Since this is a renewal application there are some additional items under the Research Strategy as well as the addition of the Progress Report Publication List. Also, per the new F-RPPR guidelines, you will be required to submit an Interim-RPPR via the Commons no later than 120 calendar days from the end date of your current grant. In this case, it will be due no later than September 30th.

Please keep in mind that the SF424 Application Instructions that I am referencing are dated November 22, 2016, and the notice regarding F-RPPRs came out on November 23, 2016. I am hoping that they updated the instructions with the new requirements in mind, but I will check periodically between now and the submission deadline to make sure that they haven’t changed it on us.

**Other Needed Information (please address the below)**

* Application Title:
* Are human subjects involved?
  + If yes, is the project exempt from federal regulations?
  + If yes, what is the exemption number?
  + Is IRB pending?
  + Does the project involve human stem cells?
  + Does the proposed project involve human embryonic stem cells?
* Does the project involve recombinant DNA?
* Does this project involve hazardous materials or equipment (this answer is nearly always yes)
* Are radiation producing equipment or radioactive materials used?
* Does the project involve use of the Regional Biocontainment Laboratory?
* Are vertebrate animals used?
  + If yes, are vertebrate animals euthanized?
  + If yes to euthanasia, is method consistent with American Veterinary Medical Association (AVMA) guidelines?
* Is proprietary / privileged information included in the application?
* Does this project have an actual or potential impact on the environment?
* Is the research performance site designated, or eligible to be designated, as a historic place?
* Does this project involve activities outside of the United States or partnerships with international collaborators?
* Is this a clinical trial?
* If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?
* FOA or RFA you are applying to? (if this is a Parent R01, the number is **PA-16-160**)
* Will there be a potentially patentable discovery or invention?
* Are biological materials going to be obtained from outside the University?
* Please provide an abstract for internal use (draft is fine).

**Final PDFs needed for submission (please use naming conventions provided) – NO HEADERS OR FOOTERS OR PAGE NUMBERS ON ANY FILES**

1. Project Summary / Abstract (AbstractJarvisMar2017.pdf) – no more than 30 lines of text
2. Project Narrative (NarrativeJarvisMar2017.pdf) – 2-3 sentences
3. Bibliography (BibliographyJarvisMar2017.pdf)
4. Facilities and Other Resources (FacilitiesJarvisMar2017.pdf) – information for all desired Co-Investigators combined into 1 PDF with your own info
5. Equipment (EquipmentJarvisMar2017.pdf) – information for all desired Co-Investigators combined into 1 PDF with your own info
6. Biosketches
   1. Separate files for your biosketch and each individual who is Key Personnel  (Co-PIs, consultants, Key Personnel at Pitt and any consortiums)
   2. No page numbers, headers or footers on any of the files
   3. Name by investigator (BiosketchJarvis.pdf)
7. Specific Aims (SpecificAimsJarvisMar2017.pdf) – limited to 1 page
8. Research Strategy (ResearchStrategyJarvisMar2017.pdf) – 12 pages
   1. In the Significance Section you must now include:
      1. Consideration of strengths of published work or preliminary data crucial to the support of the application
      2. Consideration of weaknesses of published work or preliminary data crucial to the support of the application
   2. In the Approach Section you must now include:
      1. Description of experimental design and methods
      2. Description of how the experimental design and methods will achieve robust and unbiased results
      3. Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. Strong justification is required if proposing to study only one sex (See NOT-OD-15-102 for additional details).
   3. Note that the Progress Report falls within the Research Strategy and is therefore included in the page limits for the Research Strategy.
      1. For renewal/revision applications, provide a Progress Report.
      2. Provide the beginning and ending dates for the period covered since the last competitive review.
      3. In the Progress Report, you should:
         1. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement.
         2. Explain any significant changes to the specific aims and any new directions, including changes resulting from significant budget reductions.
         3. Discuss previous participant enrollment (e.g., recruitment, retention, inclusion of women, minorities, children, etc.) for any studies meeting the NIH definition for clinical research, particularly if relevant to studies proposed in the renewal or revision application. You should not submit a PHS Inclusion Enrollment Report unless the enrollment is part of new or ongoing studies in the renewal or revision application.
      4. Do not include a list of publications, patents, or other printed materials in the Progress Report. That information will be included in the "Progress Report Publication List" attachment.
9. Progress Report Publication List
   1. List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively.
   2. Provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each of the following:
      1. Articles that fall under the Public Access Policy,
      2. Articles that were authored or co-authored by the applicant and arose from NIH support,
      3. Articles that were authored or co-authored by the applicant and arose from AHRQ funding provided after February 19, 2016 (see the Guide Notice on Policy for Public Access to AHRQ-Funded Scientific Publications).
   3. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate “PMC Journal – In Process.” NIH maintains a list of such journals.
   4. Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference.
10. Human Subjects – if you will have human subjects please let me know and I will address this separately
11. Vertebrate Animals (VertAnimalsJarvisMar2017.pdf) - The four points are as follows:
    1. Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the “Research Strategy” section. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed provide the source of the animals.
    2. Justifications: Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g. computational, human, invertebrate, in vitro).
    3. Minimization of Pain and Distress: Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain, and injury.
    4. Euthanasia: State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.
12. Select Agent Research (SelectAgentJarvisMar2017.pdf) – if needed
13. Multiple PI Leadership Plan (MPILeadershipJarvisMar2017.pdf) – if needed
14. Consortium and Contractual Arrangements (ConstortiumJarvisMar2017.pdf) – if needed
15. Letters of Support (LettersOfSupportJarvisMar2017.pdf) – combined into 1 comprehensive PDF
16. Resource Sharing Plan (ResourceSharingJarvisMar2017.pdf)
    1. Data Sharing Plan: Investigators seeking $500,000 or more in direct costs (exclusive of consortium F&A) in any year are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible. Specific Funding Opportunity Announcements may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the specific opportunity carefully and discuss their data-sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. See Data-Sharing Policy or <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>.
    2. Sharing Model Organisms: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible. See Sharing Model Organisms Policy, and NIH Guide NOT-OD-04-042.
    3. Genome Wide Association Studies (GWAS): Applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or an appropriate explanation why submission to the repository is not possible. GWAS is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight) or the presence or absence of a disease or condition. For further information see Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, NIH Guide NOT-OD-07-088, and <http://gwas.nih.gov/>.
17. Budget Justification – for standard modular, we only need to justify personnel and consortiums.  (PersonnelJarvisMar2017.pdf and ConsortiumJarvisMar2017.pdf
18. Cover Letter (CoverLetterJarvisMar2017.pdf)
19. Authentication of Key Resources Plan (AuthenticationJarvisMar2017.pdf) – 1 page limit
    1. Describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. This plan should include how you will authenticate key resources and the frequency for which you will do this for the proposed research. Authentication data do not need to be provided.
    2. The NIH is defining key biological and/or chemical resources as resources that may or may not be generated with NIH funds and
       1. may differ from laboratory to laboratory over time;
       2. may have qualities and qualifications that could influence the research data; and
       3. are integral to the proposed research.
    3. These include, but are not limited to
       1. cell lines
       2. specialty chemicals
       3. antibodies
       4. other biologics
    4. *Standard laboratory reagents do not need to be included in this plan (e.g. buffers, common biologicals, common chemicals, etc.)*