AROA™

Investigator Initiated Research Program

GUIDE FOR RESEARCHERS

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Introduction

As part of the commitment by AROA to the advancement of clinical and pre-clinical evidence worldwide, AROA believes in the need to support ethical independent research conducted by qualified third-party sponsors (Investigators). The value of this scientific evidence, together with AROA-sponsored research, is fundamental to understanding the benefit of AROA products and provides a means to explore opportunities to address unmet clinical needs with AROA's products. This is why AROA provides support to new Investigator Initiated Research (IIR) projects.

An IIR is defined as a study with scientific and medical merit developed and sponsored by an independent Investigator or academic Sponsor. An IIR may be a clinical or non-clinical study conducted without the participation of AROA, for which the IIR sponsor requests AROA to provide either funding, product or mixture of both.

As an Investigator, if your IIR proposal is accepted, AROA may provide you with financial support and/or AROA product(s). However, you will retain full responsibility and control of the design, initiation, management, data analysis, monitoring, and reporting, as the Sponsor of the study.

The purpose of this brochure is to provide a clear description of each of the essential requirements that must be fulfilled before support will be considered by AROA, and to highlight your obligations as the study Sponsor when your IIR is being supported by AROA. The following document provides an overview of the types of research, research funding focus areas and the IIR process.

Please contact your AROA Medical Affairs representative for any additional information or by emailing medical.affairs@aroa.com

Requirements to be Considered for the IIR Program

Below are the key requirements that will need to be fulfilled in order for AROA to evaluate and consider supporting your IIR.

Should you have any questions on these requirements, please contact your AROA Medical Science Liaison (MSL) or local Medical Affairs contact.

Investigator qualifications – all of the following must be met:

- Current valid license to practice medicine*
- Recent clinical research experience within the previous 3 years*
- Good clinical practice (GCP) training within the previous 3 years*

The Investigator's curriculum vitae would be obtained to ensure that the Investigator is suitably qualified and able to conduct the required evaluation and analysis.

*Only applicable for Interventional Studies

Study Criteria

- The proposed study should be for a legitimate research purpose and have scientific merit
- The study provides a means to better understand AROA's device or address an unmet medical need that could be met by AROA's product
- The research is a strategic fit that is aligned with AROA's scientific/clinical development strategy, as defined in Research Focus Areas (see Page 7)

Budget

- The final proposal (RFP) should have a detailed budget for the requested funds
- NOTE: University overhead may not exceed 35%

Resources

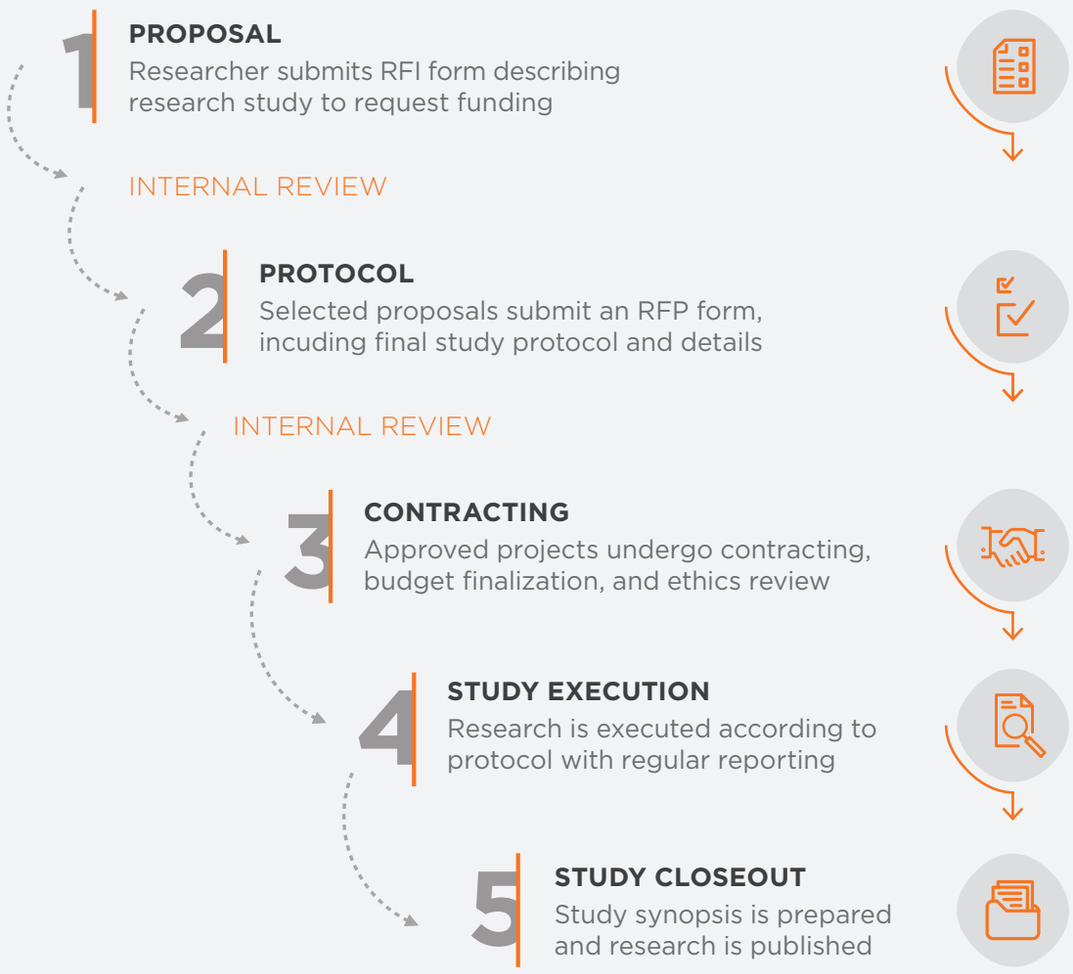
- The Investigator must have the appropriate infrastructure and resources in place and a demonstrated capability to conduct the proposed research.

AROA'S IIR PROCESS

From Submission to Close-Out

The following has been provided to give Investigators an understanding of the IIR process. Please note timing of the project review may vary.

AROA's payment for IIR will be tied to the completion of project milestones. Typically, AROA will seek to make payment tranches through the lifecycle of the project, with a final payment being made on publication of the research. Payment milestones will be defined in the Research Agreement.



RFI and RFP Forms are available from your local MSL or by contacting medical.affairs@aroa.com

Types of Research Funding Through the IIR Program

The following has been provided as a general guide for Investigators. If you have any questions about whether your proposed research would be eligible for the IIR program, please contact your AROA Medical Science Liaison (MSL) or local Medical Affairs contact.

Types of Research

- In vitro – bench testing, cell culture
- In vivo – pre-clinical animal studies
- Clinical research – research involving human subjects or samples

Types of Investigators

- Both contracted and non-contracted HCP's[1]
- Basic science (e.g. PhD) and clinical researchers (e.g. MD, DO, RN, DPM, etc)

Types of Clinical Research

- Prospective
- Retrospective
- Single arm
- Case series
- Comparative
- Clinical research requiring an IDE (or equivalent exemption)

Exclusions to the IIR Program

- AROA sponsored clinical research

AROA'S IIR PROGRAM

Research Focus Areas

The following areas of research have been identified as strategic focus areas for AROA. While AROA is open to reviewing any well-designed research proposal, those that are related to the below areas are of particular interest:

Key Research Interests

- Comparative analysis of Myriad™ vs other skin substitutes/CAMPs in acute trauma and soft tissue reconstruction
- Myriad Morcells™ (Coarse/Fine) in soft tissue reconstruction
- Myriad™ products used in management of traumatic wounds (NSTIs, open abdomen, etc)
- Myriad™ products used in combination with negative pressure wound therapy
- Functional regeneration of tissues with AROA ECM technology
- Symphony™ used in management of chronic wounds (DFU, VLU)
- Economic analysis of AROA's products

1. Note: If the Investigator has a current Consultant Agreement with AROA, local IRB and Institutional Conflict of Interest policies should be reviewed.

AROA'S IIR PROGRAM

Evaluation Criteria

Applicants must first submit an RFI to indicate their desire to seek funding through AROA's IIR program. RFIs will be reviewed and scored by a selection committee. RFIs reaching a predetermined scoring threshold will be invited to submit a full grant proposal (RFP). All RFIs, as well as invited full grant applications, will be reviewed, and scored on the following criteria:

- Clarity of research goals and objectives
- Novelty (building on existing literature)
- Clinical relevance and value
- Evidence of feasibility to execute study and achieve outcomes
- Strength of evaluation methods and measures including statistical power analysis as appropriate
- Availability of required resources
- Appropriately defined research scope, timeline, and budget
- Alignment to AROA's Research Focus Areas (Page 7)

Study Results and Publication

As part of AROA's commitment to publishing research, you are encouraged to publish the results of approved IIR projects.

As the Investigator, the content of any publication is your responsibility, and AROA will not be involved in authorship selection or writing and should not be included as a co-author of IIR publications, unless the contribution of AROA staff in preparation of the manuscript meets the threshold for authorship[2].

You should submit any publications to AROA for review at least 15–30 days prior to submission, depending on the publication type.

AROA has a commitment to public access of scientific and clinical research. As an Investigator and recipient of AROA IIR funding you will be strongly encouraged to publish any research resulting from AROA's IIR program via 'open-access' journals.

2. Refer to International Committee of Medical Journal Editors, 'Defining the Role of Authors and Contributors', https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

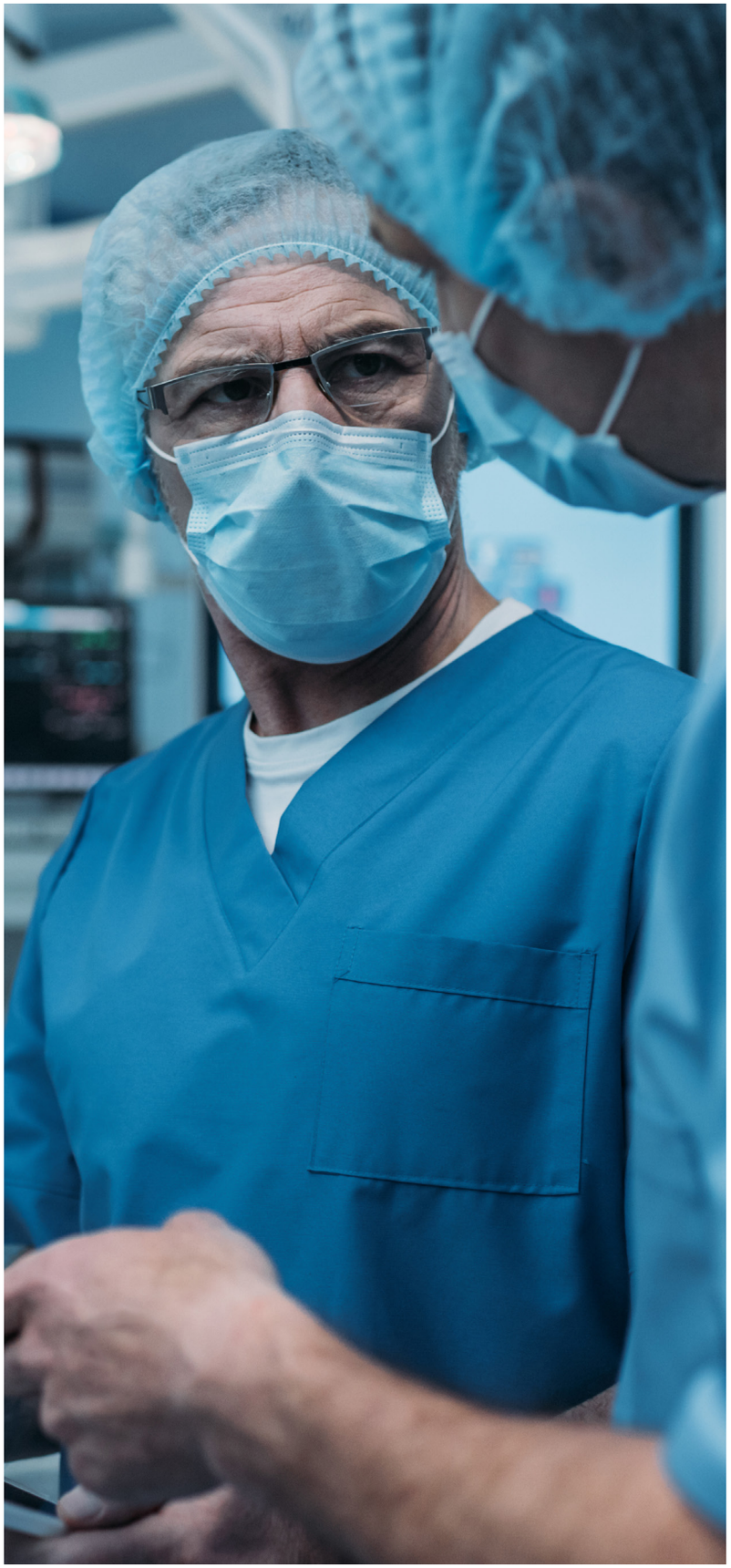
AROA'S IIR PROCESS

How can Aroa Medical Affairs assist you with your IIR project

While the IIR funding mechanism enables independence between AROA and the Investigator, AROA Medical Affairs are available to assist as needed in the planning, execution and analysis of the proposed research.

AROA Medical Affairs draws on a network of internal and external expertise that are available to IIR recipients, for:

- Study planning
- Protocol preparation
- Statistical analysis
- Medical writing
- Manuscript submission



IIR Funded Research versus Sponsored Research

There are key differences between IIR funded research and Sponsored Research. It is important for Investigators to know these differences. The following comparison has been provided to highlight these key differences as they relate to roles and responsibilities.

IIR Funded Research	AROA Sponsored Research
Research initiated by a third-party Researcher	Research initiated by AROA ('Sponsor')
Grant funding provided to offset cost of the study	AROA covers full cost of the study
Researcher ultimately responsible for execution of the study	AROA ultimately responsible for execution of the study
Researcher owns any data derived from the study	AROA owns any data derived from the study
Researcher has sole rights to publication, and the method of publication	AROA has sole rights to publication, and the method of publication
For clinical research, participant insurance coverage and liability is met by the Sponsoring Institution	For clinical research, participant insurance coverage and liability is met by AROA
Researcher responsible for IRB approval and any amendments	AROA responsible for IRB approval and any amendments
Researcher has ownership of any intellectual property	AROA has ownership of any intellectual property

Responsibilities

The following has been provided as a general guide for Investigators of proposed human subject research, requiring a IRB approval. Note: depending on the nature of the proposed research (e.g. prospective, retrospective) some activities may not be applicable.

R=responsible party; **C**=consulted

	Investigator	AROA
Development of the Research Protocol	R	C
Review of the Research Protocol		R
Distribution of updated, approved product information		R
Review local IRB/EC/IACUC requirements to ensure requirements are met	R	C
Submission of dossier to IRB/EC/IACUC at study start and annual renewal	R	
Submission of dossier to local Health Authority	R	
Registry of IIR in a public database, such as www.clinicaltrials.gov	R	
Implementation and monitoring of clinical research (including data monitoring)	R	
Contracting with third-party vendors and the management and oversight of any other participating sites or contractors	R	C
Execution of research (patient inclusion, exams conduction, etc.)	R	
Ensure that the approved protocol is adequately followed (in accordance with GCP, applicable guidelines and local and international standards)	R	
Submission of protocol amendments	R	
Review of protocol amendments	R	C
Maintaining clinical records of the study and assurance of the veracity of collected data and other attributions related to GCP	R	
Perform AE reconciliation, as required based on study type	R	
Reporting of safety data (e.g. IRB reporting), as required, based on the study type	R	
Analysis of study data, prepare interim and final study reports and forward them to AROA	R	C
Submit draft publications to AROA prior to submission to a scientific congress or journal	R	C
Independently publish the clinical trial results	R	C
Report study results to HAs, if required according to local regulations	R	

RX Only. Prior to use, be sure to read the entire Instructions For Use package insert supplied with the product.

For product questions, sampling needs, or detailed clinical questions concerning our products in the US, please call 1-877-627-6224 or email customerservice@aroa.com

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