**Application Checklist**

**Project Title:**

**PennERA Record:**

**Proposal Activity Code:**

**Funding Announcement:**

**FA/RFA Link:**

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

**Final Review:** Remaining Final Docs **-**

**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)**
  1. **Project Summary/Abstract** (30 lines of text, Arial 11, all margins 0.5”)
  2. **Project Narrative** (2-3 sentences)
  3. **Bibliography & References Cited**
  4. **Facilities & Other Resources****:**   **Penn**
  5. **Equipment:**  **Penn**
  6. **Biosketches****:**

* 1. **Budget (detailed****)  Penn**
  2. **Budget Justification  Penn**
  3. **N/A Cover Letter**
* **Research Plan (Sections 1-16) Please send all as individual docs. Research Strategy should be one PDF**

1. N/A - Introduction to Application (1 page)
2. **Specific Aims (1 page)**

1. **Research Strategy (12 pages): read RFA for specific info required**

* 1. **Significance**

* 1. **Innovation**
  2. **Approach**
     + 1. n/a Preliminary Studies for New Applications
       2. n/a Progress Report for Renewal and Revision Applications

1. N/A - Progress Report Publication List  - renewal applications only
2. N/A - Vertebrate Animals
3. N/A - Select Agent Research (skip unless you are using anything on the list
4. **Multiple PD/PI Leadership Plan**
5. **Consortium/Contractual Arrangements**
6. **Letters of Support**:
7. **Resource Sharing Plan:** **read RFA for specific info required**

**11. Data Management Sharing Plan: read RFA for specific info required**

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

* **Human Subjects Section**

1. **Human Subjects info (for RCT) STUDY 1 – 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 – 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)**