Michigan State University
College of Human Medicine
Department of Epidemiology & Biostatistics

Orientation To NIH F31 for Faculty Sponsors

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No Conflicts to Declare

Jim Anthony, Professor
Epidemiology & Biostatistics
College of Human Medicine
Michigan State University
East Lansing, Grand Rapids, & Flint, Michigan, USA
Email: janthony@msu.edu

What I Covered In The Initial F31 Session

1. NIH Training ‘Kiosk’
2. Walk Through Initial Tools & Screenshots
3. Using NIH Project Reporter Effectively
4. AREA & REAP Option (R15 if you are eligible)
5. New Requirements for Clinical Research (e.g., Lifespan)
6. Individualized NIH Project Reporter Searches

What I Will Try To Cover in This ‘Sponsors’ Session

1. Overview of the NIH Center for Scientific Study Reviewer Guidelines for F31 Application Reviews
2. The F31 Review Template
3. Specific Questions Reviewers Must Evaluate
4. Examples of Critiques
5. Using NIH Project Reporter Effectively
6. Questions?

F31 GUIDE FOR REVIEWERS

Ruth L. Kirschstein National Research Service Awards (NRSA) for Individual Predoctoral Fellows (F31)

Purpose of the Award

- Provides support for promising doctoral candidates who will be performing dissertation research and training in scientific health-related fields relevant to the missions of the participating NIH Institutes during the tenure of the award
- Provides up to five years of support for research training which leads to the PhD or equivalent research degree, the combined MD/PhD degree, or another formally combined professional degree and research doctoral degree in the biomedical, behavioral, or clinical sciences

Applications

- Must propose a dissertation research project and training program that fall in a research area within the scientific mission of the participating NIH Institutes
- Must propose training that offer an opportunity to enhance the fellow's understanding of the health-related sciences and extend his/her potential for a productive, independent research career
    - Proposed training should provide the applicant with the opportunity to interact with members of the scientific community at appropriate scientific meetings and workshops (including NIH-sponsored meetings, where available)
- Should document the need for the proposed research training and the expected value of the proposed fellowship experience as it relates to the individual’s goals for a career as an independent researcher

Applicants

- Must have a baccalaureate degree
- Must be currently enrolled in a PhD or equivalent research degree program, a formally combined MD/PhD program, or other combined professional/clinical and research doctoral in the biomedical, behavioral, or clinical sciences at an accredited domestic or foreign institution
- Must not be pursuing an MD, DDS, or other clinical, health-professional degree and/or training (with the exception of a combined degree program as mentioned above)
- Typically may receive up to 5 years of aggregate Kirschstein-NRSA support at the predoctoral level, including any combination of support from an institutional training grant (e.g., T32 or T90) and an individual fellowship award (F31)

Also not mentioned here: be a US citizen, permanent resident, or non-citizen national with US Congressional representation (e.g., American Samoa, Puerto Rico, CNMI, Guam).

Note well: Non-citizens are eligible for other NIH career development awards for which some PhD students can apply (e.g., those with MD degree). K99/R00 is a prime example.

2. The F31 Review Template

F30/F31/F32/F33 Review

Application #:

Applicant:

OVERALL IMPACT

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the fellowship will enhance the candidate's potential for, and commitment to, a productive independent scientific research career in a health-related field, in consideration of the following scored and additional review criteria. An application does not need to be strong in all categories to be judged likely to have a major impact.

Overall Impact/Merit *Write a paragraph summarizing the factors that informed your Overall Impact score.*

SCORED REVIEW CRITERIA

Reviewers will consider each of the five review criteria below in the determination of the candidate's qualifications, scientific and technical merit of the proposed research, candidate's training potential, institutional environment and commitment to training, and give a separate score for each.

1. Fellowship Applicant
Strengths • **Weaknesses** •

2. Sponsors, Collaborators, and Consultants
Strengths • **Weaknesses** •

3. Research Training Plan
Strengths • **Weaknesses** •

4. Training Potential
Strengths • **Weaknesses** •

5. Institutional Environment & Commitment to Training
Strengths • **Weaknesses** •

ADDITIONAL REVIEW CRITERIA

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.

- A response for Protections for Human Subjects, Vertebrate Animals, and Biohazards **is required from reviewers for all applications**.
- A response for Inclusion of Women, Minorities and Children **is required from reviewers** for Human Subjects Research Applications.

ADDITIONAL REVIEW CONSIDERATIONS

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score.

Training in the Responsible Conduct of Research
Click Here to Select Comments on Format (Required): • Comments on Subject Matter (Required): • Comments on Faculty Participation (Required): • Comments on Duration (Required): • Comments on Frequency (Required): •

Use the PAR Questions as a Checklist for the Application.
Make sure each one is a strength. Anticipate and address potential weaknesses.

Fellowship Applicant

https://grants.nih.gov/grants/guide/pa-files/pa-18-671.html

- Are the applicant's academic record and research experience of high quality?
- Does the applicant have the potential to develop into an independent and productive researcher?
- Does the applicant demonstrate commitment to a research career in the future?

Sponsors, Collaborators, and Consultants

- Are the sponsor(s') research qualifications (including recent publications) and track record of mentoring individuals at a similar stage appropriate for the needs of the applicant?
- Is there evidence of a match between the research and clinical interests (if applicable) of the applicant and the sponsor(s)? Do(es) the sponsor(s) demonstrate an understanding of the applicant's training needs as well as the ability and commitment to assist in meeting these needs?
- Is there evidence of adequate research funds to support the applicant's proposed research project and training for the duration of the research component of the fellowship?
- If a team of sponsors is proposed, is the team structure well justified for the mentored training plan, and are the roles of the individual members appropriate and clearly defined?
- Are the qualifications of any collaborator(s) and/or consultant(s), including their complementary expertise and previous experience in fostering the training of fellows, appropriate for the proposed project?
- If the applicant is proposing to gain experience in a clinical trial as part of his or her research training, is there evidence of the appropriate expertise, experience, resources, and ability on the part of the sponsor(s) to guide the applicant during the clinical trial research experience?

Research Training Plan

- Is the proposed research project of high scientific quality, and is it well integrated with the proposed research training plan?
- Based on the sponsor's description of his/her active research program, is the applicant's proposed research project sufficiently distinct from the sponsor's funded research for the applicant's career stage?
- Is the research project consistent with the applicant's stage of research development?
- Is the proposed time frame feasible to accomplish the proposed training?
- If proposed, will the clinical trial experience contribute to the proposed project and/or the applicant's research training?

Training Potential

- Are the proposed research project and training plan likely to provide the applicant with the requisite individualized and mentored experiences in order to obtain appropriate skills for a research career?
- Does the training plan take advantage of the applicant's strengths and address gaps in needed skills? Does the training plan document a clear need for, and value of, the proposed training?
- Does the proposed training have the potential to serve as a sound foundation that will clearly enhance the applicant's ability to develop into a productive researcher?

Institutional Environment & Commitment to Training

- Are the research facilities, resources (e.g., equipment, laboratory space, computer time, subject populations, clinical training settings) and training opportunities (e.g. seminars, workshops, professional development opportunities) adequate and appropriate?
- Is the institutional environment for the applicant's scientific development of high quality?
- Is there appropriate institutional commitment to fostering the applicant's mentored training?

Crucially Important Section Not To Be Neglected.
Do not forget 'Rigor, Reproducibility, Research Integrity; Collegiality; Professionalism.

Training in the Responsible Conduct of Research

All applications for support under this FOA must include a plan to fulfill NIH requirements for Instruction in the Responsible Conduct of Research (RCR). Taking into account the level of experience of the applicant, including any prior instruction or participation in RCR as appropriate for the applicant's career stage, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) ***Format -*** the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable); 2) ***Subject Matter -*** the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics; 3) ***Faculty Participation -*** the role of the sponsor(s) and other faculty involvement in the fellow's instruction; 4) ***Duration of Instruction -*** the number of contact hours of instruction (at least eight contact hours are required); and 5) ***Frequency of Instruction –*** instruction must occur during each career stage and at least once every four years. Plans and past record will be rated as **ACCEPTABLE** or **UNACCEPTABLE**, and the summary statement will provide the consensus of the review committee. See also: NOT-OD-10-019.

Now Let's Cover What The Reviewers Are Told To Do

Writing effective critiques for NIH FELLOWSHIP (F31 and F32) applications

This document informs reviewers about how to prepare critiques for **fellowship applications** that best support informed funding decisions by NIH institutes and give clear feedback to applicants. It includes fictitious examples of weak and strong comments for each major section in the critique template; points highlighted in red explain why comments made in the critique are considered effective or not.

General guidance for all sections of the critique:

- A fellowship award is a *training* award and NOT a research award. Judge the application for its ability to make a strong impact on candidate's Research Training and Scientific Career Development.
- Avoid general comments and provide specific details.
- When possible, note how strengths and weaknesses will affect the training goals.

- Make sure that the text within each criterion is consistent with the score.
    - Scores of 1-3 should be supported by clearly articulated strengths and only minor weaknesses.
    - Scores of 4-6 may have a balance of strengths and weaknesses.
    - Scores of 7-9 should be supported by clearly articulated major weaknesses and/or lack of strengths).
- Prioritize strengths and weaknesses by indicating if they are major (score-driving) or minor.
- Provide sufficient context to orient comments (e.g., does the comment refer to a specific aim?)
- Make sure bullets have evaluative statements that indicate your assessment of a particular aspect of the application.

What We Are Told To Write About Overall Impact

Overall Impact

Overall Impact: *What is the likelihood that the fellowship will enhance the candidate's potential for, and commitment to, an independent scientific research career in a health-related field?*

Remember:

- The science is important, but it is not the sole criteria by which these applications should be judged. Consider all criterion in determining overall impact.
- An application does not need to be strong in all categories to be judged likely to have a major impact.

Write a paragraph to support your overall impact score.

- Very briefly introduce the proposed training goals.
- Identify what the **major** score driving issues were for you. Be specific.
- Explain how you balanced or weighted the various criteria in your overall impact score.
- Given your assessment of the applicant's potential and need for the proposed training, state the degree to which the research project, training potential, sponsor(s)/collaborators, and environment will satisfy those needs.
- Balance of strengths/weaknesses should be consistent with overall score.

This may be the MOST important part of your review. It comes first but is a synthesis of all the completed sections of your critique template.

Examples To Guide Your Writing of the Application

Overly general.

On what bases is the candidate excellent?

How were these criteria weighted in your overall score

Overall Impact: *Write a paragraph summarizing the major factors in all review criteria that informed your Overall Impact score*	
LESS EFFECTIVE	**EFFECTIVE**
This is a good proposal from an excellent PhD candidate, sponsor and institution. The main hypothesis of the proposal is simple; however its physiological importance is not entirely clear. The use of XX as the main model for studying ABC differentiation can be expanded to include additional ABC cells to strengthen the relevance.	This carefully prepared application proposes training in XX and YY. It is from an applicant with outstanding scholastic preparation and evidence of productivity in all respects. The Sponsor and co-Sponsor have substantial and relevant track records mentoring PhD students and have complementary expertise. The research plan employs an interdisciplinary approach to investigate X pathogenesis and the project provides an ideal context in which to be trained in XX and, if successful, will likely lead to strong publications. However, Aim 3 relies on the success of Aims 1 and 2, and the studies in Aim 1 lack sufficient justification.

Uses clear and specific language to explain points.

Highlights the main score-drivers.

Excessive focus on research without attention to how it effects training.

Avoid wording that suggests how the application should be improved

LESS EFFECTIVE	EFFECTIVE
A more thoughtful hypothesis and experimental plan would be highly beneficial to the applicant.	However, Aim 3 relies on the success of Aims 1 and 2, and the studies in Aim 1 lack sufficient justification. The applicant will learn many new techniques and the sponsor provides a detailed description of technical and academic milestones for the applicant's training that are consistent with her goal of being a research professor—a major strength of the application. The institution has suitable equipment and facilities as well as other outstanding faculty and students with whom the applicant will interact. The strong candidate, clear engagement of the sponsor/co-sponsor, and skill development that will result from the proposed research and training mitigate the moderate weaknesses in the design of the research plan. Overall, it is likely that the activities described in this proposal will provide strong training to advance the applicant's research independence.

Indicates importance of strengths and seriousness of weaknesses when appropriate.

Explains how the strengths and weaknesses were balanced to arrive at the final score.

Fellowship Applicant

Does the applicant have the potential to develop into an independent and productive researcher in biomedical, behavioral or clinical science?

- Assess the applicant's academic record and research experience.
- Assess evidence of productivity – publications, meeting abstract presentations, contributions to collection of data.
- Evaluate letters of recommendation for detailed strengths or weaknesses.
- Evaluate whether the applicant's record to-date and proposed fellowship activities demonstrate commitment to an independent research career.

Avoid any comments that may disclose letter writers; breach confidentiality

Focus on qualities of the applicant rather than on qualities of the application

1. Fellowship Applicant	
LESS EFFECTIVE	**EFFECTIVE**
Strengths • Applicant is strong • Significant research experience • Letters of recommendation are uniformly enthusiastic. • Her grades are solid and she has been productive during her time in the W lab.	**Strengths** • The applicant demonstrates a significant track record of research productivity for her career stage, including two first author publications, four co-authored publications and two additional co-authored pubs in preparation. (major) • Letters of recommendation detail the candidate's experimental prowess, scholarly approach, and drive.
Weaknesses • Grades could be stronger. • Limited background in XX. • The research focus is poorly conceptualized. • GRE scores are poor -	**Weaknesses** • No evidence of productivity from her two years in the XX lab. • Poor undergraduate academic record - Cs, Ds, and an F. Despite vast improvement in graduate school, undergrad performance is left unaddressed by the candidate. • Limited biochemistry/organic chemistry background to prepare applicant for Aim 2.

Too general. No detail provided

How does this strengthen/ weaken the applicant's potential to benefit from the fellowship?

Pertains to another criterion, not Applicant.

GRE scores are no longer required

Detailed and clear statements of why these are strengths of the Candidate.

Clearly articulates why it is considered a weakness

Sponsor Issues

Does the sponsor(s) have the following to support the proposed training?

Research qualifications:

- Does the sponsor's record of research accomplishment suggest success for the proposed training?
- Does the sponsor and training team have the expertise for success in the proposed training?

Mentorship experience and commitment to the candidate

- How does the sponsor's mentoring history suggest that they will be a strong mentor to the applicant? In the absence of a significant mentoring history, what indicates that he/she will be a strong mentor?
- If a co-sponsor is named, are specific contributions to training noted?
  - Is there a plan for coordinated mentoring?
- Do the sponsors demonstrate a high level of commitment to the candidate by providing a personalized training plan? Do letters of collaboration convey commitment?

Adequate funds to support the proposed training

- Is there confidence that the mentoring team will have sufficient research funds over the duration of the training period? (it is appropriate to balance current funding with a history of funding awards.)

This has become crucially important.
Current university policies generally are not supportive here.

Too general, how do these "strengths" enhance training?

How does this speak to the likelihood of funding for this training?

By itself, this has no bearing on the success of the training.

How will this affect the project?

2. Sponsors, Collaborators, and Consultants	
LESS EFFECTIVE	**EFFECTIVE**
Strengths • She has published 5 papers in the last 3 years. • The sponsor is outstanding • The team is very strong. • The sponsor's group is large. • The sponsor has a good track record of funding.	**Strengths** • Over the past 3 years, the sponsor has published multiple key papers on the proposed topic important to this field. • While the sponsor has some experience in XX, she has assembled a strong team of collaborators, each expressing commitment (through strong letters), to provide essential expertise for the successful training of the candidate. • The primary sponsor has a strong record of mentoring; many of her mentees currently have faculty research positions. • The primary sponsor has sufficient funding throughout the training period.
Weaknesses • The sponsor is quite junior. • Since becoming independent, the sponsor has not published in top tier journals.	**Weaknesses** • Sponsor's experience in conducting technically complicated studies involving XX is not extensive; with the expert collaborator being off-site, it was unclear that she can provide critical guidance for XX methodology. • Expertise in MM, particularly important for completing Aims 2 and 3, is lacking.

Detailed and specific measures/ qualities

Detailed and specific concerns

Research Training Plan

Is the research plan well integrated with the candidate's goals, will it expand the candidate's conceptual understanding and is the plan of high scientific quality?

- Keep your focus on the big picture; don't get bogged down in the experimental details. Focus more on rationale.
- Has the candidate properly considered alternative outcomes or methodologies?
- Describe why you think an aspect of the approach is a strength or a weakness. Avoid just restating the key aims or other descriptive information in the application.
- Are publishable results from the work likely? Is the amount of work proposed feasible within the timeframe requested?
- Is the work proposed sufficiently distinct from the sponsor's funded research for the applicant's career stage?
- Is the scope of the work proposed appropriate for the candidate's career stage?
- Evaluate with candidate's career stage in mind. An F31 application from a second year graduate student should be assessed differently than an F32 application from a second year post-doc.

Too general Why? How?

Too general, descriptive not detailed.

3. Research Training Plan	
LESS EFFECTIVE	**EFFECTIVE**
Strengths • Approach is strong. • Using the XX method is a strength. • Experiments are complex, but the PI is so productive that she will likely be successful. • These studies will lead to new insights into ZZ disease.	**Strengths** • The studies are built on a strong driving rationale that the interaction between XX with YY results in ZZ. • The combination of XX and YY studies will establish the role of ZZ in ABC disease progression by developing methods to XYZ. • The experimental design is comprehensive and cohesively covers all aspects of XX. Alternative strategies are well thought out, with potential problems and limitations associated with YY and ZZ acknowledged. (major)
Weaknesses • The XX model system is too artificial. • The aims are too diffuse. • The measures of XX are weak. • The proposal is overly ambitious.	**Weaknesses** • The research proposed is not sufficiently novel to lead to publications, which are critical for the candidate's progress. • Use of XX in the YY model system will not faithfully mimic ZZ disease, due to A and B. • Results from the XYZ experiment may be very difficult to interpret because it will be challenging to separate the effects of XX from YY. • Aim 1 is risky, which raises questions about feasibility of getting to Aims 2 and 3, where the highest training potential exists. (moderate)

Detailed and specific reasons

Training Potential

Do the proposed research project and training plan have the potential to provide the applicant with the requisite individualized and mentored experiences that will develop his/her knowledge, research and professional skills?

- The training should be consistent with applicant's career goals in a health-related field and help them advance to the next stage. If a specific career goal has not been chosen (for an F31), the training should be consistent with the various options.
- Is the proposed research complementary to previous training (particularly for F32)? What new research areas/skills/techniques will be learned?
- The sponsor's training plan and applicant's proposed activities should address any weaknesses/gaps in the applicant's background relative to their career goal.
- The training plan and applicant activities should include non-research training appropriate to the career goals (e.g., teaching, coursework, grant-writing, presentations)

How does this training help him/her get there?

What are they and how do they advance him/her toward the career goal?

Are these gaps that needed to be filled on the career path?

4. Training Potential	
LESS EFFECTIVE	**EFFECTIVE**
Strengths • This is a super applicant who will be a *leader in the field*. • The applicant will learn many new skills. • The research plan provides training in y and z.	**Strengths** • The applicant will build on his strong previous training in x by performing wet lab and crystallography experiments appropriate for his academic career goal as a biochemist. (Major) • The applicant will take a course in y to address that gap in his background. • The applicant's planned activities include attending national meetings and making presentations. (Minor)

Detailed and clear statements of strengths and weaknesses with an indication of their relative importance

Continued from prior page

Be specific and indicate the relationship to the career goal.

Not necessarily a weakness; explain why if you think it is.

Weaknesses	Weaknesses
• Few non-research training activities are proposed. • The applicant is staying in the same field.	• The sponsor provides a generic training plan and does not indicate how he will address the applicant's lack of research training in y. • The research plan is not set up to provide the applicant timely publications that will help him be an attractive candidate in the z job market. • The sponsor does not indicate any plan to train the applicant in writing grants or publications, critical to his goal of academia.

Institutional Environment & Commitment to Training

Are the research facilities, resources and training opportunities adequate and appropriate for the candidate's scientific development?

- For F30s and F31s, the additional educational information is often a useful source of information.

- Evaluate the availability of necessary equipment, laboratory space, computational resources and core facilities.
- Assess exposure to seminars, workshops and professional development activities.
- Address the institution's record of commitment to fostering high quality trainees.

Why? In what way? Too general.

Should speak to the contributions of the environment to the training

In what way? How does this affect the training?

Detailed and specific reasons/ aspects of the institution that support (or limit) feasibility.

5. Institutional Environment & Commitment to Training	
LESS EFFECTIVE	**EFFECTIVE**
Strengths • Institutional environment, facilities and resources for the proposed research and training are excellent. • All resources, funding, and facilities are in place. • X is a leading university.	**Strengths** • The institution offers a strong environment in which to integrate clinical experiences with the basic science training via structured internships with clinicians. • The application includes strong networking activities such as mentor lunches and a year-long clinical experience course for re-entry into year 3 of medical school. • There are other groups in the XY field with which the applicant can interact. • The institution has an outstanding seminar program and the applicant will have an opportunity to host a seminar speaker.
Weaknesses • The institution is OK. • The institution's commitment is not clear.	**Weaknesses** • No institution-based career development courses (grant writing, etc.) are noted. • Critical resources are only available in co-sponsor's laboratory at an institution in a different state.

Additional Review Criteria

- Reviewers should evaluate other considerations that will apply to some applications, but not all.
- These factors do not receive a separate score but *can affect your overall impact score*.

If Human subjects, vertebrate animals, or biohazards are involved in the study then these sections of the critique MUST be evaluated and filled in.

Human Subjects and Inclusion of Women, Minorities and Children

Vertebrate Animals

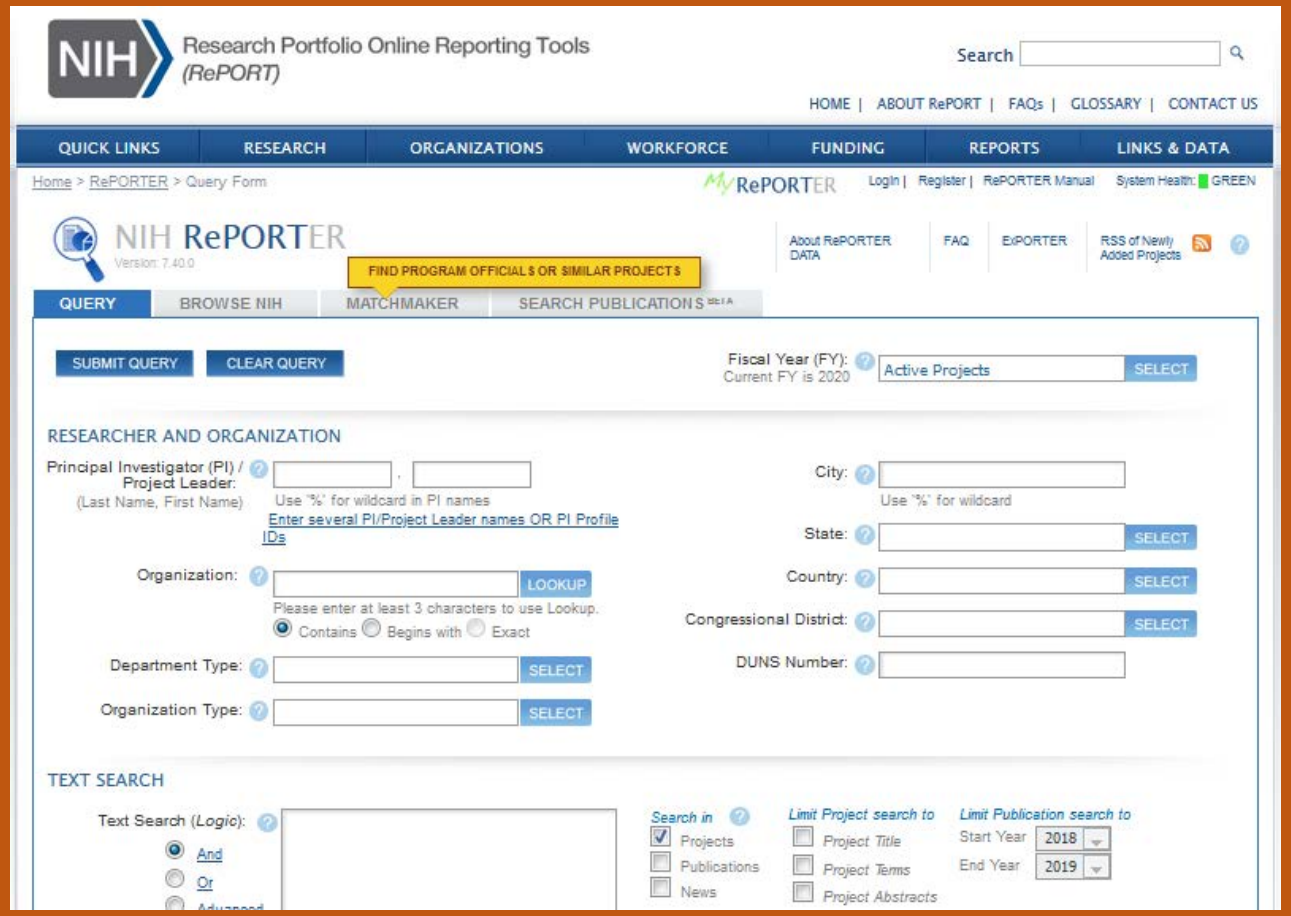
Biohazards

If the application is a Resubmission (grant number ends in **A1**), please complete.

Resubmission - Add comments in appropriate box if the application is a resubmission. This section should include comments on how and how well the applicant responded to the previous review.

I Just Covered Examples of Critiques.

Time to cover NIH Project Reporter unless you have questions that cannot wait.



https://projectreporter.nih.gov/reporter.cfm

What I Tried To Cover: Time for Your Questions

1. Overview of the NIH Center for Scientific Study Reviewer Guidelines for F31 Application Reviews
2. The F31 Review Template
3. Specific Questions Reviewers Must Evaluate
4. Examples of Critiques
5. Using NIH Project Reporter Effectively

Thank You For Your Kind Attention!
(C’est moi? No !)