

QF-82-10-02	ISR Modification and Request Form		
Issued by: R&D	Effective Date: 9/18/2020	Rev. A	Pg. 1 of 7

Please submit the completed form to ISRclinical@nextscience.com

Investigator and Institution	
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Modification/ Request Date	
Investigator-Sponsor	
Title/Role	
NPI number	
Institution	
Website	
Address	
Phone Number	
Email Address	
ISR Tracking Number	

Withdrawal of Support

Are you requesting withdrawal of support from Next Science for this study? YES NO

If yes, please provide reasoning:

Study Continuation or Termination

Is the study still expected to reach completion? YES NO

If no, please provide reasoning:

Modifications to Sub Institutions

Addition or removal of other sites in a multi-center study? YES NO

If yes, adding a sub-site, please provide the sub-site's information:

Name & Title:

Institution:

Phone:

E-mail:

If yes, removing a sub-site, please complete the following information for the sub-site that will be removed and provide the reason for a sub-site's removal:

Name & Title:

Institution:

Phone:

E-mail:

Reason for Removal:

Request for Next Science Funding

Requesting initial funds or additional funds for the support of the study? YES NO

If requesting funds, please briefly describe the reasoning here, and attach a detailed budget to this form:

Other sources of support for this research, not previously disclosed? YES NO

If yes, please specify through the detailed budget attachment.

Modifications or Requests for Next Science Products

Changes to Next Science product(s)' expected contact with other products or Next Science product(s)' manner of application? YES NO

If changes to product(s) contact, please provide reasoning and list the additional products expected to come in contact:

If changes to manner of application, please provide reasoning and describe the new manner of application:

Requesting additional Next Science product(s) **previously approved** for the study? YES NO

If yes, specify the product(s) being requested:

Additional quantity of product(s) requested (including number of units and size/volume):

Reason for requesting additional product(s):

Are the Next Science product(s) expected to have contact with the same products previously approved by Next Science? YES NO

If no, please provide a list of products (including hemostatic agents, hydroxyapatite, dressings, etc.):

Will the product(s) continue to be applied in the manner approved by Next Science? YES NO

If no, provide a detailed description of how the product(s) will be applied:

Requesting Next Science product(s) **not previously approved** for the study? YES NO

If yes, specify the product(s) being requested:

Quantity of product(s) requested (including number of units and size/volume):

Reason for requesting product(s):

Are the Next Science product(s) expected to have contact with the same products previously approved by Next Science? YES NO

If no, please provide a list of products (including hemostatic agents, hydroxyapatite, dressings, etc.):

Will the product(s) be applied in the manner approved by Next Science? YES NO

If no, provide a detailed description of how the product(s) will be applied:

Modifications to Study Protocol

Changes to Next Science-approved protocol? YES NO

If yes, please specify and describe those changes:

Estimated Time to Complete Study and Submit Manuscript for Publication

Changes to estimated study timeline? YES NO
If yes, please indicate those changes in the table below:

(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

Changes in study publication plan? YES NO

If yes, please specify changes (including targeted journals for submission of abstracts, poster or manuscript and any meetings where you intend to present resulting data):

Other Study-Related Modifications

Ongoing competing studies, not previously disclosed? YES NO

If yes, please briefly describe the studies:

Change in Additional Information

Has there been a change in conflicts of interest, contracts person, statistician contact, and/or coordinator?

YES NO

If yes, please update the below sections, as applicable.

Conflict(s) of
interest

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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: