These steps outline what is necessary to complete a research project from start to finish. The order of the steps is required for any investigator; however, which step you start will depend on if you are a new or established investigator. For example, the first steps outlining the identification of a research project may already be complete for established investigators. Each step will provide guidance and contact information for assistance along the way.

1. **IDENTIFY A RESEARCH TOPIC**
   Determine your research project by identifying and formulating a research problem. Identifying the research problem is the *most important* step in the entire research process because it will provide the groundwork for the remainder of the project. To begin, determine the research topic/subject you would like to investigate, and then list issues/problems within that topic. Write down the impact of these problems and if and how these problems will add to the general knowledge of your topic/subject. For assistance contact the Office of Academic Research Development (OARD) at OARD@BSWHealth.org.

2. **EXPLORE YOUR TOPIC WITH A LITERATURE REVIEW**
   This step involves exploring existing evidence to determine what others have learned about similar research problems. This will help you better understand the broader context of your research topic and what is already known. Assessing the various characteristics of previous studies (i.e. research design/methodology and statistics) helps you avoid duplicating a previous study and informs of what has already been completed. At this point, if you have found *too many* or *too few* sources, you may need to *narrow* or *broaden*, respectively, your topic. Identify gaps in the literature relating to the problem. Suggesting how these gaps can be filled may help lead to your research design/methodology.

The **Richard D. Haines Medical Library** is located on the third floor of the Texas A&M Health Science Center, College of Medicine Education Center. The library provides a variety of services such as full service literature searches, reference and research queries, inter-library loan, document delivery, and materials circulation. The library provides access to over 150 databases, over 65,000 electronic books, and over 52,000 electronic journals as well as study space. Professional staff is available to help assist you in making the best use of these resources. Visit them online at [http://library.sw.org/](http://library.sw.org/) or on the third floor of the Medical Education Center to learn more. For assistance, contact the Richard D. Haines Medical Library service desk at medicallibrary@sw.org.

3. **RESEARCH DESIGN, PROTOCOL/GRANT DEVELOPMENT, & FUNDING**
   The Office of Academic Research Development (OARD) guides investigators through the developmental phase of the research proposal. OARD provides help with developing a clear and strong research question and identifying appropriate research designs to test the hypothesis. Developing a research design may contain many processes outlined below.
*Seek IRB/IACUC/IBC approval if necessary – steps outlined in appendices*

**a. Develop a Clear Hypothesis –**

The hypothesis must clearly establish the focus of the study. The outcomes must be measurable and these measurements must be strong. Without a clear hypothesis, the scope of the study may become blurred and the design will become problematic.

**b. Determine Project Design/Methodology –**

A research method or set of methods must be selected that will provide the most scientific, practical, and appropriate route for answering the proposed question.

**c. Research Feasibility –**

This step may be required to provide investigators with accurate electronic feasibility analysis and is performed to ensure proper study selection and recruitment for research studies. This process consists of accessing electronic patient data to determine potential populations specific to individual study protocols. Electronic feasibility review is required on ALL studies involving human subject research. This review is performed by one of the Clinical Trial Analysts in the Research Feasibility Office. In order to initiate a feasibility request, you must first complete a Feasibility Request Form to document the request (located in iRIS – See IRB appendix to set up iRIS account). Once the feasibility form is complete, you must submit it to the Research Feasibility Office, along with a copy of the study protocol. Once this is complete, the analyst will run queries in order to determine the patient population that meets the study criteria. Upon completion of the analysis an e-mail will be sent stating the feasibility results. Contact the Research Feasibility Office at feasibility@sw.org for assistance.

**d. Biostatistics –**

This office was established to provide support to the clinical and research staff at Scott & White. Biostatisticians consult with investigators during the early stages of study development to discuss the design of your research work. This step can be performed if you need help with estimating the required sample size, randomizing listings, and statistical methodology to be used in the eventual analysis of the study data. They can provide analyses of study results, design data forms, and maintain close contact with study coordinators and research assistants. Contact the Biostatistics Group for assistance at biostat@BSWHealth.org.

**e. Biosafety –**

The Biosafety Office is responsible for oversight of biological and chemical hazard compliance for researchers. In collaboration with the Scott & White Institutional Biosafety Committee (SWIBC), this office develops and implements policies and procedures regarding the use of biohazardous and chemical agents in research facilities on the Scott & White campuses. Additionally, the Office of Biosafety is responsible for providing required laboratory safety training to all research personnel and monitoring safe practices in the laboratory. For assistance contact the Office of Biosafety.
f. **Protocol/Grant Development**
   Support is available for protocol and grant development. Assistance in identifying potential collaborators, developing specific grant components, and timely review and feedback of draft proposals and grants is provided throughout the writing process. For assistance with protocol development and grant writing activities, contact **OARD** at **OARD@BSWHealth.org**.

g. **Funding/Corporation & Foundation Department**
   If you are looking for funding opportunities, the Corporation & Foundation Department can guide you through available opportunities through foundations or corporations. The department helps to advance the services and care to individuals who need it most by securing vital funding and resources to support the projects, needs, and initiative of Scott & White Healthcare. It is the responsibility of Scott & White Healthcare Foundation with the Office of the President to serve as the coordinating agent for all types of fund raising programs, events, and solicitations of funds from individuals, employees, private foundations, businesses, associations, corporations, and organizations. For more information, contact **Corporation & Foundation** at **foundation-sw@sw.org**.

h. **Apply for a Grant**
   If you are looking for funding opportunities, the Office of Sponsored Research Administration (OSRA) conducts *external* and *internal* funding searches and alerts investigators when potential funding opportunities are available. Once you have developed your research proposal and have decided on a funding opportunity, the grant application process and budget development process are monitored by the assigned Research Project Analyst and Financial Analyst, respectively. Once the process is complete, the Research Project Analyst will submit the application on behalf of the investigator. For assistance applying for grants, contact **OSRA** at **grantsadmin@sw.org**.

j. **Research Finance/Budget Development**
   This department is available to assist PI’s with budget development for grant submissions for *internally* and *externally* funded research projects, as well as industry funded research for both *pre-award* and *post-award*. The Research Finance office is also responsible for tracking, monitoring, and project management on the post-award side. For assistance, contact **Research Finance** at **projectmanagement@sw.org**.

4. **COMPLETE REGULATORY NEEDS**
   Any and all research at Scott & White must be submitted via an integrated management tool. This tool allows the researcher to access and track all documents related to the research for the life of the project. Regulatory committees (i.e. IRB, IACUC, and IBC) also use this tool to review applications. It is up to the appropriate committee to decide if a project requires regulatory oversight, not the individual researcher. For information about the regulatory committees see Appendices A-C. Once a project is reviewed by the appropriate committee or designated as needing no regulatory oversight, the project can move into the next step (data collection).
a. **iRIS/iMedRIS**

The Integrated Medical Research Information System (also known as iRIS or iMedRIS). iRIS is an integrated management tool that supports different processes of research. It is a web-based system that enables online application submission, real-time submission tracking, review, post-approval compliance activities, and data management. The system also acts as a repository, providing investigators with easy access to submission records and study documents. It is used to process and comply with regulations and approvals of all research applications that are submitted to the IRB, IACUC and IBC. To access iMedRIS go to [https://sw.imedris.net](https://sw.imedris.net). For assistance contact [researchit@sw.org](mailto:researchit@sw.org).

b. **Regulatory**

The Regulatory Office can help investigators with Initial Review Submissions to the Institutional Review Board via the iRIS system. They can also assist the investigator in any other changes or updates that occur or need addressed during the life of a study. This service is flexible to meet your needs whether you need guidance navigating through the system or wish to have the Regulatory Office completely build your submission. For assistance, contact the Regulatory office at [Regulatory@sw.org](mailto:Regulatory@sw.org).

5. **COLLECT DATA**

Select the most appropriate method for collecting your research data. If you need help with project design, contact OARD.

6. **ANALYZE & INTERPRET DATA**

This step involves analyzing your data and interpreting it to see if your hypothesis is true or false. From this data, you will be able to draw conclusions. If your hypothesis is false, many researchers like to write a new hypothesis, stating the entire process of the scientific method over again. Even if you find your hypothesis is true, it can be re-tested in a new way. Contact OARD for assistance.

7. **DISSEMINATE FINDINGS**

Disseminating your findings may involve multiple steps. You may want to publish those results in the form of a manuscript or poster or you may want to apply for a grant. The following steps can guide you through these processes.

a. **Get Published**

The Publications Department strives to make sure manuscripts meet all journal requirements prior to submission. The department is comprised of two full-time medical editors responsible for reading and editing manuscripts for content, clarity, and overall sentence structure (subject verb agreement, etc.). They also verify reference citations using PubMed to make sure the information is correct, and that the references called out in the text match the reference list. Figures are verified and checked for their correct format for the particular journal submitted to. Once the manuscript has been read and edited, it is sent back to the author for pre-submission approval. When the author
signs off on the approved manuscript, the Publications Department initiates the submission process on behalf of the author. If the author is not registered on a particular journal website, he/she is registered and their documents/images are uploaded on their behalf. Once the submission is uploaded, the author goes into the website to give final approval, thus completing the submission process. When manuscripts are accepted pending revision, authors are also helped with revisions. The Publications Department also assists in preparing cover letters, prints any required author forms, such as copyright transfer agreements, author disclosure forms, checklists, etc., and route for signatures. Permission can also be requested from previous publications for borrowed or re-used material on behalf of the author. Contact the Publications Department at publication@BSWHealth.org.

b. Graphic Services –

Provides and assists with everything from artwork and full color medical illustrations of anatomical structures to certificates and hall signs. Clip art or hand-drawn work can be created to accompany slides and prints to provide a personalized touch for presentations. Picture mounting, posters, art work and illustrations are all handled through Graphic Services. Assistance can also be made with notepads for senior staff, changes to letterhead paper, etc.

Posters can be printed for conferences, research days, etc. To request a poster, the information must be sent to the Graphic Services department a minimum of 4 weeks ahead of your due date. Information may be in a PowerPoint slide or a word document format. Photos are printed best as jpps or tiffs and should be sent that way if possible. Items taken from a website usually have low resolution and do not reproduce well. Charts and tables need to be accurate and complete. The size of the poster should be specified as well (i.e. inches/feet and/or cm/meters). Once the information is sent to Graphic Services, a poster layout will be constructed and a pdf of the proof will be sent to you for approval. This process will be repeated as necessary. If you chose to lay your poster out yourself, make a pdf of it and send it to be printed (make sure your pdf is in its final format, as it will not be edited before printed). Approval for the poster may need to be granted by your department and needs to be completed before the poster is sent to Graphic Services for printing. There is no charge for services rendered, but allow sufficient lead time to assure timely turnaround. Check with the department on the timeframes involved before you start a project. For assistance, contact Barbara Jimenez in Graphic Services at Barbara.Jimenez@BSWHealth.org.
8. RESEARCH BUSINESS DEVELOPMENT

a. Technology Transfer –
   The Technology Transfer Office fosters innovation and facilitates the
development of new products based on clinical and academic
inventions to improve patient care and impact the public good.
The Technology Transfer Team consists of Business
Development and Legal representatives who work with
inventors at all stages of the technology transfer process to
evaluate, protect, market, and manage new inventions and
technologies. Services for investigators include: Invention
Disclosure & Assessment, Intellectual Property Protection, Marketing
& Business Development, and Structure Agreement and Manage. Contact Technology
Transfer at Inventions@BSWHealth.org.

b. Conflict of Interest –
   Oversees the Scott & White Conflict of Interest Policy, including
requirements for employees to disclose conflicts to Scott & White.
All Scott & White employees are required to disclose proposed
consulting agreements to Scott & White before executing. This
office works to identify terms that create conflicts of interest,
including financial commitment. The primary points of concern are
intellectual property (IP) ownership and use, employment
responsibilities, potential impact on patients, and fair market value compensation.
Contact Conflict of Interest at conflictofinterest@sw.org for assistance.
Appendices

Appendix A: Institutional Review Board (IRB) Steps

Authorization must be established to conduct human subject research at Scott & White. This authorization is maintained through the IRB and accomplished by the steps outlined below. The IRB is a federally mandated committee responsible for ensuring the protection of the rights and welfare of human research subjects. Ensure that IRB submission is required for your particular research project. More information about the IRB can be found at [http://researchers.sw.org/institutional-review-board/institutional-review-board-main](http://researchers.sw.org/institutional-review-board/institutional-review-board-main) or contact IRB Administrator Matt Ridley.

1. Mandatory human research protection training must be completed using an internet-based provider called Collaborative Institutional Training Initiative (CITI). This course can be found here [http://researchers.sw.org/institutional-review-board/citi-login-registration](http://researchers.sw.org/institutional-review-board/citi-login-registration).

2. An electronic research submission packet must be completed through an internet-based system called iRIS (Integrated Research Information System). iRIS is run by a vendor called iMedRIS. Access can be requested once the CITI course is complete at [https://sw.imedris.net/](https://sw.imedris.net/). iMedRIS can be accessed for all parties involved in the research or research process. This allows convenient access for documentation organization and answers to any questions.
   a. Select “Request new account” to submit a user name and password
   b. When your project is ready to be electronically submitted, select “Add a New Project” under the “Research Assistant” area.
   c. Complete the application for IRB review
   d. A feasibility study is required for all human subject research. Contact the Research Feasibility to start this process. Once the feasibility assessment is complete, the PI will be informed and the assessment will also be uploaded into iMedRIS.
   e. Attach any other relevant documentation (protocol/research plan, data collection forms/consent forms, flyers, posters, emails, etc.)
   f. An internal review submission packet with automatically be created once the above steps are completed. You can return to the submission draft by clicking on “My Projects” and select “Initial Review Submission Form” followed by “Edit/View.”

3. After IRB approval, the IRB must be kept informed of any modifications in the research protocol and must be provided with periodic progress reports (dates determined by the IRB). Forms that may need to be submitted to the IRB after approval are listed below.
   a. Adverse Event Form
   b. Key Study Personnel Change Form
   c. Study Update/Change Request
   d. Monitor or Auditor Report Form
   e. Protocol Deviation/Violation Form
   f. Request for Protocol Exception
The IACUC has the responsibility of overseeing the animal research program, animal facilities and policies ensuring appropriate care, ethical use, and humane treatment of animals. The IACUC Compliance/Support Office assists the IACUC in support of these goals, and ensures compliance with federal, state and institutional regulations and guidelines. More information about IACUC can be found at swresearchsecure.sw.org (username: swresearch; password: temple) or contact the IACUC Manager, Nathalie Conway-James.

1. Submit the Animal Use Protocol (AUP) to IACUC. All animal use studies require an AUP, including pilot studies. This protocol can be found on their website listed above.
   a. Submit grant applications as well if project is being funded by a grant
   b. If any hazardous agents are to be used, the appropriate hazard form is sent with the AUP to be approved by the safety officer, Francis Novembre, Ph.D. at Francis.Novembre@BSWHealth.org.
2. The AUP is reviewed by the IACUC office
   a. Full Committee Review (FCR) – required for all new and de novo AUPs or is performed for major amendments. PI’s proposal is presented at a convened meeting with the IACUC quorum present. The FCR can approve, request additional modifications or revision, or disapprove.
   b. Designated Member Review (DMR) – required for minor changes to the proposal, progress reports, or minor amendments. The DMR can approve, request additional modifications, or request a FCR.
3. Once the PI obtains IACUC approval, the Department of Comparative Medicine (DMC) should be contacted (Angie Hitt, Associate Director of Operations). The DMC support research through humane animal care through providing:
   a. Housing and care for rodents, rabbits, ferrets, non-human primates, and swine
   b. Specialized housing for biohazard projects
   c. Rodent quarantine facilities
   d. Surgical facility
   e. Technical support services
   f. Animal use training services
Appendix C: Institutional Biosafety Committee (IBC) Steps

The Institutional Biosafety Committee, or IBC, is a federally mandated committee responsible for ensuring the safe and ethical use of recombinant DNA and other biohazardous agents. The Scott & White IBC reviews all research that involves biological toxins, microbial agents or other agents that are infectious to humans, animals or plants, recombinant DNA molecules, and/or genetically altered organisms or agents, including organisms and viruses containing recombinant DNA molecules, synthetic DNA molecules, human or non-human primate derived cells, tissues or OPIM and nanomaterials. The IBC maintains and promotes an open and cooperative relationship with investigators and the Scott & White community. We strive to educate the Scott & White community concerning the regulatory requirements for the use of recombinant DNA and biohazardous material. For more information please contact Lauren Ellis, IBC Compliance Manager, at 254-215-9031 or Lauren.Ellis@BSWHealth.org.
Appendix D: Frequently Asked Questions

1. **My application was funded, what’s next?**
   Depending on the type of proposal or study, you may need approval from one of the following Review Boards:

   - **Human:** IRB Process- Your assigned Research Project Analyst will assist in developing and submitting the IRB application.
   - **Animal:** IACUC Process
   - *IBC approval could be required if applicable

2. **How soon can I start my research?**
   It varies upon studies. Once the Research Compliance Approval Process is complete, the funds will be released and you may start your research.

3. **My Application was not funded…what now?**
   The Office of Academic Research Development will review your application and discuss areas of your application that may need improvement.

   If you choose to reapply, contact your Research Project Analyst regarding the resubmission process.

4. **How do I handle my post-award financial activity?**
   Contact [Jeremy Ray](mailto:JeremyRay) for assistance.