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Ancillary documents for NIH grant applications: The pages beyond the science

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Abstract

Preparing a grant proposal is no small feat, especially for research (R-series) grants from the National Institutes of Health. The National Institutes of Health is the largest public funder of biomedical research in the world, and as such, procuring a research grant from the National Institutes of Health is one of the ultimate benchmarks of success for a surgeon–scientist. Most investigators are familiar with the page limits for most R-series grants (12 pages for an R01 and 6 pages for an R21), with the addition of a single page allotted for the specific aims. Interestingly, despite the usual focus on the aforementioned research section, the rest of the application can routinely consist of an additional 100 to 150 pages, which means that pages allotted for the specific aims and research strategy represent only 10% of the complete application package. For busy surgeons, it is this abundance of ancillary documentation that can make preparing a research grant particularly onerous. Fortunately, for some, support exists within the department to help prepare much of this documentation by drawing from previous sources, templates, and boiler-plate language that has been developed. Although these resources can significantly reduce the burden on individual investigators, there is a danger of leaning on generalized templates that can dilute the message of the overall grant proposal and introduce extraneous or incorrect information that can ultimately impact the cohesiveness and ultimately the competitiveness of the grant. The focus of this article is to educate surgeon–scientists regarding the purpose and importance of the ancillary information required for National Institutes of Health research grants and how to make the most of institutional resources while tailoring these materials to create a cohesive, competitive grant application.

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Significance of the Ancillary Documents

Although the bulk of the overall impact score on a grant will depend primarily on the quality of the science laid out in the research strategy, there are aspects of the scoring criteria that can only be gleaned from the ancillary documentation. As a reminder, the 5 criteria used to score a National Institutes of Health (NIH) research grant (and which are used by many other funding agencies) are: Significance, Innovation, Investigators, Approach, and Environment.[1] Significance, Innovation, and Approach are clearly addressed in the research strategy; however, the scoring for Investigators and Environment relies heavily on information provided in the biosketches, facilities and equipment, and letters of support. Furthermore, the Approach score can be affected by information provided in the human participants and vertebrate animals sections of the application. Whereas other sections, such as the authentication and resource sharing pages, are not explicitly scored, problems in these sections can result in delays in funding if not appropriately addressed. Creating de novo versions of these resources can feel like an insurmountable task, especially for young surgeon–scientists trying to balance starting a research career with establishing a clinical program. Indeed, even with institutional and mentor resources to draw from, it can take up to 6 months to compile a first NIH research grant application. The good news, though, is that this initial investment of time and effort will pay dividends by simplifying the process for later applications. The discussion below reviews the purpose of each section and provides tips to improve your application and make it cohesive. For experienced surgeon–scientists, these tips can help revive tired, boilerplate language and improve future submissions.

Overview

We systematically reviewed each of the required documents in a standard R-series NIH grant proposal (Table I), providing information on the purpose of each document and how it may affect the criteria scores and overall impact score. Additionally, we provided tips on how to make the document attractive to reviewers. This discussion did not cover documents specific to other types of applications, such as career development (K-series) or project (P- or U-) grants. Additional information on crafting a career development grant can be found in previous publications.[2–6] However, much of the discussion here will cover documents that are applicable to these grants as well as many grants from other agencies that use the NIH format. It is also important to keep apprised of format changes and requirements for NIH submissions that are periodically updated by the NIH.

Biosketch

Among the ancillary documents, the biosketch is perhaps the most well-known and ubiquitous. Used by most foundation- and government-based funding agencies, the NIH biosketch is the standard form to communicate an investigator's unique and specific expertise relevant to the proposed project.[7] Because of its importance and widespread use, many resources have been created to help investigators craft a clear and competitive biosketch, including SciENcv,[8] which can pull directly from an investigator's eRA Commons and MyNCBI bibliography. Other biosketch examples have been published by the National Institute of Allergy and Infectious Diseases and others.[9] Ultimately, the purpose of the biosketch is to, within the 5-page limit, support the investigator's or their collaborator's

ability to do the research proposed through a description of previous education, research efforts, funding, and expertise. Information provided in the biosketch will directly affect the criteria score for investigators by providing reviewers an overview of the research team's experience, training, and accomplishments in the field up to that point.[9] A sample of the current biosketch format can be found at https://grants.nih.gov/grants/forms/non-fellowship-biosketch-sample-2021.docx.[9]

Personal Statement—With the new format for biosketches introduced January 25, 2022,[10] the personal statement has taken on new importance. Previously, information on previous funding was provided in Section D of the biosketch, but now this information must be incorporated into the personal statement section in a more limited form. Given this emphasis on the personal statement, one of the worst things an investigator can do is to use a generic personal statement for a given grant proposal. This applies to both the principal investigator (PI) and their collaborators (Key Personnel) who provide biosketches for the application. To craft a compelling personal statement, the text should first address the investigator's unique qualifications to perform the project, including training and background that led to the present project, in a logical narrative format. For example, the statement could begin with a description of the investigator's training at Example University, which included gaining expertise in *in vivo* animal models, clinical data analysis techniques, and assays for drug screening, but more importantly, led to seminal findings that supported the idea for the current proposal. Next, the personal statement should describe the overarching goal of the present proposal and the resources available to ensure its success, including collaborative relationships with key team members. This is an excellent place to highlight working relationships with collaborators on the project, including past successes and how they will contribute to the present proposal. Information about relationships between investigators should be consistent, and collaborators should be sure to include a statement about their specific contributions to the work proposed (i.e., what work they will perform as part of the project team).

At the end of the personal statement, investigators can highlight up to 4 publications, as well as current and past funding sources. Note that these should not necessarily be limited to only the highest impact articles, nor should it include a laundry list of every funded project. Selection of publications should consider the following criteria: (1) are the publications relevant to the project, (2) do the publications highlight seminal contributions to the field, and (3) do the publications highlight past work with key collaborators? Selecting relevant, high-impact sources that highlight both the qualifications of the investigator and the effectiveness of the scientific team will give a very positive impression to reviewers. Similarly, when selecting which funded projects to highlight, precedence should be given to current and past projects with relevance to the current proposal or that highlight past collaborations with current team members. Note that there is no limit on the number of funded projects that can be highlighted; however, careful selection can ease the burden on reviewers and ensure that they see key projects that support the investigator's qualifications for the present work.

Contributions to Science—The second key component of the biosketch is the Contributions to Science section. This section is meant to highlight 3 to 5 key areas of the investigator's research and their impact that supports the investigator's dedication and eminence within the field of study. A short introductory paragraph for each area should highlight the investigator's major findings and their impact on the field, followed by up to 4 relevant publications. For early-stage investigators, this may include work done during training and fellowship, which may or may not have direct relevance to the project at hand. In this case, the paragraph introducing the contribution may highlight key skills or laboratory techniques relevant to the project. In any case, the key message should communicate the specific contribution of the investigator. Even if the contribution was as part of a training program, the text should specify what knowledge, technical ability, or scientific ideas the investigator individually contributed and the result of the overall effort. Experienced investigators may have more contributions to science than the 5 allowed. In this case, the investigator has the luxury of choosing to highlight the contributions that are most directly relevant to the current application. In both cases, contributions should be listed in order of relevance to the project proposed, with the 4 relevant publications for each listed in chronological order.

Common Pitfalls—The first common pitfall in a biosketch is not using the biosketch to support the application. This is a frequent mistake in which investigators use a template or boilerplate format instead of taking advantage of the opportunity to highlight the specific merits of the application and describe how you as an investigator are uniquely suited to accomplish the goals set forth in the application. Another common mistake is to include old or irrelevant biosketches from collaborators. A collaborator's biosketch should support the feasibility of the application, and a lack of attention to detail will negatively impact the investigator score. Finally, the biosketch can be used to highlight relationships within the investigative team, bring attention to special attributes of the team, and demonstrate the robustness of the collaboration. This is a very effective method to demonstrate a functional and cohesive team, which is especially important if the team does not have a long track record of grant funding or publishing together.

In summary, the biosketch is a key component of the score for Investigators as part of an NIH grant review. Information should always be tailored to the present application, whether the investigator is the PI or other key personnel. Highlighting relevant publications, past collaborations, and contributions to science is key to letting reviewers know why you and your team are the right group to accomplish the goals of the project.

Facilities and Equipment

Facilities and equipment pages are the most likely of all the ancillary documents to be an afterthought, often using material copy-pasted from other sources into an amalgam of information with no flow or connection to the application. Although there is no need to reinvent the wheel for each new application, it is worth an investment of time to create a cohesive initial version and regularly keep the information up to date. The purpose of the Facilities and Equipment attachments is to assure the reviewers that you have the resources necessary to complete the research plan. These resources include everything from key

pieces of equipment to institutional infrastructure. This is one of the few places available to communicate relevant information about the research environment, and therefore it is a key part of the Environment scoring criteria. Reviewers will use the information in these pages to assess whether there is sufficient institutional support, access to key equipment, availability of safety training and equipment, and other physical resources (eg, core facilities, animal facilities, bench space, etc) to complete the research. Importantly, for surgeon–scientists, this is also a place to highlight the clinical resources available within the institution. Is the institution a major referral center for your study population of interest? Is it located in an area of high diversity? Do you have access to shared resources like data analysts or research coordinators? Are there active collaborations with other institutions that also provide resources for the work? All of these aspects of the environment are critical to include in your Facilities description, not only to prove that the research can be done but also to show that the institution is uniquely equipped to support it.

To add emphasis to what can otherwise be a wall of text, the Facilities and Equipment pages can incorporate visual elements. Pictures of key pieces of equipment or space diagrams showing proximity of resources can draw attention to important resources or aspects of the environment that support the research and make the information more palatable for the reviewers. A concern that is sometimes raised about early-stage investigators is whether there is dedicated lab space to accomplish the work. As such, a diagram of the lab highlighting the investigator's allocated space can effectively demonstrate that resource. It is also important to keep general information about your institutional resources and equipment up to date. Did your institution move up in *U.S. News and World Report* rankings? Did you purchase new pieces of equipment? Are there new core facilities available to help with the project? Taking an hour just once a year to ensure that all this information is up to date is a small cost to add relevance to these documents. It does the application no favors to have outdated or irrelevant information that a reviewer must trawl through to form their opinion on the research environment.

Budget and Budget Justification

There are many aspects to consider when putting together the budget for a project, and specific considerations for the best way to accomplish this have been described elsewhere.[6] Overall, the budget is simply the formal request for the funds required to complete the project and the justification as to why they are needed. Although the budget and justification are not scoreable parts of the application, it is important to remember that the reviewers can provide recommendations to the funding agency about the level of funding. For example, if a reviewer felt that there were too many people being funded on the grant for the work proposed, they could recommend that the funding agency cut the salaries in the final award. Therefore, it is important to properly estimate and justify all costs associated with a proposal.

The best thing an applicant can do to make the budget compelling is to thoroughly justify all costs. This is especially important in the personnel section. Each person supported by the grant should have a well-defined role and specific tasks they will have responsibility for. An effective way to communicate this is to highlight in which part of the aims each person will

make their contribution. Vague, overlapping, or ill-defined roles can lead reviewers to think that the personnel budget is inflated. The NIH study section discussion on budget occurs after the grant is discussed and, if the reviewer believes the budget is not justified, they will then recommend reducing the budget and will be specific in what cuts they recommend. A highly detailed and convincing budget section will dissuade reviewers from suggesting a budget reduction because they won't be able to articulate what exactly to cut. This is true as well for other costs associated with the research. For clinical projects, costs can often be broken down into discrete, billable actions that inform the per-patient cost of the research. Many institutions have research administrators or accounting specialists that can assist surgeon–scientists with defining each cost and whether it should be covered by the award or by the participant as part of their standard care. Basic and translational science projects can be a bit more nebulous because costs for general laboratory supplies, animal care and use, and biological assays can vary depending on challenges encountered during the project performance. Still, it is important to be as detailed as possible, providing cost estimates for each category and a description of how the estimate was calculated. Remember, there is no page limit on the budget justification, so it costs nothing to add detail that may prevent cuts to the budget. It is impossible to accomplish the science without the necessary financial support, so spend time making the budget realistic and appropriate.

Human Participants and Vertebrate Animals

For many surgeon–scientists, the involvement of human participants or vertebrate animals in research is a matter of course. The purpose of these sections is to ensure that humans and animals are properly protected and that their involvement is well-justified. These sections can influence the score for the Approach criteria, which is often a major driver of the overall impact score for a project. Reviewers will be evaluating the procedures being used, whether the approach will answer the scientific question posed, and whether protections are in place to address the risks of the study. Involvement of either human participants or animals must be carefully justified, given the potential risks of the study. Alternative models and rigorous methods must be proposed that will ensure that the data obtained from the research will be relevant and reproducible.

An excellent starting point for these sections is an approved Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) protocol. Although IRB or IACUC approval is not required before an NIH application, submitting these protocols ahead of time can provide critical feedback to refine the research methods before an application. These documents will have much of the required information in an easily accessible format; however, it is important to note that some information may need to be tailored to the specific project being proposed. It is common for surgeon–scientists to have so-called "umbrella protocols" that cover animal use for multiple projects or human biological sample collection for retrospective studies. In this case, information gleaned from the IRB or IACUC protocol must be tailored specifically to the proposal. For example, consider a protocol to collect cancer biopsies and outcomes data that includes using a subset of samples either already collected or prospectively collected during the performance period in their proposed research project. In addition to information about the human participant involvement and procedures likely already listed in the IRB, the investigator needs to describe and justify how the

retrospective sample subset will be chosen. They will also need to provide an expected breakdown of race, ethnicity, and sex, as well as plans to include patients of all (or specific) ages, for the prospective population and justify any exclusions. For animal protocols, only those procedures proposed in the research should be included, and an accurate estimate of the number of animals along with the species, strain, ages, and sex distribution should be given.

The key point for both sections is to read the section descriptions carefully. Make sure that the information requested is covered, which may be different from that required by the IRB or IACUC. Another critical component is the description of the statistical analysis to be used in studies involving humans or animals. Power calculations are an absolute necessity to justify the group sizes, and this can be described both in these sections and in the research strategy. Similarly, the plan for performing statistical analysis (eg, tests to be used, group comparisons, thresholds for significance, etc.) can be included in both locations. Furthermore, when possible, plans to include an equal distribution of male/female participants (for both humans and animals) and an appropriately diverse population (humans) should be described. Exceptions to this exist, particularly for conditions that disproportionately affect a certain sex or racial/ethnic group, but these should be stated and justified. Finally, make sure the procedures, group sizes, and other critical pieces of information in these sections are consistent with the research strategy. The worst thing an investigator can do is to confuse the reviewer by listing different group sizes or procedures, which can impact the Approach score. More detail as to the components of the vertebrate animal section and human participants section can be found on the NIH website.[11]

Letters of Support

Letters of support are meant to demonstrate a collaborator's commitment of time, expertise, or resources to the project. The applicant should review the funding opportunity announcement from the granting agency to determine whether any letters are required, which can vary depending on the type of award submission. Frequently, letters of support are optional, but they can provide documentation of the commitment from the institution or department chair that promises protected time from clinical duties, dedicated lab space, or additional research resources, which can be particularly important for early career investigators. There are multiple schools of thought regarding letters of support; some investigators request letters of support from each person listed as key personnel on the grant, whereas some only request letters from a select group of critical contributors or from other collaborators who can provide technical assistance on certain techniques but are not supported by the grant. Regardless of the approach to letter requests, reviewers will use these letters as a supplement to judge whether there is sufficient support for the project, particularly for techniques that may not be directly within the PI's area of expertise, which can affect the Investigators criteria score.

The approach to making letters of support effective is similar to the biosketch, in that the letter of support should detail the nature of the collaborators' and PI's scientific relationship, any previous work together, and the specific expertise or resources that the collaborator will provide to support the completion of the research project. As with the biosketch personal

statement, a generic letter is not effective. Rather, the letter should reference specific techniques or parts of the aims for which the collaborator is uniquely qualified to assist, or access to equipment, animal models, or patient populations that are critical to the project. Although there is no limit to the number of support letters that can be included, investigators should prioritize letters that support key aspects of the research, particularly those for which outside expertise is necessary.

Authentication of Key Biological and/or Chemical Resources and Resource Sharing Plans

Authentication and Resource Sharing pages describe how the researchers will abide by NIH requirements to ensure the validity of key biological or chemical resources used in the research[12] and to affirm that any research resources developed with NIH support will be shared with the research community. These sections are not explicitly evaluated as part of the criteria scores but instead are graded on a pass/fail basis (i.e., the plan is deemed either acceptable or unacceptable). The key to both sections is relevance and brevity. The NIH guidelines state that the Authentication of Key Biological and/or Chemical Resources attachment should not exceed 1 page.[12] Investigators should be careful not to include any research methods in this section, instead focusing on how they will validate resources that "differ from laboratory to laboratory, or over time" or for which variance in quality could influence the data produced. Examples of this include plans for how the investigators will periodically confirm the identity and purity of cell lines or genomic identity of transgenic animals. These methods are not part of the research plan but are instead meant to ensure that the cells, animals, and other materials used in the research are what the researchers think they are. Similarly, the Resource Sharing Plan should include 3 straightforward sections, as applicable. First, a simple list of any new model organisms being developed (eg, breeding a novel transgenic animal or creation of a new knockout cell line) and the plan for making these organisms available to the research community. Second, a plan for sharing large-scale genomic data (eg, from genome-wide association studies or -omics analysis), and finally, a plan to share research data generated if the budget is >$500,000 in direct costs per year. If your study does not meet any of the criteria above, this section may not be required.[1]

Other Documents

The section descriptions above are relevant to any research or career development application submitted to the NIH, but the following documents are only needed in certain situations.

Introduction to Application

One of the most common extra documents researchers will encounter is the introduction to application attachment that is required for resubmission applications. The purpose of this document is to address the previous reviewers' criticisms of the application and to show how the current application has been improved to minimize those concerns. Although the application may not go back to the same reviewers, new reviewers can use this information

[1]For applications after January 25, 2023, a new policy for data management and sharing (NOT-OD-21-013) will be in effect. Guidance documents for these new changes continue to be updated. See https://grants.nih.gov/policy/sharing.htm for the latest information.

to assess how well the applicant responded to previous critiques, which can color their perception of the new application. Remember that reviewers will *not* have access to the previous application; they can only view the current application and the previous summary statement, so clearly addressing previous critiques in this section is paramount.

Concise language and strategic combination of critiques into themes are keys to make this page impactful. Instead of a laundry list of critiques and responses, it can be helpful to organize individual critiques into overall themes. For example, perhaps multiple reviewers had issues with the previous research and preliminary data supporting one of the aim hypotheses. Instead of addressing each critique individually, the applicant could state that reviewers did not think that the rigor of previous research supported their hypothesis and then proceed to describe new publications and preliminary data they have added to address this issue. Similarly, various individual critiques about the research approach can be addressed with similar language by highlighting key changes to the strategy that broadly address these issues. Because space is limited to 1 page, hitting multiple points at once by organizing critiques into themes can consolidate the text and make it easier for reviewers to quickly grasp the key changes to the application. Finally, it can be helpful to begin and end this attachment with an acknowledgement of the positive comments provided by the previous reviewers. Although most of the focus will be on how you addressed critiques, bookending the discussion with a few quotes highlighting what the past reviewers found most compelling about the proposal can prime the new reviewers to also see the strengths of the revised application.

The Multiple PI Plan

In 2007, the NIH allowed multiple PIs (MPIs) to be included in one proposal as an effort to support team science.[13] This is an important and encouraging trend for surgeon–scientists,[14] because the combination of limited protected research time and other factors can make it challenging to compete for research grants.[15] Partnering with other surgeon–scientists or PhD researchers can give a much-needed boost to the feasibility of the project by distributing the responsibility for overseeing project performance. Furthermore, MPI applications tend to receive larger amounts of funding.[16] If applicants decide to pursue this route, an additional attachment is required: the MPI Project Leadership Plan. The purpose of this plan is to delineate the roles of each PI within the project and how they will handle project oversight and any conflicts that arise. Reviewers will take this document into account when determining the criteria score for Investigators.

There are a few ways to add emphasis to the MPI Plan. First is to provide narrative around the partnership between the PIs. Have the groups been working together for some time? Is this a new collaboration? How did the present project evolve? Some of this information may be repeated in some form in the biosketch and letters of support, but this attachment is an opportunity to reiterate key points and provide additional context for the decision to pursue the MPI mechanism. Second, the MPI plan should provide a clear delineation of leadership and contributions for each PI. It can be helpful to do this visually by providing a schematic that color codes each PI’s contribution within each of the aims and sub-aims. Finally, the MPI plan should outline meeting schedules and methods for addressing conflicts.

Timeline of Developing Ancillary Documents

For experienced investigators, the discussion thus far has hopefully provided tips to improve existing versions of these documents for future applications. However, for early career surgeon–scientists looking to submit their first NIH application, the amount of documentation to be generated can feel daunting. Herein, we put forth a suggested timeline for developing these documents, breaking down the dependencies between parts of the application and providing tips for how to approach the process (Figure 1).

Before Starting Your Application

Some documents can be generated even before starting on the research strategy. In addition, some documents may be reused from other grant applications. These include the biosketch, facilities, and equipment pages. Although these documents will need to be revisited later in the process to add details about the proposal, a basic draft can be generated at any time. Many examples of biosketches are available online and through individual institutions. We recommend the use of SciENcv[9] to produce tailored biosketches quickly and easily for each new project. Departmental or institutional administrators often have access to boilerplate information about the clinical and research resources at the institution that can serve as the basis for the Facilities description. New investigators can also request examples from mentors or other funded investigators at their institution to serve as a template. This can also be a good opportunity for the PIs of multiple PI applications to begin drafting and discussing the MPI plan.

After Drafting the Research Strategy

For most other documents, it is critical to have a draft of the research strategy available for reference. Even if it is not completely finalized, a rough draft will allow the investigator to assess what resources will be developed (Resource Sharing) or need to be validated on a regular basis (Authentication). Once most of the research strategy has been finalized, then the budget, justification, human participant, and vertebrate animal sections can be drafted. Most institutions require the budget and justification to be completed early in the process, which emphasizes the importance of starting work on the research strategy early.

Before Submitting

Before submitting the final application, investigators should read through all documents in the application package to check for consistency. Enlisting collaborators and other helpers in the process can also help catch mistakes. Common problem areas are changes to patient or animal numbers or references to specific parts of aims resulting from last minute changes to the approach. To make the application consistent, there should be uniformity in numbers, references, and key concepts across all documents in the application, not just the research strategy.

In conclusion, the ancillary documentation for an NIH application can seem like a daunting task. It is the majority of the approximately 100- to 150-page application compared with the 13 pages of science. Ironically, we spend more time as investigators perfecting our science and frequently leave these other parts of the application until the last minute.

It is strongly recommended for investigators to develop their own cadre of ancillary document materials that should be periodically updated and should be personalized for each individual application. Identify resources within your institution from which you can obtain boilerplate template forms, then tailor them to your own needs and use them for subsequent grant applications. Although the ancillary documentation cannot make up for a lackluster scientific application, it is nevertheless important to recognize the significance of these documents because they can drive the criteria scores and impact the fundability of an otherwise strong application.

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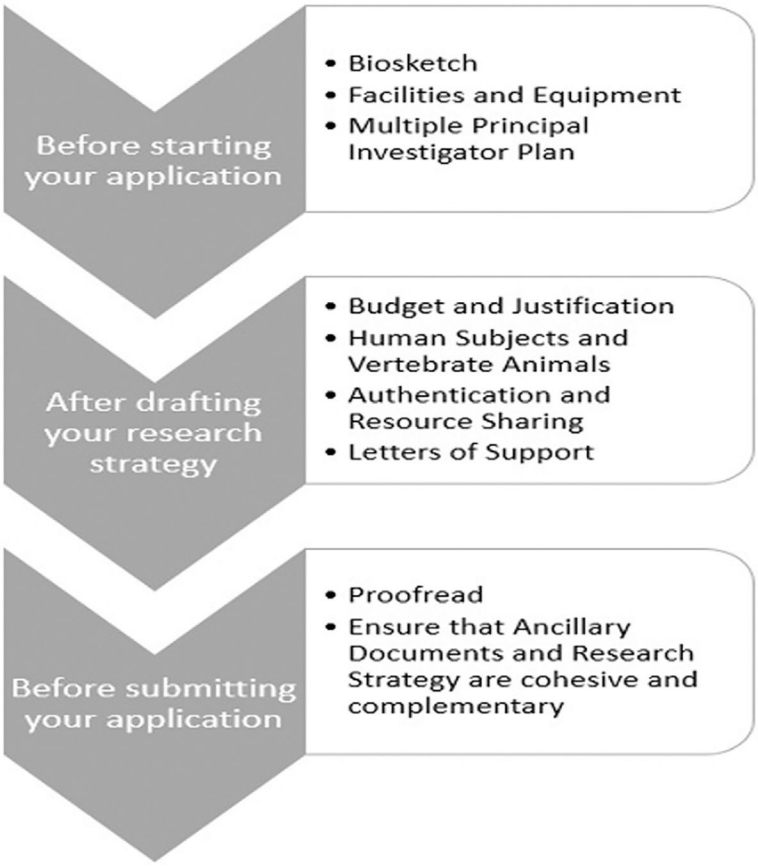

Figure 1.
Timeline of developing ancillary documents.

Table 1

Summary of ancillary documents

Biosketch	Describes why you are uniquely suited to complete the proposed project
Facilities and Equipment	Lists the resources you have that will allow you to achieve successful completion of the proposed project
Budget and Justification	Request for financial support with rationale for amount requested
Human Participants and Vertebrate Animals	Ensures compliance with regulatory processes for studies involving human participants or vertebrate animals
Letters of Support	Demonstrates important collaborative relationships, general support of your proposal, or availability of specific resources
Authentication and Resource Sharing	Fulfills an NIH requirement to validate biological or chemical resources used in your project and describe how you plan to disseminate new resources to the scientific community
Other Documents (for specific applications)	Includes introduction page (for grant resubmissions), multiple principal investigator plan (for grants involving multiple principal investigators)

NIH, National Institutes of Health.