# UNIVERSITY OF SYDNEY PROTOCOL FOR THE EXECUTION OF DOCUMENTS

Mark to note

This document should be completed and attached to any recommendation to a delegate to execute a document. Pages 1 and 2 relate to the key features of the transaction that is represented by the document to be executed; page 3 (the Document Process Checklist) relates to the approval process.

Summarise the transaction being recommended for execution	IRMA CT32236 SNow MTAO0001152	
	Type of Agreement: Material Transfer Agreement (Outgoing) with Kings College London	
	USyd Researcher: Tihana Divnic-Resnik	
	USyd IP: N/A	
	Background for Director:	
	This is a low risk MTA on a USYD template (with amendments). USYD are providing saliva and plaque samples from the Dental school for use by KCL who will be examining the Lipid-A content to see whether this is a reliable marker for a periodontitis screening test.	
	KCL are NOT a reportable entity under foreign arrangements laws.	
List the documents to be executed, including the parties and the method of execution <sup>1</sup>	Material Transfer Agreement - DocuSign d of	
Outline the risks and benefits for the	Risks: ⊠ Low □ Moderate □ High	
University from entering into the transaction including relative to other options considered	Not formally assessed but risks will be contained to this project, if any.	
	Benefits: Public good research by KCL	
Indicate extent of the University's commitment, face value and in-kind (\$);	Face Value: N/A	
risk value approx (\$) <sup>2</sup>	In-kind: N/A	
	Risk value: Low	
If the transaction involves a contract between USyd and a private sector entity, and the total or accumulative value of the contract is equal to or greater than or equal to \$150k, you must provide details to Finance/Records or OGC (TBC) for inclusion in register of contracts which is publically available as required by the Government Information (Public Access)  Act NSW 2009 (GIPA). Grounds may exist for deleting some of the information in the register of contracts if there is any overriding public interest against disclosure of that matter. Have you considered whether such grounds exist? Have these been discussed with USYD OGC?	NA □ Yes □ No ☒	

<sup>&</sup>lt;sup>1</sup> For example, whether the document needs to be witnessed or executed under seal

Where there are resource implications for faculties or divisions other than the faculty/division recommending the execution of the document, provide evidence of sign-off by those faculties/divisions

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between USYD and a private sector entity under which the contractor is required to provide services to the public on behalf of USYD?	Tes ☐ No ☐  If Yes: Provide details of the service, refer to clause number and advise if the clause includes immediate right of access to USyd to certain information held by the contractor.  Yes ☐ No ☐  If yes:  A. Is the Client based overseas, or an Australian subsidiary of an overseas company? Yes ☐ No ☐  B. Is there a partner to the agreement who is based overseas, or an Australian subsidiary of an overseas company? Yes ☐ No ☐  If either of the above is Yes:  1. Has Donna Capararo (Government Sanctions and Export Controls) and/or Helen Brown (OGC) been consulted? Yes ☐ No ☐  2. Has the academic been alerted to the need to conduct a check using the Department of Defence online tool?: (https://dsgl.defence.gov.au/Pages/Home.aspx) Yes ☐ No ☐  3. Has an appropriate clause been included in the agreement? Yes ☐ No ☐  4. Other Actions that need to be taken: N/A to this type of material		
Are there any issues of compliance with legislation, USYD (Research Agreements) policy and guidelines? How will compliance be assured?			
Defence Trade Controls Act.  https://intranet.sydney.edu.au/research-support/government-regulations-and-reporting/export-controls.html			
Intellectual Property Rights.	□ N/A □ Option □ Licence to Commercial Entity		
Mark relevant box.	□ Licence to other University □ Assignment ☒ Other:  New IP created by KCL owned by KCL.  Background IP of USYD retained by USYD.  Mutual right to use the other's for non-commercial purposes only.  Yes ☒   No □  Yes ☒ No □		
Is the document a standard USyd template?			
Were any substantive amendments made to standard USyd template?			
If the document is not a standard USyd template, has documentation been prepared or reviewed by USYD OGC? If OGC raised concerns, how have they been addressed <sup>4</sup>	Yes □ No ☒  Reviewed and negotiated by Deb in Research Portfolio capacity – happy with negotiated edits.		
Summarise expert advice obtained on due diligence, intellectual property, financial issues, insurance, tax and stamp duty <sup>5</sup>	⊠ N/A		

Contact USYD OGC if you need more information regarding whether services are "to the public".
 If a USYD OGC authorised template document has been used, indicate here
 Relevant advice should be attached

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Do	Give details of consultation process				
	Who has delegated authority for the execution of the documents <sup>6</sup>	<ul> <li>☑ Director, Post Award, Research Operations ☐ Executive Director,</li> <li>Research Operations ☐ DVC(R) ☐ Vice-Chancellor</li> </ul>			
	Officer making recommendation and date	Name: Deb Hook  Date: 5 July 2021			
		Date. 3 daily 2021			

This PED should be attached to the hard copy of a document recommended for execution by the Delegate and kept on file. If a hard copy is not required a scanned copy of the PED should be uploaded to the relevant RIMS or IRMA file.

<sup>&</sup>lt;sup>6</sup> Cite relevant delegation or Council resolution

Ref: CT32236



# THE UNIVERSITY OF SYDNEY Inter-Institutional Material Transfer Agreement

	Agreement		
Parties			
University	The University of Sydney, a body corporate under the University of Sydney Act 1989, ABN: 15 211 513 464, of c/o Research Portfolio, Level 3 Administration Building (F23), The University of Sydney, NSW 2006 Australia		
Project Officer	Attention: Director, Post Award Telephone: +61 2 8627 8111		
	Email: research.support@sydney.edu.au		
Recipient	King's College London, a university incorporated in England by Royal Charter, of Strand, London, WC2R 2LS, United Kingdom		
Project Officer	Attention: Head of Contracts Telephone: +44 (0)20 7848 6781		
	Email: <u>laura.weiss@kcl.ac.uk</u>		
Details			
Effective Date	The effective date of this agreement is:		
Does the Material include biological materials?	Yes		
Material	Saliva samples taken from 90 participants (270 samples); and		
(clause 1.1)	Samples of subgingival plaque (biofilm) taken from 90 participants with the paper points (270 samples) from the Westmead Oral Health Biobank, School of Dentistry, University of Sydney,		
	and, if the Material includes biological materials, includes any Progeny and any Unmodified Derivatives as applicable but does not include Modifications.		
Supply Details (clause 1.1)	Material will be stored at -80 degrees in the Westmead Oral Health Biobank.		
	The samples will be anonymised and stored in the designated freezer until they are ready to be collected by the FeDex express courier agent on behalf of the Recipient. All samples will be packed and prepared for transportation following the <i>«Instructions for packaging, marking, and labeling Biological Substance, Category B (UN 3373) shipments for FedEx Express® services ».</i>		
Location (clause 1.2)	The Material may be used at Guy's Hospital, 18th Floor, Great Maze Pond, SE19RT, London, ACT 2142, United Kingdom		
Research Purpose	To conduct the research project:		
(clause 1.2)	Development of lipid-A-based population screening test & chair-side diagnostics for personalised, point-of-care periodontal therapy		
	as further described in Schedule 1.		
Recipient Personnel	Zaric Svetislav		
(clause 1.2)	svetislav.zaric@kcl.ac.uk		
Reports (clause 6)	A final report outlining the results of the Research Purpose to be submitted to the University within three months following the conclusion of the Research Purpose or the Expiry Date (whichever occurs first).		
Data (clause 2)	Anonymised participant number, diagnosis and site where plaque samples were taken from.		

File name: MATERIAL\_TRANSFER/93\_2

Date

(Outgoing – To non-commercial recipient) Inter-Institutional Material Transfer Agreement [007][8-May-20]				
Third Party Rights (clause 4.5)	Third party obligations are currently in place in relation to the Material and/or Data: YES			
Expiry Date (clause 7.1)	Not applicable			
Special Terms				
This agreement is subject to the following special terms:  Not Applicable.				
Note: Unless indicated otherwise, all capitalised terms in column 1 of the Details have the meaning given in column 2. <b>EXECUTED</b> as an agreement on the terms of the Details and General Terms.				
SIGNED for and on behalf of THE UNIVERSITY OF SYDNEY by its duly authorised representative:				
Docusigned by:  Mark Kay  C88AD4F3EB9444D  Signature  Mark Kay				
Printed Name Director, Post Award Position 7/7/2021				
Date				
SIGNED for and on behalf of THE ORGANISATION by its duly authorised representative:				
DocuSigned by:  Signature  DocuSigned by:  Signature		Signature		
Printed Name		Printed Name		
Position		Position		

**Note:** By executing this agreement each signatory represents that he or she is authorised to sign on behalf of their entity. The effective date of this agreement will be the Effective Date specified in the Details or if no Effective Date is specified in the Details the date on which the agreement has been executed by ALL Parties.

Date

# **General Terms**

#### 1 Material

#### 1.1 Supply

The University agrees to supply the Material and the Data to the Recipient for the Research Purpose in accordance with the Supply Details.

#### 1.2 Use

The Recipient agrees to limit the use of the Material and Data so that it is used:

- (a) only at the Location;
- (b) only for the Research Purpose;
- (c) only under the direction of the Recipient Personnel; and
- (d) not for any commercial or profit-making purpose.

#### 1.3 Biological materials

If the Material includes biological materials, the Recipient agrees not to use the Material in human subjects or in clinical trials involving human subjects without the written permission of the University.

# 1.4 Compliance with regulations and policy

The Recipient agrees to use, and ensure the use of, the Material and Data in accordance with all applicable statutes, regulations and codes of conduct, including those relating to research involving humans, animals or DNA, and only after first obtaining necessary approvals from its relevant ethics committee(s).

#### 1.5 Limited transfer

The Recipient must not transfer the Material or Data to any other party other than a party working under the direct supervision of the Recipient Personnel at the Location unless it obtains the prior written consent of the University. The Recipient will promptly submit any requests to transfer the Material or the Data to the University for approval, such approval to be withheld in the University's absolute discretion.

#### 1.6 Security and safety measures

The Recipient will establish and implement appropriate policies and procedures to:

- (a) safeguard the Material and the Data against disclosure to other parties with the same degree of care as it exercises with its own materials of a similar nature;
- (b) maintain the Material and Data under appropriate and safe conditions and in accordance with any directions by the University; and

(c) keep the Material and Data in such a way that it is clearly identifiable as the property of the University.

#### 2 Data

#### 2.1 Limited use and disclosure

The Recipient must take all action necessary to maintain the secrecy of the Data and, without limiting the foregoing, will not:

- (a) use the Data other than for the performance of the Research Purpose;
- (b) disclose the Data to any other person other than its employees who reasonably require access to the Data in the performance of the Research Purpose; or
- (c) manufacture any product or use any process based on such Data or otherwise commercialise anything based on that Data except with University approval under clause 4.4 (Registrable IPRs).

#### 2.2 Scope of obligations

In this agreement, the term Data means the information specified as such in the Details as provided by the University to the Recipient but excludes information which:

- (a) is in or becomes part of the public domain other than through a breach of this agreement;
- (b) the Recipient can prove by contemporaneous written documentation was already known to it at the time of disclosure by the University; or
- (c) the Recipient acquires from a third party lawfully entitled to disclose it.

## 3 Monetary obligations

#### 3.1 Delivery costs

All costs relating to the delivery of the Materials and Data to the Recipient under this agreement will be borne by the Recipient, unless otherwise specified by the University.

# 4 Ownership rights

#### 4.1 Tangible property

The Recipient acknowledges that the University will continue to own the Material and Data, and own Progeny and Unmodified Derivatives, and that the Recipient will hold that property on the University's behalf as bailee. Ownership of Modifications will be dealt with subject to clause 4.4 (Registrable IPRs).

#### 4.2 Intellectual Property Rights

The Recipient acknowledges that:

- (a) the ownership of IPRs in the Material and Data remains with the University ('Background IP');
- (b) the University owns IPRs relating to Progeny and Unmodified Derivatives;
- (c) the ownership of IPRs relating to
  Modifications will be dealt with subject to
  clause 4.3 (Ownership of New IPRs); and
- (d) no licence of the IPRs in the Material and
  Data to the Recipient beyond the rights
  provided by this agreement is implied by
  the Recipient's use of the Material or Data.

#### 4.3 Ownership of New IPRs

- The ownership of new IPRs arising from (a) the Recipient's use of or access to the Materials and/or Data, including any IPRs in any inventions created by the Recipient or in any Modifications ("New IPRs"), will be owned by the Recipient ('Recipient New IPR'), except (i) where such discoveries and inventions constitute modifications of the University's datasets, designs, images or databases or (ii) where they incorporate, embed or otherwise contain the University's Background IP and can only be used by also using all or part of the University's Background IP, in which circumstances they shall be owned by the University ('University New IPR').
- (b) The Recipient grants to the University an automatic, non-exclusive, fully paid-up, royalty-free, licence to use Recipient New IPR for its academic research and educational purposes, and the University hereby covenants not to sue the Recipient for use of the University New IPR and any Background IP necessary to be able to use such University New IPR for the Recipient's non-commercial, internal, academic research and educational purposes. Any commercialisation of New IPRs will first require the parties to negotiate and agree a commercialisation agreement.
- (c) The Recipient will provide details of any New IPRs to the University within a reasonable time period from the date of creation of the New IPRs and will comply with any other reasonable reporting requirements in relation to New IPRs which are notified by the University.

#### 4.4 Registrable IPRs

If the use of the Material or Data by the Recipient results in any IPRs which are capable of being registered, and which may be commercially useful, but which are not owned exclusively by the University under clause 4.2 (Intellectual Property Rights), including any New IPRs under clause 4.3

- (Ownership of New IPRs), then the parties will negotiate to determine:
- (a) inventorship and the relative contributions between the parties;
- (b) what, if any, IPRs registration applications will be made, the party responsible for registration and maintenance and the apportionment of any associated costs; and
- (c) the process of commercialisation.

#### 4.5 Pre-existing rights

The provision of the Material and Data to Recipient will not alter or detract from any Third Party Rights in the Material and Data.

#### 5 Publication

#### 5.1 Publication rights

Subject to clause 5.2 (Acknowledgments), this agreement will not be interpreted as preventing or delaying publication of research findings resulting from use of the Material, Modifications or Data by the Recipient.

#### 5.2 Acknowledgments

The Recipient agrees to appropriately acknowledge the source of the Material or Data in all publications which contain, refer to or use the Material or Data and, if requested, agrees to send the University a copy of any such publications at the time of submission or publication.

## 6 Warranties and liability

#### 6.1 No warranties

The Recipient acknowledges that the Material is experimental in nature and may have hazardous properties. To the extent permitted by law and subject to clause 6.3 (Statutory terms), the University makes no representation or warranty that the Material or Data is fit for the particular purpose for which it is required by the Recipient. The University expressly excludes and disclaims any warranties that;

- (a) the use of the Material or Data for the Research Purpose will not infringe any third party IPRs or other rights or that;
- (b) the Recipient is able to perform the Research Purpose or to use or commercialise the research results.

#### 6.2 Implied warranties

To the extent permitted by law and subject to clause 6.3 (Statutory terms), the University excludes all implied terms, representations and warranties whether statutory or otherwise, relating to the subject matter of this agreement.

#### 6.3 Statutory terms

Where any statute implies in this agreement any term, and that statute voids or prohibits provisions under a contract which exclude or modify the operation of such term, such term is deemed to be included in this agreement. However, the University's liability for breach of such term will be, if permitted by law, limited (at the University's option) to replacement of the goods or supply of equivalent goods, or the payment of the costs of replacing the goods or of acquiring equivalent goods.

#### 6.4 Liability limit

Subject to clause 6.3 (Statutory terms), the University's total liability to the Recipient for loss or damage of any kind, however caused, due to the Recipient's negligence, breach of contract, breach of any law, in equity, under indemnities or otherwise, arising from or in any way related to this agreement, the Material or the Data is limited to AU\$2,000.

#### 6.5 Liability for use

The Recipient assumes all liability for direct losses which may arise from the Recipient's use, storage or disposal of the Material and Data. The Recipient indemnifies the University for any liability, direct loss, direct costs, and direct expenses (including legal costs and expenses) incurred or suffered by the University from any claim or demand by any other person due to or arising from the use, storage or disposal of the Material or Data by the Recipient, except to the extent caused by the gross negligence or wilful misconduct of the University.

#### 7 Termination

#### 7.1 Termination events

This agreement will terminate on the earliest of:

- (a) completion of the research associated with the Research Purpose; or
- (b) written notice by the University following a breach by the Recipient of a terms of this agreement which the Recipient failed to remedy within 14 days after receiving notice requiring them to do so; or
- (c) 30 days written notice by either party without reason (subject to clause 7.3 (Request to defer termination)); or
- (d) the Expiry Date.

#### 7.2 Consequences

On termination of this agreement under clause 7.1 (Termination events), the Recipient agrees to:

(a) discontinue its use of the Material and Data and either return to the University or, at the option of the University, destroy the Data and any remaining Material and certify that destruction to the University; and

(b) either destroy any Modifications or remain bound by the terms of clause 4 (Ownership rights) as they apply to Modifications.

#### 7.3 Request to defer termination

In the event the University terminates this Agreement under sub-clause 7.1(b) (Termination events), the Recipient may request the effective date of termination be deferred for a period of up to one year to permit completion of research in progress. The University may only withhold approval to defer termination on reasonable grounds, including imminent health risk, obligations to third parties or IPRs infringement.

#### 7.4 No prejudice

Termination of this agreement is without prejudice to the rights of the terminating party to obtain damages for any breach of this agreement.

#### 7.5 Survival

Clauses 2 (Data), 4 (Ownership rights), 6 (Warranties and liability), 7.2 (Consequences) and 8 (Disputes) survive the termination of this agreement for any reason.

## 8 Disputes

Any dispute relating to this agreement ("Dispute") must, prior to a party initiating litigation (other than for equitable or interlocutory relief), be dealt with as follows:

- (a) the affected party will notify the other with details of the Dispute ("**Dispute Notice**") and, within 7 days of receiving the Dispute Notice, the Project Officers will confer and attempt to resolve the Dispute;
- (b) if unresolved within 14 days of the Dispute Notice, the Dispute will be escalated to two executives from each party who will confer and attempt to resolve the Dispute;
- (c) if still unresolved within a further 14 days of being escalated, either party may refer the Dispute promptly for resolution using Alternative Dispute Resolution techniques by the International Chamber of Commerce. Any decision reached in this way shall be final and binding upon the Parties involved. Nothing in this clause shall prevent or impede the College from being free to apply for interim relief in any court of competent jurisdiction seeking to require the Recipient to cease using and/or return Material or Data in the event of a breach of this Agreement.;
- (d) the parties will cooperate to enable the dispute resolution within 45 days
- (e) the fees of dispute resolution will be paid by the parties in equal proportions.

#### 9 General

#### 9.1 Terms and entire agreement

This agreement consists of these General Terms, the Details, the Special Terms and any annexures or schedules expressly incorporated and it constitutes the entire agreement of the parties about its subject matter and supersedes all previous agreements, understandings and negotiations on that subject matter.

#### 9.2 Inconsistency

If there is an inconsistency between a provision of the Details, the Special Terms, any annexures or schedules expressly incorporated and these General Terms then the first-mentioned terms prevail.

### 9.3 No representations or warranties

The Recipient acknowledges that in entering into this agreement it has not relied on any representations or warranties about its subject matter except as expressly provided by this agreement.

#### 9.4 Variation and waiver

A provision of this agreement or a right created under it may not be waived or varied except in writing, signed by the party or parties to be bound. A failure or delay in exercise of a right arising from a breach of this agreement does not constitute a waiver of that right.

#### 9.5 Governing law

This agreement is governed by the law in force in New South Wales, Australia. Each party submits to the non-exclusive jurisdiction of the courts of that place.

#### 9.6 Counterparts

This agreement may be executed in counterparts. All counterparts when taken together are to be taken to constitute one instrument.

#### 9.7 No exclusivity

The Recipient is not acquiring the Material or the Data on an exclusive basis and this agreement will not preclude the University from providing the Material or the Data to another party.

#### 9.8 Consideration

This agreement is entered into in consideration of the parties incurring obligations and giving rights under this agreement and for other valuable consideration.

#### 9.9 General interpretation

Unless the contrary intention appears, in this agreement:

(a) references to University statutes, regulations, policies, rules or code include references to those statutes, regulations, policies, rules or codes as amended, updated or replaced from time to time;

- (b) references to the singular includes the plural and vice versa;
- (c) references to person or individuals include a firm, a body corporate, a partnership, a joint venture, an unincorporated body or association, or any government agency;
- (d) the words "include" and "including" are not used as, nor are they to be interpreted as, words of limitation;
- (e) headings are for convenience only and do not affect interpretation;
- reference to a party means a party to this agreement and includes the party's executors, administrators, successors and permitted assign;
- (g) references to dollars or AU\$ is toAustralian dollars, unless otherwise stated;
- (h) a provision of this agreement will not be construed to the disadvantage of a party merely because that party was responsible for the preparation of the agreement or the inclusion of the provision in the agreement;
- (i) if an act must be done on a specified day which is not a business day, it must be done instead on the next business day; and
- (j) where consent or approval is to be provided under the terms of this agreement, that consent or approval must not be withheld unreasonably.

#### 10 Definitions

The following words have these meanings in this agreement:

**IPRs** means all registered and unregistered rights in relation to present and future copyright, trade marks, designs, know-how, patents, confidential information and all other intellectual property as defined in article 2 of the Convention establishing the World Intellectual Property Organisation 1967.

**Modifications** means any substances created by the Recipient through use of the Material which contain or incorporate the Material.

**Progeny** means an unmodified descendant from the Material, such as virus from virus, cell from cell, organism from organism.

Unmodified Derivatives means substances created by Recipient which constitute an unmodified functional sub-unit or an expression product of the Material, for example: sub-clones of unmodified cell lines; purified or fractionated sub-sets of the Material; proteins expressed from DNA and/or RNA; DNA or RNA supplied by Provider; polyclonal and/or monoclonal antibodies secreted by a  $(Outgoing-To\ non-commercial\ recipient)\ Inter-Institutional\ Material\ Transfer\ Agreement\ [007][8-May-20]$ 

hybridoma cell lines; or sub-sets of the Material such as novel plasmids or vectors.

# Schedule 1

Project title: Development of lipid-A-based population screening test & chair-side diagnostics for personalised, point-of-care periodontal therapy

# Planned project duration: October 2021 – December 2023 Brief project description:

Periodontitis is a chronic inflammatory disease of the tissues supporting the teeth and one of the main causes of tooth loss. It is induced by bacteria present in a shallow crevice between the gums and the teeth that trigger the host inflammatory response. This exacerbated host inflammatory response is responsible for tissue damage and the loss of the bone that supports teeth. Despite being very prevalent oral disease, diagnostic procedure and treatment option for periodontitis have not changed significantly for more than a century. It is usually diagnosed too late, on the base of the bone loss that has already occurred and treated, not very successfully, by mechanical removal of subgingival deposites. Therefore, there is a great need for new diagnostic approaches and treatment options for this widespread disease.

Bacterial species that are responsible for development of periodontal diseases are able to produce a very potent substance, lipopolysaccharide (LPS), that triggers the host inflammatory response. If this type of bacterial antigens is detected in the oral cavity before the development or in early stages of the disease, effective preventive regimen could be employed and harmful consequences avoided. Our plan is to collect saliva and subgingival deposites samples (subgingival dental plaque) from patients with periodontitis, gingivitis and healthy controls who are treated at the Periodontal Clinics in Sydney Dental Hospital (SDH) and Westmead Centre for Oral Health (WCOH), Sydney, Australia. The samples will be stored at the Westmead Oral Health Biobank until send to King's school for further analysis. LPS will be extracted from these samples and its chemical composition (with a focus on Lipid-A, its most potent part) will be examined in the research laboratories of the King's School. The chemical composition and inflammatory potential of LPS will be compared between healthy, patients with gingivitis EWA and patients with periodontitis as well as between samples from the same periodontitis patient taken before and after routine periodontal treatment. By this mean we hope to establish salivary and subgingival LPS profile as an easily detectable, bacterially produced biomarker, for periodontitis.