "yes" or "no" to this section in full to be compliant with ICJME requirements. If you select "yes," you must describe a plan. If you are unsure or do not have a plan, select "no." This answer can be changed later, if necessary.

References

- ☐ Optional

Now what?

- ☐ Once the entry is complete, **click the green button at the top of the record until it is submitted** (complete, approve, release).
- ☐ There may be comments to address after the record is submitted and reviewed by clinicaltrials.gov PRS.
- ☐ Add study staff to access list in clinicaltrials.gov as needed by clicking "edit" on the record summary screen and checking the box next to the appropriate individuals.
- ☐ **Be sure to keep the clinicaltrials.gov record up to date and ensure changes in the trial are reflected in clinicaltrials.gov**. **There may be civil monetary penalties or withholding of future grant funds if the record is not updated appropriately.**
- ☐ Be proactive and change anticipated dates to actual dates after the first participant is consented and when the study has met its primary and study completion dates.
- ☐ Contact Kasandra Lambert, OSPA Clinical Trial Compliance Administrator, at kvlamb2@uky.edu or OSPAClinicalTrials@uky.edu with any questions or for assistance registering a trial.