THE UNIVERSITY OF ARIZONA HEALTH SCIENCES
Research Administration

CLINICALTRIALS.GOV REGISTRATION & RESULTS REPORTING CHECKLIST

Purpose: This form is for researchers to use to conduct a self-assessment of their ClinicalTrials.gov study record during registration or results submission on the Protocol Registration and Results System (PRS).

All registrations and result submissions are reviewed by PRS reviewers before being posted publicly on ClinicalTrials.gov. PRS reviewers may request changes to the registration or results submission prior to publication. This checklist may be used as a tool to ensure that the registration or result submission meets PRS review criteria.

Additional information related to ClinicalTrials.gov Registration and Results Reporting can be found at: UAHS RA Regulatory website, UA Guidelines for ClinicalTrials.gov Registration, ClinicalTrials.gov Support Materials, and ClinicalTrials.gov PRS Quality Control Review Criteria.

STUDY INFORMATION	
UA IRB #	
Study Title	
PI Name	
Date Self-Assessment Completed	
Person Completing Self-Assessment	

Registration		
Section	**Checklist**	**Examples**
Timeline	❑ Allow yourself up to 2 hours to complete registration of the study record.	
General	❑ Record Owner is the PI. ❑ Sponsor is University of Arizona. ❑ Responsible Party is the PI. ❑ Other staff involved in registering and reporting are on the Access List. ❑ Unique Protocol ID is the UA IRB number. ❑ Secondary IDs include federal grant or contract numbers.	If the record was created by another staff member, send a request to regulatory@arizona.edu to update the Record Owner to the PI.
Formatting	❑ Study record is written in the 3rd person; do not use personal pronouns. ❑ Spell-check for errors/typos. ❑ All acronyms are defined on their first use. ❑ Interventions are referred to by the same name throughout the study record.	Instead of "we, I, our, you, them" – use "the investigator(s)" and "participant(s)"

	❑ Free-text fields are blank if there is no information to report, and they do not contain text such as "TBD," "Pending," "N/A," "None," or similar.	
Study Description	❑ Written in complete sentences and do not have formatting errors such as incorrect spacing or indentations and sentences that are missing periods. ❑ In the Detailed Description: do not include the entire protocol and do not duplicate information recorded in other data elements, such as Eligibility. ❑ Clearly state the study's hypothesis or the purpose of the study (for interventional and observational studies). ❑ Write in language intended for the lay public, do not include study design terms. ❑ Do not include references in this section. References can be listed in the References section at the end of the study record.	
Outcome Measures	**Titles** ❑ Outcome Measure Title states what is being measured and the metric for how the collected measurement data will be aggregated. ❑ Each outcome measure contains only one unique unit of measurement. **Descriptions** ❑ Outcome Measure Description includes how the measurement was taken, methods of assessment, and/or calculations performed to summarize the data. ❑ If measurement is based on a scale, explain the scale range, and values that are considered better or worse outcomes. **Time Frames** ❑ Each Time Frame includes only one time point, unless specified that the measure is a change between 2 time points. ❑ Time points are specific. ❑ Time-to-event measures include the cutoff point.	**Titles** "Change from Baseline in Pain Scores on the Visual Analog Scale at 6 Weeks" "Number of Participants with Treatment Related Adverse Events as Assessed by CTCAE v4.0" **Descriptions** "SPS-11 is a validated, self-reported instrument assessing average pain intensity over the past 24 hour period. Possible scores range from 0 (no pain) to 10 (worst possible pain). Change = Week 24 score – Baseline score." **Time Frames** "1 year," "through study completion, an average of 1 year," "post-intervention at 12 months," "baseline, 24 months"
Completion	❑ Don't forget to release your study record for PRS Review. Click "Entry Complete," then "Approve," then "Release." ❑ After review, the record may be returned to you by the PRS Reviewer in order to make corrections. **All Major Issues must be corrected and then the study record re-submitted for PRS Review within 15 calendar days.**	

Results	
Section	**Checklist**
Timeline	❑ Allow yourself up to 40 hours to complete results entry of your study record.
Participant Flow	❑ Protocol Enrollment is the number of participants who agreed to participate in the study following completion of the informed consent process; this number should not conflict with the number of Participants Started.

	❑ Arms and arm descriptions specified are consistent with the protocol section. ❑ Number of Participants Started refers to total number of participants assigned to each arm. ❑ The number of discrete stages or intervals of activity in the study is divided into appropriate periods.
Baseline Characteristics	❑ Measure description is specified for all study-specific measures; include scale ranges and specify which values are considered to be a better or worse outcome. ❑ "Count of Participants" or "Count of Units" is selected as the Measure Type when appropriate.
Outcome Measures	❑ Required to report results on all pre-specified primary and secondary outcome measures. ❑ Outcome Measure Title states what is being measured (see examples from Registration checklist). ❑ Outcome Measure Description includes how the measurement was taken, methods of assessment, and/or calculations performed to summarize the data. ❑ If measurement is based on a scale, explain the scale range, and values that are considered better or worse outcomes. ❑ Number of Units analyzed is indicated if the units of analysis are not participants (e.g. "eyes" "implants"); otherwise Number of Participants is used. ❑ Time frame includes only one time point, unless specified that the measure is a change between 2 time points. ❑ Sum of all results entered for each arm equals overall number of participants analyzed and information provided in Participant Flow.
Adverse Events	❑ Specific period of time over which AEs were assessed/collected is expressed from the participants' perspective (e.g., "8 weeks after participant received first dose"). ❑ Arms titles/descriptions consistent with other sections in the record. ❑ Number of Participants At Risk is consistent with numbers in the Participant Flow section.
Documents	❑ Upload a copy of the full study protocol, including all IRB approved amendments, if study is an applicable clinical trial with a Primary Completion Date on or after January 18, 2017. Certain information may be able to be redacted. ❑ Upload statistical analysis plan (if separate from the protocol) if study is an applicable clinical trial with a Primary Completion Date on or after January 18, 2017. ❑ Each document includes a cover page with: Official Title of the study, PI Name, NCT number, and the date of the document. ❑ If conducting a federally supported clinical trial, upload one IRB approved copy of the consent form that was used to enroll participants.
Completion	❑ Don't forget to release your study record for PRS Review. Click "Entry Complete," then "Approve," then "Release." ❑ After review, the record may be returned to you by the PRS Reviewer in order to make corrections. **All Major Issues must be corrected and then the study record re-submitted for PRS Review within 25 calendar days.**

Updates

❑ If the study plan changes (anticipated start date, anticipated completion date) or the status changes (not yet recruiting, recruiting, active, or completed), then updates must be made to the study **record within 30 days of the change**.

❑ Study records must be reviewed and verified as up to date every 12 months, even if nothing has changed with the study status.