**K23 Application Checklist**

**Project Title:** TBD

**PennERA Record: TBD**

**Proposal Activity Code: K23 Clinical Trial**

**Funding Announcement:**

**FA/RFA Link:**

**PSOM Review:** Draft abstract, draft science, final budget & budget Justification **– DATE**

**Final Review:** Remaining Final Docs **– DATE**

**PHS Assignment Request Form –** Optional form used to communicate specific application assignment and review requests to the Division of Receipt and Referral (DRR) and to Scientific Review Officers (SROs). This information will not be part of your application, and it will not be made available to program staff or provided to reviewers.

* **Project Information (Sections A – G)**
* **Project Summary/Abstract** (30 lines of text, Arial 11, all margins 0.5”)
* **Project Narrative** (2-3 sentences)
* **Bibliography & References Cited**
* **Facilities & Other Resources****:**
* **Equipment**
* **Biosketches****:**
* **Other Support for MENTORS ONLY:**

Provide information on the following items for each of the mentor’s and co-mentor’s current and pending research support relevant to the candidate’s research plan. Each mentor/co-mentor(s)’s “Current & Pending Support” attachment is limited to 3 pages.

* **Budget**

* **Budget Justification**
* **Cover Letter**
* **Candidate Section**

**Candidate Background**

**Career Goal and Objectives**

**Candidate’s Plan for Career Development**

* **Research Plan Section**

**Specific Aims**

**Research Strategy (one pdf)**

**Training in the Responsible Conduct of Research**

* **Other Candidate Information Section**

**Candidate’s Plan to Provide Mentoring**

* **Mentor, Co-Mentor, Consultant, Collaborators Section**

**Plans and Statements of Mentor and Co-Mentor(s)**

**Letters of Support**:

* **Environmental and Institutional Commitments to the Candidate**

**Description of Institutional Environment**

**Institutional Commitment to the Candidates Research Career Development**

* **Other Research Plan Sections**

**Vertebrate Animals (if applicable)**

**Select Agent Research (if applicable)**

**Consortium/Contractual Arrangements (if applicable)**

**Resource Sharing (If applicable)**

**Data Management Sharing Plan**

**Authentication of Key Biological and/or Chemical Resources**

* **Reference Letters**

**Must be uploaded by the referee in the NIH Commons by the time of application submission or application will be considered incomplete**

* **Human Subjects and Clinical Trials Information Section (Please use separate form provided for this info)**

1. **Human Subjects info (for RCT) Study 1 Checklist– NO INTERVENTION**

**Section 1  Basic Info (online text, PennERA)**

**Section 2  Study Population Characteristics (all separate docs and uploads to PennERA)**

**Inclusion Across the Lifespan**

**Inclusion of Women and Minorities**

**Recruitment and Retention Plan**

**Study Timeline**

**Inclusion Enrollment Report**

**Section 3: Protection and Monitoring Plans:**

**3.1 Protection of Human Subjects(separate doc, upload)**

**3.2 Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?**

If yes, describe the single IRB plan (separate doc, upload)

3.3 Data and Safety Monitoring Plan **(separate doc, upload)**

**3.4 Will a Data and Safety Monitoring Board be appointed for this study?**

**3.5 Overall Structure of the Study Team (separate doc, upload)**

1. **Human Subjects info (for RCT) STUDY 2 Checklist – INTERVENTION LIST**

**Section 1  Basic Info (online text, PennERA)**

**Section 2  Study Population Characteristics (all separate docs and uploads to PennERA)**

**Inclusion Across the Lifespan**

**Inclusion of Women and Minorities**

**Recruitment and Retention Plan**

**Study Timeline**

**Inclusion Enrollment Report**

**Section 3: Protection and Monitoring Plans:**

**3.1 Protection of Human Subjects (separate doc, upload)**

**3.2 Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?**

If yes, describe the single IRB plan (separate doc, upload)

**3.3 Data and Safety Monitoring Plan** **(separate doc, upload)**

**3.4 Will a Data and Safety Monitoring Board be appointed for this study?**

**3.5 Overall Structure of the Study Team (separate doc, upload)**

**Section 4:**  **Protocol Synopsis**

**4.1 Study Design (online text, PennERA)**

**4.2 Outcome Measures (online text, PennERA)**

**4.3 Statistical Design and Power (separate doc, upload)**

**4.4 Subject Participation Duration (online text, PennERA)**

**4.5 Will the study use an FDA-regulated intervention? (online text, PennERA)**

**4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational**

**New Drug (IND)/Investigational Device Exemption (IDE) status(separate doc, upload)**

**4.6 Is this an applicable clinical trial under FDAAA? (online text, PennERA)**

**4.7 Dissemination Plan (separate doc, upload)**