LIBR
Laureate Institute for Brain Research

THE UNIVERSITY of TULSA

K Club, Week 10

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Today's Topics

- Training in Responsible Conduct of Research
- Bibliography + References Cited
- Project Summary/Abstract
- Project Narrative
- Action Items

K Application Sections

Research

- **Specific Aims** (1 page)
- **Research Strategy** (6 pages: **Significance, Innovation, Approach**)
- **Training in Responsible Conduct of Research** (1 page)
- **Project Summary / Abstract** (30 lines of text)
- **Project Narrative** (3 sentences)
- **Protection of Human Subjects from Research Risk**
- **Inclusion of Women and Minorities**
- **Inclusion of Individuals Across the Lifespan**
- **Inclusion Enrollment Report**
- **Budget + Budget Justification**
- **Bibliography + References Cited**

Career

- **Candidate Information and Goals for Career Development** (6 pages: **Candidate Background, Career Goals/Objectives, Career Development/Training Plan**)
- **Plans and Statements of Mentor and Co-Mentors** (6 pages)
- **NIH Biosketches** for you, Mentor, Co-Mentors (max 5 pages each)
- **Three Letters of Reference**
- **Letters of Support from Collaborators, Contributors and Consultants** (6 pages max)
- **Cover Letter**

Setting

- **Facilities and Other Resources**
- **Equipment**
- **Environment and Institutional Commitment to Candidate**
- **Resource Sharing Plan**

re·spon·si·ble

/rəˈspänsəb(ə)l/

adjective

having an obligation to do something, or having control over or care for someone, as part of one's job or role.

"the department **responsible for** education"

Similar: in charge of | in control of | at the helm of | accountable for | liable for

- being the primary cause of something and so able to be blamed or credited for it.

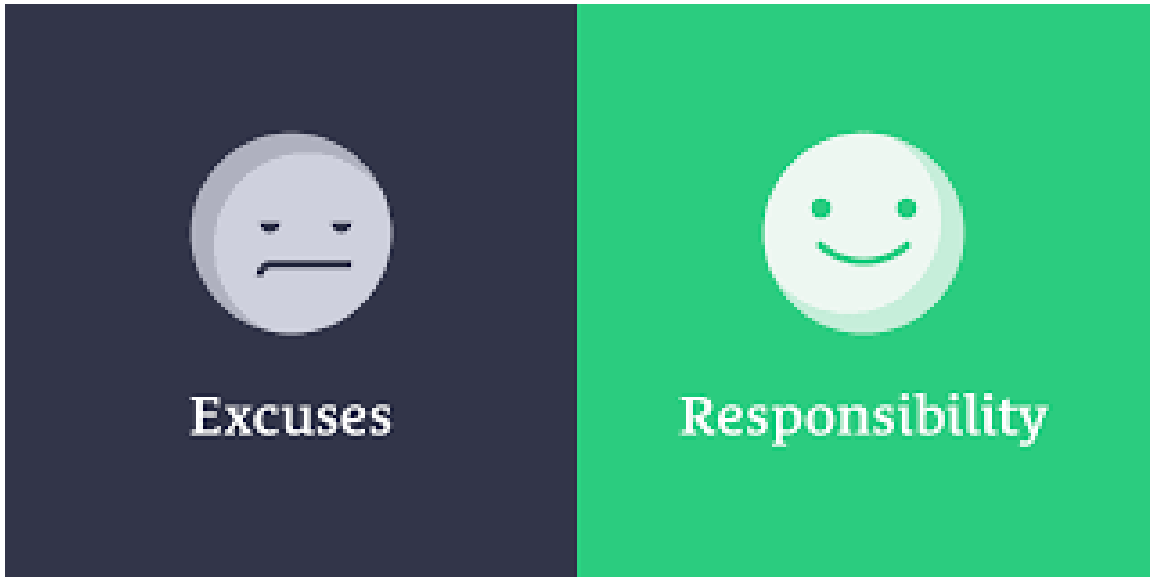
  "the gene was responsible for a rare type of eye cancer"

  Similar: accountable | answerable | to blame | behind | at the bottom of

- (of a job or position) involving important duties, independent decision-making, or control over others.

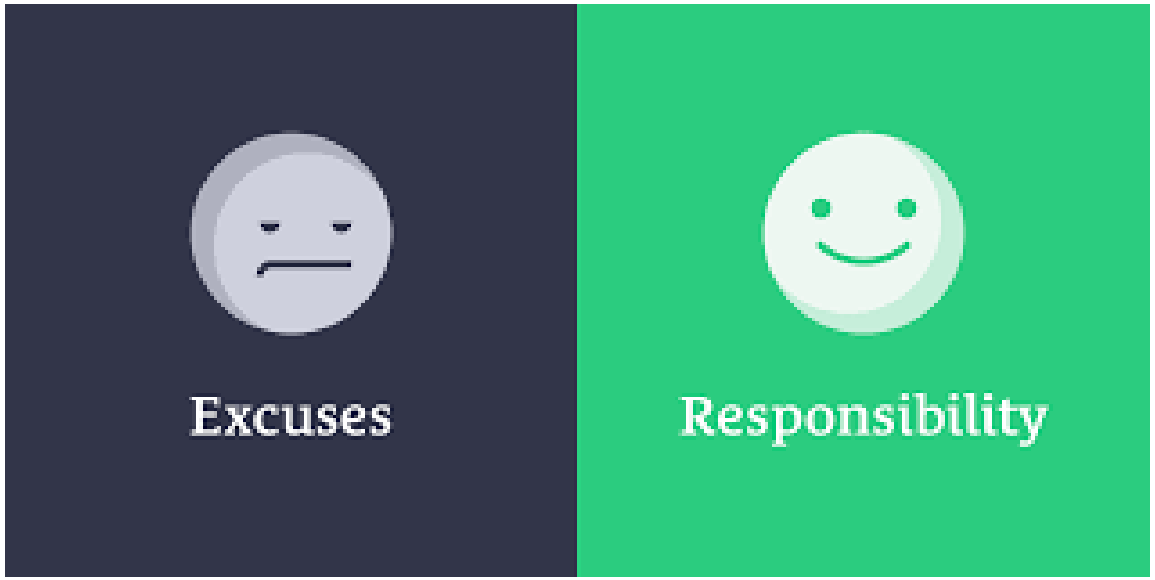
  Similar: important | powerful | authoritative | executive | decision-making

Training in Responsible Conduct of Research (1 page)



- This section is where you show that:
  - You have taken classes, workshops, and/or online training on ethics related to human subjects research
  - If you haven't taken a research ethics class, you need to document that you will take one (explain when, where, and how many hours)
  - You will be engaged in research ethics activities during the K99/R00 phase
    - Online CITI training
    - Conferences / Workshops
    - Class
    - Instruction by Mentors (how often, which ones?)

Why does NIH require this section?



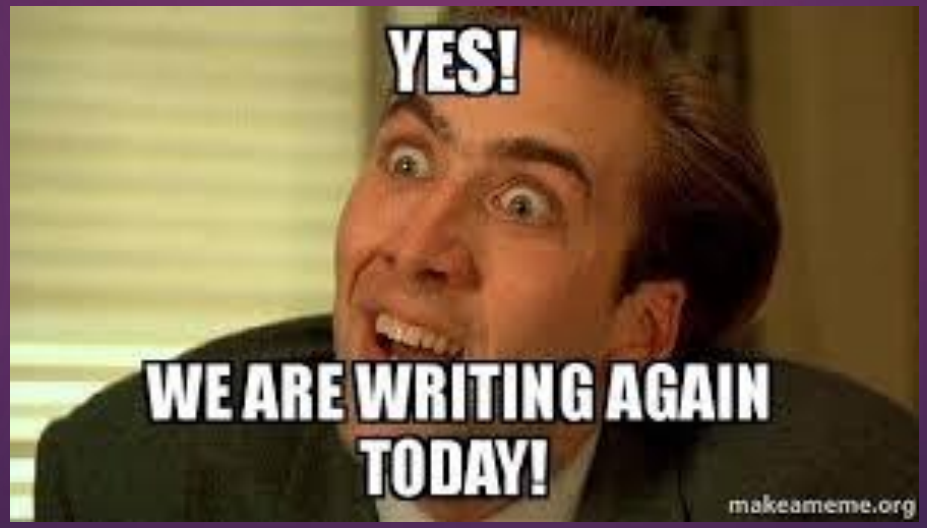
- They want to make sure that you can achieve your K99/R00 research goals without:
  - Violating subject privacy / confidentiality / informed consent rules
  - Having multiple adverse events that were within your control
  - Losing subjects due to poor recruitment/retention
  - Losing data due to negligence

Training in Responsible Conduct of Research (1 page)

- Document prior CITI training and when you completed it
- Document any Ethics or Clinical Trials courses you have taken and when
- Describe your plan for do more instruction during the grant years, covering all FIVE of the following:
  - **Format**
    - Describe 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)
  - **Subject Matter**
    - Describe the breadth of subject matter (e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics)
  - **Faculty Participation**
    - Describe the role of the mentor(s) and other faculty involvement in the instruction
  - **Duration of Instruction**
    - Describe the number of contact hours of instruction, taking into consideration the duration of the program
  - **Frequency of Instruction**
    - Instruction must occur during each career stage and at least once every four years. Document any prior instruction during the applicant's current career stage, including the inclusive dates instruction was last completed

Example

- Presented in next few slides
- Use this info to help you write your **Training in Responsible Conduct of Research** section



- **Info on Ethics class completed:**
  - **Format:** “In my doctoral training program, the Oklahoma State University (OSU), I completed a semester-long course titled “Ethics & Professional Development” (PSYC5193).”
  - **Subject Matter: “**This course covered topics including ethical considerations for teaching, mentorship, research, and clinical applications of psychology; furthermore, the course included formal instruction on the American Psychological Association ethics code.”

- **Info on CITI training completed:**
  - **Format:** “Beginning with undergraduate research assistantships (2011), I have completed annual online training in Responsible Conduct of Research (Collaborative Institutional Training Initiative) across my research positions at OSU, Medical University of South Carolina (MUSC), Ralph H. Johnson VAMC (RHJVAMC), and Laureate Institute for Brain Research.”

- **Info on CITI training to be completed during the award period:**
  - “I will continue to complete this training annually for the duration of the award period.”
  - **Subject Matter: “**These trainings include topics such as: conflict of interest, research integrity, human subjects research, research misconduct, and HIPPA Researcher Privacy Requirements.”

- **Faculty Participation:** “With regard to the proposed training plan, ethical consideration related to particular career development goals with be integrated into monthly didactic meetings led by my Primary Mentor and Co-Mentors.”
- **Frequency of Instruction, Format:** “One entire didactic meeting per year will be dedicated to ethical considerations specific to the particular didactic (e.g., ethical considerations for experimental behavioral neuroimaging research or ethical consideration of culturally informed research with American Indian communities).”
- **Frequency of Instruction, Format: “**I will also attend the workshop Professional Ethics in Research and Practice through the Oklahoma State University Department of Psychology, which is offered each fall.”
- **Subject Matter: “**The workshop covers conflict of interest, data ownership and management, considerations for vulnerable populations, disseminating and publishing scientific data.”
- “I will also attend any trainings in responsible conduct of research offered by NIH K awardees throughout the mentored phase of the proposal.”

- “As such, I will receive extensive training in responsible conduct of research *across a wide range of topics* (relevant to clinical and cultural neuroscience, as well as psychological research more broadly) and in a variety of formats (i.e., online training, individualized and interactive didactics, formal in-person workshops).”

- “This training will be a consistent feature of the career development plan, involving my mentorship team, regional faculty, and associated members of K institutional awardees.”

Were all 5 bases covered?

- **It would be good to add info about DURATION here!!!**
  - How many total hours was the Ethics class from grad school?
  - How many hours was CITI training?
  - Are the didactic meetings hourly every month?
  - How long is the Workshop at OSU? One day? 4 hours?

Bibliography + References Cited

- Here is where you list any citations used in:
  - **Specific Aims**
  - **Significance**
  - **Innovation**
  - **Approach**
  - **Protection of Human Subjects from Research Risk**
  - **Inclusion of Women and Minorities**
  - **{Any other sections that are relevant}**

Bibliography + References Cited

- NIH does not require a specific citation format, so go with your favorite or whatever standard your **Primary Mentor** recommends
- The use of "et al." in place of listing all authors of a publication is acceptable practice
- Remember to comply with NIH's public access policy, citing the PMC reference number (PMCID) for each citation when applicable
- **https://www.ncbi.nlm.nih.gov/pmc/pmctopmid/**
- There is no page limit on this section!

Narrative

PUBLIC HEALTH
Healthy People In Healthy Communities

PUBLIC HEALTH

HEALTH PROMOTION
SURVEILLANCE
RESEARCH
MONITORING
PUBLIC HEALTH
ANALYSIS
RISK
OUTBREAKS
COMMUNICATION
EPIDEMICS
DISEASE PREVENTION

Project Narrative (3 sentences)

- This section will be read by every reviewer as well as NIH staff assigning your application to a particular reviewer study section, so you want to make this project sound as important as possible

- How is your proposed study relevant to public health?
  - It is recommended that you start out this section by saying: “The proposed research is relevant to public health because…”

- How does your proposed study relate to the mission of the particular center that you are targeting for funding?
  - Examples: National Institute of Mental Health, National Institute on Drug Abuse, National Institute on Alcohol Abuse and Alcoholism, etc.
  - Conclude with a sentence that relates either to NIH’s mission or to the center at NIH that you’re targeting for funding: “The project is relevant to NIH’s mission because…”

Project Narrative: Example

- **Relevance to public health:**
  - **“**As of November 2016, recreational marijuana has been legalized in eleven of the fifty United States (Washington, Oregon, Colorado, California, Nevada, Montana, North Dakota, Arkansas, Florida, Massachusetts, and Maine).”
  - “As states continue to proceed with legalization, there is a *crucial need* to more fully understand the impact of recent as well as cumulative effects of marijuana use on decision-making function in young adults.”
- **Relevance to the Center you are applying to (e.g., NIDA):**
  - “Research to further understand the impact of varying levels of marijuana and comorbid substance use could *serve to inform future policy on what amount/duration of use is equated with impairment*, and could *aid in the development of screening tools to target young adults for early intervention*.”

Project Summary/ Abstract

Project Summary (≤ 30 lines of text)

- 2nd most important section of your grant after **Specific Aims**
- This needs to be a “stand-alone” document (readers need to understand everything in this one without reading anything else in your grant)
- Do NOT write this section in First-Person (e.g., “I” or “we”)
- First, describe gap in knowledge / unmet need that will drive your project
- Next, copy/paste your **Specific Aims** and explain the primary methods and approaches that will be used to accomplish them
- Finish with a conclusion combining the project’s (a) **Significance**, (b) **Innovation**, and (c) **Generality Regarding Positive Impact**

Action Items

- Complete drafts of the following and send to your **Primary Mentor**:
  - **Training in Responsible Conduct of Research**
  - **Project Narrative**
  - **Project Summary/Abstract**
- Work on formatting your **Bibliography + References Cited** section, making sure that your citations are correct across documents
- Revisit what outstanding sections still need feedback from your **Co-Mentors and/or Consultants, Collaborators, or Contributors**