

# **NARAP**

# **National Alliance of Research Associates Programs**

# Hospital, Emergency Department Chairs and Potential Program Directors' Frequently Asked Questions

Thank you for your interest in NARAP!

One of the advantages of working with such a diverse group of researchers, administrators and educators as you will find in NARAP are the great questions that come up. Even after more than 20 years of experience setting up RA programs across the country, we continue to learn from those thinking about joining us as well as all those already part of the organization.CQI at its best!

Here are some of the most common questions we get. The answers I pose are based on the NARAP's current structure and the model program at St. Vincent's Medical Center in Bridgeport, CT. We expect the answers to these and newer questions will change as multi-center experience evolves the model.

#### The Basics

How does NARAP help start and maintain RA Programs? What is the relationship between NARAP and its Affiliates' RA Programs? How much does it cost to be a NARAP Affiliate?

#### Program Management

Who should be RA Program Directors? How much time will be required from the Directors of RA Programs? Who supervises the RAs on shift?

#### Line-RAs

What are the qualifications for a student to be a Line-RA? How are they selected?

Are Line-RAs medical students?

How are Line-Line-RAs recruited?

How are Line-RAs credentialed into the hospital?

How are Line-RAs trained?

How much does it cost to be a Line-RA?

What kinds of problems arise with Line-RAs?

#### Chief Research Associates

How are Chief RAs recruited and selected? What are the Chief RAs' roles and responsibilities? How are the Chief RAs trained?

#### Money

Are the Line-RAs paid?
How are the Chief RAs compensated?
Are the Program Directors compensated for participating in NARAP?

Does a Research Associates Program really cost **NO** money? How does NARAP support itself financially?

#### Legal

Do hospitals join NARAP as "member" institutions? What about HIPAA and other similar hospital requirements?

#### Research

Do RAs enroll participants in studies by themselves? How do RAs fit into the mission and research interests of a Department of Emergency Medicine? How does NARAP fit into the interests of a Department of Emergency Medicine? What about community hospitals without current research interests?

# The Basics

# How does NARAP help start and maintain RA programs?

Refined with over twenty-plus years of experience, NARAP brings its model for the development or expansion of other RA Programs. We've worked hard to invent the wheel, making and correcting a myriad of mistakes and missteps. Let us help you jumpstart your RA Program more efficiently and avoid the pitfalls. Join together in an organization where you can share in the collective wisdom of top-notch researchers and other Program Directors.

This starts with direct contact with Dr. Keith Bradley, MD, CEO/CMO of NARAP. He will guide you through the process of starting your program.

After initial discussion indicating a presumption to move forward, a three-day site visit is best to include discussions with hospital and department administrators, physicians and nurses and health professions advisers from local colleges and universities. This culminates in a Grand Rounds presentation on the new RA Program.

Recognizing this is the 21<sup>st</sup> century, such sessions via conference calls and screen sharing are a reasonable alternative. This same mechanism is used for scheduled Program Directors and Chief RAs meetings to share problems, collaborate on solutions and promote beast practices.

There are NARAP Chief RAs for Communications and Database Management that work with the Chief RAs of the NARAP Affiliates in these areas. Dr. Bradley and members of the NARAP team welcome requests for any assistance they can provide for Affiliate RA Programs to succeed.

On its password-protected portion of this site, NARAP will share with Program Directors the process of starting their programs through a series of manuals and webinars. There are trainings for Chief RAs and Line RAs.

Templates for shift evaluations and letters of evaluation are available.

NARAP and its Affiliates are synergistic partners with the same goal of expanding great clinical research while minimizing costs. Improvements and success for each Affiliate and for NARAP as a whole is to the benefit of all. A rising tide brings up all ships.

# What is the relationship between NARAP and its Affiliates' RA Programs?

Each RA Program is under the sole control of its Affiliate hospital. NARAP is there to consult, assist, guide, help the Affiliate programs, but does not direct or manage them in anyway. NARAP provides the model; the Affiliate RA Programs implement the model as they see fit. However, this is a model that has twenty plus years of experience behind it. Affiliates join NARAP to take advantage from the model. Recognizing modifications of the model are needed to fit local circumstances, the experience has been that the closer a RA Program follows the model, the greater the chance for success.

We request that if a Program is going to do something significantly outside the model that they let us know. Maybe it is a terrific idea that NARAP will share with all the Affiliates so they too may benefit. Maybe it is something that has already been tried and not succeeded and the Affiliate may want to reconsider. Ultimately, the Affiliate may do as they choose. We only ask that they report to NARAP on its success or problems.

# How much does it cost to be a NARAP Affiliate?

Nothing.

No money ever changes hands between NARAP and its Affiliates for NARAP's services.

All NARAP asks from its Affiliates are letters of support for our grant applications. We have to sing for our supper with our Affiliates providing the choir!

If an Affiliate submits a proposal for a national, multi-center study, NARAP must be included in all grant requests.

Affiliates are asked to cover expenses for any site visits.

# **Program Management**

# Who should be RA Program Directors?

Among RA Programs at NARAP Affiliates, there are MDs, DOs, RNs, PAs and research managers who are Program Directors. Much more than the initials after the name, it is the skills they bring to the position that are most important. Qualifications should include vision for the value of a RA program to facilitate research and to advance their career goals, enthusiasm for the job, excellent teaching abilities and good management skills.

While quite often this is the Research Director in academic programs, there are a number of other people who might particularly benefit from the position. If they are without a particular career interest, a senior resident, fellow or junior faculty at the beginning of their careers could find this job particularly advantageous. As the one providing RAs to facilitate the research in their emergency department, a Program Director has to have intimate involvement in a study from initiation through publication, most often to the level of authorship. What a way to kick start a research career!

# How much time will be required from the Director of RA Programs?

This is the most common question I've heard from those considering the development of a RA Program. We are all incredibly busy and the thought of adding "one more little thing" is daunting. The model we have developed specifically looks to minimize physician time and resources while maximizing the potential of the Program at each NARAP institution.

Key to this is the Chief RAs, the post-bacs who work about twenty (20) hours per week for the Program. They do the "grunt work" of day-to-day operations for the program, such as scheduling, checking in with the line RAs each week, assessing the data base and research materials for issues, inputting data for the template letters of evaluation, and taking first call 24/7 for RA problems or concerns. On the longer range aspects of program development, the Chiefs also do the recruiting, website development and management, internal and external communications, and maintaining contact with the RAs' health professions advisers.

Separating out my full-time work as the NARAP Director, here is an accounting of the time I spend specifically as the Director of the RA Program at St. Vincent's:

- I meet with the Chiefs for two hours once a week to review their areas of responsibility (recruiting, personnel, communications, database management), to assess progress on tasks assigned from the previous week, and to make new task assignments.
- I give 2-3 talks per semester at the Training sessions. The Chiefs do most of the management of orientation and the teaching, while I supervise to make sure everything is going according to plan.
- The "management by walking around" that I do to randomly observe how RAs are doing is something that most Directors will incorporate as part of their observations of ED function while on their normal shifts.
- I spend about fifteen (15) minutes per RA letter of evaluation which are about 90% formatted with a description of their work and data from their performance over the semester, e.g., # approached, enrolled, late arrivals/early departures, etc, which the Chiefs' enter.
- There will be a monthly meeting of NARAP Program Directors via webinar to discuss study and program issues, but these will be kept to about half an hour.
- For those attending ACEP and/or SAEM national meetings, we will try and carve out some time for NARAP Directors to meet.

Of course, this does not include the time spent developing their own institution's studies, but a Director would need to do that whether or not they have a RA Program. Indeed Chief RAs and even line-RAs in the summer can do (and are usually eager to do) a great deal to help in study development. Literature searches, database development, IRB paperwork and protocol piloting are among the jobs RAs have done in our program to advance the research.

# Who supervises the RAs on shift in the ED.

That depends on their role in the studies during a given semester. For NARAP screening studies, the RAs function relatively autonomously, initiating the research on their own, moving from room to room looking to enroll as many patients and their visitors as possible.

For other studies, their role might be to simply identify potential participants and notify the researcher for the actual enrollment. Perhaps they are used to scribe the data into the database for the investigator. Here their research supervision would be much more direct.

With five Chief RAs, we suggest assigning them each to a weekday, with the weekends coverage split among them. Among their duties as Chief of the Day is to take call for any Line-RA issues or questions. Since they are required to be in the hospital at some time on their Day, Chiefs look to vary this so they meet up with their Line-RAs on a rotating basis.

First Participant, Mid- and End-of-Semester evaluations are direct supervision of RAs work by the Program Director or one of the Chiefs.

I take second-call after the Chiefs for issues they cannot handle. I get maybe two calls per semester on average.

Just as they are for everyone in the emergency department, the emergency physicians are the on-site supervisor. In the twenty-plus years of the RA Program, there has never been a personnel problem that the emergency physician has had to intervene.

At the beginning of their shifts, RAs identify an emergency physician who will fill out their shift evaluation. This check-off list is based on their casual observations of the RA throughout their four hours in the department.

# **Line RAs**

# What are the qualifications for a student to be a RA? How are they selected?

RAs must be bona fide students or graduates from a college or university with intent to explore the health professions as a career option.

We require an application which we use for tracking RA alumni and to get a handle on which schools are sending us candidates.

Medical schools with their extensive admissions processes have a hard time figuring out what to do with all the information they collect, including interviews. So, at SVMC, we don't even try. There are no academic requirements or test scores in the application process. On the assumption that they know them as well as anyone, we ask for a simple letter of support from the applicant's Health Professions Adviser stating they are a student at their school, are considering the health professions and are appropriate for the program.

We use the Date/Time stamp on their PayPal payment to determine which new RAs are eligible for the program in a given semester, their sequence on a wait list and the time/day of the week gives the order in which they will choose their shift.

# Are RAs medical students?

No, RAs are college students, "pre-meds," and those interested in a career in a wide variety of health professions. Compared to medical students, there are more of them and they have a greater need for clinical experience in addition to their school work.

#### How are Line-RAs recruited?

The heart of recruiting Line-RAs is word of mouth. RAs head back to the dorms after a shift and tell their roommates what a great time they had. In lab the next day, they tell their classmates how valuable the experience is for their discernment, qualification and development towards a career in the health professions ... or words to that effect! The ripple spreads across the pond from there.

Connections with the Health Professions Advisers at local colleges and universities are essential to the process. Communications with them about the dates of Training Day for upcoming semesters, particularly with advertisements from templates NARAP provides that they can post to their student email lists. A Chief RA is assigned as a liaison to each school to maintain this contact.

Speaking engagements at pre-med meetings are particularly helpful. While at the beginning the Program Director may want to do a few of these, ultimately this is a Chief RA function after proper training and initial observation.

All NARAP Affiliates should have a website. Social media sites are also helpful. Regular updates and newsletters can build enthusiasm. These areas are the responsibility of the Chief RA for Communication.

The NARAP website features links to the Affiliates' site. Given his status as an Emeritus Health Professions Adviser, Dr. Bradley has access to the listserve of the National Association of Advisers for the Health Professions (NAAHP) and posts announcements of opportunities at Affiliates at regular intervals.

# How are RAs credentialed into the hospital?

At St. Vincent's, we work with the volunteer office and get the RAs into the hospital through their already established process. The Chief responsible for recruiting in our program coordinates the applications of our RAs and shepherds them through the credentialing process.

I'm sure each hospital will have a separate procedure, but part of what the Chief RAs will do following their training with us is to work with the credentialing systems at their home institutions.

# How are RAs trained?

We recommend a four-step process:

- 1. On-line (access given on acceptance into the program)
  - a. NARAP didactics
    - i. how to be a good RA
    - ii. the science behind the current study
    - iii. how to enroll a participant in the current study
  - b. Ethics
    - i. confidentiality
    - ii. informed consent
  - c. Individual RA Program didactics
    - i. current studies
    - ii. required trainings for volunteers, such as safety, ED etiquette, etc.
  - d. Regulatory trainings
    - i. NIH research (http://phrp.nihtraining.com/users/login.php),
    - ii. HIPAA
- 2. Training Day (focused solely on practicing how to enroll participants in the study(s)
  - a. demonstration by the Chief RAs
  - b. group practice by Days
  - c. role-play practice
- 3. First Participant (supervised enrollment of participants until proficient)
- 4. Mid-Semester Forum
  - a. points of emphasis
  - b. feed-back from RAs

#### How much does it cost to be a RA?

At St. Vincent's, new RAs pay \$200 for the first semester. This includes all the requirements to serve as a volunteer (a Criminal Background Check, Drug Test, and Health Record Review for vaccinations), 2 uniform "Green Shirts" and a \$50 administrative fee.

If we had the funding, the volunteer fees would be the first to go. However, considering that a college textbook routinely costs \$200, our fee seems reasonable against that perspective.

Some NARAP Affiliates are able to absorb some or all of the costs.

#### What kinds of problems arise with RAs?

For the RA Program at St. Vincent's and its prior iterations there really have not been any significant problems or issues. With well over 50,000 participants enrolled in various studies, there has not been a single patient complaint.

The concern that RAs would be "in the way" has proven to be unfounded. Part of their training is that whenever a clinician walks into the room with an RA enrolling a participant, the RA is to preemptively ask< "Would you like me to step out?"

Rather the opposite is found more often. Staff appreciate having RAs around, particularly in providing another interaction that patients and their visitors appreciate as value added to their ED visit. Common questions I get during the inter-semester breaks are "Where are the Green Shirts? When are the RAs coming back?"

# **Chief Research Associates**

# How are Chief RAs recruited and selected?

Post-Bacs, those with a year or more between college and medical school are the largest growing segment of those applying to medical school. Whether they are graduating seniors or career-changers that have completed their college degrees, they have a year during which they are in the application cycle during which they can focus on building their professional résumé for medicine.

Ideal candidates for Chief RA positions have the same characteristics as successful medical school applicants ... plus. Chiefs need to have the academic credentials, grades and MCATs, and extracurricular background to get into medical school so they can focus their efforts on the RA Program. Since most Program Directors are at least a few years removed from the application process, judging these factors among Chief candidates may be difficult. In addition to having worked with thousands of RAs headed for medical school, Dr. Bradley was a Health Professions Adviser at a university for seven years and has remained active in pre-med affairs. He can advise Program Directors on this aspect of choosing their Chiefs.

Plus ... Chief RAs need to have the interpersonal skills to be good teachers and role-models for the Line-RAs. They need to have public speaking abilities to give recruiting talks at local colleges. The particular responsibilities assigned to individual Chiefs require their own competencies. For example, the Chief for Database needs significant computer skills and the Chief for Communication should have excellent writing abilities. Most importantly, Chiefs should be enthused with the prospects of clinical research, see the unique opportunity the position has for their career building and the work ethic to handle the various commitments that their year as a Chief will bring.

Recruiting and selecting five Chief RAs is the initial key step in establishing a program. Once a hospital becomes a NARAP Affiliate, Dr. Bradley will announce the establishment of the RA Program there and place a recruiting notice for Chiefs on the list serve of the National Association of Advisers for the Health Professions (NAAHP).

Establishing relationships with the Health Professions Advisers at local colleges and universities will provide an important source of the first Chief RAs. This is particularly important for establishing that beyond between the RA Program and the primary source of Line-RAs, particularly during the fall and spring semesters.

After a few semesters, a Program is likely to find the majority of their Chief RAs from among those who have already served as Line-RAs.

# What are the Chief RAs' roles and responsibilities?

Chief RAs are the back-bone of a RA Program. Under the supervision of the Program Director, they are the middle-managers responsible for the tactical and day-to-day running of the program.

While all the Chiefs collaborate on the various aspects of the program, each has a primary area of focus: Recruiting, Personnel, Database, Communications and a Senior Chief.

Each also takes ownership as Chief of the Day for one of the days of the days of the week with weekends split among them. The Chief of the Day

- is on first-call by cell phone to the Line-RAs on that day
- comes into the hospital to take care of the administrative aspects of the program
- insures that the data collected on the previous day is checked and issues address
- is the primary liaison to the Program for those Line-RAs over the semester for any issues
- coordinates First Participant, Mid- and End-of-Semester evaluations for their Line-RAs

Chiefs are involved in all aspects of the research from initiation and design of a study, through IRB approval, Line RA training and daily study monitoring, through to data analysis, writing, presentation and publication of the results.

The Chief RAs begin their work in May and commit to their Program until they leave for medical school the following summer. In this way the outgoing Chiefs train the incoming Chiefs on their duties, thus providing continuity much like the transition in residencies.

# How are the Chief RAs trained?

The first Chief RAs for a program are a very special cohort in the life of that program. In addition to having key roles in initiating a program, they will also set the tone for future Chiefs. But, who sets the tone for this first group of Chiefs?

We recommend that the first class of Chief RAs from a new Program come to St. Vincent's Medical Center in Bridgeport, for a week-long Boot Camp alongside the incoming Chiefs in that model program. There they will:

- serve four shifts as Line RAs enrolling participants in the current NARAP national study, as their Line RAs will do in the following semesters
- trained in the Chief RA roles and responsibilities with didactic and practical work
- work with the other Chiefs from their institution to prepare the tools and practice the leadership functions so they are immediate ready to begin their Program's development when they return home.

There will be web-based national meetings among NARAP Chiefs throughout the year to identify and develop solutions for whatever issues may arise and to report on best practices.

After the first year, this is a "train the trainer" model with continuing NARAP assistance.

We recognize that not all Chief RAs have the time or resources to make such a one-week commitment, so we have streamlined the process to a series of on-line webinars and classes. Not ideal, but a workable substitute for the week in Connecticut.

We have found that NARAP Affiliates that have sent their Chiefs to the full week of training have often had a smoother initiation for their program.

# Money

#### Are Line-RAs paid?

Heaven forbid! The whole concept hinges on the Line-RAs' volunteering their four hours per week for something besides money. Their compensation is the clinical experience, participation in clinical research and a letter of evaluation on their performance.

# How are the Chief RAs compensated?

Just like line-RAs only more so. Look for them to build their career even further by working on other research and/or quality improvement projects to the point of authorship.

All of the Chief RAs in the RA Program at St. Vincent's have had full-time jobs or equivalent responsibilities.

With funding, I would suggest Chief RAs getting a stipend of the equivalent of ½ the average college graduates starting salary without benefits.

# Are Program Directors compensated for participating in NARAP?

No money changes hands between NARAP and Affiliates

However, the goal NARAP has for its Affiliates is for RAs to facilitate their in-house studies, especially those that are funded. We recommend that Line-RAs serve their shifts in pairs. The first RA does the NARAP study. Have the second RA do your funded study and when they're not doing the funded study have them do the NARAP study!

# Does a Research Associates Program really cost NO money?

Well okay, you've got me there. You do have to invest in at least two (2) laptop computers/tablets with internet access and maybe some donuts for each semester's Training Day, but that's it.

The Program Director's time is, of course, a "cost." Arranging for data collection is really a part of any clinical research. Without a RA Program, someone with that responsibility for the study would still be doing it and it certainly would cost a lot more money!

# How does NARAP support itself financially?

Ah, you've been talking with my wife again!

NARAP is a 501c3, non-profit organization that is funded through grants, donations, fund-raisers and sale of the "Green Shirts." Any support and referrals of people who might be interested in our work and our vision would be greatly appreciated.

From its Affiliates, NARAP asks for

- letters of support for our grant applications so NARAP can sing for our supper with our Affiliates providing the choir!
- to be used to support our grant applications, reports on
  - o studies being done utilizing RAs that are not part of a NARAP study
  - o numbers of RAs from each college per semester

o results of Chief RAs applications to health professional school

Also, if an Affiliate asks NARAP to participate with them in a national, multi-center study, NARAP must be included in all grant funding requests.

# Legal

# Do RA Programs join NARAP as "members"?

Hospitals are not "members" of NARAP, but rather are independent Affiliates.

# What about HIPAA and other similar hospital requirements?

HIPPA training and whatever other ethical and regulatory requirements NARAP Affiliate institutions have should be covered with on-line didactics available as soon as a prospective RA is accepted into the program and amplified at Training Day, as needed. Some of the preliminary work can be done as courses available from a number of sources on-line.

At St. Vincent's, we use the NIH research on-line course (<a href="http://phrp.nihtraining.com/users/login.php">http://phrp.nihtraining.com/users/login.php</a>), supplemented with a talk during Training and the hospital's HIPAA course.

# Research

# Do RAs enroll participants in studies by themselves?

RAs facilitate the research. They enroll participants under the responsibility of the study investigators.

Study design dictates the role RAs play in enrollment strategies.

The NARAP studies on the emergency department as a platform for public health screenings are designed for them to initiate and complete enrollments. Their characteristics for this include

- potential participant identification is very straight forward.
- research questions asked are very concrete with answer options generally from drop-down menus.
- RAs are not asked to make interpretations that require professional-level judgments
- questions are tightly scripted and read. RAs do not have to remember anything week to week.
- data collection through REDCap is controlled walking the RA through the protocol and not allowing them to proceed to a new question without recording an answer to the previous one

RAs are particularly good for "fly-on-the-wall" research in which they are asked to record times that events happen. For example, the SPEED ("Serving Patients Efficiently in the Emergency Department) study at St. Vincent's, RAs simply tapped the "T" key on the computer when the emergency physician introduced themselves to the patient, when they made the disposition decision, and when various tasks prior to discharge were done.

While RAs are not appropriate for more complex studies, they still can have a role in facilitating the research. They can assist by

- identifying potential participants
- informing the investigator
- gathering study material
- reading the informed consent so the investigator can concentrate on the participant's questions

- scribing for the investigator
- finding results of tests
- doing whatever an investigator thinks a smart, motivated individual can do to help accomplish the research

# How do RAs fit into the mission and research interests of a Department of Emergency Medicine?

Of course, RAs provide a very efficient and economical resource to get clinical research done in the emergency department. In addition, they

- open up opportunities for more interdepartmental studies that initiate in the emergency department
- continue facilitating primary care screenings based on the results of prior studies as value-added to the emergency visit.
- are informal ombudsmen and women providing another avenue of conversation for patients
- give the emergency physicians, nurses and staff the chance to influence by their words and actions those who will follow in their footsteps.
- are a source of community outreach, linkage with the local colleges and universities and positive media publicity.

And it doesn't cost any real money!

# How does NARAP fit into the interests of a Department of Emergency Medicine?

NARAP offers a model for how to set up and maintain a RA Program in an efficient and supportive manner.

#### **NARAP** Affiliates

- have a tool to get their research done with unprecedented numbers of participants and with minimum impact on clinical personnel and departmental resources
- are part of a network of similar programs that offers the opportunity for expanding their research to a national, multi-center level
- benefit from being key players and integral parts of NARAP's expansion toward its potential to transform how primary care screenings and other public health measures are implemented in the U.S. and how future health professionals are chosen.

And it doesn't cost any real money!

# What about community hospitals without current research interests?

Certainly, a RA Program could engender research interests and all that accompanies such an addition to all aspects of an emergency department.

In the near term, however, a RA Program can

- provide a community service through the NARAP studies on facilitating primary health care screening
- engender positive publicity from participation in national-level research
- fulfill public health requirements under the Affordable Care Act

A full discussion can be found at Community Hospitals.

And it doesn't cost any real money!