RESEARCH RESOURCE MANUAL

GUIDE for WRITING A PROPOSAL &

RESOURCES FOR INVESTIGATOR INITIATED RESEARCH

Greenville Health System

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1. Introduction and Welcome

Welcome to the world of research! We are very excited that you are interested in becoming engaged in research. Greenville Health System (GHS) would like to extend their support for your research endeavors and hope that the information in this manual assists your journey into clinical inquiry with relevant guidance tools.

This manual is a guide to some of the basics of the research process and information on negotiating the process for approval of research at GHS. We want to encourage all healthcare professionals to learn about research, build upon your academic preparation in research, and provide information on available resources.

There is a research mentoring group at GHS; Interprofessional Research Forum. For more information go to link: https://hsc.ghs.org/research/irf/ or send an email message to: researchforum@ghs.org

The Inter professional Research Forum (IRF) was formed to optimize scholarly activity by providing guidance and expertise for both beginner and advanced researchers engaged in all phases of the research process in an informal setting with access to multiple resources. This consultative group is a resource to assist collaboration for research at and with Greenville Health System.

There are resources for developing and conducting research online at GHS:
Online resources for Research:

Available on the ghs.org website under heading of Education and Research
https://hsc.ghs.org/research/resources/

Nursing services has developed a nursing research libguide that has many resources for all the steps in the research process and is available for use by any discipline.
Go to: https://ghs.libguides.com/Nursing

2. Getting Started in Research

The first step in getting started on your research is to define a research question. The acronym *PICO* will help you define the parameters of your research:

P The (sample) **POPULATION**

- Must be clear or will be difficult to determine what evidence in literature is pertinent to search and/or to use
- Consider factors such as: age, gender, setting where population found, group vs. individuals, do you have access to this population

I **INTERVENTION** or Treatment

- Be specific

- What is being studied? Examples: an action, phenomena that is occurring, an attitude or perception change, change in current way of doing something,..
- What would affect how your population would respond differently

C **COMPARED** to…..

- How your action or treatment is different from something that already exists?
- Begins to set up the design of your study for how your data will be meaningful

O **OUTCOME** of interest

- May be more than one outcome
- Helps you focus your evidence search
- Determines what you are ultimately trying to determine about your population

Plus……..

T Over what period of **Time**

- Can you complete data collection and finalize within a year? 2 years? months?
- Is it a pilot study over a short period of days, weeks..

Refer to **Appendix I** for a sample PICO Worksheet.

Another acronym that will help determine whether your research question is applicable is *FINER*. The elements of a good question can be defined as:

F = **Feasible**

I = **Interesting**

N = **Novel**

E = **Ethical**

R = **Relevant**

PICO Example:

- P ---- *Do Adult sedated patients in critical care unit who are randomly assigned into two groups*
- *I ----who have their feet placed in new heel protector/ contracture prevention device (Boot A)*
- *C ---- as compared with elevation of heels off the mattress on bed (no boot)*
- *O ---- have reduction in the incidence of stage 1 or 2 heel ulcers with the use of the new boot (A)*

3. Searching the Literature for Evidence

Conducting a literature search must be done in order to develop your research question and hypothesis. It helps identify what evidence and research is currently available, identifies where

gaps may be, and provides support or identifies the need for further research for nursing practice. While it may seem daunting, there are many resources available at GHS to simplify and aid this process. One of the most important resources to conduct a literature search is to contact the medical librarian. They are experts in this and are eager to assist staff. It's recommended to use a structured approach and keep good records.

Steps for a literature search:

1. **Identify your topic.**

Based upon your research question, search for your topic using key word search.

2. **Select additional key words or subject headings**

The medical librarian can advise you as to which subject headings to use for your particular topic or research question.
Identify key words to narrow down your search. Using the advance search option is very important in this step.
Example: You may use additional key words e.g. pain, bruising, injection time, subcutaneous injection, sub-q injection techniques, and other words relevant to the topic.

3. **Select a database to search.**

The GHS Health Sciences Library (library.ghsnet.ghs.org/) has a website with electronic databases (http://search.epnet.com) available inside GHS facilities. You can also refer to the resources listed in Appendix II. The most popular and comprehensive nursing database is CINAHL through EBSCO. Cochrane Database is also popular although some informative review articles are quite lengthy. Use the advanced search option and remember to use additional modifiers available on the search page e.g. evidence based practice (EBP), gender, age limiters, etc. The medical librarian can also be very helpful. Librarians can be reached at *library@ghs.org.*

4. **Obtain the articles.**

Articles that are not available in full text or PDF may be accessed by the medical librarians. Be sure to maintain an accurate reference on the articles you access to prevent duplication.

5. **Critique the articles.**

Once you have all the articles you need to read critique and rate the evidence level for each one. Critiquing the articles will help generate new knowledge related to your topic and help organize just what evidence is available.

4. Strength of Evidence

Rate the evidence- Evidence rating is important to let the reader know the strength of the evidence. The higher the level of evidence the stronger the research is to support the practice. An article that is a systematic review or meta-analysis is a higher or stronger level of evidence than an article that describes one single study. That's not to say that lower levels of evidence are not supportive of a practice, it is a way of grading the evidence that you have found. The design of the study and the end point measurements affect the strength of the evidence.

Types of evidence:

Systematic Review: This is the strongest level of evidence. Authors search and find all the research available on a particular topic, combine the research information, and create a single analysis.

Meta- Analysis: This is a type of systematic review that combines all the quantitative data from multiple studies. This method takes research with smaller sample sizes and combines it into a large sample population adding to the strength of the research.

Randomized controlled studies (RCT): These are experimental research studies where study participants are randomized into an experimental or control group over a period of time to study a variable or outcome. Study participants have equal chance of being assigned to a control or experimental group.

Quasi-experimental studies: This type of research study can involve groups exposed to a variable or outcome but there is no randomization, and is also research that seeks to clarify why events happen or examine causality.

Cohort Studies: Study that involves two groups of patients where one receives an exposure of interest and the other does not. These differ from RCT's in that there is not randomization and they are observational.

Case Control studies: These research studies are a descriptive report on patients with an outcome of interest. There are no controls or experimental groups and are usually include a small number of patients.

Descriptive research study: Describes results of a research study on a small number of patients where there is no randomization or experimental manipulation. These include quantitative research designs where numerical data is presented and also qualitative research designs which discuss the creation or generation of a theory.

5. Writing a Research Proposal

A Research Proposal is a well- organized, well thought out, well-constructed summary of the aspects of research answering all important details regarding the research.

A Research proposal is not a simple completion of a form or application with a few short sentences.

Components of a typical investigator initiated proposal:

A. Abstract or Brief Summary of the study
B. Aim of the study
    a. research questions
    b. hypotheses
C. Framework/ Theoretical knowledge
D. Review of Literature with critique and indicate level of evidence as applicable
E. Research Design with Methodology
F. Sample with inclusion and exclusion criteria
G. Consent and protection of human subjects
    a. Recruitment
H. Data Collection including description of instruments and validity & reliability of tools being used and include permission to use the tool(s) are copyrighted
    a. Data management to protect privacy and confidentiality

I. Data Analysis includes statistical methods to be used for quantitative methods and/or qualitative analysis methods
J. References should be current and most relevant evidence to support the research

A. The Abstract or Brief Summary of the Study is usually 100 to 250 words and fits on one page. When submitting to a publication, the editor may request an abstract or when submitting to a conference for an oral/podium or poster presentation, an abstract may be requested.

The abstract introduces the reader to the broad questions the study will address and the background information on why you are doing the research. It is not necessary to include an abstract in your submission to approve your study.

Refer to **Appendix III** Writing an Abstract

B. The **Aim** of the study addresses the problem to be addressed where there is a gap in knowledge, or the research question. The aim can be formatted as statements of the problem, research questions, or the hypothesis formed by the researcher.

- The **Research Question** integrates the problem/aim with the study design to include one or more variables.
  The acronym *PICO* outline for a question as indicated in previous section about "getting started in research," will help you define the parameters of your research:

- **Hypotheses** identify the variables to be manipulated such as in your PICO question and define the type of research and are predicative of the outcomes. Be as specific as possible in what you predict what your outcomes to be and how each outcome will be measured.

C. Framework identifies a concept, relationship, and/or theory that provide the basis for the study.

D. Review of Literature is very important because it helps you find out what information is available about your topic and support why your study is needed. The Literature Review will let you know early on in your research development stage, how much information is available and if the findings of the studies agree. Try to review studies similar in design and outcomes as your own potential study. As you conduct your review of literature, be aware of some key details that could limit the applicability of each article to cite in your study or use in development, such as sample size used, and the age of the study. Except for "landmark" studies, the research should be less than five years old or most current available in the literature and of highest evidence. You may choose to write separate literature reviews for each article, or you may synthesize similar articles. Can write the review in an evidence summary table if desired and more appropriate for your study. A

systematic or integrative review of the literature may be a good way to synthesize relevant studies.

E. Research Designs specifically outline the method used to answer the research question or achieve the aim, describes the setting in which the research will be conducted, and the methodology to be used.

Some select different types are:

1. Descriptive-describes new situations, events or concepts
2. Randomized controlled studies (RCT): study participants are randomized into an experimental or control group over a period of time to study a variable or outcome. Study participants have equal chance of being assigned to a control or experimental group.
3. Quasi-experimental-examines causal relationships or effects of one variable on another; frequently describe the type of study in a clinical setting
4. Correlational-examines the relationships concepts or ideas e.g. wine consumption and cholesterol level
5. Longitudinal-study something over a long period of time-Framingham Heart Study
6. Qualitative-used in behavioral and social sciences, helps themes emerge, helps develop theory
7. Cohort**:** involves two groups of participants, one receives an exposure of interest or intervention and the other does not. The groups are followed prospectively. There is no randomization.
8. Case Control: two existing groups with different outcomes are identified and compared with some identifiable causation. There are no controls or experimental groups and are usually include a small sample size. Can be used in rare disease situations.

F. Sample parameters of your research project help you answer the following questions:

- Who are the subjects you are going to include?
- Establish the inclusion or exclusion criteria for the sample and rationale?
- Who will you study, when will you study, where will you study them, and how long will you study them?
- How many do you intend to enroll in your study?
- May need to seek out statistician for assistance in determining adequate sample size to achieve power and effect

G. Consent

Follow the guidelines required by the organization's Office of Human Research Protection (OHRP) and referred to as the IRB. The IRB submission is electronic and called "eIRB". For more information about the OHRP office and the requirements at GHS go to: (http://university.ghs.org/research-protection/) . Policies and procedures are online and there is a specific section on informed consent. You will need to determine how you will obtain

consent or meet criteria to waive consent. There will be questions addressing this rationale in the eIRB submission.

H. Data Collection

Collecting Your Data

This section of your research addresses the details of how data will be collected, who will collect it, how will they collect, for how long will they collect, and where will they collect. You will also indicate in this section what tool will you use and how it rates for validity and reliability. You will also need to provide information on how you will assure confidentiality of the data and where will the data be stored. Your proposal must include a copy of the data collection tool(s), data collection sheet with all data identified or a case report form.

GHS has REDCap ™ available as data collection software. For more information go to: https://redcap.ghs.org/

1. Use of Data and Private Health Information (PHI).

GHS has policies and procedures for obtaining and using data. The release of protected health information is subject to stringent regulation and protections. Those regulations require that adequate safe guards be in place to prevent the intentional or un-intentional disclosure of information to parties who should not have access to that data. They are applicable to data which contains Protected Health Information and there are 18 identifiers that must be considered in your IRB application if being used to collect data.

2. Any data set that will be used for public presentation (oral, poster, video, etc. in any setting local, educational, national, college or otherwise) or submission for publication is considered research and must be submitted for IRB approval. In addition all releases of data sets from GHS sources for research purposes may be subject to including a data use agreement or data sharing agreement

3. Using Tools and Instruments

As a researcher, **you don't want to develop your own instruments**. You need to utilize instruments that have been tested and used in other studies. Only use tools that have been tested for A. *validity* and B. *reliabilit*y. Look for articles describing the psychometric testing done in the development of a tool such as a questionnaire or survey.

A. **Validity** - does it measure what it is supposed to measure without bias?

Measurements of Validity:

1. **Construct** validity – most Important level –Items are designed to measure a specifically defined domain through a scientific process.
2. **Criterion** validity – ***concurrent*** - how well does the measure relate to other manifestations of the construct and does it ***predict*** performance?

3. **Convergent** validity – are results of this tool similar to other tests?
4. **Discriminant** validity – does it measure what it is not supposed to measure, in other words, does it *discriminate?*
5. **Face** validity---lowest level - as the name suggests, is a measure of how representative a research project is 'at face value,' and whether it appears to be a good project.

B. **Reliability** answers to what extent a test is *repeatable* with consistent scores. Reliability estimates determine how much variability in scores is due to measurement error or due to variability in true score. This is known as internal consistency. For example: if you give the same instrument to a group of individuals at two different times, are their responses the same if there has not been any intervention or event that would change their responses.

Search the literature for psychometric testing used in development and in application of the research instrument/tool.

Internal consistency is commonly measured by Cronbach's Alpha. Cronbach's alpha is a statistic that measures how well a set of variables or items measures a single, one-dimensional latent aspect of individuals. The statistical reliability is said to be low if you measure a certain level of control at one point and a significantly different value when you perform the experiment at another time. However, if the reliability is low, this means that the experiment that you have performed is difficult to be reproduced with similar results then the validity of the experiment decreases.
Guidelines for reliability as noted in reporting Cronbach's alpha scores:
.90 high reliability
.80 moderate reliability
.70 low reliability

Review the diagrams below to better understand simple validity and reliability.

An internet site addressing validity and reliability is: https://explorable.com/validity-and-reliability

Other considerations about tools

- Length- is it feasible to ask participants to take the amount of time needed to complete the tool; if too long, participants may not complete the tool
- Complexity- consider the literacy, applicability and ease of use
- Relevance to your question- is it the appropriate tool; is there evidence to support what this tool is aimed at measuring
- Sensitivity to change

Permission to use a tool/instrument for research

Determine who "owns" the tool. If the instrument is copyrighted you will need to contact the author or copyright holder for permission to use the tool. Authors generally are eager for other researchers to use their tool. Ask the author for any accompanying information about tool, validity/reliability, and how to score it.
If the tool is published and is outlined or formatted to view as a complete instrument, it generally becomes property of the publisher unless otherwise indicated. Contact the editor of the journal or book to obtain permission. If unsure, contact the editor of the journal. You may find complete information about the research instrument via Google Scholar and information about obtaining permission or possibly any expenses for use of the tool defined by the author. Determine if the tool is copyrighted and would have" ©" in citation of the tool. You must include permission to use the tool in your proposal. Describe in detail in the narrative how you obtained permission. Include letter(s) received, and/or email(s) received as evidence of permission in the submission of your proposal for approval.

Be sure to include information that it is "*used with permission of…….. "* or name of who owns the tool. The author or copyright holder may provide specific wording that must be used when citing the tool.
Always obtain information about scoring of the tool which is key to being able to analyze the tool results.

Include information about instruments in the design/ methods section of the proposal:

- Describe your instrument objectively
- Describe reliability of the instrument and state the statistical information
- Describe the validity of the instrument and supporting statistics
- Describe how the instrument will be used
- Indicate permission to use the tool and how obtained and include documentation of how permission obtained (email, letter)

I. Data Analysis

Statistical analysis will depend on what type of study used for your research. Contact a biostatistician for assistance as early as possible in developing and in planning for the analysis of your data. It will important to discuss with a statistician how to collect your data, set up of a spreadsheet for the data, and whether you are using a data collection program, such as

REDCap™. If you are a student doing a research study, you will be directed to consult with your school faculty for assistance with statistics.

Data Analysis Example:

- *Student's t-test will be used to determine if there is a statistically significant difference between NK function in women with depressive symptoms, compared to age and gender of matched control subjects.*

J. References

Include a listing of references cited in the proposal using APA format unless directed otherwise. References should be 5 years old or less, unless there has not been more current high level of evidence reported about your topic. Use APA format unless otherwise indicated. If you plan to publish your study, you may want to determine what the editor of the proposed journal/publication requires for the style for formatting of references.
Be sure to include internet references.

7. Training Requirements (CITI)

You and your co-investigators will be required to complete Collaborative Institutional Training Initiative (CITI) training which is required by the GHS OHRP/ IRB. If you register using your GHS sign on, then in your IRB submission the information about your CITI training will automatically be included. Also, there is an option to download copies of CITI Certificates if needed and for any investigators not affiliated with GHS. Be sure to start the CITI training as soon as possible since there are several modules required.
For further Information about CITI go to:
https://hsc.ghs.org/research/research-protection/citi-research-training/

CITI training must updated every three years to be current at GHS. Refresher courses are available through CITI, if your initial training is current.

8. Defining research and projects

Human Research is any ***research*** or ***clinical investigation*** that involves ***human subjects.*** A subject may either be a healthy individual (healthcare staff, visitor,) or a patient. These criteria may apply to a research study, quality improvement project or evidence based project.

DHHS regulations define ***research*** as a ***systematic investigation***, including research development, testing and evaluation, designed to ***develop or contribute to generalizable knowledge*** (45 CFR 46.102(d)).

Systematic Investigation:

- A ***systematic investigation*** is an activity that involves preplanned data collection (quantitative or qualitative, retrospective or prospective) and data analysis to answer a question.

- Activities are not research if they *do not* involve a systematic approach involving a predetermined method for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory.

- Examples of activities that typically ***are*** systematic investigations:
    - Medical chart review
    - Analysis of data and specimens
    - Surveys and questionnaires
    - Interviews and focus groups
    - Observational studies
    - Epidemiological studies
    - Social or educational program evaluations
    - Cognitive and perceptual experiments
    - Test development

Generalizable Knowledge:

- Activities designed (with intent) to ***develop or contribute to generalizable knowledge*** are those designed to draw general conclusions, inform policy, or generalize finding beyond a single individual or an internal program (e.g., publication or presentation).

IMPORTANT NOTE: The ***intent*** to develop or contribute to generalizable knowledge makes an activity research. Results do not have to be published or presented to qualify the activity as research.

9. Institutional Review Approval at GHS

The Office of Human Research Protection (OHRP) is the support structure for the Institutional Review Committees at GHS. If you are conducting research, IRB approval is required. For projects, other than research (quality improvement, evidence based) and you are collecting information from living individuals, conducting retrospective medical record reviews, extracting data from databases using any identifiers, or using proprietary data of GHS, IRB approval is required. The types or reviews are: full committee, expedited or exempt. For exempt review, you still must submit an application to the IRB who will determine whether the study/project meets exempt criteria or other level of review, the investigator cannot predetermine on their own that a study is exempt. The office works with investigators to protect the rights and welfare of research participants. Staff pre-reviews submissions to the Institutional Review Committees, providing feedback, consultation, and interpretation of applicable regulations.

The Institutional Review Committee oversees a varied, high-volume body of research. You can find more information and the necessary forms at: http://university.ghs.org/research-protection/. Any questions regarding specifics of the IRB submission need to be directed to an IRB coordinator. Scientific review is required as a pre-review and signed form by the appropriate Vice Chair must be downloaded in your eIRB submission. If you are obtaining informed signed consent you must use the GHS IRB consent template and have the IRB coordinator pre review your consent.

10. Research and Grant Resources at GHS

The Office of Sponsored Programs (OSP) assists with efforts at GHS to seek outside funding for research, including all pre-award activities and post-award management. The office disseminates information concerning appropriate funding opportunities, offering guidance on the development and submission of proposals, and in the negotiation and award of grants and contracts. All grant submissions involving GHS as primary award for sub award, must be coordinated through the OSP office.

In addition, the office provides assistance in managing various administrative issues arising from extramurally-funded research. Serving as the primary liaison between GHS and outside sponsors, the Office of Sponsored Programs ensures accountability and adherence to the standards of external funding entities, and compliance with federal and state guidelines as well as GHS fiscal policies. It is the central administrative office responsible for submitting proposals and coordinating the acceptance of awards on behalf of GHS.

The GHS Office of Sponsored Programs is managed through a partnership with the Office of Sponsored Programs at Clemson University. Explore guidelines and resources at: http://university.ghs.org/grants/

Appendix I

PICOT Question Worksheet

Evidence Based Practice Project
Implementation Process Worksheet
Step 1 Begin with – what is your clinical question?

P - Population – *who*

_____

_____

I - Intervention, treatment - *how & what*

_____

_____

C - Compared to – *why*

_____

_____

O - Outcome of Interest [what do you expect]

_____

_____

T - over what period of time

_____

Appendix II

Evidence-Based Resource List

Loretta Westcott, ML
Health Sciences Library
Greenville Hospital System University Medical Center
(864) 455-8938 or lwestcott@ghs.org

Databases:

Cochrane Database of Systematic Reviews

http://search.epnet.com **username=greenville** **password=library**

The Cochrane Database of Systematic Reviews contains full-text articles and protocols focusing on the effects of healthcare. Cochrane includes or excludes studies on the basis of stringent quality criteria to minimize bias. Data is often combined using meta-analysis to increase the power of findings. References and abstracts to Cochrane Reviews can be found on their website (with limited full-text) or through PubMed.

CINAHL plus with full-text

http://search.epnet.com **username=greenville** **password=library**

CINAHL Plus® with Full Text is a robust collection of full text for nursing & allied health journals, providing full text for more than 770 journals indexed in CINAHL®. This authoritative file contains full text for many of the most used journals in the CINAHL index, with no embargo. CINAHL Plus with Full Text is the core research tool for all areas of nursing and allied health literature. Full text coverage dates back to 1937.

EBSCO Medline

http://search.epnet.com **username=greenville** **password=library**

Medline, developed by the National Library of Medicine, contains bibliographic references, abstracts, and limited full-text information drawn from life sciences literature. Nearly 5,000 journals are represented with more than 28 million records across healthcare disciplines. Through special features such as "EBM Reviews" searches can be focused to include guidelines, clinical trials, and systematic reviews.

National Guideline Clearinghouse (NGC)

http://www.ngc.gov

The National Guideline Clearinghouse offers free online access to evidence-based clinical practice guidelines. Guidelines must be produced under the auspices of a relevant professional organization. Updated weekly, the NGC is produced by AHRQ and contains:

- Summaries about each guideline and its development
- A utility for side-by-side comparisons of the attributes of 2 or more guidelines
- Links to full-text guidelines

Other Web Resources:

Agency for Health Care Policy and Research (AHRQ)

http://www.ahrq.gov

Established by the U.S. Congress, AHRQ "sponsors and conducts research that provides evidence-based information on healthcare outcomes." Full-text documents on evidence reports and technical methods papers produced by the associated Evidence-based Practice Centers are available at no cost. AHRQ sponsors the National Guideline Clearinghouse.

Zynx Health – Zynx Evidence

https://www.zynx.com/reference/default.aspx

The Zynx Evidence portion of Zynx Health provides evidence-based clinical content and best practice guidance for health professionals in the hospital setting. Modules within Zynx Evidence address clinical conditions, procedures, and patient problems.

Journals:

Worldviews on Evidence-Based Nursing

Worldviews on Evidence-Based Nursing is a peer-reviewed journal from Sigma Theta Tau, Nursing Honor Society, and Blackwell Publishing. This journal features:

- Article summaries with best practice applications and recommendations for clinical practice
- Original articles and features that present research, to develop the knowledge base about evidence-based nursing

Knowledge Resources:

American Nurses Association (ANA) Research Toolkit

http://nursingworld.org/Research-Toolkit

"ANA has developed a Research Toolkit to help you provide evidence-based care that promotes quality health outcomes for individuals, families, communities and health care systems. The Toolkit can also assist you in shaping health policy at the bedside, within an organization, and at the local, state and national level. The toolkit offers an introduction to research and evidence-based practice."

UpToDate

http://www.uptodate.com

UpToDate is an evidence-based, physician-authored clinical decision support resource which clinicians trust to make the right point-of-care decisions. More than 6,500 world-renowned physician authors, editors, and peer reviewers use a rigorous editorial process to synthesize the most recent medical information into trusted, evidence-based recommendations.

Appendix III

Writing an Abstract

The scientific abstract is usually divided into five unique sections: Title and Author Information, Introduction, Methods, Results, and Conclusions. The following paragraphs summarize what is expected in each of these sections. NOTE the requirements for number of allowed words.

Title and Author Information: The title should summarize the abstract and convince the reviewers that the topic is important, relevant, and innovative. To create a winning title, write out 6 to 10 key words found in the abstract and string them into various sentences. Once you have a sentence that adequately conveys the meaning of the work, try to condense the title yet still convey the essential message. Some organizations require a special format for the title, such as all uppercase letters, all bolded, or in italics. Be sure to check the instructions. Following the title, the names of all authors and their institutional affiliations are listed. It is assumed the first author listed will be primary contact or primary presenter. Determine if the first author needs to meet any eligibility requirements. For example, the first author may need to be a member of the professional society sponsoring the research meeting. This information is always included with the abstract instructions.

Introduction: This usually consists of several sentences outlining the question addressed by the research. Make the first sentence of the introduction as interesting and dramatic as possible. If space permits, provide a concise review of what is known about the problem addressed by the research, what remains unknown, and how your research project fills the knowledge gaps. The final sentence of the introduction describes the purpose of the study or the study's primary hypothesis.

Methods: This section must be detailed enough to judge the validity of the work. For most clinical research abstracts, the following areas are specifically mentioned: research design; research setting; number of patients enrolled in the study and how they were selected; a description of the intervention (if appropriate); and a listing of the outcome variables and how they were measured. Finally, the statistical methods used to analyze the data are described.

Results: This section begins with a description of the subjects that were included and excluded from the study. For those excluded, provide the reason for their exclusion. Next, list the frequencies of the most important outcome variables. If possible, present comparisons of the outcome variables between various subgroups within the study (treated vs. untreated, young vs. old, male vs. female, and so forth). This type of data can be efficiently presented in a table, which is an excellent use of space. Check the rules to see if tables can be used in the abstract. Numerical results should include standard deviations or 95% confidence limits and the level of statistical significance. If the results are not statistically significant, present the power of your study (beta-error rate) to detect a difference.

Conclusion: State concisely what can be concluded and its implications. The conclusions must be supported by the data presented in the abstract; never present unsubstantiated personal opinion. If there is room, address the generalizability of the results to populations other than that studied and the weaknesses or limitations of the study.