

# File Checklist for a Standard R01 (Forms H)



There are now **THREE** separate parent funding announcements for R01 submissions; **PA-20-183** for those projects that propose Clinical Trials, **PA-20-184** for Basic Experimental Studies with Humans Required (Clinical Trials Required), and **PA-20-185** for Non-Clinical but can include both animal or humans. To verify that these have not changed, please go to <https://grants.nih.gov/funding/searchguide/index.html#/> and search for R01 Parent. It is crucial to confirm that the IC you are targeting is participating in the Parent Announcement. If you are not applying to the parent funding announcement, make sure you; check if there is more than one call for the same PA/PAR; if not, make sure it is listed as clinical trial optional. If you are unsure, please reach out to CAA for verification.

File Type	Comments	Page Limits
Cover letter	<b>Optional</b> <u>only include</u> if conveying specific information including; why a proposal is being submitted late, if you need to communicate official information such as approval to exceed the \$500K cap, if you are going to generate large scale genomic data, if a subcontractor is only participating in part of the project or if required by the PA/PAR. If you are including <u>Human Fetal Tissue from elective abortions</u> , you <b>MUST</b> include a cover letter with a statement regarding HFT involvement. Otherwise it is recommended that you include the assignment request form	No page limit but normally not longer than two pages
Human Fetal Tissue	If you answer yes to the use of Human Fetal Tissue obtained from elective abortions, it is mandatory that you upload two additional files: HFT Compliance Assurance and HFT Sample IRB Consent Form. <b>NOTE if you are using HFT from elective abortions and including two files you are NOT allowed to use the Modular Budget form regardless of amount being requested per year.</b>	No limit
Abstract*	The same one should be uploaded on the internal routing program	½ page or 30 lines. OPS is validating this limit and will send the package back for revisions if over.
Narrative*	Should be in lay language	¼ page or 2-3 sentences, OPS is validating this limit and will send the package back for revisions if over.
Facilities and other resources	The same one should be uploaded on the internal routing program	No limit for latest updates on SOM Core Facilities visit, <a href="https://osa.stonybrookmedicine.edu/caa/ChecklistandTemplates">https://osa.stonybrookmedicine.edu/caa/ChecklistandTemplates</a>
Equipment	The same one should be uploaded on the internal routing program.	No limit. Note: <i>this now its own file and needs to a separate upload. It should no longer be part of the facilities file.</i>
Bibliography & References Cited	If you are the author or co-author of the cited material the PMCI or PMC number needs to be included in the listed	No limit (unless stated). Hyperlinks are not allowed in this section anymore.

Bios*	Make sure using the most current form, expires in 2024 <a href="https://grants.nih.gov/grants/forms/biosketch.htm">https://grants.nih.gov/grants/forms/biosketch.htm</a>	5-page limit sample <a href="https://osa.stonybrookmedicine.edu/caa/forms">https://osa.stonybrookmedicine.edu/caa/forms</a>
Specific Aims*		1-page limit
Research Strategy*		12-page limit
Vertebrate Animals	Should only be uploaded if working with Animals.	No limit but there are specific items that need to be addressed
Consortium / Contractual agreement	Our Letter of Commitment form should not be used in this section; it is for internal purposes only. <a href="https://www.stonybrook.edu/commcms/osp-oqm/pdf/Subrecipient%20Commitment%20Form%202022.pdf">https://www.stonybrook.edu/commcms/osp-oqm/pdf/Subrecipient%20Commitment%20Form%202022.pdf</a>	No Limit Our Business office now requires that this form be completed and signed by both our PI and the sub site business office/PI. Please contact Andria Adler for a copy of this form
Letters of Support		No Limit unless stated in the FA
Resource Sharing Plan*	These are the tools you use in the process of doing your research; this includes Sharing Model Organisms and Research Tools. See notes below for more details	No Limit but normally not longer than a page
Other Plans*	Data Management and Sharing Plan is now a mandatory upload. This what you learned in the process of doing your research The 2023 Data Management and Sharing (DMS) policy expects the submission of a DMS Plan that describes how the applicant will manage and share scientific data generated from NIH funds. To reduce the burden on applicants and staff, NIH now expects a single data sharing plan at time of funding application that satisfies both the Genomic Data Sharing (GDS) Policy and the DMS Policy (NOT-OD-22-198) – see notes below for more details	<i>NIH has provided templates for this document, please contact Andria for a copy, Andria.Adler@stonybrook.edu</i>
Authentication of key biological and / or chemical resources*		No Limit
Introduction	Mandatory for <b>resubmissions</b>	1-page limit, unless otherwise stated
Progress Report Publication List	Should be included for <b>renewal</b> submissions	No page limit
Budget justification	The same one should be uploaded on the internal routing program. <i>You need to include the cost of Data Management and Sharing even if you are requesting funds.</i>	No limit but for a modular budget you only need to address personnel cost. <i>If submitting a modular budget you will need also include a separate file, "Additional Narrative Justification for the Data Management and Sharing cost even if you are not requesting funds</i>
Other Attachments	#12 on the Other Project Information tab	This is limited to specific documents detailed in the program announcement

	Appendix	#12 on the Research Plan tab	Very rarely used anymore and only when specified in the program announcement
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\* Most often-mandatory documents

There are also optional forms that need to be added:

- Module Budget (requesting \$250,000 per year or less),
- RR Detailed Budget (requesting \$250,001 – 499,998 per year, if over, in most cases, you need PO approval),
- RR Subaward Budget, and
- Assignment Request Form.

If you use HFT from elective abortions, you are NOT allowed to use the Modular Budget form regardless of the requested amount per year.

**Note:**

1. You should always read the specific FA to see if it deviates from the standard requirements. You should also see if any other files or appendix material are allowed or required. If it is not specified, these items should not be included. Contact The Office of Clinical Award Administration at 638-4490/[SOMCAA@stonybrookmedicine.edu](mailto:SOMCAA@stonybrookmedicine.edu) if you have questions about a complete submission.
2. *You can only include hyperlinks in your biosketch and only for PMC ID links and a grants.gov link to your publications.*
3. *On a detailed budget, you must add "Data Management and Sharing Cost" as an other cost each year, even if you are not requesting funds. If that item is not there, you will get an error message*
4. *Data Management and Sharing Plan: Applicants subject to the [NIH Data Management and Sharing Policy](#) and the [NIH Genomic Data Sharing Policy](#) must attach a single Plan including elements for both policies. For more on the applicability of each policy, [see the research subject to the NIH Data Management and Sharing Policy](#) and the [research subject to the NIH Genomic Data Sharing Policy](#).*
5. *Research Sharing Plan Content: **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. **For more information**, see the [NIH Grants Policy Statement, Section 8.2.3.2: Sharing Model Organisms](#).*

Research Tools: NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, they must be made readily available to qualified individuals within the scientific community for research purposes. For more information, see the [Research Tools Policy on the NIH Scientific Data Sharing Website](#) and the [NIH Grants Policy Statement, Section 8.2.3: Sharing Research Resources](#).

6. UEI numbers are used instead of DUNS numbers throughout the application. Please ask your project partners for their UEI when requesting project information.

If your project has, human subjects refer to the separate checklist for that section.