

**FINAL REPORT  
ON THREE FOCUS GROUPS  
WITH EARLY CAREER  
CLINICAL RESEARCHERS  
ABOUT THE K 23 AWARD PROGRAM**

By

Luc Henderson  
Brenda Lee  
Amber Marino

For

The Association of American Medical Colleges  
And  
The National Institutes of Health

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# **I. INTRODUCTION**

## **A. Study Background and Purpose**

The Association of American Medical Colleges (AAMC) is a non-profit organization dedicated to advancing medical education, biomedical and health sciences research, and patient care. The AAMC, with the partial support of the National Institutes of Health commissioned RIVA Market Research to conduct focus groups with recipients of the K 23 clinical research development award program.

The purpose of this study is to obtain the perceptions, opinions, beliefs, and attitudes (POBAs) of applicants and grantees of the K 23 award program. AAMC and NIH would like to better understand the benefits and challenges that K 23 applicants and awardees face. The AAMC desired to explore several key issues including:

- ❖ How the K 23 award fits in with the clinical research career development plans and interests of awardees
- ❖ The quality of mentorship to the K 23 awardees
- ❖ Adequacy of institutional facilities and support, including commitment to protected time for research for awardees
- ❖ Adequacy of K 23 support for research
- ❖ Awardee plans for the future

The understanding gained from this study will be used by the client team for short and long-term strategic planning.

## **B. Methodology**

Three focus groups were conducted on March 8, 2001 at the Crystal Gateway Marriott in Arlington, Virginia as a kick-off to the AAMC conference. The two-hour groups were conducted simultaneously in conference rooms equipped with live video feed and audio taping equipment. Members from both AAMC and NIH were present to view the groups.

Luc Henderson, Brenda Lee, and Amber Marino of RIVA Market Research moderated the focus groups and analyzed the data for this report.

## **C. Statement of Limitations**

Focus groups seek to develop insight and direction, rather than quantitatively precise measures. Because of the limited number of respondents and the restrictions of recruiting, this research must be considered in a qualitative frame of reference.

The reader is reminded that this report is intended to clarify cloudy issues and point out the direction for future research. The data presented here cannot be projected to a universe of similar respondents.

The value of focus groups is in their ability to provide observers with unfiltered comments from a segment of the target population and for the decision-makers to gain insight into the beliefs, attitudes, and perceptions of the target audience.

## II. EXECUTIVE SUMMARY

This section of the report summarizes the findings of the three focus groups. An in-depth analysis, complete with respondent verbatims, can be found in Section III – Detailed Key Findings.

### K 23 Participants – Their Background

- Respondents spoke with a great deal of enthusiasm about the various paths that led them to clinical research. **Several mentioned that they did not expect to develop an interest in clinical research when they began their training and that they had common experiences that led them to a career in clinical research.**
- **Most of these respondents stated that clinical research allows them to deliver improved methods of caring for patients by bridging their training in patient care with their interests in the sciences.**
- In detailing the critical stages to a clinical research career, respondents noted the difficulty in becoming an established independent investigator. **The numerous obstacles, such as funding, finding a mentor, and training, create feelings of uncertainty and angst.**
- **Respondents commented that while patient care and expanding knowledge are the highlights of clinical research, regulatory issues are burdensome, bureaucratic realities.**
- **The quest for funding was a constant concern and discussion theme.** It presents an ongoing threat to launching and maintaining a career as an independent investigator.
- **The respondents felt that their zest for the field of clinical research sustains them in the face of numerous obstacles.**

### K 23 Awards Programs

- **K 23 awards are viewed as training and a “jumpstart” to a career in clinical research, as well as a validation that the awardee is a viable clinical researcher.** The award also provides proof that researchers are committed to a career in clinical research.
- Only a few of the respondents have applied for an R01 at this juncture, and the others noted that it is too early in their K 23 award program to successfully compete. **However, most of the respondents fully expect to make an R01 submission at a later date.**

- **Several respondents articulated that obtaining an R01 is a specific professional goal because it is considered a tremendous mark of success when pursuing a career in clinical research and establishing ones' self as an independent investigator.**
- **Many of the respondents commented that there is professional tension among the various scientific and medical professionals within their institutions.** They explained that the lack of understanding or common language across fields of study might cause this tension.

### Mentor Relationship

- **Mentors provide direction, professional contacts, resources, and research and field knowledge** in order to mold the next generation of clinical researchers.
- Respondents also spoke of the transition of their mentor/mentee relationship during the duration of their K 23 grant. The early period of the research program necessitates a teacher/student relationship. **Overtime, the neophyte investigator becomes more established as a researcher and the relationship typically transitions to more of a collegial one.**
- **Since the award, many of the respondents mentioned that, in some ways, their role has shifted from mentee to mentor to prospective K 23 applicants at their home institution.** Because the K 23 award is so new, many prospective researchers and medical institutions are not familiar with the process.

### Support From the Facility/Institution

- Respondents expressed the frustration that is involved in weeding through processes and regulations to conduct clinical research.
- Most of the respondents indicated that their institutions are supportive on some level. However, the degree of support varies based on its experience with clinical researchers. **Some institutions like the fact that clinical researchers bring in money in the form of grants and potentially could bring them notoriety as well.** However, this conflicts with the hospitals direct mission and greatest source of revenue—patient care.
- **The K 23-mandated “protected time” appears to be most vulnerable to infringement even with the most supportive program environments.** This is the case because even with salary support, the very concept of “protected time” appears to work against the hospitals primary mission.

- **A degree of animosity exists between the clinical researchers and the basic researchers.** They discussed that, by comparison, clinical researchers are treated like second-class citizens.
- The respondents discussed that clinical researchers are very involved with patients. **As a result, the institution and fellow medical care professionals come to view them as a resource for clinical care, affecting their available time for research.**

### **K 23 – The Ideal Program – Building a Successful Clinical Research Award Workforce**

- Respondents spoke to several themes in addressing the policy issues that the NIH should address. The three most mentioned themes were funding, research training, and protected time compliance.
- Respondents were very clear that they appreciate the opportunities that the K 23 award provides. **However, they offered suggestions to improve the award itself and the process for obtaining it.** The recommendations for improvements fell into the following three categories:
  - ◆ Awareness/Advocacy—pre-application concerns, e.g. sources of information
  - ◆ Program Support/Enhancement—issues regarding the actual program
  - ◆ Career Development—post K 23 funding

### III. DETAILED KEY FINDINGS

The following information is a detailed description of the results of three focus group sessions with early career clinical researchers. Respondent verbatims are presented in italics.

#### A. K 23 Participants – Their Background

Respondents spoke with a great deal of enthusiasm about the various paths that led them to clinical research. Several mentioned that they did not expect to develop an interest in clinical research when they began their training and that they had common experiences that led them to a career in clinical research.

- Persuasion by a mentor in the field
- Boredom with the “routineness” of clinical care
- A realization that basic research could only provide a portion of the answer

*“...My epiphany for clinical research came when I found a mentor in our division in rheumatology who actually had his group with him...And all those people do a lot of clinical research....So, I kind of fell into that kind of environment and found that it’s interesting to me.”*

*“I was a clinician full-time for three years and it got to the point where I was sort of doing things without thinking about them. I realized that I missed the part of residency and medical school where you thought about things so I got involved with clinical research because it gave me a break from all the patient care that I was doing. It sort of revived me.”*

Most of these respondents stated that clinical research allows them to deliver improved methods of caring for patients by bridging their training in patient care with their interests in the sciences. They proudly described their work as *exciting, fun, challenging, unique, and vital*.

*“The reason I’m not in private practice is I like the thought that I may be just expanding that window of science a little bit further rather than just taking care of patients day in and day out.”*

*“You have a lot of PhD’s who do one thing or another. Than you have a lot of purely clinical people that do something else, but they don’ t talk...because their vocabulary is so different. [As a clinical researcher] you’re understanding is more developed, more relevant, and more easily able to be implemented in terms of an intervention for patients.”*

*“My plan is to be a bridge person and learn the basic science and the molecular. I go there and they have no idea how we work and when I go back, I realized that the other people have no idea how the basic scientists work. I think it is maybe more of lack of understanding...We just don’t know what the other person does so we don’t do very well in collaboration.”*

### **The Critical Stages to Clinical Research**

Although most respondents indicated that they had stumbled into clinical research, their discussion uncovered a critical path which requires years of commitment.

In detailing the critical stages to a clinical research career, respondents noted the difficulty in becoming an established independent investigator. The numerous obstacles, such as funding, finding a mentor, and training, create feelings of uncertainty and angst. For most, clinical research is their true calling and private practice is considered the “fallback position.”

*“The certainty that your job will continue is not there in a way that I think for most people who have done clinical training. This is not the case in science. You have to continue to prove yourself and even if you are good, it doesn’t guarantee anything.”*

## Clinical Research Word Associations

When asked to brainstorm the words associated with “clinical research” the responses were sprinkled with frustrations associated with the job. Examples of words or phrases generated during the brainstorming include:



All of the focus groups identified the three best word associations. They made selections that fall into the following three categories:

- Regulatory Issues
- Patient Care
- Expanding Knowledge

Respondents commented that while patient care and expanding knowledge are the highlights of clinical research, regulatory issues are burdensome, bureaucratic realities.

*“To me it’s much more of a noble calling or goal to say, “Well, not only did I treat all these patients, but I changed the way they were treated so that more patients were treated better and more people got better as a result.”*

*“The regulatory thing...it just seems some times that it is a mountain that I have to climb over sometimes and I wonder if what I am doing is worthwhile.”*

*“It is not just paperwork. It is just rules and regulations that are mind boggling and really hard to deal with and then there are various layers of them within the institution all the way to the FDA basically.”*

The quest for funding was a constant concern and discussion theme. Clearly, as indicated by the critical stages to clinical research, lack of funding presents an ongoing threat to launching and maintaining a career as an independent investigator.

*“I think the major obstacle to doing clinical research for most people these days is funding. We are all pretty much supported through salary support but, if you don’t have that, it is hard to get going, because of the economic pressures of the hospital.”*

*“It was a very nerve wracking process for me because come this July there would be no guaranteed funding from my department and I had no other funding as yet—come manifest. It was either get it now or depend on some other source of funding if my department was going to do that.”*

The respondents felt that their zest for the field of clinical research sustains them in the face of numerous obstacles. In so many ways, they are in a perpetual tug-of-war on a number of parameters. Below are examples of the conflicting issues.

<b>Juxtaposing The Career of Research and Clinical Care</b>	
<u><b>As a Researcher...</b></u>	<u><b>As a Clinician...</b></u>
<ul style="list-style-type: none"> <li>▪ Grants provide funding that allows grantees to begin their trek towards being an independent investigator.</li> </ul> <p style="text-align: center;"><i>“You have to become something other than your mentor.”</i></p> <p style="text-align: center;"><i>“Clinical responsibilities are huge and they don’t stop when you go home. The beeper is always on and the burden of the patients that you take care of.”</i></p>	<p>The grantee is an <i>employee</i> of a hospital, with patient care as the primary source of revenue.</p>
<ul style="list-style-type: none"> <li>▪ There is pressure to produce results and <i>published papers</i>.</li> </ul> <p style="text-align: center;"><i>“At some places your colleagues [clinicians] feel they are doing all the work and you are just sitting at a desk.”</i></p> <p style="text-align: center;"><i>“It is sort of interesting. In academia it is publish or perish.”</i></p>	<p>There is pressure to share the load of <i>patient care</i>.</p>
<ul style="list-style-type: none"> <li>▪ Successful investigative research requires innovative pursuits and a degree of <i>autonomy</i>.</li> </ul> <p style="text-align: center;"><i>“The approval process and layers of regulations are just overwhelming.”</i></p>	<p>Patient safety is critical, thus prompting the implementation of stifling <i>Bureaucratic and regulatory controls</i>.</p>
<ul style="list-style-type: none"> <li>▪ Your hours are manageable and should promote <i>work/life balance</i>.</li> </ul> <p style="text-align: center;"><i>“And, they are both researchers and yet they have families...”</i></p> <p style="text-align: center;"><i>“...while you are in the middle of writing a paper five patients call in seizing [having a seizure] and interruptions are frustrating.”</i></p>	<p>The unpredictability of patient care makes life <i>hectic</i>.</p>
<ul style="list-style-type: none"> <li>▪ You are pursuing a professional passion, with the promise of job <i>insecurity</i>.</li> </ul>	<p>You are pursuing a professional passion of working with patients. There is <i>security</i> in knowing that there will always be a need for doctors.</p>
<ul style="list-style-type: none"> <li>▪ You work across disciplines &amp; you become <i>knowledgeable across fields</i> – you are a “bridge.”</li> </ul>	<p>You are an <i>expert</i> in a particular field of study.</p>

## B. K 23 Awards Program

Nearly all of the respondents that were present were K 23 awardees although a few indicated that they have transitioned their 3-year CAP awards to K 23 awards. They overwhelmingly agreed that the award program is a great “jump-start” to their careers as investigators due to the funding, mentoring, and interdisciplinary collaboration. The award also provides proof that researchers are committed to a career in clinical research.

*“It’s a bridge between someone who could not function as an independent investigator and hopefully will be functioning as an independent investigator.”*

*“You can use this program as a career development program. It is not a program designed particularly as your research project. That is what makes it nice is that a substantial portion of it is supposed to be directed at working epidemiology, statistics and training in IRB, and learning the ethics of clinical trials and that is really what makes a difference.”*

*“It’s been extremely helpful...in really marking the difference between being a fellow and beginning on my own...as a researcher.”*

*“When I started out I did six or seven clinics a week and I attended for three months [while] trying to do clinical research, writing my grants on nights and weekends and you just get burned out and then you make a lot of mistakes.”*

*“At some point I want to increase my clinical again, but not until I am a better clinical researcher. I need this time to focus on that.”*

## 1. K 23/CAP Award

Respondents discussed an array of issues associated with the K 23 award. They noted that the benefits far outweigh the drawbacks.

K 23 Award Program	
Benefits	Drawbacks
<ul style="list-style-type: none"> <li>◆ Mandates protected time.</li> <li>◆ Salary support creates independence; the award is even transportable.</li> <li>◆ Long-term funding promotes greater professional development, ensures employment and thereby creates a sense of security.</li> <li>◆ Legitimizes the researcher.</li> <li>◆ Jump-starts a career.</li> <li>◆ Allows time to study with emphasis on interdisciplinary exposure.</li> <li>◆ “Space” to round-out clinical training with development as a scientist.</li> </ul>	<ul style="list-style-type: none"> <li>◆ Restricting clinical time to 25% is a struggle.</li> <li>◆ \$25,000 does not cover the cost of large research projects.</li> <li>◆ The mentor/mentee component could set the mentee up to be used as “free labor.”</li> <li>◆ Need supplemental sources of funding for:               <ul style="list-style-type: none"> <li>- Administrative support</li> <li>- Unexpected project expenses</li> </ul> </li> <li>◆ The 75% support prevents awardees from applying for other federal grants.</li> </ul>

## 2. R01 Grant (Traditional Research Project Grant)

Only a few of the respondents have applied for an R01 at this juncture, and the others noted that it is too early in their K 23 award program to successfully compete. However, most of the respondents fully expect to make an R01 submission at a later date.

Several respondents articulated that obtaining an R01 is a specific professional goal because it is considered a tremendous mark of success when pursuing a career in clinical research and establishing ones’ self as an independent investigator. For most respondents, the K 23 award allows them the “space” to obtain the training and research experience needed to successfully apply for an R01.

*“The K 23 is junior high school. The R01 is high school.”*

*“I think this is training to help you get to a better level where you are sufficient to be on your own.”*

### **3. Interdisciplinary Nature of Clinical Research**

Many of the respondents commented that there is professional tension among the various scientific and medical professionals within their institutions. They explained that the lack of understanding or common language across fields of study might cause this tension. The general feeling is that clinical research, with the support of the K 23 award, provides a vehicle to bridge medical fields and allows recipients to engage colleagues from different disciplines. Consequently, they indicated that their interdisciplinary experiences have been positive.

*“I think that it is pretty safe to say it is a big plus. The fact that you get this type of training that you may not have had coming in.”*

*“As a part of this K award I am actually getting a degree in clinical epidemiology and we have a center, which is a very multidisciplinary group, so I have actually geneticists that are actually interested in genetic epidemiology, cardiologists, neurologists, pediatricians all in one group. So that has helped me quite a bit in meeting people in other basic sciences or from other parts of the university in the medical center and foster those relationships. So it has been very good.”*

### **4. Career Expectations and Development**

A few respondents indicated that in order to be promoted within an academic hospital, a K 23 award is essential. Their institutions view these awards as validation of not only the study, but the viability of the researcher as well.

*“If you don’t have a grant from NIH you are not going to get promoted. It is another of those unwritten rules that are out there that are important for your career development...by the nature of this award it helps to identify you as somebody that is working on things that make the department heads want you to stay around.”*

## C. Mentor Relationship

On an unaided basis, respondents agree that having a mentor is key to becoming a successful clinical researcher. In fact, for many it is the most important determinant. Mentors provide direction, professional contacts, resources, and research and field knowledge in order to mold the next generation of clinical researchers.

*“I think it is critical for people who are trying to find a mentor that you have to look at their track record because clearly there are people out there who are well-respected clinical researchers and are far along in their career and could be good mentors. If you look at the track record of people who have been mentee’s and none of them have done academics....”*

*“I hear so many horror stories of people in the process who would easily get a K 23 and have great ideas and are very talented and dedicated except their mentor is a jerk and they are stuck in a way. The person I mentioned that is going to come over to our department won a \$40,000 fellowship from medical school and then his mentor was so ticked off about it...he said, ‘I am sorry, you really can’t have access to my data.’ So, this person who won a very prestigious award, his mentor basically fired him for getting the award and I think that is about as extreme a story as you can have.”*

## 1. Qualities of a Mentor

Respondents were asked to rate their mentors using a set of characteristics outlined in a publication by Judith Swazey and Melissa Anderson. The following two charts are a compilation of their responses and the bolded characteristics indicate the attributes respondents felt are most essential for a strong mentor. [NOTE: Not all respondents responded to each mentor characteristic.]

<b>Has your mentor:</b>			
	<b>Yes</b>	<b>No</b>	<b>Comments</b>
Taught cognitive knowledge and skills	<b>26</b>	<b>2</b>	
Impress professional values and ethical preparedness	<b>28</b>	<b>1</b>	
Provided advice, encouragement, and criticism	<b>27</b>	<b>1</b>	
Facilitated learning appropriate risk-taking behavior	<b>20</b>	<b>2</b>	Some respondents were unsure of what this meant.
Strengthened communication, professional, and institutional skills	<b>25</b>	<b>3</b>	
Fostered involvement in research and scholarly activity	<b>26</b>	<b>2</b>	<i>"Give a lot of independence."</i>
Facilitated entry into initial career positions and advancement	<b>23</b>	<b>5</b>	<i>"This was particularly difficult, but less support for this provided than I desired."</i>
Provided links to scientific/scholarly societies	<b>21</b>	<b>6</b>	<i>"Doesn't belong to any, but links to internet groups, journal clubs, educational committees, etc." "Looked out for contract positions in department." "Encourage joining AMFR/GCRC Scholar program."</i>

<b>Is your mentor:</b>			
	<b>Yes</b>	<b>No</b>	<b>Comments</b>
Available and accessible in terms of time and commitment	<b>24</b>	<b>2</b>	<i>“Very busy, but still makes time.” “Anytime.”</i>
A substantive contributor to the literature	<b>27</b>	<b>0</b>	<i>“Always has been.”</i>
More generative than narcissistic	<b>26</b>	<b>1</b>	
Self-confident	<b>26</b>	<b>1</b>	
Open	<b>27</b>	<b>0</b>	
Patient	<b>25</b>	<b>1</b>	<i>“Most of the time.”</i>
Mature	<b>27</b>	<b>0</b>	
Overprotective	<b>5</b>	<b>21</b>	<i>“Looks out for my interests strongly, but not overprotective.” “Have 2 mentor’s, 1 can be little controlling but not overly so.”</i>
Too controlling	<b>0</b>	<b>23</b>	<i>“Demanding, not necessarily too controlling.” “Criticisms usually harsh, but on target.” “Mentor requires tasks to be performed in certain manner ‘his personal style’. If these tasks are performed in a different manner he may consider the performance ‘not up to par’, but I think the job is adequate, just performed in a different style.”</i>
Harshly critical	<b>0</b>	<b>24</b>	
Manipulative	<b>1</b>	<b>25</b>	
Exploitative	<b>1</b>	<b>25</b>	

With a few exceptions, respondents were pleased with the level of mentoring that they are currently receiving.

*“[It is a] challenge having a world renowned basic scientist (essentially) as a mentor for clinical investigation—overall it has gone very well.”*

*“Foremost [my mentor is], a magnificent teacher and fosters independence, gradually and with adequate support.”*

*“I was lucky enough to have a wonderful mentor. Not the one on my K 23, who is listed more for scientific reasons.”*

*“Overall [my mentor is], well-connected to agencies critical to career development (coop group, FDA, NCI-CTEP).”*

*“[Mentor must] be a leader in the field.”*

*"[Mentor must have] familiarity and experience with funding sources. Experience and success with prior mentee's, lab group, and environmental organization."*

## **2. Mentorship**

Prior to applying for the K 23 award, many respondents indicated that they already had a mentor. However, several of them noted that they currently have more than one. They mentioned selecting a new mentor for the K 23 award program because of their clinical research capabilities or field of interest.

Respondents also spoke of the transition of their mentor/mentee relationship during the duration of their K 23 grant. The early period of the research program necessitates a teacher/student relationship. Overtime, the neophyte investigator becomes more established as a researcher and the relationship typically transitions to more of a collegial one. They stated that change is a natural progression to becoming a contributing clinical researcher and a necessary step in establishing themselves as an investigator.

*"I think I started out wanting more of a teacher, someone you can ask every question and then as it is evolving it is more like a partner. My mentor said to me that it seems funny to be called his mentor because he thinks of me more as a colleague. So, it is just the relationship changing in a good way."*

*"What actually happened over the three years that we have worked together is that we are actually collaborating and the relationship is collegial in this way, which is totally delightful to both of us. There are things I know that she does not know at all and there are things she knows that I do not know at all. We really need each other."*

*"You have to have a project [aside from your mentor's project]. You have to have different skills, especially if you want to be in the same institution."*

Since the award, many of the respondents mentioned that, in some ways, their role has shifted from mentee to mentor. Because the K 23 award is so new, many prospective researchers and medical institutions are not familiar with the process. As such, these respondents have become the “go to” person for the information needs of prospective researchers. Some respondents complained about the time infringement of this type of counseling, but the underlying tone was one of pride at being recognized as having accomplished some level of success.

*“I was invited by my department to explain to all the division heads what is a K award because they don’t have that on their radar.”*

*“Everybody is sent to me to talk about how you do it [K 23]. ”*

*“We should be the mentors for the next group or wave coming up and I think that’s part of it. You can go to them and say think about these things when you’re in that process because in retrospect I learned these things, but no one told me these things before.”*

## **D. Support from the Facility/Institution**

Respondents expressed the frustration that is involved in weeding through processes and regulations to conduct clinical research. They stated that their institutions do not have the commitment or infrastructures to deal with issues that arise as a result of practicing clinical researchers. In addition, the cost to conduct a clinical trial is prohibitive given the amount of the K 23 grant.

*“You go to a hospital administrator...and say ‘I want a bed for four days so I can do a clinical research project.’ They’ll laugh at you and say. ‘What are you nuts?’”*

### **1. Supporting Program Environment**

Most of the respondents indicated that their institutions are supportive on some level. However, the degree of support varies based on its experience with clinical researchers. Some institutions like the fact that clinical researchers bring in money in the form of grants and potentially could bring them notoriety as well. However, this conflicts with the hospitals direct mission and greatest source of revenue—patient care.

*“I think institutions--academic institutions--value research so highly that you really can’t be faculty unless you do it. And yet, you don’t get paid for doing it. The reason they like you is that you are bringing your own money.”*

The K 23-mandated “protected time” appears to be most vulnerable to infringement even with the most supportive program environments. This is the case because even with salary support, the very concept of “protected time” appears to work against the hospitals primary mission. Despite the fact that clinical research improves patient care in the long-term, the hospitals and institutions are focused on short-term patient care and revenue generation.

*“Other people that have grants that are being forced by a chairman to work more than 25%, were paid by the taxpayers to do this job and they’re breaking the rules.”*

*“I guarantee I do more than 25% outside and I think all the clinical researchers that I know of did more than 25%.”*

## **2. Clinical vs. Basic Research**

Respondents indicated that “basic research professionals” receive higher levels of funding and respect and also attain fewer patient-care expectations. They discussed that, by comparison, clinical researchers are treated like second-class citizens. A number of respondents indicated that some level of animosity exists between clinical researchers and basic researchers or full-time clinicians. According to respondents, this situation can be attributed to the following elements:

- More sources of funding are available to basic researchers
- There is a lack of understanding of the science of clinical research
- Basic scientists are not asked as frequently to trade off research time to care for patients

Clinical researchers seem to struggle to obtain professional respect within their field of study and among scientists. They stated that the basic scientists discount the degree of variability and complexity required to conduct clinical research.

*“You hear basic scientists complain that their study is ruined because their cells died. All they have to do is unfreeze some new cell samples and start again. They don’t understand the myriad of variables that clinical researchers must manage to successfully complete a study.”*

*“So if you think about why you are doing this, one of the key elements I think is, being established at a university or whatever academic type institution and getting respect from your peers for having done that.”*

The respondents discussed that clinical researchers are very involved with patients. As a result, the institution and fellow medical care professionals come to view them as a resource for clinical care, affecting their available time for research. Basic scientists do not regularly work with patients in the course of their research, excluding them from consideration in assuming more patient care responsibility.

*“We often hear this sort of thing that they [basic researchers] are doing the real research.”*

*“My chairman says to me, “Your study is prospective, longitudinal and you’re not going to have data for years. What are you going to do in the meantime.”*

## **E. K 23 – The Ideal Program – Building a Successful Clinical Research Award Workforce**

### **1. Policy Concerns to be Addressed by NIH**

Respondents addressed the broad question, “To assure a successful clinical research program what are the key policy issues that should be addressed?” There was a myriad of responses and several reoccurring themes.

- ◆ Provide and coordinate funding opportunities to maximize resources available to clinical researchers.
  - ➔ Infrastructure to support clinical research center
  - ➔ Available and trained personnel to support research
  - ➔ Funds for administrative support
  - ➔ Coordinate with other grants to maximize support
  - ➔ Supplemental funding source
  
- ◆ Formal research training
  - ➔ Statistics
  - ➔ Epidemiology
  - ➔ Study design
  - ➔ Ethics and regulatory issues
  
- ◆ Protected time compliance
  
- ◆ Promote successful mentoring
  - ➔ Identify strong mentor candidates at institutions
  
- ◆ Improve the proposal review process
  - ➔ Faster review and responses
  
- ◆ Conduct “how to” workshops

- ◆ Separate review conducted by other clinical researchers
- ◆ Clinical research public relations effort
  - ➔ Develop clinical research as a distinct discipline
  - ➔ Insure that institutions have relevant information regarding programs to support clinical research
  - ➔ Develop clearer instructions on the website
- ◆ Commensurate with funding for basic scientists

## **2. Elements of the Ideal Plan**

Respondents were very clear that they appreciate the opportunities that the K 23 award provides. However, they offered suggestions to improve the award itself and the process for obtaining it. The recommendations for improvements fell into the following three categories:

- ◆ Awareness/Advocacy—pre-application concerns, e.g. sources of information
- ◆ Program Support/Enhancement—issues regarding the actual program
- ◆ Career Development—post K 23 funding

The following chart provides more detail about their recommendations.

**Elements of the Ideal Plan**

<u><b>Awareness/Advocacy</b></u>	<u><b>Program Support/Enhancement</b></u>	<u><b>Career Development</b></u>
<ul style="list-style-type: none"> <li>○ NIH Contact</li> <li>○ NIH updated forms and website</li> </ul>	<ul style="list-style-type: none"> <li>○ Separate Review Process for Clinical Research Proposals</li> <li>○ Central formalized course on Clinical Trials Regulations</li> <li>○ Decrease 75% Effort to 50%</li> <li>○ Make sure of Institutional Compliance</li> <li>○ Medical School loan payback</li> <li>○ Formalized evaluation of mentor &amp; Institution</li> <li>○ Increased Awareness/Support of Clinical Research</li> <li>○ Introduce Clinical Research in Residency or Medical School</li> <li>○ Administrative funding               <ul style="list-style-type: none"> <li>- Indirect costs limit</li> <li>- Trial costs</li> <li>- Supplemental funds</li> <li>- Other federal salary</li> </ul> </li> <li>○ K-Award Meetings</li> </ul>	<ul style="list-style-type: none"> <li>○ Continued/Increased Support of K30 Program</li> <li>○ Develop a game plan for after K 23 reviewed by clinical researchers</li> </ul>

*“...I wanted [clinical research] to become my life’s work of personal satisfaction and affecting the lives of others, and the knowledge of others, and the well-being of others.”*

## **IV. SUMMARY**

The study objectives were met in that The Association of American Medical Colleges and The National Institutes of Health gained insight into the perceptions, opinions, beliefs, and attitudes (POBAs) of applicants and grantees of the K 23 award program. The main objectives were to understand:

- How the K 23 award fits in with the clinical research career development plans and interests of awardees
- The quality of mentorship to the K 23 awardees
- Adequacy of institutional facilities and support, including commitment to protected time for research for awardees
- Adequacy of K 23 support for research
- Awardee plans for the future

The AAMC and the NIH will use the understanding gained from this study for short and long-term strategic planning. RIVA Market Research is pleased to serve as the research supplier for this qualitative study.