Clinical Research Centre
Data Release Form

Office use only:-
Request ID#: _____
Date received: ___/___/___

SECTION 1: PROJECT /STUDY DETAILS *(to be completed by requestor)*			
1.	Request data from (name of the registry):		
2.	Type of Research project / study	☐ Registry ☐ Others, specify _____	
3.	NMRR project ID (if available):		
4.	Name of the project / study:		
5.	Organization / Hospital / Agency responsible for the project		
6.	Name of the person in charge (requestor):		
7.	Designation:		
8.	Phone / fax numbers:		
9.	Email:		
10.	Address:		
11.	Date of submission / request:	☐☐/☐☐/☐☐☐☐ (dd/mm/yyyy)	
12.	Date data release is expected:	☐☐/☐☐/☐☐☐☐ (dd/mm/yyyy)	
13.	Urgency of the request	❍ Low ❍ Medium ❍ High	
14.	Purpose of the data request:	☐ Research ☐ Business ☐ Not available ☐ Clinical Planning ☐ Subject data ☐ Others, specify _____	
15.	Attached together with this form	A Study proposal / protocol *(address as well the benefits / overall importance of this project)*	❍ Yes ❍ No ❍ Not applicable ❍ Not available
		Ethics committee approvals / statement	❍ Yes ❍ No ❍ Not applicable ❍ Not available
		Study sponsor approval or other documentation of permission received, specify _____	❍ Yes ❍ No ❍ Not applicable ❍ Not available
		Curriculum Vitae of the person in charge *(name in item no. 6 above)*	❍ Yes ❍ No ❍ Not applicable ❍ Not available
16.	Affiliates :-	❍ Yes *(complete the table below)* ❍ No	❍ Not applicable

Clinical Epidemiology Unit, CRC
2nd Floor MMA House,
124 Jalan Pahang, 53000 Kuala Lumpur, Malaysia
Tel: 03-40443060/ 40443070; Fax: 03-40443080

Affiliates / key research personnel (Other key persons with access to the data):-				
#	Name	Designation	Organization / Institute / Agency name	Email address

SECTION 2: DETAILS OF THE DATA REQUEST *(to be completed by requestor)*		
17.	Indicate how the data will be used	☐ Own department / Unit use ☐ Own Hospital / Agency / Organization use ☐ Department / Unit/ Hospital/ Agency / Hospital, other than own, specify_____ ☐ Educational purposes ☐ Research ☐ Publication ☐ Public policy ☐ Others, specify_____
18.	Duration use of the data	☐☐/☐☐/☐☐☐☐ (dd/mm/yyyy) to ☐☐/☐☐/☐☐☐☐ (dd/mm/yyyy)
19.	Disposition of the Data *(including any printouts or copies that contain individual identifiers)*	Estimated Date: ☐☐/☐☐/☐☐☐☐ (dd/mm/yyyy) Method:
20.	Indicate how project / study results will be disseminated and identify target audience	
21.	Data security measures to be used *(state where and how the data will be stored and maintained)*	
22.	Years required (of the data)	☐☐☐☐ to ☐☐☐☐ or specify: _____
23.	Type of data required	☐ Tabulation / summary / aggregated data ☐ Records files with identifiers ☐ Records files without identifiers ☐ Others, specify _____
24.	List of data elements requested *(please attached a copy of the list if it is too long)* or the summary data / tables with the descriptions	
25.	Format of the data files	☐ Excel ☐ Text ☐ Others, specify _____
26.	Additional information / Comments (if any)	

SECTION 3: DECLARATION BY APPLICANT: *(to be completed by requestor)*
• I hereby acknowledge that upon approval the data given to me will be used for the purpose outlined in the original request as above and agreed upon at the time of provision of the data and will not communicated to other parties. • I will give the above mentioned registry and CRC prior notice of any intended publication for provision of the data and will acknowledge the above mentioned registry and CRC as the source data. • I will take responsibility and guarantee the security and confidentially of the data throughout the duration of my access / custodianship. • I will not grant a third party access to the data unless the third party has obtained written approval from above mentioned registry and CRC • Any information obtained from this data released may only be published in aggregate tables or as part of the analysis of the data • No individual person or organization is to be identified at any stage of the analysis or subsequent reporting unless consent has been obtained. • I will provide registry with a copy of all published and pertinent results when accepted for publications
SIGNATURE OF REQUESTOR:
NAME OF REQUESTOR:
DATE: (dd/mm/yyyy)

Note:
if there is a change of purpose / scope, a new data release form must be submitted prior to the requestor used of the released data. The requestor is require to report in writing to the registry or CRC when data are disposed of, returned or destroyed as agreed. The data custodian / data access officer will contact you after processing your initial request and may need you to supply additional information

SECTION 4: CORRESPONDENCE ADDRESS (for office use only)
All correspondence regarding this application should be directed to (Respective Project / Registry Manager to complete):
Name/Affiliation:
Address:
Telephone/Fax:
Email:

SECTION 5: APPROVAL (for office use only)			
Status: (request for data approved)	❍ Yes →	If yes, any conditions of approval, specify:	_____
	❍ No →	If No, reason for refusal, specify:	_____
	❍ Other status, _____	Any comments:	_____

SIGNATURE :
NAME :
DESIGNATION:
DATE: (dd/mm/yyyy)

(if more than one signature is required):

SIGNATURE :	
NAME :	
DESIGNATION:	
DATE: (dd/mm/yyyy)	

SIGNATURE :	
NAME :	
DESIGNATION:	
DATE: (dd/mm/yyyy)	

SECTION 6: DATA ACCESS OFFICER / PROJECT MANAGER (for office use only)

SIGNATURE :	
NAME :	
DATE: (dd/mm/yyyy)	

- Date request sent to database administrator / data manager / project manager: ☐☐/☐☐/☐☐☐☐
- Date of data release to the requestor: ☐☐/☐☐/☐☐☐☐
- Method of data transfer:
  - ☐ FTP
  - ☐ Web application
  - ☐ Specific folder within CRC Network
  - ☐ CD /DVD
  - ☐ Others, specify _____
- Date of acknowledgement of the data receipt: ☐☐/☐☐/☐☐☐☐
- Method of confirming the data transfer / release has been completed and successful:
  - ☐ Mail
  - ☐ Fax
  - ☐ email
  - ☐ Others, specify:_____
- Comments (if any):

This Agreement is entered into this ____ Day of _____ by and between

Study / registry Name
(hereinafter "study / registry")

and

An individual or institution requesting for to release of data
(hereinafter "Requesting party")

WHEREAS, the Requesting party wish to request the study / registry to release data for a specified purpose as set forth in the Application Form;

WHEREAS, in agreeing to this request, it shall be necessary for the study / registry to disclose confidential, sensitive or proprietary information to the Requesting party;

WHEREAS, the Requesting party desires to receive all such data, information and materials subject to the term and conditions set forth herein;

1. Requesting party agrees to abide by applicable regulation or legislation with respect to data confidentiality and patient rights.
2. Requesting party shall comply with the same requirements for information security such as those observed by the study / registry.
3. Requesting party's obligation to maintain confidentiality continues indefinitely.
4. Requesting party shall not purposely disclose confidential, sensitive or proprietary information received from the registry / study to other parties, except to individuals known to be authorized to receive such information. Such individuals shall act with due care to avoid the inadvertent disclosure of such information to anyone else.
5. All confidential, sensitive or proprietary material shall be used for the purposes set forth and for no other purpose without the prior written consent of the study / registry.
6. All confidential, sensitive or proprietary material shall remain the exclusive property of the study / registry and shall be promptly returned or destroyed upon request of the study / registry .
7. Requesting party shall notify in writing the Chairperson of the study / registry Governance Board when the data are disposed of, returned to the study / registry or destroyed upon request of the study / registry.
8. Requesting party shall ensure that no publication of results will enable any individual to be identified.
9. Requesting party agrees not to contact persons or their relatives whose identities have been provided in confidence by the study / registry unless a written authorization to do so has first been obtained from the treating physician or cardiologist.
10. Where appropriate, Requesting party shall seek approvals by ethical committees for the intended use of the data the Requesting party is seeking from the study / registry. Where such approval has been obtained, the Requesting party shall inform the study / registry
11. Requesting party shall provide the Chairperson of the study / registry Governance Board with an annual status report on the data.

12. Requesting party shall provide Chairperson of the study / registry Governance Board with a copy of all published results when accepted for publication or, if not published, all pertinent results at the time of disposal of the data.
13. Requesting party shall state in all published results that the analysis and interpretation are those of the author and not the study / registry.
14. Requesting party shall give due acknowledgement to the study / registry for the provision of the data.
15. the study / registry reserve the right to charge Requesting party a processing fee, such amount to be determined.
16. Requesting party agrees that any breach of this Agreement may result in irreparable injury and damage to the study / registry that may not be adequately compensated in monetary terms, and for which there may be no adequate remedy at law. Requesting party therefore gives consent and agrees that the study / registry shall obtain injunctions, orders or decrees as may be necessary to protect information, material or data that the study / registry considers and treats as confidential, sensitive or proprietary.
17. No rights or licenses, expressed or implied, are hereby granted to Requesting party under or in any patents, know-how, copyrights, trade secret, or trademark of the study / registry as a result of, or related to, this Agreement.
18. This Agreement and the relationship and subject matter thereof shall not be disclosed to any third party without the prior written consent of the study / registry.
19. The failure of the study / registry to enforce any provision of this Agreement shall not operate as a waiver of such provision or of any other provision of this Agreement.
20. This Agreement shall be constructed under the laws of Malaysia, and any action instituted pursuant to the terms of this Agreement shall be brought in the Court of Malaysia.

IN WITNESS THEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives on the date first written above.

CHAIRPERSON/ PROJECT MANAGER of the above study / registry

SIGNATURE :
NAME :
TITLE:
DATE: (dd/mm/yyyy)

REQUESTING PARTY's NAME:-

SIGNATURE :
NAME :
DESIGNATION:
DATE: (dd/mm/yyyy)