NIH Application Checklist

- [ ] Abstract: 30 lines of text
- [ ] Narrative: 3 sentences
- [ ] Facilities and Other Resources: If there are multiple sites, describe the resources available at each site.
- [ ] Equipment
- [ ] Other Attachments: Only if required by the FOA
- [ ] Biosketches: All Key Personnel and Other Significant Contributors

- [ ] Introduction: For Resubmissions or where indicated by the FOA
- [ ] Specific Aims: 1 page
- [ ] Research Strategy: Limit based on type (R01/U01-12 pages, R03/R21-6 pages)
- [ ] Progress Report Publication List: Only for renewal applications
- [ ] Vertebrate Animals
- [ ] Select Agent Research
- [ ] Multi-PI Leadership Plan
- [ ] Consortium/Contractual Arrangements
- [ ] Letters of Support

- [ ] Resource Sharing Plan
- [ ] Authentication of Key Biologics
- [ ] Appendix: If applicable
- [ ] Budget Justification: If detail budget is required
- [ ] Personnel Justification: If modular budget is required
- [ ] Subawards: Needed for each subaward
  - [ ] Letter of Intent
  - [ ] Budget: On NIH format pages if detail budget is required
  - [ ] Budget Justification
  - [ ] Statement of Work
  - [ ] Contact info for Sponsored Projects contact
- [ ] Human Subjects: If yes, see human Subjects Worksheet

NIH Human Subjects Worksheet

Please complete the questions on this sheet and note the uploads needed (listed on the bottom of page)

Study Title:

Is this Study Exempt? <select> If yes, provide Exemption Number:

Does the study involve human participants? <select>
Are the participants prospectively assigned to an intervention? <select>
Is the study designed to evaluate the effect of the intervention on the participants? <select>
Is the effect that will be evaluated a health-related biomedical or behavioral out-come? <select>

If you answered "Yes" to all of the previous 4 questions, there is an additional section(s) that need to be completed. Please see the instructions in Section 4 – Protocol Synopsis in the NIH Application Guide and provide this information to your administrator. Also, please consult the FOA if any Other Clinical Trial-Related Attachments are required (Section 5 of the application)

Conditions or Focus of Study (up to 255 characters)

Inclusion/Exclusion Criteria (up to 15,000 Characters)

Age Limit: Minimum Age Maximum Age
Recruitment Status <select>
Enrollment of First Subject: Anticipated Actual
Inclusion and Enrollment Report

Planned

	Not Hispanic/Latino F	Not Hispanic/Latino M	Hispanic/Latino F	Hispanic/Latino M	TOTAL
American Indian/Alaska Native					0
Asian					0
Native Hawaiian or Other Pacific Islander					0
Black or African American					0
White					0
More than one race					0
TOTAL	0	0	0	0	0

Cumulative/Actual

	Not Hispanic/Latino F	Not Hispanic/Latino M	Hispanic/Latino F	Hispanic/Latino M	TOTAL
American Indian/Alaska Native					0
Asian					0
Native Hawaiian or Other Pacific Islander					0
Black or African American					0
White					0
More than one race					0
TOTAL	0	0	0	0	0

Is this a multi-site study that will use the same protocol to conduct non-exempt HS research at more than one domestic site? <select>
If yes, Single-IRB upload required

Will a Data and Safety Monitoring Board be appointed for this study? <select>
Answer is required if you answered "Yes" to all 4 questions at the top of this worksheet.

UPLOADS

- ☐ Inclusion of Women, Minorities, and Children
- ☐ Recruitment and Retention Plan
- ☐ Study Timeline
- ☐ Protection of Human Subjects
- ☐ Data and Safety Monitoring Plan: Required for Clinical Trials (answered “Yes” to all the questions at the top of this worksheet) and other studies that have significant risks to participants.
- ☐ Overall Structure of the Study Team: Required if you answered “Yes” to all the questions at the top of this worksheet.