***ASBrS Study Concept Submission Form***

All research proposals involving the society membership must be reviewed by the Society’s Research Committee and approved by the Board of Directors. Please return the completed form along with a copy of your proposal to the Society Office.

|  |  |
| --- | --- |
| **Date:** |  |
| **Title of the study:** |  |
| **Principal investigator:** |  |
| **Co-investigator(s):** |  |
|  |  |
|  |  |
|  |  |
| **Statistician:** |  |

**Abstract**

*State the application’s broad, long-term objectives and specific aims, making reference to the clinical relevance of the project and the reason this study should be performed within the membership of the American Society of Breast Surgeons. Describe concisely the research design and methods for achieving these goals*

### Research Plan

*The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document. Be specific and informative, and avoid redundancies.*

*Organize the items in sections I through IV to answer these questions: (1) What do you intend to do? (2) Why is the work important? (3) What has already been done? (4) How are you going to do the work?*

## I. Specific Aims

Introduce this section by declaring the broad, long-term objectives of your research efforts. List the specific research aims of this particular research proposal. State the hypotheses to be tested

**II. Background and Significance**

In this section, briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and clinical relevance of the research described in this application by relating the specific aims to the broad, long-term objectives

**III. Research Design and Methods**

*In this section, describe the research design and the procedures to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted. Include a description of statistical analysis. Describe any new methodology and its advantage over existing methodologies. A recommended format for this section including subsections follows*:

**a. Study Design or Overview** *- Describe the study design and rationale for choosing the study design.*

**b. Study Subjects** *- Describe how study subjects will be selected. List eligibility and exclusion criteria.*

**c. Sample Size** *- Explain how many subjects will be studied and whether sufficient subjects will be available based on statistical tests of hypotheses.*

**d. Data Collection** *- Describe the data to be collected and any laboratory techniques that will be used.*

**e. Data Handling** *- Explain how data will be prepared for analysis. Will data be entered into a computer for analysis? Explain steps taken to assure accurate and complete data collection. Describe data storage and archiving.*

**f. Data Analysis** *- Explain details of data analysis, descriptive statistics, tests of hypothesis, and expected formats for presenting results.*

**g. Feasibility and Time Frame** *- Describe a realistic time frame for completing the work. Include evidence that the subjects planned for inclusion in this study exist and can be recruited, entered, and maintained throughout the study in the timeframe proposed.*

**h. Time to Complete the Survey** *– What is the estimated time to complete the survey? Beta testing or survey validation is required before the committee will review your survey. Please describe how the beta testing or validation process changed your survey. If you are submitting a Mastery research proposal, type N/A in this field*

**IV. Human Subjects**

**Recruitment of Subjects:** *Describe plans for the recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. Include a description of expected minority recruitment.*

**Potential Risks:** *Describe potential risks (physical, psychological, social, legal, or otherwise) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.*

**Protection:** *Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects.*

**Benefits:** *Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. If a test article (investigational new drug, device, or biologic) is involved, name the test article. State whether the 30-day interval between submission of applicant certification to the Food and Drug Administration and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the Food and Drug Administration.*

**V. References:**

**VI. Budget:**

*The American Society of Breast Surgeons does not provide funding for research projects. A budget is requested for review of your proposal.*

*The researcher(s) will be responsible for the cost of Society staff time for Mastery of Breast Surgery studies. We will provide an estimated cost upon receiving a full proposal outlining the scope of work. Contact us for additional information.*

**VII. Conflict of Interest:**

*Please describe any financial or strategic business relationships for yourself and your co-investigators. If this study is sponsored by industry, please describe the sponsorship below. If there are no conflicts of interest, please type N/A in the box below.*

Please return this form along with a copy of your abstract and survey or proposal to [lrandel@breastsurgeons.org](mailto:lrandel@breastsurgeons.org).