NEXT SCIENCE®

NEXT SCIENCE Investigator Sponsored Research Proposal Form

Please submit completed form (ISRclinical@nextscience.com)

Investigator and Institution	
Request date	
Investigator-Sponsor	*Please also attach resume/CV* *Applicable Good clinical practice/human subject protection certification/trainings*
Title/Role	
NPI number	
Sub Investigator(s), if any	*Please also attach resume/CV* *Applicable Good clinical practice/human subject protection certification/trainings*
Institution	
Institution type	☐ Outpatient ☐ Inpatient ☐ Research Group ☐ Other, please specify: _____ ☐ Nonhospital-based clinic ☐ Physician group practice ☐ Surgery Center
Website	
Physical address	
Phone Number	
Email Address	
Multi Center Study	☐ YES ☐ NO *If yes, please provide sub-site information below. Add more sites as needed.* Name & Title: Institution: Phone: E-mail:
Proposal	
Next Science Product(s) to be studied	
Control or comparator product, if any.	

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Indication(s)	
Please describe the current standard of care for this indication and/or disease state.	
If standard of care is used for control and is different from the one described above, describe your study standard of care.	
List all the products that would be used in conjunction with or is expected to have contact with the Next Science study products	*This could include hemostatic agents, antiseptic agents, hydroxyapatite, dressings, etc.*
Include a detailed description of how the product will be applied.	*This information is critical for a precise determination of on/off-label status. The following examples would be considered off-label use:* • *Application of SurgX™ in the eyes* • *Application of BlastX™ as an oral rinse* *For this reason, it is important for proposals to indicate the use and administration of the product.*
Study phase	☐ Pilot ☐ Phase I/Early Feasibility ☐ Phase II/Traditional Feasibility ☐ Phase III/Pivotal ☐ Phase IV/Post market ☐ Other, please specify:_____
Type of Study	☐ Clinical ☐ Other (Specify: _____)

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Study Design	☐ Meta Analysis of Randomized Trials ☐ Prospective with randomization to treatment or control ☐ Prospective treatment cohort compared with historical control ☐ Prospective treatment cohort with descriptive results only (comparison with literature results for control, or no comparison at all) ☐ Retrospective treatment cohort compared to retrospective control cohort ☐ Retrospective treatment cohort: with descriptive results only (comparisons to literature results for control, or not comparison at all) ☐ Other, please describe: _____
Study Title	
Hypothesis	
Study Objectives	
Background and Rationale	
References	*Provide list here and attach full articles (not abstracts) in PDF version. Highlight section(s) throughout articles which are referenced in this application.*
Inclusion Criteria	*Please list proposed inclusion criteria.*

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Exclusion Criteria	*Please list proposed exclusion criteria.*
Primary Endpoint	*Please clearly describe the primary endpoint, which is a variable measured on each subject. Include timing as applicable.*
Secondary Endpoint(s)	*Please clearly describe the secondary endpoint, which is a variable measured on each subject. Include timing as applicable.*
Safety Data to be Collected	
Number of Subjects in the Study	*Please include the total number of subjects overall as well as for each arm/cohort. Example: 50 total subjects (25 in the product investigational group and 25 in the control group).*
Study population	*Please list gender, age, disease state etc.* *Example: (Male and female >18 years old to <90 years old having venous leg ulcers that have failed to meet 4 week wound area reduction trajectories)*

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Statistical Justification for Number of Subjects	*Please review instructions listed in the Appendix*
Statistical Analysis Plan	*Please review instructions listed in the Appendix*
Will Health Economics or Patient Report Outcomes (PROs) data be collected?	☐ YES ☐ NO *If yes, please describe the instruments to be used, the timing of the assessments, and the planned analyses.*
Do you have access to an IRB/Ethics committee?	☐ YES ☐ NO
IRB type:	☐ Institutional:_____ ☐ Central:_____
Has the study been reviewed and approved by an IRB?	☐ YES, Please attach the IRB approval letter. ☐ NO, Anticipated submission date:_____ **Note:** IRB approval letter must be supplied to Next Science, prior to release of product/funds. ☐ Other, Specify (submitted, pending approval, etc.):_____ _____
Do you have any ongoing competing studies?	☐ YES ☐ NO If yes, please list and describe: _____ _____
Do you have adequate space for secure storage of study product?	☐ YES ☐ NO If yes, please describe: _____ _____

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Do you have a dedicated study Coordinator or other personnel to collect study data?		☐ YES ☐ NO *If yes and requesting funds toward coordinator effort, please include this as a line item within the budget and provide rates.*
Coordinator(s) name and bio/suffix		*Please also attach resume/CV*
Describe your experience with using the product.		
Do you have experience with the proposed methods and study design?		☐ YES ☐ NO If yes, please describe: _____ _____ _____ _____
Next Science Support Requested		
Describe any support that is required for this study.	Funding:	Are you seeking monetary support from Next Science for this research? ☐ YES ☐ NO If yes, please specify through detailed budget attachment.
	Product	*(If requesting product, list each product name, size/volume, and number of units)*
	External support	Are you seeking monetary support from sources other than Next Science for this research? ☐ YES ☐ NO *(If requesting funding, please attach a summary of external funds and/or other type of support for this study)*

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Estimated Time to Complete Study and Submit Manuscript for Publication

(Please replace "__" values with your estimates, to the nearest month)

A	Time from Next Science Committee Approval to Contract Approval (2 months minimum):	2 months
B	Time from Next Science Committee Approval to Draft Protocol To Next Science:	☐ months
C	Next Science Review of protocol, including discussion with investigator (1 month minimum.	1 month
D	Time from receipt of Next Science reviewed protocol to First Subject enrolled (include IRB approval time and any other logistic requirements at institution)	☐ months
E	Total time from First Subject enrolled to last subject treated	☐ months
F	Total follow-up time per subject	☐ months
G	Total time to clean/lock data and analyze	☐ months
H	Total time from analysis completion to final report draft	☐ months
I	Next Science review of final report	1 month
J	Review of Next Science comments, finalize publication, submit	☐ months
	Total Time (Months) from Proposal Approval to Submitting the Publication to the Journal (add A – J)	☐ **months**

Detailed Publication Plan	*Please specify targeted journals for submission of abstracts, poster, and manuscript. Also, please specify any meetings where you intend to present resulting data.*

Additional Information

Do you have any potential conflicts of interest for this study and/or by receiving Next Science's support for this study?	☐ YES ☐ NO If yes, please disclose all potential conflicts of interest here.

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Contracts Person(s)	Name & Title:	
	Institution:	
	Phone:	
	E-mail:	
Statistician Contact(s)	Name & Title:	
	Institution:	
	Phone:	
	E-mail:	
Coordinator Contact(s)	Name & Title:	
	Institution:	
	Phone:	
	E-mail:	

I understand that completion of this form is a request and does not guarantee support from Next Science, LLC. The Next Science Investigator-Sponsored Research Committee will review all submitted proposals and communicate whether or not support has been granted.

_____

Investigator-Sponsor Signature

_____

Date

APPENDIX

Instructions for Completing the Proposal Form

Primary/Secondary Endpoint:

Please describe the primary and secondary endpoints, which are variables measured on each subject. Include data collection timepoints as applicable.

Sample Size:

Please include the total number of subjects overall as well as for each arm/cohort. Example: 50 total subjects (25 in the product investigational group and 25 in the control group).

Sample Size Justification:

1. *If the study has any statistical hypothesis testing; is randomized; has more than one treatment group; or has a control group(s), then provide justification for the sample size via the following:*
    a. *the power to achieve statistical significance for the primary endpoint.*
    b. *the planned type 1 error rate, and whether this error rate is 1-sided or 2-sided;*
    c. *the anticipated effect in each treatment group, along with any variability assumptions required to determine the sample size (please also provide a justification for these assumptions, e.g., if you assume that your population will have a complication rate of 20%, please justify how you selected 20%)*
    d. *the statistical hypothesis test that will be used to assess the primary endpoint;*
    e. *an explanation of how missing data will be treated in the analysis; and*
    f. *the name and version of the statistical software you used to compute your sample size, or a copy of the reference used; please provide a copy of the output from the commercial software if possible.*
2. *If the study is a feasibility study and no statistical hypothesis tests are planned, please state this. Note that results from trials based on feasibility are considered less scientifically rigorous than comparative trials, and therefore may be less likely to be accepted by the committee. If any statistical hypothesis testing is planned, please provide the power of the test and please provide the information required in #1.*

Example: We assume that subjects in the standard of care group will have a complication rate of xx%, while subjects in the Product group will have a complication rate of yy%. We base these assumptions on (literature references). Under these assumptions, n subjects per group will provide 80% power to detect a difference between control and Product, using the Chi-square test (without continuity correction) at 2-sided alpha=5%.

Statistical Analysis Plan:

Please describe your planned statistical analysis in detail, including (at a minimum), the answers to the following questions, if you plan to perform statistical testing:

1. *What statistical test(s) will be used to analyze the primary endpoint and secondary endpoints?*
2. *Will you adjust for multiplicity across different endpoints or time points? How will overall type 1 error be maintained?*
3. *How will you handle dropouts in the analysis of your primary endpoint? If any, what are the stopping rules for individual subjects? If there are specific stopping rules, how will these subjects be handled in the analysis?*
4. *If you are performing a time-to-event analysis, please clearly describe how subjects without events will be censored.*
5. *Do you have any interim analyses planned? (if yes, answer 5a-5d)*
    a. *Is it possible to stop the trial at the interim analysis due to achievement of efficacy goals? If yes, what is the p-value criterion for this decision?*
    b. *Is it possible to stop the trial at the interim analysis due to futility? If yes, what statistical criteria are used to determine whether to stop? Are these statistical futility criteria "binding", that is, is the study required to be stopped if the statistical futility is met?*
    c. *Do you plan to re-assess sample size at the interim analysis? If so, what statistical criteria will be used (include references if applicable)?*
    d. *What statistical methodology have you used to determine interim analysis rules (so that type 1 error is preserved)?*
6. *If you plan to use historical control, what is the source of the historical control? How will you select subjects from this source in a non-biased way so that they can serve as an appropriate control (matching, propensity scoring, etc.)?*