

Generic Validations Summary

(Specific to NIH applications but usable for other sponsors as a checklist)

- 'Pre-applications are not allowed, unless specifically indicated for a mechanism (e.g., X02).
- If a resubmission, revision, or renewal, Federal Identifier must match a prior grant in the IMPAC II database.
- If a resubmission, prior grant must have been reviewed but not awarded.
- Allow up to 3 revisions/amendments (with warning on the third). Note: NIH policy to allow only two revisions/amendments (now called resubmission in Grants.gov) of an application (unless an exception is granted because of a change in study section between revisions/amendments, etc.) remains in place. The software is coded to allow for exceptions. The Warning provided on the third revision/amendment will alert staff to verify appropriateness and permissibility of the revision/amendment.
- DUNS for applicant organization must match DUNS recorded in the commons for that organization. (New Brunswick 0019128640000, Camden 6252165560000, Newark 1300292050000)
- State required for US and Canada, must be blank for all others.
- Zip code required for US.
- Type of application accepted: New, Resubmission, Revision or Renewal.
- Either Exemption Number or Assurance Number must be specified if Human Subjects are involved.
- Exemption Number must be "E1" through "E6"
- Provide warning if Human Subject Assurance Number doesn't match IPF human subject assurance number for this organization. (FWA00003913)
- If Vertebrate animals are used, one of the following must be provided: a. Assurance Number + IACUC Approval Date, b. Assurance Number + IACUC Approval Pending, c. The word 'None'
- Animal welfare assurance number should match animal welfare assurance number for this organization. (A3263-01)
- Project Summary limited to one page.
- Project Narrative (Public Health Relevance Statement) limited to one page.
- Provide warning if PD/PI name doesn't match name in Commons account, unless application is for Change of PI.
- Commons ID must be provided on the Key Person page for the PD/PI, and entered in exactly as listed in ERA Commons.
- The Commons account must be affiliated with the applicant organization.
- Biosketch limited to four pages.
- Accept 'Additional' Senior/Key Person Profiles and attachments only if all distinct profiles have been listed.
- Budget start date, if provided, must be the same as the project start date.

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- PD/PI listed on budget page must be the same as PD/PI designated for the application.
- Provide warning if both academic and calendar months have been provided for a person for a budget year.
- Provide warning if Other Direct Costs for the project budget is not equal to the sum of Total Direct and Indirect Costs for all consortium/contractual budgets.
- A fee cannot be entered for a subaward/consortium budget.
- Provide a warning if PD/PI degrees don't match a subset of degrees listed on the Commons, or if no degrees have been included.
- An answer is required to Human Subjects Clinical Trial (Y/N) if the answer to 'Human Subjects Involved' is "Yes".
- An answer to Human Subjects NIH-Defined Phase III Clinical Trial (Y/N) is required if the answer to 'Human Subjects Clinical Trial' is "Yes".
- If HESC involved='Y', must include cell lines or 'Can't be Referenced'. Cell lines must match cell lines in IMPAC II database.
- For a modular budget, direct costs must be $\leq 250K$, and must be a multiple of 25K for each budget year.
- Name of former PI must be included if application is for change of PI.
- Introduction must be included for resubmissions.
- Progress Report must be included for renewals.
- Research Design and Methods required for all submissions, unless specifically excepted for the mechanism.
- Inclusion of Women and Minorities, Targeted/Planned Enrollment Table, and Inclusion of children required if Human Subjects is true and Exemption is not E4.
- Data and Safety Monitoring Plan required if Human Subjects is true and Clinical Trial question is true.
- Vertebrate Animals attachment required if vertebrate animals are used.
- Appendixes limited to 10
- Research Plan Components Sections, items 2-5 are limited to 25 pages.