ALL DOCS DUE TO JENNI KUNG 1 WEEK AHEAD OF DEADLINE

R01 CHECKLIST

1. **Biosketches** for yourself and co-investigators, and any collaborators.
2. **Letters of Support** as necessary
3. **PHS** ASSIGNMENT REQUEST FORM (optional)
    - Assign to institute: list up to 3 – list of institutes here
    - Do not assign to institute: list up to 3
    - Assign to study section: list up to 3 – list of study sections/ special review panels here
    - Do not assign to study section: list up to 3
    - List individuals who should not review your application and why
    - Identify scientific areas of expertise needed to review your application – list up to 5, 40 characters max per field.

4. **Cover Letter** - optional. If you are requesting study sections/institutes, please use the assignment request form!
5. **Project Summary** – no more than 30 lines of text
6. **Project Narrative** – no more than 6 lines of text; 2-3 sentences
7. **Bibilography & References Cited**
8. **Facilities and Resources** – no page limit standard doc available, let me know if you need a copy
9. **Major Equipment** – no page limit
10. **Budget –** Evelina and I can work with you on this
11. **Budget Justification –** no page limit

Research Plan Section

12. **Introduction** – only for resubmissions or revisions 1 page only
13. **Specific Aims** – 1 page limit.
14. **Research Strategy –** 12 page limit.
15. **Progress Report Publication List** (Renewal Applications only)

Other Research Plan Sections

1. **Vertebrate Animals** – if applicable, no page limit. Template and sample available
2. **Select Agent Research** – if applicable
3. **Multiple PD/PI Leadership Plan** – if applicable
4. **Consortium/Contractual Arrangements –** if applicable
5. **Resource Sharing Plan** – Data sharing plan REQUIRED
6. **Authentication of Key Biological and/or Chemical Resources** – if applicable, 1 page. Samples are available
7. **Appendix** - if applicable:
   A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 allowable appendix attachments are needed, combine the remaining information into attachment #10. The only allowable appendix materials are:
    - Blank data collection forms, blank survey forms, and blank questionnaire forms - or screenshots thereof
    - Simple lists of interview questions

   Note: In your blank forms and lists, do not include items such as: data, data compilations, lists of variables or acronyms, data analyses, publications, manuals, instructions, descriptions or drawings/figures/diagrams of data collection methods or machines/devices.
    - Blank informed consent/assent forms

- Other items only if they are specified in the FOA as allowable appendix materials

Human Subjects Section

IF NO TO HUMAN SUBJECTS:

Does the proposed research involve human specimens and/or data? (yes/no)

If Yes, provide an explanation of why the application does not involve human subjects research. This justification should include:

- information on who is providing the data/biological specimens and their role in the proposed research;
- a description of the identifiers that will be associated with the human specimens and data;
- a list of who has access to subjects' identities; and
- information about the manner in which the privacy of research participants and confidentiality of data will be protected.

IF YES TO HUMAN SUBJECTS

Study Population Characteristics

1. Conditions/Focus of Study
2. Eligibility Criteria
3. Age limits: min/max (max can be N/A)
4. Inclusion of Women, Minorities and children
5. Recruitment and Retention Plan (not required if exempt 4)
6. Recruitment Status – Choose one of the following: (not required if exempt 4)
    a. Not yet recruiting
    b. Recruiting
    c. Enrolling by invitation
    d. Active, not recruiting
    e. Completed
    f. Suspended
    g. Terminated (halted prematurely)
    h. Withdrawn (No Participants Enrolled)
7. Study Timeline (not required if exempt 4)
8. Enrollment of First Subject – Date (actual or anticipated) (not required if exempt 4)
9. Planned Enrollment Table OR cumulative enrollment table if it is an existing dataset. (not required if exempt 4)

10. Section 3 – protection of human subjects
    a. Protection of Human Subjects
    b. 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
    c. Data Safety Monitoring Plan (only if clinical trial)
    d. Will a Data and Safety Monitoring Board be appointed for this study? (only if clinical trial)
11. Overall Structure of study team (only if clinical trial)
12. Section 4 – protocol synopsis (only if clinical trial)