

Undertaking Form on the use of Data provided by the Hospital Authority

In consideration of the Hospital Authority (HA) agreeing to provide				
	[the Entity] Note 1 wit			
data v	within the scope identified in Schedule 1 ("Data"), the Entity undertakes and agrees that:			
(a)	the Data will be used solely and specifically by the Entity only for the purposes of the Study			
	identified in Schedule 1 ("the Study");			
(b)	all Data will be kept confidential at all times and destroyed pursuant to Clause 12;			
(c)	only the authorized users specified in Schedule 2 ("the Users") will be given access to the Data			
	and, prior to such access, the Users will be placed under obligations of confidentiality no les			
	onerous than those on the Entity;			
(d)	the Entity will comply, and procure that the Users comply with the terms and conditions of use			
	of the Data set out below and in this Undertaking; and			
(e)	if the Entity and/or any or the Users fails to comply with the terms or fulfill their obligation			
	hereunder, the Entity shall be fully liable to HA for any costs, losses or damage to HA resulting			
	from, incidental to or in connection with such non-compliance or failure.			

Note 1: Please state the full name of the entity, such as a university or charitable institution or organization. Names which only contain a faculty, department or division of any university, institution or organization are not acceptable.

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Terms and Conditions:

- 1. The Data belongs to HA and is provided to the Entity on a confidential basis for the sole purpose of the Entity and/or the Users performing scientific research solely for the Study. The Data and the derived findings must <u>not</u> be put to commercial use. For the purpose of this Undertaking Form, "commercial use" means that any intended use of the Data and/or the derived findings is (a) directly or indirectly for profit; and/or (b) to produce goods, works, services or data for generating income or other business use.
- 2. If the Entity wishes to request to amend or extend the scope of the Data within one year from the date when the Data is first provided by HA to the Entity, HA may have the sole discretion to decide whether to accept such request without substantial evaluation and approval, provided that ALL of the following conditions are met:
 - (i) the request is made pursuant to the Study with the same principal investigator, Users, study objectives and Study protocol;
 - (ii) valid ethics approval and patient consent (if applicable) have been obtained; and
 - (iii) the request is to seek the same nature, type or category of the originally approved Data of an amended or extended period.

Otherwise, a full vetting process will be conducted by HA for determining whether to accept such request.

- 3. The Entity and the Users must <u>not</u> use the Data for any projects / purposes other than the Study, except with HA's prior written approval (such approval may be given or withheld at HA's sole discretion and may be given subject to conditions).
- 4. The Entity and the Users must <u>not</u> cross-match or link up or attempt to cross-match or link up information on any individual patient in the Data with any of the patient's personal or clinical information held by or made known to the Entity and/or the Users, or which is collected or made available to the Entity and/or the Users for projects / purposes other than the Study, unless patient's prior written consent to this data matching or linking has been sought.
- 5. The Entity and the Users must <u>not</u> contact or attempt to contact any individual person listed on the Data or any other third parties associated with that person.

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- 6. The Entity and the Users must <u>not</u> transmit or release the Data, in whole or in part and in whatever form or media, to any other parties without HA's prior written approval.
- 7. The Entity and the Users must <u>not</u> transmit or release the Data, in whole or in part and in whatever form or media, to any party or place outside Hong Kong.
- 8. The Entity and the Users must acknowledge HA in all publications in which data or analyses from the Data are quoted or presented ("**Publications**"). The Entity and the Users shall <u>not</u> disclose or make reference to the identity of any individual in the Data in any Publication, and shall ensure that no Publication shall contain any confidential information which the Entity and/or any User is subject to strict confidentiality requirements (except the Data published in accordance with this Form) and/or any information that can identify any individual, household or organization.
- 9. HA reserves its full rights and discretion on all matters pertaining to the use of the Data, particularly the release, interpretation and usage of data / output.
- 10. The Entity shall comply with, and procure that the Users comply with, all laws, rules and regulations applicable to their use of the Data. The Entity and the Users shall fully comply with their duties under the law relating to the protection of personal data including those under the Personal Data (Privacy) Ordinance and its principles in all aspects.
- 11. The Entity and the Users agree to keep the Data in safe and secure custody and take all necessary and appropriate technical and organizational security measures to protect the Data against unauthorized or accidental access, processing, erasure, loss or use, having particular regard to:
 - (i) the nature, type or category of Data and the damage or harm that could be resulted from such incident;
 - (ii) the physical location where the Data is stored;
 - (iii) any security measures incorporated (whether by automated means or otherwise) into any equipment in which the Data is stored;
 - (iv) any measures taken for ensuring the integrity, prudence and competence of the Users; and
 - (v) any measures taken for ensuring the secure transmission of the Data.

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- 12. The Entity and the Users agree to ensure, and to confirm in writing to HA, the permanent destruction or deletion of the Data from their computer system or other records in whatever form or medium with the completion and submission of the **Declaration of Data Destruction** (a template of which is provided in Schedule 3 and may be revised by HA from time to time) to HA within (i) 12 months of the Study Completion Date, or (ii) 5 years from the date when the Data is provided by HA to the Entity, whichever is earlier.
- 13. The Entity and the Users agree to promptly notify HA if it becomes aware of any incident or suspected or actual case of unauthorized or accidental access, processing erasure, loss or use of Data.

14. The Entity must:

- (i) permit HA and its authorized agents to conduct an audit or inspection of its premises, records and information systems and make available to HA all information, as reasonably necessary to demonstrate its and the Users' compliance with the obligations under this Undertaking; and
- (ii) provide reasonable access and assistance to HA and its authorized agents for carrying out the audit or inspection under this Clause 14. The Entity may provide HA such access and assistance during its normal operating hours and HA shall use reasonable care to ensure that the audit or inspection does not interfere with the Entity's usual operations.
- 15. The Entity shall defend, indemnify, and hold harmless HA and any of its officers, employees, agents, and affiliates (each an "Indemnified Person", together hereinafter referred to as the "Indemnified Persons") from and against any and all liability, claims, losses, damages, costs or expenses (including legal fees) which any Indemnified Person may hereafter incur, or be required to pay as a result of any negligence or default of the Entity and/or any of the Users, its officers, employees, agents and affiliates in connection with the Entity's use or analysis (whether through the Users or otherwise) of the Data, or as a result of any breach of this Undertaking. The Entity shall promptly notify HA upon learning of the institution or threatened institution of any such liability, claim, lawsuit, losses, damages, costs, and expenses against HA and shall cooperate with HA in the defence or settlement thereof at HA's request. The Entity hereby agrees to provide, at its own expense, attorneys to defend against any actions brought or filed against the Indemnified Persons with respect to the indemnity contained herein.

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- 16. The Entity agrees to promptly notify HA if:
 - (i) the list of Users in Schedule 2 changes; or
 - (ii) the Study will or may involve any entity (which has not been stated in the data request application form for the Study submitted to HA) in any form, including as project sponsor, coordinator, consultant or financial or technical supporter, regardless of whether such entity may or may not have access to the Data.
- 17. Without prejudice to any other right or remedy that HA may have, if HA is aware of or suspects any non-compliance or contravention of the terms hereunder by the Entity or any User ("**Breaching User**"), or if there is any change to the list of Users or involving entities which the Entity shall be required to notify HA pursuant to Clause 16,
 - (i) HA shall have the sole discretion to:
 - (a) immediately suspend the use and/or access to the Data by the Entity and/or the Breaching User for a fixed or indefinite period of time as determined by the HA in its sole discretion up to the time of permanent destruction, deletion and removal of such Data pursuant to Clause 12. The HA may notify the Entity of the suspension and require the Entity to investigate and/or remedy the suspected noncompliance or contravention within a time period specified by HA;
 - (b) require the Entity to permanently destroy, delete or remove the Data immediately or within such period as specified by HA prior to the specified time for permanent destruction, deletion and removal of the Data pursuant to Clause 12 and the Entity shall accordingly destroy, delete and remove the Data permanently and submit the completed Declaration of Data Destruction to HA;
 - (c) report to the relevant Research Ethics Committee;
 - (d) reject any future data request from the Entity or the Breaching User for a fixed or indefinite period of time as solely determined by HA; and/or
 - (e) issue warning letter or letter of reprimand to the Entity and/or the Breaching User; and
 - (ii) HA reserves the right to:
 - (a) discuss with the Entity on the appropriate sanction to be imposed by the Entity on the Breaching User and jointly determine with the Entity such sanction on the Breaching User, such as the removal of the Breaching User from the relevant research team;
 - (b) require a halt to the relevant research project;

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- (c) prohibit the issuance of any Publication; and/or
- (d) demand for retraction of any Publication.
- 18. To the extent permitted by law, HA does not guarantee and excludes any and all liability for any claim, action, proceeding, payment, loss or damages suffered by the Entity or any of the Users that may arise as a result of or in connection with the suspension of use and/or access or permanent destruction, deletion and removal of the Data by the Entity and/or the Users under Clause 17.
- 19. The use of the Data is for statistics and research purposes for the Study. Only aggregated data will be presented. The Entity and the Users shall <u>not</u> disclose or make any reference to the identity of any patient in the Data in any published documents.
- 20. The Data are collected for HA internal use only and the quality of the Data may not achieve the standard for scientific research. The Data is provided by HA without any liability or warranty as to quality, accuracy, timeliness, non-infringement or fitness for a particular purpose. To the extent permitted by law, HA does not guarantee and excludes any and all liability for any claim, action, proceeding, payment, loss or damages suffered by the Entity or its Users that may arise as a result of or in connection with the provision of Data by HA hereunder. Upon the provision of the Data to the Entity and the Users, HA reserves its full rights and discretion to respond to any further enquiries.
- 21. This Undertaking shall be governed by the laws of Hong Kong. The Entity acknowledges that any breach by it or the Users of this Undertaking may cause damage to HA not remediable in damages and that HA may pursue equitable remedies on an actual or potential breach by the Entity or the User as an alternative to damages.

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The Entity

Authorized Signature & Chop	:	
Name and Title of Person Authorized to Represent the Entity ^{Note 2}	:	
Name of Entity Note 1	:	
Address	:	
Contact Tel. No.	:	E-mail:
Date	:	
Principal Investigator		
Name	:	
Signature	:	
Title / Post / Rank	:	
Department	:	
Entity	:	
Address	:	
Contact Tel. No.	:	E-mail:
Date		

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Schedule 1 - Details of the Study / Data Request

1. Title of Scientific Research (the Study):
2. Source of Funding:
3. Study Period: Study Start Date: (DD / MM / YYYY) Study Completion Date: (DD / MM / YYYY)
4. Data Requested Please refer to the attached Data Request Application Form.
5. How and where will the Data be handled and stored during and after the completion of th Study?
The Data will be kept in a physical location in Hong Kong as specified below:
Please specify <u>a local address</u> and <u>server location for storing the Data</u> , that can only be accessed by
the Users, and the Data will be permanently destroyed within 12 months of the Study Completic
Date. <u>Declaration of Data Destruction</u> , duly completed, will be sent to HA for records.

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6.	Are there other data protection measures e.g. policies, protocols or guidelines, access right control and management, other infrastructure security measures (e.g. presence of firewall, intrusion detection, data encryption etc.), staff training to ensure that the Users will
	comply with the obligations under this Undertaking? Please specify below.
7.	Who will be responsible for data safekeeping?
	(Nama T:41a)
of	
	e main contact for the data safekeeping issues.
UII	main comment for the data barenceping issues.

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Schedule 2 - List of Authorized Users (e.g. principal investigators, research team members, co-investigators from private sector)

Note: If space is inadequate, please use separate sheet.

	Name	Title /Post /Rank	Department / Entity	Contact Tel No.	E-mail Address	Signature*
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						

^{*} By signing herein, each of the Users confirms that he/she acknowledges and fully understands the Undertaking Form on the use of Data provided by the Hospital Authority for the Study (the "Undertaking") and agrees to comply with all applicable terms and conditions under the Undertaking.

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Schedule 3 - Declaration of Data Destruction

The undersigned,		(Name)
of		(the Entity),
certifies that all Hospital	Authority (HA) data (the "Data"), provided to the Entity for the Scientific
Research (the "Study") v	vith Title	
(Study Completion Date:		_ (DD/MM/YYYY)), as specified in the submitted
"Undertaking Form on th	e Use of Data provide	ed by the Hospital Authority" (the "Undertaking
Form") together with any	y materials in any form	n that incorporate, reference or contain any of the
Data, have been permane	ently destroyed or dele	ted from the computer system or our records and the
records of the Users (as d	lefined in the Undertal	king Form) in whatever form or medium on
/	(DD/MM/YYYY). For	r the purpose of this Declaration, "destruction" or
"deletion" of the Data ha	s occurred by a metho	d or methods that protect(s) the confidentiality of the
proprietary data, employi	ing a method or metho	ods of destruction or deletion such as shredding or
burning or otherwise rend	dering the media to no	n-readable form.
Principal Investigator	:	
Signature	:	
Title / Post / Rank	:	
Department	:	
Entity	:	
Address	:	
Contact Tel. No.	:	E-mail:
Date	:	

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