******NIH REQUIRED DOUMENTS**

 **R01/R03/R21 PI CHECKLIST – FORMS-F**

Updated 12/2020

*Office of Grants and Contracts Administration*

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| GENERAL INFORMATION  |
|[ ]  11 points or larger. Recommended: black font, using Arial, Georgia, Helvetica, or Palatino Linotype |[ ]  Smaller text in figures/graphs/diagrams/charts allowed but must be legible  |
|[ ]  0.5” inch margins |[ ]  No headers or footers |[ ]  [No electronic signatures](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm#electronicsignatures) |[ ]  No URLS except for citations in Research Strategy and Biosketch |
|[ ]  All files in PDF; Doc names 50 characters or less |[ ]  **No** Co-PI role used. (If Multiple PI, list as PI) |  |  |
|[ ]  Recommended file name convention: *PILastName\_DocumentTitle.pdf* |[ ]  **E-mail all docs to grantgov@colorado.edu AND Proposal Analyst** |
| R&R Cover Page  |
| [ ]  | **Cover Letter** (Optional) - Required if project has/is: **•** [Late application](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) **•** Sub Budgets not included for entire project period**•** Human Fetal Tissue (HFT) **•** Large-scale genomic data **•** Video Format:* Addressed to Division of Receipt and Referral; Application Title; Title of FOA
* See [FORMS-F Application Guide’s Cover Page Attachment](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.200-sf-424-%28r%26r%29-form.htm?Highlight=cover%20letter#21) for details on information to be provided.
* Do not request assignment of proposal to specific NIH Institute here; address in Assignment Request Form.
 | *PILastName\_CoverLetter.pdf* |
| [ASSIGNMENT REQUEST FORM](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.600-phs-assignment-request-form.htm) (Optional)  |
|[ ]  **Assignment Request Form** (Optional):* Complete and provide if you want to identify requested Institute/Center, Study Section, or Reviewers not to include.
 | *PILastName\_Assignment.pdf* |
| [COVER PAGE SUPPLEMENT](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.210-phs-398-cover-page-supplement-form.htm?Highlight=human%20fetal%20tissue)  |
|[ ]  Do you have Human Fetal Tissue (HFT)? **If yes – you must provide the following 2 docs:** **Note**: For more details on HFT requirements, visit:  [FORMS-F Application Guide’s HFT Section](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.210-phs-398-cover-page-supplement-form.htm?Highlight=human%20fetal%20tissue#4) |
|[ ]  **HFT Compliance Assurance** (Required if applicable): * Provide a signed letter (from PI), assuring the HFT donating organization adheres to the requirements of the informed consent process and documenting that HFT was not obtained or acquired for valuable consideration.
 | **Must be named:** *HFTComplianceAssurance.pdf* |
|[ ]  **HFT Sample IRB Consent** (Required if applicable):* Must be a blank sample IRB Consent Form.
 | **Must be named:** *HFTSampleIRBConsentForm.pdf* |
| [SENIOR/Key Personnel Profile](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.240-r%26r-seniorkey-person-profile-%28expanded%29-form.htm) |

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| [ ]  | Inform Proposal Analyst of all involved on project: [Senior/Key Personnel](https://grants.nih.gov/grants/glossary.htm#SeniorKeyPersonnel) (PI/Co-I/etc.) or any [Other Significant Contributor](https://grants.nih.gov/grants/glossary.htm#OtherSignificantContributorsOSCs)s (OSC) |

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| [ ]  | **Biosketch** (Required for PI, Co-Is, and OSCs):* 5-page limit; Use [NIH Biosketch FORMS-F page available here](https://grants.nih.gov/grants/forms/biosketch.htm)
 | *SKPLastName\_Biosketch.pdf* |
|  | [ ]  | A. Personal Statement*Optional to include products -* 4 products max  | [ ]  | B. Positions and Honors*Chronological Order Recommended* |
|  | [ ]  | C. Contributions to Science  | [ ]  | D. Research Support - *Not Other Support; should include overall goals of the project.*  |
|  |  | [ ]  | 5 Contributions to Science max per Biosketch |  | [ ]  | Ongoing Research Support  |
|  |  | [ ]  | 4 products max per Contributions to Science*Recommend* [*PMCIDs*](https://publicaccess.nih.gov/policy.htm)*’ inclusion for all pubs listed in bio authored/co-authored by applicant.* |  | [ ]  | Research Support within Past 3 Years |
|  |  | [ ]  | URL allowed to full list of publish work, must be a Federal site. NIH’s [My Bibliography](http://www.ncbi.nlm.nih.gov/books/NBK53595/) is recommended.  |  | [ ]  | *Do not include person months or direct costs.*  |

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| [OTHER PROJECT INFORMATION](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.220-r%26r-other-project-information-form.htm) |
|[ ]  **Project Summary/Abstract** (Required):* 30 lines of text; Description of proposed work
 | *PILastName\_Summary.pdf* |
|[ ]  **Project Narrative** (Required):* 3 sentences maximum; Describe relevance to public health
 | *PILastName\_Narrative.pdf* |
|[ ]  **Bibliography & References Cited** (Required):* No page limit; URLs allowed
* Recommend including [PMCIDs](https://publicaccess.nih.gov/include-pmcid-citations.htm)’ for all pubs listed in bio authored/co-authored by applicant and fall under [Public Access Policy](https://publicaccess.nih.gov/policy.htm)
 | *PILastName\_References.pdf* |
|[ ]  **Facilities & Other Resources** (Required):* No page limit; Describe CU and all sub/performance sites and any biohazards facilities
 | *PILastName\_Facilities.pdf* |
|[ ]  **Equipment** (Required):* No page limit List major items of equipment already available for this project
* If no equipment on project, provide doc stating “No Equipment” (or similar)
 | *PILastName\_Equipment.pdf* |
|[ ]  **Other Attachments** – Provide Other Attachments **only** if FOA requests, or if Foreign Justification required. |
|  |[ ]  [**Foreign Justification**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.220-r%26r-other-project-information-form.htm#6) (Required if answered “Yes” to International Activities/Collaboration; ***Note****: International conferences are not considered international collaboration.*):* Describe special resources or characteristics of the research project, including the reasons why the facilities or other aspects of the proposed project are more appropriate than a domestic setting.
 | **Must be named:** *Foreign Justification.pdf* |
| Budget |
| * As of 10/2018, PIs may choose whether to inflate or flat-budget salaries because NIH is reducing awards by inflated amounts. PA to confirm PI’s preference. NIH recommends using inflated costs when possible.
* If personnel is over salary cap, use [current NIH salary cap](https://grants.nih.gov/grants/policy/salcap_summary.htm) for budgeting. 2020 cap of $197,300 for 12-month period (equates to $147,975 cap for 9-month appointment).
* If research is HFT, **must use R&R Detailed Budget and cannot use modular.**
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| [R&R DETAILED budget](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.300-r%26r-budget-form.htm) \* *(Only Use if $250,001 or MORE Direct Costs per year)* |
| [ ]  | **Budget Justification** (Required for R&R Detailed Budget)* See [OGCA Budget Justification Template](https://uaf.edu/ogca/resources/forms/index.php) for guidance on required statements
* Contributed (unpaid) AY time detailed - Time is considered committed effort
* ***Human Fetal Tissue Costs***\* – Include the quantity/types/sources of the HFT, including the stage of fetal development. Information must be included even if the HFT costs have no funds requested; **Must be clearly labeled**
 | *PILastName\_Justification.pdf* |
| [MODULAR BUDGET](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.320-phs-398-modular-budget-form.htm) \* *(Only Use if $250,000 or less Direct Costs per year)* |
| [ ]  | **Personnel Justification*** Provide all personnel effort, names, roles, and effort in person-months
* Contributed (unpaid) AY time detailed - Time is considered committed effort
* Do not provide salary information; other rate information is not necessary
 | *PILastName\_Personnel.pdf* |
| [ ]  | **Consortium Justification**\** Provide an estimate of total consortium/subaward costs (DC+IDC) for each budget period, rounded to the nearest $1,000
* List the individuals/orgs of sub sites and indicate if domestic/foreign site
* Provide all sub personnel effort, names, roles, and effort in person-months
* Do not provide salary information; other rate information is not necessary
 | *PILastName\_Consortium.pdf* |
| [ ]  | **Additional Narrative Justification**\** Should explain any variation in number of modules requested annually
	+ **Note**: Not required for FOAs with DC limits that do not spread evenly across budget periods (example: R21s)
* Quotes may be included here, but not required
* Should describe direct costs excluded from total direct costs (MTDC Base)
 | *PILastName\_AdditionalJust.pdf* |
| [PHS 398 RESEARCH PLAN](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.400-phs-398-research-plan-form.htm)  |
|[ ]  **Introduction to Application** (Required, if resubmission or revision):* 1 page limit; Summarizes substantial changes to the application; only applicable for resubmission or revision, or if FOA denotes requirement
 | *PILastName\_Introduction.pdf* |
|[ ]  **Specific Aims** (Required):* 1 page limit; State concisely the goals of the proposed research and summarize the expected outcome
 | *PILastName\_SpecificAims.pdf* |
|[ ]  **Research Strategy** (Required):* R03/R21: 6-page limit; R01: 12-page limit.
* Sections must be labeled with following headers:

**1. Significance 2. Innovation 3. Approach*** If Human Fetal Tissue (HFT), include HFT info in 3. Approach section under a subsection entitled “**Human Fetal Tissue Research Approach**“; details included under “[Special Instructions” section of Approach](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.400-phs-398-research-plan-form.htm?Highlight=research%20plan#3)
* Progress Report for Renewal and Revision Applications\* - Section only required if a renewal application; must fall within Research Strategy page limits
 | *PILastName\_ResearchStrategy.pdf* |
|[ ]  **Progress Report Publication List** \* (Required for renewal applications):* No page limit;List title and complete references to all publications resulting from project since it was last reviewed competitively.
* Recommend [PMCIDs](https://publicaccess.nih.gov/include-pmcid-citations.htm)’ inclusion for all pubs listed in bio authored/co-authored by applicant and fall under [Public Access Policy](https://publicaccess.nih.gov/policy.htm)
 | *PILastName\_Publications.pdf* |
|[ ]  **Vertebrate *Animals*** *\** (Required if Animal research):* No page limit; Provide: Description of Procedures; Justifications; Minimization of Pain and Distress
* Describe proposed animal activities conducted at all performance sites
* Explain when/how animals are expected to be used; if plans not finalized
 | *PILastName\_Vertebrate.pdf* |
|[ ]  **Select Agent Research** \* (Required if [activities involve use of select agents](http://www.selectagents.gov/)):* No page limit; should identify select agents, registration status, and description of facilities to use select agents
* If only use of [excluded select agents](http://www.selectagents.gov/SelectAgentsandToxinsExclusions.html), note which strains and that it has been excluded.
 | *PILastName\_SelectAgent.pdf* |
|[ ]  **Multiple PD/PI Leadership Plan** \* (Required only if more than 1 PI, not applicable to Co-Is):* No page limit; should describe rationale for choosing a multiple PD/PI approach, and governance/organizational structure of leadership team
 | *PILastName\_LeadershipPlan.pdf* |
|[ ]  **Consortium/Contractual Arrangements** \* (Required if there is a subcontract):* No page limit; use [OCGA template here](https://uaf.edu/ogca/resources/forms/index.php)
* Describe the programmatic, fiscal, and administrative arrangements to be made between the applicant org and the consortium org/s
 | *PILastName\_Contractual.pdf* |
|[ ]  **Letters of Support** (Optional):* No page limit; all letters of support in a single PDF document
* [No electronic signatures](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm#electronicsignatures)
* Letters should describe terms of a collaboration or consultation; must not contain data/figures/tables/graphs, preliminary data, methods, background and significance details that are expected to be found in Research Strategy
 | *PILastName\_SupportLetters.pdf* |
|[ ]  **Resource Sharing Plan(s)** \* (Required if DC of $500k or more in any budget year, if required by FOA, or if required below; otherwise highly encouraged):* No page limit; provide how final research data will be shared, or explain why data-sharing is not possible
	+ If applying to NIAAA with Human Subjects, must include NIAAA Data Archive Sharing Plan - [NIAAADA DSP template](https://nda.nih.gov/niaaa/pre-award/application.html) encouraged; Costs associated with submitting data to the NIAAADA should be included in grant applications. A cost estimation tool (“[NDA Cost Estimation Tool](https://nda.nih.gov/niaaa/pre-award/application.html)”) for data sharing is available for this purpose
	+ If applying to NIMH with Human Subjects, must include Resource Sharing Plan
	+ If app includes: Sharing Model Organisms or Genomic Data Sharing (GWAS), include Resource Sharing Plan
 | *PILastName\_ResourceSharing.pdf* |
|[ ]  **Authentication of Key Biological and/or Chemical Resources** \* (Required if applicable) * No page limit but 1 page recommended
* Describe methods to ensure the identity and validity of key biological and/or chemical resources
 | *PILastName\_Authentication.pdf* |
|[ ]  **Appendix** \* (Not typically allowed unless requested by FOA):* FOA will specify if any special appendix instructions; carefully review [NIH Appendix Policy](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-098.html)
* Allowable Appendix Items for Inclusion:
	+ Summary sheet encouraged but not required
	+ Blank data collection forms, blank survey forms and blank questionnaire forms (Do not include instruction pages)
	+ Simple lists of interview questions
	+ Blank informed consent/assent forms
 | *PILastName\_DescriptiveName.pdf* |
| [PHS Human Subjects and Clinical Trials Information](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm) \* |
| Human Specimens and/or Data? ***If yes, include:*** |
|[ ]  [**Explanation for Use of Human Specimens and/or Data not considered to be Human Subjects Research**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#UseOf) (Required if proposals have human specimens and/or data):* Provide an explanation for any use of human specimens and/or data not considered to be human subjects research
* **Note**: Proposals with **or** without Human Subjects (HS) may still have Human Specimens/Data; to determine whether PI’s research is classified as HS research or not, use [Research Involving Private Information or Biological Specimens flowchart](https://grants.nih.gov/grants/policy/hs/private-information-biospecimens-flowchart.pdf)
 | *PILastName\_* *HumanSpecimens.pdf* |
|[ ]  **Human Subjects (HS) Study Record** \* (Required for all HS-research proposals): * Proposal Analyst will provide you with HS Study Record to input responses, upload documents, and complete appropriate sections (detailed below)
* **File Names under 50 characters in length**; Study Titles under 600 characters in length
* No page limit to uploaded documents in Study Record, but there may be limitations on entered text; please see Study Record
* PIs are encouraged to group studies that use the same HS population & same research protocols into one Study Record; if more than one study, separate Study Records will need to be uploaded
* 4 Clinical Trial Questionnaire responses: If all yes, then research is considered to be a CT
* Ensure FOA matches HS requirements
 |
|[ ]  Delayed Onset Study(ies) * Include if HS research, but cannot describe the study at the time of application
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|  |[ ]  Delayed Onset Study Justification* Provide justification why HS study information is not available at the time of application
* Info for a delayed onset study is not available at the time of proposal, so no full Study Record allowed
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| ***Required Study Record Sections based on Type of Research:***  | ***Human Subjects, Exemption 4*** | ***Human Subjects, no CT*** | ***Clinical Trial (CT)*** |
|[ ]  **Section 1 - Basic Information** Complete all fields | Required | Required | Required |
|[ ]  **Section 2 - Study Population Characteristics** Complete all fields | Not Required | Required | Required |
|  |[ ]  [**Inclusion of Individuals Across the Lifespan**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2.3.a):* Exclusion of any specific age/age range group should be justified.
 | Not Required | Required | Required |
|  |[ ]  [**Inclusion of Women and Minorities**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2.4):* Describe planned distribution of subjects by sex/gender/race/ ethnicity and rationale for selection
* Describe proposed outreach programs
* Provide reasons for limiting any group
 | Not Required | Required | Required |
|  |[ ]  [**Recruitment and Retention Plan**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2.5):* Describe how you will recruit and retain participants in your study
 | Not Required | Required if study has human participants | Required |
|  |[ ]  [**Study Timeline**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2.7):* Provide description/diagram describing study timeline
 | Optional | Optional | Required |
|  |[ ]  [**Inclusion Enrollment Report**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2.9):* PI will need to select button to have Inclusion Enrollment Report appear within the record; complete report as needed
* If app includes a study recruiting subjects at more than one site, PIs may create one IER or separate, multiple IERs to enable reporting by study or site
 | Not Required | Required | Required |
|[ ]  **Section 3 - Protection and Monitoring Plans** Complete if required | Required | Required | Required |
|  |[ ]  [**Protection of Human Subjects**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.1):* Include following sections:
1. Risks to Human Subjects
	1. Human Subjects Involvement, Characteristics, and Design
	2. Study Procedures, Materials, and Potential Risks
2. Adequacy of Protection Against Risks
	1. Informed Consent and Assent
	2. Protections Against Risk
	3. Vulnerable Subjects *(if relevant)*
3. Potential Benefits of the Proposed Research to Research Participants and Others
4. Importance of the Knowledge to be Gained
 | Required | Required | Required |
|  |[ ]  [**Single IRB Plan**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.2)* Yes/No response must be provided
* Doc not required at proposal phase; sIRB details required at JIT
 | Select N/A | Required **at JIT** only if Multi-Site Study | Required **at JIT** only if Multi-Site Study |
|  |[ ]  [**Data and Safety Monitoring Plan**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.3)(DSMP)* Provide DSMP that is commensurate with the risks of the trial, its size, and its complexity
 | Optional | Optional | Required |
|  |[ ]  [**Overall Structure of the Study Team**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.5)* Brief overview of the organizational/administrative structure and function of the study team
 | Optional | Optional | Required |
|[ ]  **Section 4 - Protocol Synopsis** Do not complete unless required | Do not complete or upload | Do not complete or upload | Required |
|  |[ ]  [**Statistical Design and Power**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#4.3)* Specify the number of subjects planned, the expected effect size, the power, and the statistical methods
 |  |  | Required |
|  |[ ]  [**FDA Regulated Intervention**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#4.5)* Provide summary describing the availability of study agents, support for acquisition/administration of study agents
 |  |  | Required for FDA-reg. inter. study  |
|  |[ ]  [**Dissemination Plan**](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#4.7)* Explain briefly dissemination of NIH CT information and how policy expectations will be met
 |  |  | Required |
|[ ]  **Section 5 - Other Clinical Trial-related Attachments**  | Do not complete or upload | Do not complete or upload | As required by FOA |
|  |[ ]  [Other CT-related Attachments](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#5.1) * Only include documents required by FOA
 |  |  |  |