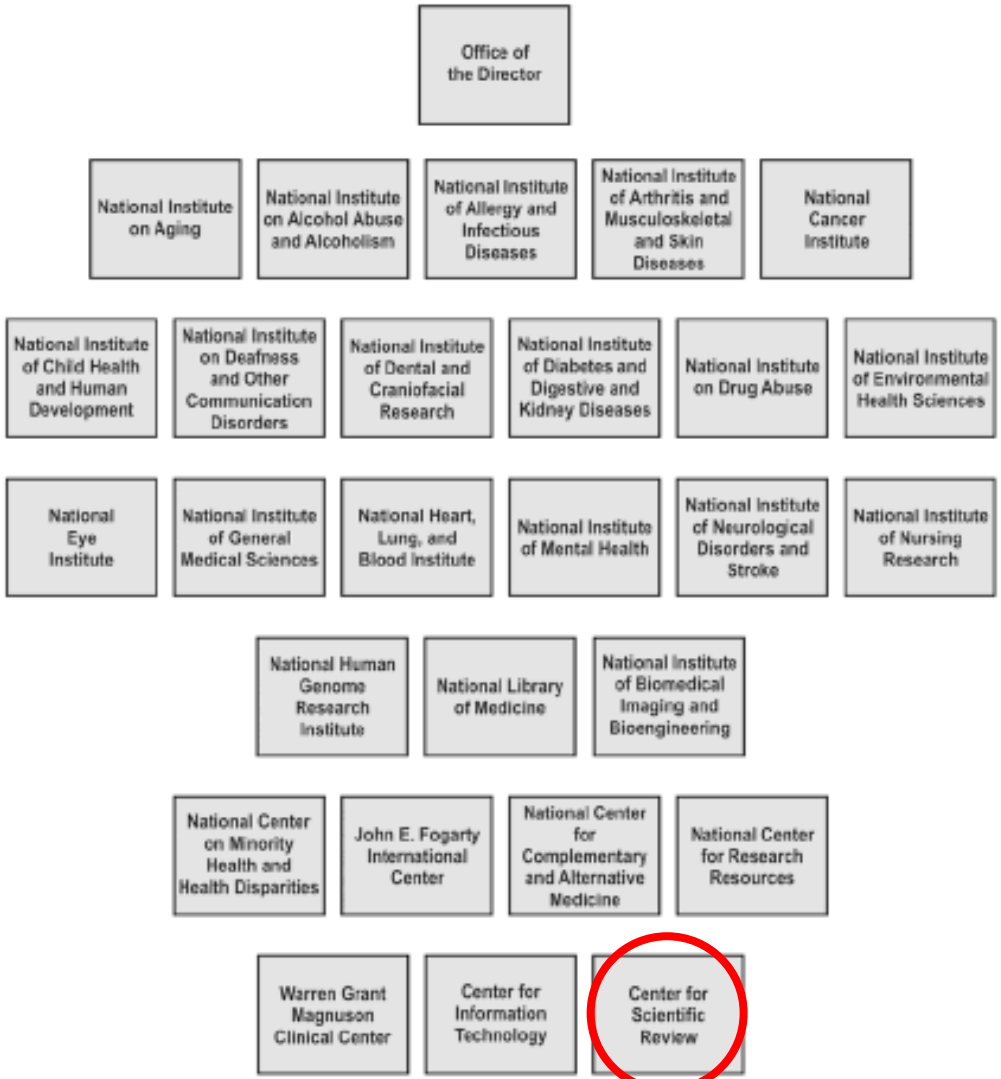
Writing a Career Development/K Award

Jonathan Katz, MD
Associate Professor of Medicine
Department of Medicine, Gastroenterology Division

How does the review process work?

NIH: 27 Institutes and Centers



Source: NIH Office of Research Facilities

Scientific Review Groups (aka "study sections") are managed by NIH Institutes and Centers

Center for Scientific Review (CSR)

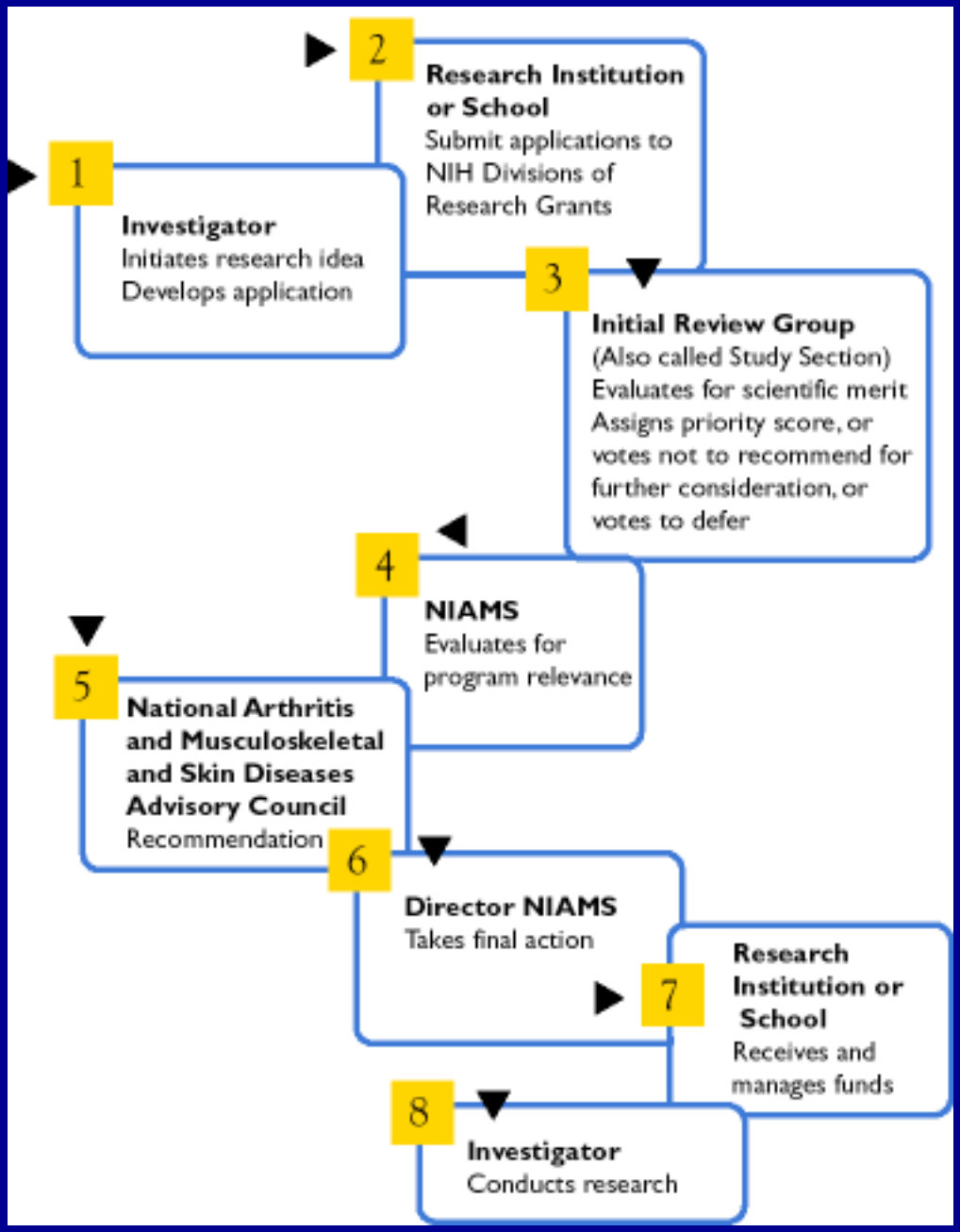
The Center for Scientific Review (CSR) is the portal for NIH grant applications and their review for scientific merit. CSR organizes the peer review groups or study sections that evaluate the majority (70%) of the research grant applications sent to NIH. CSR also receives all grant applications for NIH, as well as for some other components of the U.S. Department of Health and Human Services (DHHS).

http://public.csr.nih.gov/Pages/default.aspx

Other Institutes/Centers

Grants may be reviewed by study sections managed by other NIH Institutes and Centers

https://public.era.nih.gov/pubroster/



Source: NIAMS

K series *new*	**Research Career Development**	**February 12**	**June 12**	**October 12**
K series *renewal, resubmission, revision*	**Research Career Development**	**March 12**	**July 12**	**November 12**

Review and Award Cycles

	Cycle I	Cycle II	Cycle III
Scientific Merit Review	June - July	October - November	February - March
Advisory Council Round	August or October *	January	May
Earliest Project Start Date	September or December *	April	July

NOTES:

The actual date of the Advisory Council may occur in the month before or after the month listed. For example, some ICs may actually hold the January Advisory Council meeting in February or the October Advisory Council meeting in September.

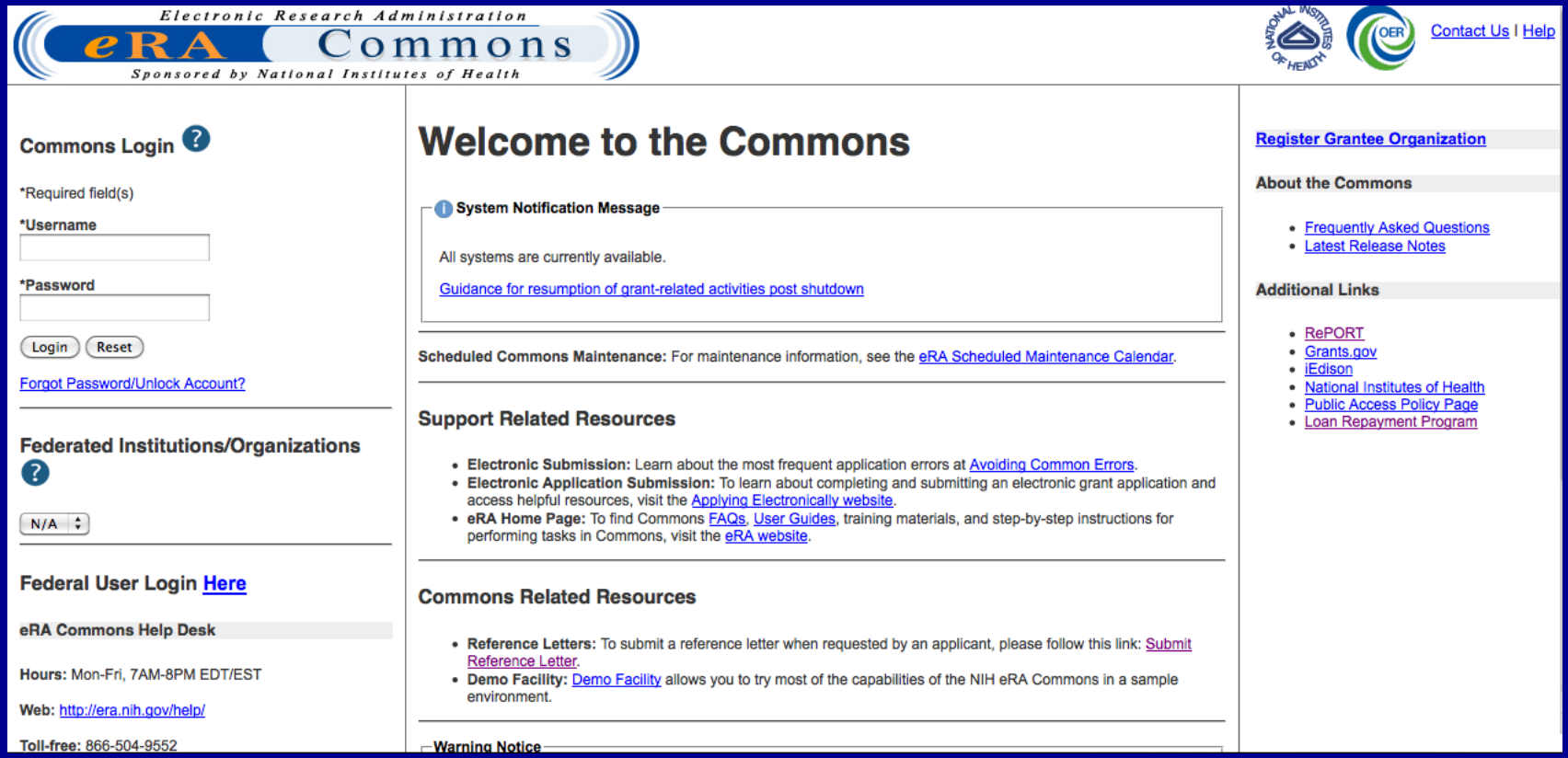
Awarding components may not always be able to honor the requested start date of an application. Before incurring any pre-award obligations or expenditures applicants should be aware of NIH policy governing pre-award costs prior to receiving a Notice of Award. See the NIH Grants Policy Statement.

* Advisory Council Round for Cycle I applications may be August or October, and their earliest project start date may be September or December respectively.

http://grants.nih.gov/grants/funding/submissionschedule.htm

eRA Commons

https://public.era.nih.gov/commons/commonsInit.do

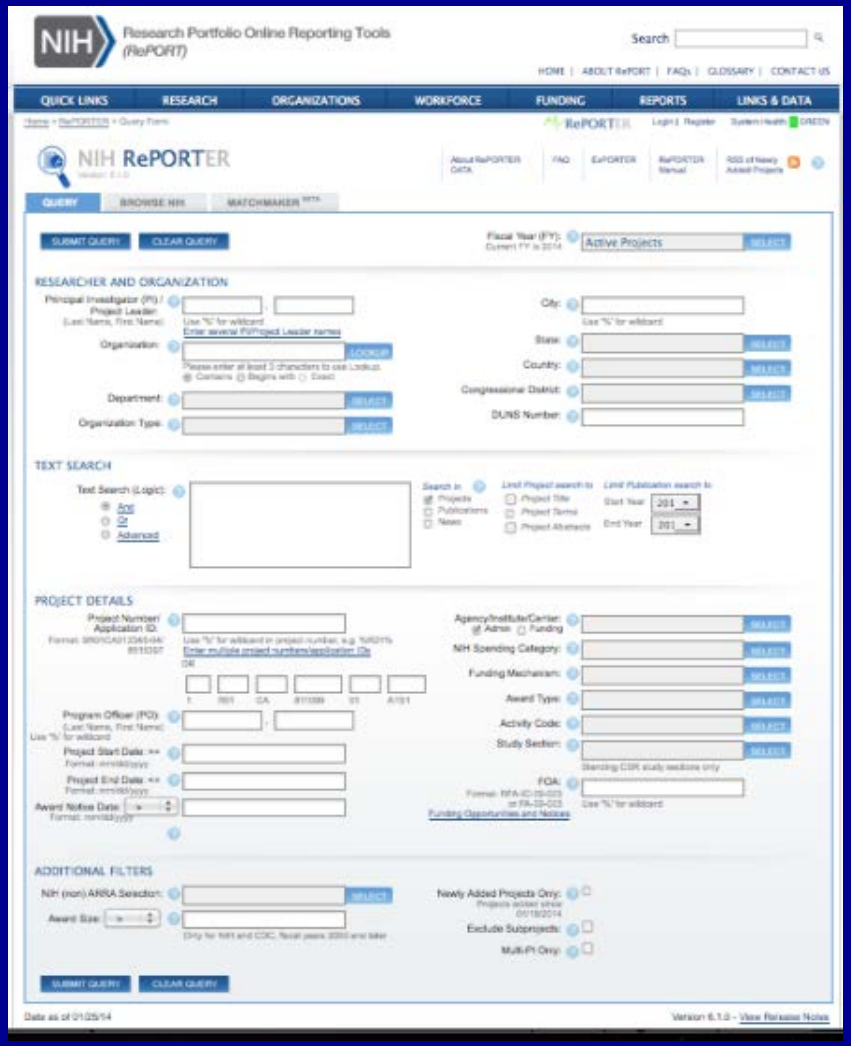


- Grant status including submitted grants, study section assignment, scores, etc
- RPPR (non-competing renewals)

NIH RePORTER

Planning your grant – is anyone else doing it

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



Whom do I contact with questions?

Prior to submission – Program Officer*

example of question:

"Is my grant more appropriate for a K08 or K23 mechanism?"

After submission but before review – Scientific Review Officer

example of question:

"What is the deadline to submit supplementary information?"

After review – Program Officer*

example of question:

"What is the likelihood of funding?"

"What should I do for my resubmission?"

*Get to know your Program Officer.

What does a K-award application look like?

NIH K Awards

(K01, K08, K23, K99/R00, and others – also R03; vary by institute)
http://grants.nih.gov/training/careerdevelopmentawards.htm

- K01 Mentored Research Scientist Development Award
  - Career development in a new area of research; 3-5 years; salary determined by sponsoring institution
- K08 Mentored Clinical Scientist Development Award
  - Career development of the clinical research scientist; 3-5 years; 75% effort
- K23 Mentored Patient Oriented Research Career Development Award
  - Career development of the clinical research scientist in patient oriented research; 3-5 years; 75% effort
- K99/R00 Pathway to Independence (PI) Award
  - Support for individuals with a terminal clinical or research doctorate degree to foster the transition of postdoctoral scientists from mentored training environments to research independence (R01 support) earlier in their career; up to 5 years
    - Mentored Phase (K99); up to 2 years
    - Independent Investigator Phase (R00); up to 3 years
  - K99-R00 Transition
    - Evaluation by NIH extramural program staff
      - Success in K99 phase
      - Commitment of candidate's institution to his/her career development
    - Extramural institutional appointment – full-time tenure-track position at the assistant professor level (or equivalent) not contingent on transfer of the K99/R00 award

Parts of a K Award

Project Summary/Abstract
Project Narrative
Bibliography & References Cited
Facilities & Other Resources
Equipment
NIH Biosketches (senior/key personnel and Other Significant Contributors)
Budget

FORMS, ETC

Introduction to Application (for Resubmissions only)

Candidate's Background
Career Goals and Objectives
Career Development/Training Activities During Award Period
Training in the Responsible Conduct of Research
Statements by Mentor, Co-mentor(s), Consultants, Contributors
Description of Institutional Environment
Institutional Commitment to Candidate's Research Career Development

CAREER DEVELOPMENT

Specific Aims
Research Strategy

RESEARCH

Human Subjects Sections (if applicable)
Vertebrate Animals (if applicable)
Select Agent Research (if applicable)
Consortium/Contractual Arrangements (if applicable)
Resource Sharing Plan (if applicable but doesn't hurt to include something since some reviewers do not understand requirements for this section)

REGULATORY

Appendix (very specific requirements "Do not use the appendix to circumvent the page limits…"

Review of a K Award

Review Criteria:

- Candidate
- Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring
- Research Plan
- Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)
- Environment and Institutional Commitment to the Candidate

Note that these factors do not receive individual scores but CAN affect your overall score!

Additional Review Criteria include the following;

- Protection of Human Subjects from Research Risk
- Inclusion of Women, Minorities, and Children in Research
- Care and Use of Vertebrate Animals in Research
- Biohazards
- Resubmission Applications
- Renewal Applications (as applicable)

Additional Review Considerations include the following:

- Training in the Responsible Conduct of Research
- Select Agents
- Resource Sharing Plans
- Budget and Period of Support

Cover letter

- Request Institute(s) and/or Center(s) for funding consideration
- Request IRG (study section) for review
- Specify type of reviewer who should review the grant (do not name names – they will be excluded!)
- Can specify reviewers who should be excluded (e.g. competitors) but be careful

See also http://www.niaid.nih.gov/researchfunding/grant/strategy/pages/4coverletter.aspx

Candidate's background and career development

- Use the candidate's background to tie things together
  - How did your interest in the themes of your grant developed (i.e. medical school to residency to fellowship, etc.)?
  - How do your various achievements support your ability to become an independent investigator?
  - Address any potential concerns in your application (e.g. a few years where you focused on something else, were exclusively clinical, etc.).

- Propose a career development plan that is distinct from what you are doing now
  - Address gaps in your knowledge
    - Additional coursework, workshops, etc.
    - New techniques from mentors, collaborators
    - Including a table with a time-course is very helpful
  - Don't simply propose to go to lab meetings and other group meetings – if you don't convince reviewers that you need additional training and mentorship, reviewers may question why you are applying for a career development grant and not an independent award!

Developing your proposal and specific aims

http://public.csr.nih.gov/aboutcsr/NewsAPublications/Publications/Pages/InsidersGuide.aspxnd

- Make your aims hypothesis-driven whenever possible.
- Propose mechanistic aims (avoid language like “we will look for..” in favor of language like “we will define…”).
- Avoid contingent aims (i.e. if aim 1 is not successful, aims 2 and 3 cannot be performed – e.g. aim 1 is identifying targets by next generation sequencing and aims 2 and 3 are validating those targets).
- Don’t be unfocused or “overly ambitious” – don’t propose more than you can reasonably accomplish in your K-award time-frame.
- Limit your aims and sub-aims – there is no correct number but 2-3 is typical.

Letters of Reference

- Minimum of 3, no more than 5 letters submitted directly through eRA Commons and due by the application receipt deadline date
- Choose well-established scientists with a personal connection who can address your strengths and potential to become an independent investigator - letters should be strong, personal, and specific.
- Keep in mind those individuals who may be expected to write letters (e.g. thesis advisor, prior postdoctoral mentor) and think carefully before excluding them.
- **Take the initiative to track the letters and send reminders** (your letter writers are busy and your letter may not be their top priority; it is your responsibility to ensure that your letters are submitted on time).

Statements by the mentor(s)

- Mentor's (and Co-Mentor's) track record of successful mentoring of trainees
- Nature of the supervision and mentoring including metrics for monitoring the candidate's research, publications, and progression towards independence
- Description of the advisory committee
- Plan for career progression of the candidate from the mentored stage to an independent research investigator - how your career path will be distinct from that of your mentor?
- **Clear statement** of what aspects of the proposed research the candidate will be able to take into an independent position

Institutional Commitment

- Institutional commitment should **NOT** be contingent upon receipt of the career development award.
- Letter must contain assurances that the candidate will be able to devote a minimum of 75% effort (i.e. 9 person-months) to research.
- Description of office and laboratory space, equipment, and other resources and facilities (including access to clinical and/or other research populations, cores, and other facilities) to carry out the proposed research.

A few other key points

- Write for an experienced scientist but not necessarily an expert in your field
- Refer to the NIH guidelines
  - For example, the NIH gives clear guidelines for points to include in RCR and vertebrate animals sections – use these
- Don’t propose more than you can do in the allotted time
- Stay focused throughout your application – training and research plan should fit together like a hand in a glove
- Review the NIH review criteria for your grant mechanism (think like a reviewer!)
  - http://grants.nih.gov/grants/peer/critiques/k.htm

Okay, I submitted my grant.
Now what?

- What does a study section do? How does it work?
  - A typical study section may have more than 30 members, of whom only three or so will be assigned to read your entire grant. Most reviewers will likely not have read your grant in its entirely.

- How is my grant scored?

- What documents will I receive from the review?

- Should I keep modifying my grant or embark on an entirely direction?
  - NIH policy as of April 2014 - “NIH now allows following an unsuccessful resubmission (A1) application, applicants may submit the same idea as a new (A0) application for the next appropriate due date”

    http://grants.nih.gov/grants/policy/amendedapps.htm

Scoring – Research

Overall Impact:
The likelihood for a project to exert a sustained, powerful influence on research field(s) involved

Overall Impact	High	Medium	Low
Score	1 2 3	4 5 6	7 8 9

Evaluating Overall Impact:
Consider the 5 criteria: significance, investigator, innovation, approach, environment (weighted based on reviewer's judgment) and other score influences, e.g. human subjects, animal welfare, inclusion plans, and biohazards

e.g. Applications are addressing a problem of high importance/interest in the field. May have some or no weaknesses.

e.g. Applications may be addressing a problem of high importance in the field, but weaknesses in the criteria bring down the overall impact to medium.

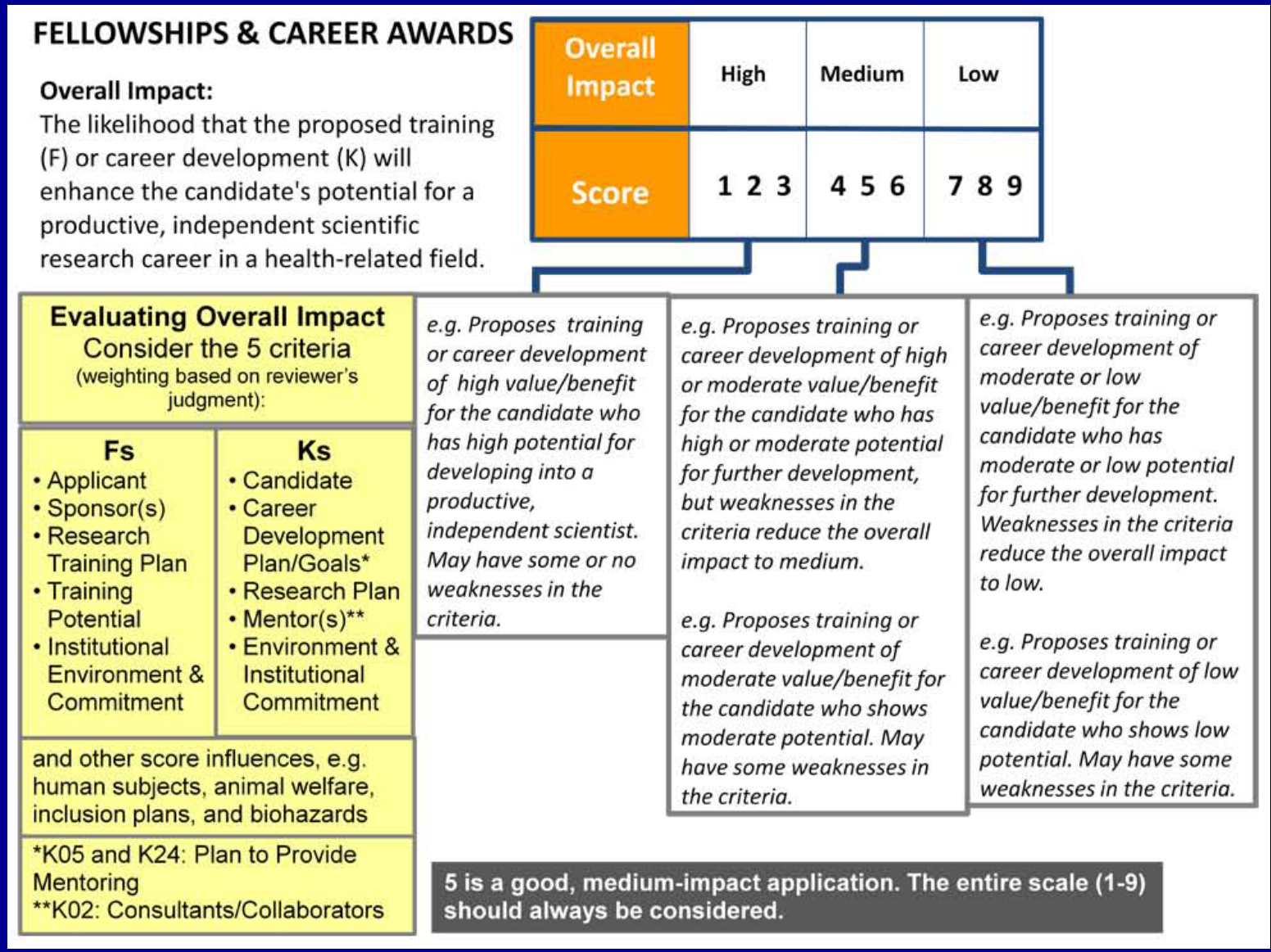
e.g. Applications may be addressing a problem of moderate importance in the field, with some or no weaknesses

e.g. Applications may be addressing a problem of moderate/high importance in the field, but weaknesses in the criteria bring down the overall impact to low.

e.g. Applications may be addressing a problem of low or no importance in the field, with some or no weaknesses.

5 is a good medium-impact application, and the entire scale (1-9) should always be considered.

Scoring – Training



Panel discussion:
Other topics, questions?