INVESTIGATOR INITIATED STUDY
APPLICATION FORM

Accel Heal
ELECTRICAL STIMULATION WOUND THERAPY

The purpose of this form is for you (the investigator) to provide information about your proposed independent investigator study (IIS) to allow Accel-Heal Technologies Limited to evaluate your proposal.

Please complete this form in English. When complete, please return this form to customerservices@accelheal.com
Only studies that use Accel-Heal in an on-label indication should be submitted

Date form completed	
Form completed by	
Are you the principal investigator?	**Yes** ☐ **No** ☐
If no, please specify the principal investigator	

INVESTIGATOR DETAILS

	For person completing form	**For a second investigator / contact (complete if applicable)**
Name		
Position		
Area of medical speciality		
Affiliation		
Postal address (including country)		
Email address(es)		
Phone number(s)		

STUDY TITLE AND OVERVIEW

In the box below, please provide the title and a brief overview of the project	
Title	
Overview	

STUDY DESIGN

STUDY DETAILS		**Notes and considerations**
Please specify the type of clinical study *e.g. RCT, prospective non-comparative study, retrospective comparative study, case series, quality improvement program, experimental study, computer model etc*		
If this is a comparative study, please specify the treatment arms	**Arm 1:** **Arm 2:**	

Specify the primary objective				
Please detail how the primary objective will be measured and reported				*Note: i.e. what is the primary endpoint? Validated, objective measures should be used in preference to subjective measures, wherever possible.*
Specify any secondary objectives				
Please detail how any other objectives will be measured and reported				
STUDY POPULATION				
Condition or indication				
Number of patients to be enrolled				*Note: If the number of patients has been formally calculated based on statistical methods, please specify briefly how this was done.*
Duration of live phase of study (treatment phase)				
Duration of follow up (once treatment phase has finished)				*Note: it is preferable to follow patients up to complete closure wherever possible or to 24 weeks from beginning of treatment.*
STUDY TIMEPOINTS				
Specify all study timepoints				*Note: including any pre-treatment timepoints, baseline evaluations and any long-term follow up*
ETHICAL CONSIDERATIONS				
Does your study proposal have ethical approval from your institutional review board (IRB)?	**Yes**	**No**	**N/A**	*Note: support from Accel-Heal Technologies Limited is contingent on ethical approval being gained from an appropriate IRB for the study. Documentary evidence will be required. If the IRB agree that ethical approval for the proposed study, please provide written evidence to this effect.*
If no, do you intend to seek ethical approval from your IRB before commencing the study	**Yes**	**No**	**N/A**	
Will informed and signed patient consent be obtained	**Yes**	**No**	**N/A**	*Note: informed and signed consent is essential for any studies involving patients, unless your IRB agrees that it is not necessary.* *Please also be aware that any clinical data entering the public domain, or shared with Accel-Heal, needs to be anonymised, in line with data protection laws.*
Will the study be registered?	**Yes**	**No**	**N/A**	*Note: an example of an appropriate clinical trial registry is clinicaltrials.gov. Registration of prospective studies is considered best practice.*

DATA ANALYSIS		
Please describe how data will be captured and analysed		
Please provide details of planned statistical analysis (if applicable)		*A statistical plan can be uploaded to the application if applicable*
TIMELINES		
Proposed IRB date		
Proposed start of data capture (e.g. first patient enrolled)		
Proposed end of data capture (e.g. last patient completed follow up)		
Proposed date of completion of analysis and reporting		
PLAN FOR DISSEMINATION		
Please specify the publication plan for the proposed study (please select all that apply)	**Conference poster** ☐ **Conference oral presentation** ☐ **Peer reviewed publication** ☐	

SUPPORT REQUESTED

PRODUCT		
Number of Accel-Heal units required		
RESOURCE		**If yes, please specify**
Scientific advice	**Yes** ☐ **No** ☐	
Statistical expertise	**Yes** ☐ **No** ☐	
Preparation of abstracts / posters / manuscripts	**Yes** ☐ **No** ☐	
Other	**Yes** ☐ **No** ☐	

SUPPORTING DOCUMENTS

Please include the following files where possible:

DOCUMENT TYPE	ATTACHED
CV of principal investigator	Yes ☐ No ☐
Study protocol	Yes ☐ No ☐
Study statistical plan	Yes ☐ No ☐
IRB approval (if already received)	Yes ☐ No ☐
Other relevant documentation	Yes ☐ No ☐

SIGNATURES

By signing, you consent to Accel-Heal Technologies Limited contacting you via the contact details provided above, in relation to this application.

Person completing the form	Second contact (where applicable)
Name:	Name:
Position:	Position:
Date: / /	Date: / /

Thank you for taking the time to complete this form. Please submit this form electronically, along with the specified supporting documents to the following email address:

customerservices@accelheal.com

Accel-Heal Technologies Limited will confirm receipt of the proposal by return email and will contact you regarding your proposal once all due considerations have been made.