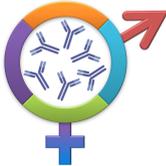


Title	  GENDER-NET Plus Promoting gender equality in H2020 and the ERA G-DEFINER  <small>This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 741216.</small>
	SOP 01 - Development, Approval and Review documents
Document type	SOP
Version N.	1.1
Date:	July 22nd 2019

	NAME	DATE
PREPARED BY	Rosalba Miceli	July 22nd 2019
REVIEWED BY		
APPROVED BY		
PURPOSE: SOPs are documents containing detailed written instructions relating to common or important tasks and practices. This SOP describes the preferred method for preparing, approving and review the documents in the G DEFINER project.		

Abbreviations

Acronyms	Description
DCU- SVUH	Dublin City University, Dublin -St Vincent's University Hospital, Ireland
G-DEFINER	Gender Difference in side effects of Immunotherapy: a possible clue to optimize cancer treatment
INT	Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy
Onk-Pat KI	Dept of Oncology-Pathology, Karolinska University Hospital, Sweden
OUH	Oslo University Hospital – The Radium Hospital, Norway
PI	Principal Investigator

Related documents

Document type	Title
SOP	SOP 01 appendix - template. Template to be used for preparing documents
SOP	SOP 01 appendix – list. List of all the G-DEFINER documents

Title	 <p style="text-align: center;">SOP 01 - Development, Approval and Review documents</p>
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1. Scope and applicability

This SOP applies to all the documents (including SOPs) generated to manage the different tasks within the G-DEFINER project conducted by INT, Onk-Pat KI, OUH and UCD-SVUH. The purpose of this procedure is to provide instruction on how the documents should be produced, so that they are prepared in a consistent manner, registered, disseminated and updated.

2. Responsibilities

G-DEFINER team (Researchers, Nurses and Data Managers).

3. Procedure

3.1 Writing

- The document is prepared using the **template**: SOP 01 appendix - template.docx.
- The document is saved using as file name: *[document type] + [document number, if necessary] + [short title] + [Version number] + [Date]*.
Example: SOP 01 - SOP of SOPs and list 0.0-08.05.2019.docx.
- The document writer will send by e-mail all the document files (main and appendices) to all the PIs for revision.
- A document should be written as soon as a standard procedure for a G-DEFINER activity, or a form, or an annex is required. It must be written by a suitable member (by experience and competency) of the G-DEFINER team.
-

3.2 After creating the document

- The G-DEFINER PI updates the list files (SOP 01 appendix – list.docx) with the newly created document.
- During the revision process, the PI registers all the document versions and updates the version numbers.
- After the revision process, the PI send by e-mail the final approved document to all the G-DEFINER members.

3.3 Amendments and advancements

- All G-DEFINER researchers can amend the documents.
- The person in charge for modification will send by e-mail the modified document files are send to all the site CIs for revision.
- The PI registers all the versions, updating the version numbers.
- After the revision process, the PI will send by e-mail the final approved document to all the G-DEFINER members.

4. Dissemination

- **After document creation**, the writer will send by e-mail all the document files (main and appendices) to the site PIs for revision.

Title	 <p data-bbox="475 309 1279 398" style="text-align: center;">SOP 01 - Development, Approval and Review documents</p>
Document type	SOP
Version N.	1.1
Date:	July 22nd 2019

- **After the revision process:** the PI will send by e-mail the final approved document to all the G-DEFINER members.
- **After document amendments:** the PI will send by e-mail the final approved document to all the G-DEFINER members.

5. Document history

Version N.	Date	Reviewer	Details of changes
0.1	May 8 th 2019	RM	Creation
0.2	May 23 rd 2019	RM	Title modification (from "SOP of SOPs", to "SOP for drafting document, to make the SOP more general.
1.0	May 29 th 2019	RM	Title modification (from "SOP for drafting document", to "Development, Approval and Review documents".
			Added specific par. for SOP (page 36 doc "(U)bs47124.pdf")
1.1	July 22 nd 2019	RM	Modified CI (chief investigator) in PI (principal investigator)