Janssen-Taiwan 合作計畫 - 2020 研究案徵求公告

(ITRI 2020 Grant Call in Collaboration with Janssen)

> 主辦單位: Janssen Biotech, Inc. (下稱: Janssen)

工業技術研究院(下稱:工研院)

▶ 徵案宗旨

美國 Janssen Biotech, Inc. (Janssen) 一直致力於疾病早期治療之相關研究。為了整合技術創新與商業模式,追求更顯著的早期治療效果,以推動醫療保健的新典範,因而發起"Janssen-Taiwan 合作計畫"。

工研院生醫所基於推動台灣生醫科學研究發展之宗旨,也為提升台灣研究單位、 企業、醫院、學校與國際企業、研究機構合作之經驗值,以及增進台灣生醫產業相關 技術創新之附加價值與國際競爭力,在科技部與經濟部共同支持之下,與Janssen 共同 投入經費執行本徵案計畫。為執行"Janssen-Taiwan 合作計畫"所需,並由工研院發布 "Janssen-Taiwan 合作計畫 - 2020 研究案徵求公告" (以下稱:本徵案計畫)。

> 參加資格

中華民國設立登記之大學、研究所、醫院、其他學術研究機構、新創事業、企業、 法人及其所屬單位(包括工研院各研究所)或由前述各機構跨界合作組隊者,均可提 案(下稱:提案團隊)。

請注意提案團隊必須填寫完成附件 A 的 Healthcare Compliance Screening Questionnaire 且需通過資格篩選,以確認是否符合參加資格。

▶ 時程規劃

徵案時間	即日起至 2020 年 5 月 14 日
徵選結果通知	預計 2020 年 8 月 18 日
獲選計畫簽約	預計 2020 年 11 月 21 日

> 活動相關資訊請連結 https://jti.itri.org.tw/index.aspx 網站查詢。

> 徵案標的

徵求國內生醫領域符合參加資格之提案團隊提出研究計畫,研究計畫應為下列領 域,且提出以解決下列任一重要問題為目標之可能方案(下稱:徵案標的):

標的領域:

- 1. 肺癌及其人工智慧之應用(Lung Cancer /AI)
- 2. 傳染性疾病預防(Infectious Diseases)
- 3. 小兒疾病的偵測、診斷及預防(Healthy Baby / Big Data)
- 4. 成人疾病預防及其人工智慧與大數據之應用(Disease Prevention / Big Data / AI)

優先探討之重要方向:

- 肺癌及其人工智慧之應用(Lung Cancer /AI)
 ▶如何以非慣行方法(目前為 CT 醫療影像)更早地辨識出肺癌患者?
 ▶如何辨識肺癌高危險群,以及如何讓他們受到保護?
 ▶如何運用虛擬實境或遊戲化等數位療法,減少有吸煙習慣的肺癌患者?
 傳染性疾病預防(Infectious Diseases)
 ▶可長效預防病毒性呼吸道感染疾病的新型非疫苗技術(針對病毒或宿主)為何?
- 3. 小兒疾病的偵測、診斷及預防(Healthy Baby / Big Data)
 - ▶ 如何事先預測嬰兒會罹患哪些早期生命疾病,例如異位性皮膚炎、哮喘及過敏等。
 - ▶ 哪些新型非侵入性的儀器設備可以用來幫助嬰兒檢測及監測疾病?
 - ▶ 幫助嬰兒發育的營養方法為何?
- 4. 成人疾病預防及其人工智慧與大數據之應用(Disease Prevention / Big Data / AI)
 - ▶ 可用於檢測成人健康狀況變化的非侵入性的儀器設備為何?
 - ▶ 穿戴式設備和傳感器如何監測成年人的健康?
 - ▶ 哪種類型的家庭診斷方式可被用來監測成人或家庭的健康狀況?
 - ▶ 整體而言大數據如何應用於疾病的事前診斷?

> 提案方式

提案團隊請於徵案時間截止日至 2020 年 5 月 14 日下午 5 時整(含)前發送電子 郵件至 jtioffice@itri.org.tw 信箱(請於電子郵件主旨上註明「Janssen-Taiwan 合作計畫: 20120 研究案徵求公告」,並請於電子郵件內文中陳明:提案團隊所屬單位名稱、計畫 名稱、聯絡方式、計畫主持人姓名、職稱),上傳提案文件予聯絡人。

提案文件:

- 1. 提案團隊計畫主持人簡歷;
- 2. 提案技術發展狀況(計畫書);
- 3. 非機密之摘要、說明、與關鍵字;
- 4. 提案之應用及/或與徵案標的之相關性;
- 5. 提案預算(包含管理費用/間接費用)、提案團隊的投入、查核點;
- 6. 填寫完成附件 A 的 research grant co-funding healthcare compliance due diligence questionnaire;
- 提案團隊是否同意依附件 B 之內容簽署研究契約之確認書(為免疑義,特別說 明,即使填寫不同意附件 B 之內容,提案計畫仍可以參加徵選)
- 8. 簽署如附件 C 的 Statement Against Corrupt Practices;
- 9. 簽署如附件 D 的 Statement of Compliance with Federal Animal Welfare Regulations;
- 10. 提案團隊的每位成員均簽署如附件 E 的"Notification and Consent Regarding Collection, Processing and Use of Personal Information";
- 11. 提案團隊與 Janssen 或其關係企業(包括任何 J & J 公司關係企業)的競爭對手沒 有實質的關聯性之聲明。

> 評選方式

- 主辦單位將指派人選組成評選委員會。評選委員會將就提案團隊資格、提案文件進行綜合審查評比。審查標準請詳見<u>https://jti.itri.org.tw/index.aspx</u>網站「提案申請」 項下「其他參考資料」的「申請說明」("Application Instructions")。
- 進入決選的提案團隊,委員會將請提案團隊就提案規劃進行簡報說明。屆時請提案 團隊備妥簡報電子檔及書面文件。(簡報日期視審查進度,由委員會個別通知提案 團隊。)
- 每件獲選提案所取得之研究經費將由評選委員會於評選決議中核定,並以正式公函 通知獲選團隊。

▶ 經費取得

- 1. 在獲選團隊收到獲選通知後 120 日內,應與工研院及 Janssen 簽訂研究契約(以下稱:研究契約)。
- 承上,獲選團隊若是企業或經濟部下轄的法人,除於前述期間內與工研院及 Janssen 簽訂研究契約外,獲選團隊並需配合主辦單位將提案計畫另送經濟部審核 通過。
- 3. 獲選團隊應簽訂附件 B (研究及優先選擇權授權契約重要條款)。
- 獲選團隊應簽訂附件C(廉潔保證文件)。
- 5. 獲選團隊應簽訂附件 D (符合聯邦動物福利法規的聲明)。

簽署以上全部文件後,主辦單位將撥付第一期研究經費。

> Other Specifications

- 1. 提案計畫之全程,請勿超過36個月。
- 2. 提案團隊應自行負擔參加本徵案計畫全程之所有費用與支出。
- 提案計畫獲選與否,由評選委員會依其考量全權決定。主辦單位及其代表人、代理人、受雇人、外聘顧問、或其他輔助人,均不因提案團隊參與本徵案計畫所受 之損害或所失之利益負擔任何責任。
- 提案計畫獲選與否,並不以提案團隊接受附件B的智慧財產議約條件為必要,但 評選委員會將考慮提案團隊是否接受附件B的條件,作為評選考量之一。
- 5. 獲選計畫所簽訂之計畫內容不得申請、爭取、或接受其他來源之經費。
- 獲選計畫所取得之研究經費,應全額用於執行獲選計畫(管理費用/間接費用不超 過10%)。
- 獲選團隊因參與本徵案計畫相關的任何政府所課徵的所有稅捐,以及獲選計畫取 得之研究經費所衍生之稅捐,均由獲選團隊自行負擔。
- 獲選團隊就補助經費應設獨立帳戶專帳管理,並同意主辦單位所指定之代表就該 獨立帳戶進行查核。
- 除非提案計畫書已經載明,並獲得評選委員會之同意,獲選團隊不能將獲選計畫 之全部或一部轉包、分包第三人,或以其內容與第三人合作研究。
- 獲選團隊應配合工研院遵守所有中華民國行政院經濟部與科技部所制訂之相關法規。
- 獲選計畫應就研究計畫自行投保適當之保險,以承擔執行本計畫所發生的任何損失。
- 主辦單位若認為獲選計畫之執行不如預期,或獲選計畫未經同意中途更換計畫主持人,任一主辦單位得不附理由通知獲選團隊終止研究契約。
- 13. 因主辦單位應收集與處理提案團隊的個人資料,包含姓名、地址、及其他聯繫資訊;這些資訊將被提供給主辦單位的受雇人、代理人、代表人、外部顧問等。主辦單位同意將依照中華民國個人資料保護法所訂定的規範在本徵案計畫中處理、使用個人資料。
- 14. 研究契約終止或期間屆滿,未使用之研究費用應返還主辦單位。
- 15. 主辦單位保有本聯合徵案計畫相關細則變更之權力,設若有任何更動,皆以本聯 合徵案計畫所屬網站 <u>https://jti.itri.org.tw/index.aspx</u>公告為準,不再另行通知。
- 16.本徵案計畫之準據法依中華民國法律。與本徵案計畫相關之訴訟,或經協商仍不 能解決之爭議,將以台灣新竹地方法院為管轄法院。至於將來獲選計畫所簽訂之 研究契約所衍生之爭議,其準據法與管轄法院,將依研究契約之約定。

> 聯絡方式

如有任何疑問,請向主辦單位聯絡窗口詢問,如下: 聯絡人: 邱小容 工業技術研究院/ Janssen Taiwan Initiative 計畫辦公室

電話: (03) 591-3740

E-Mail: jtioffice@itri.org.tw

地址:新竹縣竹東鎮中興路4段195號52館135室

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附件 A

RESEARCH GRANT CO-FUNDING HEALTHCARE COMPLIANCE DUE DILIGENCE QUESTIONNAIRE

These questions are designed to demonstrate J&J's compliance intentions regarding its Healthcare Compliance Policies and various potentially applicable laws and regulations.

For the purposes of this Questionnaire:

"Health Care Professionals" or "HCPs" means:

- 1. All physicians;
- 2. Any other individual, institution or entity with the ability to prescribe, acquire or influence the prescription or acquisition of healthcare products or services at issue, and either of the following:
 - a. The products at issue are regulated or registered as medicinal products or devices (or their equivalents) in the applicable country; or
 - b. The products or services at issue are subject to reimbursement by government or third parties; or, are offered for sale with products or services subject to such.

"Family Members" means one of the following relationships: mother, father, spouse, civil union partner, sister, brother, son, daughter, grandchild, grandparent, any of the preceding who where applicable, are "step" relatives, mother-in-law, father-in-law, sister-in-law, brother-in-law, son-in-law, and daughter-in-law.

Notes:

- 1. Please check the boxes for the appropriate answer where the option is provided, or provide the appropriate answer in the space provided.
- 2. 'You' in the questions below refer to (1) the applicant of this Research Grant Co-funding, or(2) the principal researcher of the proposal which will be submitted to the Event.
- 3. If there is insufficient space in the right column to provide your answers, please add additional pages as necessary.
- 4. For listed companies, 'shareholders' in the questions below refer to shareholders holding equal to or more than 10% of stocks or voting rights.

1. Are you participating in this Research	Government-linked Entity. Please go to Section
Grant Co-funding as an employee of	G.
a government-linked entity or a	Corporate Entity. Please go to Section C.
corporate entity?	
SECTION G – For Participants from Government-linked Entities	

2. Which government-linked entity(ies)	Name of Government-linked Entity:
do you work for? Please list all.	,
	Please go to 3a.
3a. Are you a HCP (Health Care	Yes. Please go to 3b.
Professional)?	□ No. Please go to 4.
3b. If so, please provide the following details.	HCP License: Past
i. Is the HCP licensed or practicing?	
ii. Area of practice	
iii. Current affiliations (e.g., hospitals,	Are you currently practicing as a HCP? Yes No
universities, ACOs, formulary	
committees, procurement	Area of Practice:
committees, product review	
committees, product advisory	Current Affiliations:
committees, Boards, etc.)	
iv. Do you have any influence on the	Do you have any influence on the use,
use, recommendation,	recommendation, procurement or approval of J&J
procurement or approval of J&J	products?
products?	Yes. Please provide details.
V. Do you have any prior or current	
relationships with J&J or any J&J	
subsidiary? (e.g., a paid speaker	Prior relationships with J&J:
or consultant to any J&J products,	
engaged in J&J company	
sponsored research, engaged in a	Current relationship with J&J (including J&J
clinical study funded by a J&J	subsidiaries):
Company, etc.)	Please go to 4.
4. Are you currently a customer of J&J	Yes. Please go to 5a.
products or services?	🗌 No. Please go to 5a.
5a. Are any of your family members	
employees of J&J?	Yes. Please go to 5b.
	□ No
	Name:
5b. If 'Yes', please provide details.	Relationship:
SECTION C – For Company Participants	
section e l'or company randipants	

6a. Are there any owners (shareholde	ers Yes. Please go to6b.
or partners) of your company or	
institution who are HCPs (Health Care Professionals)?	No. Please go to 7a.
6b. If so, please provide the names of	Name:
these HCPs and details of their	Position in Company:
economic interest and position with	HCP License: Past
your company.	
i. Is the HCP licensed or practicing	Is the HCP currently practicing? Yes
ii. Area of practice	No
iii. % ownership of company	Area of Practice:
iv. Current affiliations (e.g.,	
hospitals, universities, ACOs,	
formulary committees,	Current Affiliations:
procurement committees,	
product review committees,	Does the HCP have any influence on the use,
product advisory committees,	recommendation, procurement or approval of J&J
Boards, etc.)	products?
v. Does the HCP have any influen	e Yes. Please provide details.
on the use, recommendation,	
procurement or approval of J&	
products?	Prior relationships with J&J:
vi. Does the HCP have any prior or	
current relationships with J&J o	r Current relationship with J&J (including J&J
any J&J subsidiary? (e.g., a paid	subsidiaries):
speaker or consultant to any J&	J
products, engaged in J&J	Involved with research proposal/project?
company sponsored research,	└── Yes └── No
engaged in a clinical study fund	ed Name:
by a J&J Company, etc.)	Position in Company:
vii. Will the HCP be involved in this	HCP License: 🔲 Past
research proposal/project?	Current
	Is the HCP currently practicing? Yes No
	Area of Practice:
	Company Ownership: %
	Current Affiliations:
	Does the HCP have any influence on the use,
	recommendation, procurement or approval of J&J
	products?
	Yes. Please provide details.
	□ No

		Prior relationships with J&J:
		Current relationship with J&J (including J&J
		subsidiaries):
		Involved with research proposal/project?
		Yes No
		Please go to 7a.
	o any HCPs own options to obtain es in your company?	Yes. Please go to 7b.
511010		
76 16	co. place provide the pamer of	No. Please go to 8a.
	so, please provide the names of HCPs and details of their	Name:
econ	omic interest and position with	Position in Company: HCP License:
-	company.	
i.	Is the HCP licensed and	Is the HCP currently practicing? Yes
	practicing?	No
ii. 	Area of practice	Area of Practice:
	% ownership of company Current affiliations (e.g.,	Company Ownership: %
10.	hospitals, universities, ACOs,	Current Affiliations:
	formulary committees,	
	procurement committees,	Does the HCP have any influence on the use,
	product review committees,	recommendation, procurement or approval of J&J
	product advisory committees,	products?
	Boards, etc.)	Yes. Please provide details.
v.	Does the HCP have any prior or	
	current relationships with J&J or	L No
	any J&J subsidiary? (e.g., a paid	Prior relationships with J&J:
	speaker or consultant to any J&J	
	products, engaged in J&J	Current relationship with J&J (including J&J
	company sponsored research,	subsidiaries):
	engaged in a clinical study funded by a J&J Company, etc.)	
vi	Will the HCP be involved in this	Involved with research proposal/project?
vi.	research proposal/project?	Yes No

	Name:
	Position in Company:
	HCP License: 🔲 Past
	Current
	Is the HCP currently practicing? Yes
	No
	Area of Practice:
	Company Ownership: %
	Current Affiliations:
	Does the HCP have any influence on the use,
	recommendation, procurement or approval of J&J
	products?
	Yes. Please provide details.
	Prior relationships with J&J:
	Current relationship with J&J (including J&J
	subsidiaries):
	Involved with research proposal/project?
	Please go to 8a.
8a. Do any HCPs hold debt instruments	Yes. Please go to 8b.
in your company?	
	No. Please go to 9a.
	No. Ficase go to 5a.

8b. If	so, please provide the names of	Name:
these	HCPs and details of their	Position in Company:
	omic interest and position with	HCP License: Past
-	company.	
i.	Is the HCP licensed and	
	practicing?	Is the HCP currently practicing? Yes
ii.	Area of practice	No
iii.	% ownership of company	Area of Practice:
iv.	Current affiliations (e.g.,	Company Ownership: %
	hospitals, universities, ACOs,	Current Affiliations:
	formulary committees,	
	procurement committees,	Does the HCP have any influence on the use,
	product review committees,	recommendation, procurement or approval of J&J
	product advisory committees,	products?
	Boards, etc.)	Yes. Please provide details.
ν.	Does the HCP have any influence	
	on the use, recommendation,	
	procurement or approval of J&J	Prior relationships with J&J:
	products?	
		Current relationship with J&J (including J&J
		subsidiaries):
		Involved with research proposal/project?
		L Yes No

vi	Does the HCP have any prior or	Name:
v1.	current relationships with J&J or	Position in Company:
	any J&J subsidiary? (e.g., a paid	HCP License: Past
	speaker or consultant to any J&J	
	products, engaged in J&J	Area of Practice:
	company sponsored research,	
	• • •	
	engaged in a clinical study funded	Current Affiliations:
	by a J&J Company, etc.)	
VII.	Will the HCP be involved in this	Does the HCP have any influence on the use,
	research proposal/project?	recommendation, procurement or approval of J&J
		products?
		Yes. Please provide details.
		L No
		Prior relationships with J&J:
		Compart valation ship with 191 (in shuding 191
		Current relationship with J&J (including J&J
		subsidiaries):
		Invelved with recorded area cal/arciast?
		Involved with research proposal/project?
		L Yes No
		Please go to 9a.
9a. A	re any key personnel (Board	Yes. Please go to 9b.
mem	bers, Officers of the Company, key	
empl	oyees) an HCP?	No. Please go to 10a.

9b. If so, please provide the names of	Name:
these HCPs and details of their	
economic interest and position with	Position in Company:
your company.	HCP License: Past
i. Is the HCP licensed and practicing?	Current
ii. Area of practice	Is the HCP currently practicing? Yes
iii. % ownership of company	No
iv. Current affiliations (e.g., hospitals,	Area of Practice:
universities, ACOs, formulary	Company Ownership: %
committees, procurement	Current Affiliations:
committees, product review	
committees, product advisory	Does the HCP have any influence on the use,
committees, Boards, etc.)	recommendation, procurement or approval of J&J
v. Does the HCP have any influence	products?
on the use, recommendation,	Yes. Please provide details.
procurement or approval of J&J	
products?	□ No
	Prior relationships with J&J:
	Concerns relation with 101 (in alcohing 101
	Current relationship with J&J (including J&J
	subsidiaries):
	Involved with research proposal/project?
	Yes No

vi. Does the HCP have any prior or	Name:
current relationships with J&J or	Position in Company:
any J&J subsidiary? (e.g., a paid	HCP License: 🔲 Past
speaker or consultant to any J&J	Current
products, engaged in J&J	Is the HCP currently practicing? 🔲 Yes 🗌
company sponsored research,	No
engaged in a clinical study funded	Area of Practice:
by a J&J Company, etc.)	Company Ownership: %
vii. Will the HCP be involved in this	Current Affiliations:
research proposal/project?	
	Does the HCP have any influence on the use,
	recommendation, procurement or approval of J&J
	products?
	Yes. Please provide details.
	□ No
	Prior relationships with J&J:
	Current relationship with J&J (including J&J
	subsidiaries):
	Involved with research proposal/project?
	Yes No
	Please go to 10a.
10a. Are your company owners,	Yes. Please go to 10b.
partners, shareholders, or key decision	
makers a Government Official or	No. Please go to 11a.
affiliated with a Government Official?	
10b. If 'Yes', please provide name(s) and	Name:
the individual's(s') position(s).	Position:
	Government Institution/Agency:
	Name:
	Position:
	Government Institution/Agency:
	Please go to 11a.

11a. Are your company owners,	Yes. Please go to 11b.
partners, shareholders, key decision	
makers currently working for a	No. Please go to 12a.
government-owned or a government-	
linked institution (e.g., a public	
hospital) which is or could potentially	
be a J&J customer? Note: This includes	
providing advisory, consulting or part-	
time services.	
11b. If 'Yes", please provide name of	
the government-owned or government-	Please go to 12a.
linked institution(s).	
12a. Are any of the family members of	Yes. Please go to 12b.
the owners, principals, or board	
members of your company or your	
parent company employees of J&J?	
	Name:
12b. If 'Yes', please provide details.	Relationship:

COMPLETED BY	
Signature	
Name	
Date	

附件 B

Terms Sheet for Research Agreement and License Option

This term sheet (the "**Term Sheet**") sets forth the basic terms and conditions of the Research Agreement that the applicant ("**you**" or "**Institution**") will be required to agree to with Janssen Biotech Inc. ("JBI") or its affiliate (excluding JBI's affiliates in the People's Republic of China), and/or Industrial Technology Research Institute ("**ITRI**") (together, the "**Sponsors**") and execute as a condition to receiving research funding for the proposed research program.

Please review the basic terms and conditions of the Research Agreement detailed below. By signing the acknowledgement at the end of this Term Sheet, you are indicating that you accept the terms and conditions contained herein, subject to their incorporation together with all other terms and conditions in the Research Agreement. You also acknowledge that this Term Sheet does not contain all the terms and conditions to be included in the Research Agreement and the Sponsors reserve the right to include additional terms and conditions not specified herein in the Research Agreement.

For clarity, you are not required to acknowledge your agreement to the terms and conditions set forth in this Term Sheet as a condition to applying for the research funding. However, the Sponsors will consider whether you have acknowledged and agreed to the terms and conditions set forth in this Term Sheet when selecting potential candidates to receive research funding.

Parties	 JBI or its affiliate (excluding JBI's affiliates in the People's Republic of China) ITRI Applicant ("Institution")
Research Program	 Institution will conduct the research in accordance with the timelines, milestones, and deliverables set forth in the mutually agreed upon research program.
	• The parties will establish a joint steering committee, with equal membership from each party, to monitor the progress of the research program, to review research results, and to modify the research program by unanimous decision.
	 Research funding will be provided in accordance with an agreed-upon budget and payment schedule and will be used exclusively for the research.

	 Institution may not obtain any other funding to conduct the research without each Sponsor's consent. 						
	• Except as otherwise provided in its proposals received by selection committee, Institution may not engage any subcontractors or collaborators without each Sponsor's consent.						
	 Institution will obtain and maintain adequate insurance to cover any liability arising from its conduct of the research. 						
	• Each Sponsor may terminate the research program for any reason upon thirty (30) days' notice or immediately at any time if the Sponsors are not satisfied with the progress of the research.						
Principal Investigator	 Institution will designate a principal investigator to conduct and directly supervise the research program. 						
	• Each Sponsor may terminate the research program in the event the principal investigator ceases to be involved in the research program or Institution is unable to find a replacement principal investigator acceptable to each Sponsor.						
Research Agreement							
Ownership of Program Technology	 For the avoidance of doubt, JBI does not intend to contribute any technology to Institution to conduct research, provided however, in the event that there is any dispute with regard to whether JBI has contributed technology to a particular Institution or research program, such dispute shall be resolved by binding arbitration pursuant to the Governing Law/Dispute Resolution section below. 						
	 Ownership of all technology developed under the research program shall be determined based on inventorship, and for all other technology which inventorship does not apply, will be owned by Institution, except, if JBI provides any technology to Institution to conduct the research, JBI will own any technology that uses, is based on, or is an improvement to any JBI technology (regardless of inventorship, including such technology jointly developed by Institution and JBI, or developed solely by Institution). 						

	Inventorship for purposes of the Research Agreement shall be determined in accordance with United States natent law
	determined in accordance with United States patent law.
Research License	 Institution grants to JBI a non-exclusive, worldwide, royalty- free, non-transferable, perpetual license under the program technology and related products owned by Institution (the "Licensed Technology") to make and use Licensed Technology solely for JBI's internal research or educational purposes (which may include research performed with one or more third party collaborators) (excluding the use of any Licensed Technology in clinical studies and in research sponsored by a business or for- profit entity (or an affiliate of a business or for-profit entity)) and to have any of the foregoing performed on JBI's behalf by a third party service Applicant.
JBI Right of First Negotiation and Trailing Right of First Refusal	 At the conclusion or termination of the research program, Institution will in good faith provide to JBI a data package containing sufficient information to enable JBI to (i) determine whether to exercise its right of first negotiation and (ii) negotiate for itself or its designee or assignee an exclusive, worldwide license to the Licensed Technology (the "Data Package"). Institution further agrees that it shall provide any supplemental information requested by JBI to facilitate JBI's determination on whether to exercise its right of first negotiation and to negotiate for itself or its designee or assignee the License.
	• <u>Right of First Negotiation</u> . Institution grants to JBI, for a period starting from the effective date of the Research Agreement and continuing until the day that is sixty (60) days following the delivery of the Data Package (" ROFN Exercise Period "), the exclusive option to negotiate for itself or its designee or assignee an exclusive, worldwide license to the Licensed Technology upon the terms set forth in the License section below ("License") (such option, the "JBI Option"). For the avoidance of doubt, the Institution and JBI acknowledge and agree that the terms set forth in the License section below are non-negotiable and any negotiations relating to the definitive License shall be limited to those matters not set forth below (subject to written waiver by JBI). In the event JBI exercises the JBI Option during the ROFN Exercise Notice"), Institution

shall negotiate in good faith and exclusively with JBI and/or one or more affiliates of JBI for any such affiliate for a period of one hundred and eighty (180) days from the date of the Exercise Notice (the "**Exclusive Negotiation Period**") to enter into a License with the Institution.

- From the effective date of the Research Agreement and until the expiration of the Exclusive Negotiation Period has ended, Institution may not (i) transfer any Licensed Technology to a third party, (ii) solicit, initiate, continue or engage in any negotiations or discussions (nor disclose or furnish to any other party any information concerning your assets or business in contemplation of a Transaction) relating to Licensed Technology, or consider or respond to any indication of interest, offer or proposal, to enter into any agreement or understanding to consummate a Transaction relating to Licensed Technology, or (iii) enter into any Transaction with a third party relating to Licensed Technology without the prior written consent of JBI.
- "Transaction" shall mean any transaction (i) which \cap would sell, license, transfer, assign or otherwise make available (A) any Rights in or to any of Institution's significant assets or a significant portion of Institution's assets (including, without limitation, any of the Rights (as defined below)) or (B) any of Institution's capital stock or other equity interest or (ii) which would involve any business combination or merger, in either case, involving Institution or any of Institution's Affiliates in their capacities as such. The term "Rights" shall include all inventions, developments, patents, patent applications, know-how or other proprietary rights or products owned, developed or acquired (whether through license or otherwise) by the Institution related to Licensed Technology.
- <u>Right of Last Refusal</u>. For a period of one hundred twenty (120) calendar days following the expiration of the Exclusive

	Negotiation Period (the "Tail Period " and, the last date of such period, the "Expiration Date "), the Institution shall not consummate or agree to consummate a Transaction with any other party (a "Third Party") without first giving prompt notice thereof to JBI in writing (the "Proposed Transaction Notice ") (i) specifying the pricing, terms, conditions and other material provisions of such proposed Transaction, (ii) identifying the proposed Third Party and (iii) providing a copy of a written agreement in principal or letter of intent setting forth the terms of such proposed Transaction, if any such written agreement or letter of intent exists. In the event that JBI elects to consummate a transaction upon the same pricing, terms, conditions and other material provisions as specified in the Proposed Transaction Notice, JBI shall have thirty (30) calendar days to so notify Institution and Institution shall use all reasonable commercial efforts to facilitate the consummation of such Transaction with JBI and/or its affiliates within sixty (60) calendar days following the receipt of such notification (such sixty (60) day period, the "Negotiation Period "). Notwithstanding the foregoing, upon the Expiration Date all					
	together with all rights to receive Notices, to cause a Negotiation Period to occur and to receive any additional Proposed Transaction Notices based on changes in transaction terms, shall terminate upon the Expiration Date.					
	• The Parties hereby acknowledge and agree that the Parties shall have no obligation (in each party's sole discretion) to enter into a definitive agreement concerning a Transaction. Institution hereby represents and warrants to JBI that the granting of the Right of First Negotiation, Right of Last Refusal and other terms provided herein will not conflict with or infringe upon the rights of any other person or entity.					
Termination	• In the event of the expiration of the term or any termination of the Research Agreement, all unused funds shall be promptly returned to the Sponsors.					

Governing Law/Dispute Resolution License	 The Research Agreement will be governed by the laws of the State of New York. The parties will resolve any disputes arising from the Research Agreement via arbitration in Hong Kong according to the rules of the Hong Kong International Arbitration Center. Institution will grant to JBI an exclusive, worldwide, royalty-bearing, sub-licensable license under the Licensed Technology to develop, manufacture, and commercialize the Licensed Technology and related products in any field.
	• JBI and Institution will each appoint an alliance manager to be the point of contact and to coordinate between the parties.
Development and Commercialization	 JBI will, in its sole discretion, determine whether to develop and commercialize the Licensed Technology and related products.
	 JBI will be solely responsible for all decisions regarding the development, manufacturing, and commercialization of the Licensed Technology and related products.
	 JBI will pay to Institution certain milestones and royalties as determined by the Parties following JBI's exercise of the JBI Option, subject to customary royalty-reductions for generic entry, loss of patent rights, and third-party obligations.
	• The royalty term will terminate, on a product-by-product and country-by-country basis, upon the earliest of (i) the expiration of the latest to expire of Institution's patents covering the Licensed Technology, (ii) the expiration of any data exclusivity, or (iii) 10 years after the first commercial sale of a related product.
	 Institution will have customary audit rights.
	 Institution will provide customary representations and warranties regarding the Licensed Technology, including non- infringement.
Ownership of Technology Developed Under the Exclusive License	 JBI will own any technology and intellectual property developed in connection with the development, manufacturing, and commercialization of the Licensed

	Technology and related products and will be solely responsib for filing, prosecuting, and maintaining any patent rights.					
Governing Law/Dispute Resolution	• The License will be governed by the laws of the State of New York.					
	 The parties will resolve any disputes arising from the License via arbitration in Hong Kong according to the rules of the Hong Kong International Arbitration Center. 					

ACKNOWLEDGED AND AGREED

By: _____ Name: Organization: Title:

附件 C

Statement Against Corrupt Practices

Compliance with Anti-Corruption Laws

Notwithstanding anything to the contrary in the Research Agreement, Applicant hereby agrees that:

- Applicant has not and shall not perform any actions that are prohibited by local and other anti-corruption laws (collectively "Anti-Corruption Laws") that may be applicable all parties to the Research Agreement;
- (ii) Applicant has not and shall not, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other third party related to the transaction with the purpose of influencing decisions related to Johnson & Johnson (the "Company"), its affiliates and/or its business in a manner that would violate Anti-Corruption Laws;
- (iii) Applicant has not and shall not retain any government official or government employee in the performance of the Research Agreement unless it has been approved by Company and, if necessary, by the competent authority or authorities and such government official's or employee's employer. Furthermore, Applicant shall immediately advise Company in writing in the event Applicant becomes aware that any person engaged in the performance of the Research Agreement becomes a government official or employee, a political party official or a candidate for political office. The requirements of this subsection shall not apply with respect to employees of an Applicant that is a government owned entity;
- (iv) Applicant shall designate an individual within its organization to receive training from Company on Anti-Corruption Laws as well as applicable rules on interactions with health care professionals, as mutually agreed to by the parties. Such designated individual shall then provide such training on Anti-Corruption Laws, using applicable training materials to be provided by Company, on at least an annual basis to all persons employed by Applicant who perform work in connection with the Company and interact with government officials or health care professionals in the normal course of their responsibilities. Upon Company's and Applicant's mutual agreement, such training may also be provided directly by Company to such employees of Applicant. Applicant shall also provide such training or training materials to any subcontractors it uses in the performance of the Research Agreement (to the extent the use of such subcontractors by Intermediary is permitted under the Research Agreement.) Any

training and materials provided by Company does not relieve Applicant of any obligations it has independent of the Research Agreement and Applicant shall not rely on Company's training and materials for any such obligations;

- (v) Applicant shall certify on an annual basis in a format to be provided by Company that:
 - a. training and training materials on Anti-Corruption Laws as well as applicable rules on interactions with health care professionals, have been provided to all persons employed by Applicant who perform work for Company and interact with government officials or health care professionals in the normal course of their responsibilities and that it has provided the Company training and training materials to subcontractors used by Applicant in the performance of the Research Agreement;
 - b. to the best of Applicant's knowledge, there have been no violations of Anti-Corruption Laws by Applicant or persons employed by or subcontractors used by Applicant in the performance of the Research Agreement;
 - personnel of Applicant who may be designated as "Key Personnel" by mutual agreement of Company and Applicant have not changed, except as noted in a schedule attached to the certification provided by Applicant;
 - d. Applicant has made no changes in its use of subcontractors to perform the services for the Company under the Research Agreement, except as (1) permitted under the Research Agreement and (2) noted in a schedule attached to the certification provided by Applicant; and
 - e. Applicant has maintained true and accurate records necessary to demonstrate compliance with the requirements of this Exhibit.
- (vi) Applicant shall maintain and provide Company and its auditors and other representatives with access to records (financial and otherwise) and supporting documentation related to the subject matter of the Research Agreement as may be requested by Company in order to document or verify compliance with the provisions of this Exhibit; and
- (vii) if Applicant fails to comply with any of the provisions of this Exhibit, such failure shall be deemed to be a material breach of the Research Agreement and, upon any such failure, Company shall have the right to terminate the Research Agreement with immediate effect upon written notice to Applicant without Company having any financial liability or other liability of any nature whatsoever resulting from any such termination.

ACKNOWLEDGED AND AGREED

Ву:	
Name:	
Organization:	
Title:	

附件 D

Statement of Compliance with Federal Animal Welfare Regulations

Notwithstanding anything to the contrary in the Research Agreement, Applicant hereby agrees that:

In the event of a necessary relocation, Applicant must immediately contact JRD.

The Applicant represents and warrants that the procurement, delivery, preparation, supply, housing, care, and disposition of animals or animal tissues used for the purposes stated in the Research Agreement shall be in compliance with all applicable laws, regulations, governmental guidelines, and industry standards with respect to laboratory animal welfare and safeguarding of animal welfare, such as, but not limited to (i) the United States Animal Welfare Act, (ii) the rules and regulations of the National Institutes of Health (NIH), U.S. Department of Agriculture (USDA), or other governmental agencies; (iii) any guidelines, rules and regulations of the European Union and its national regulations; (iv) the Regulations for the Administration of Affairs Concerning Experimental Animals of the country in which Applicant locates and other applicable laws, regulations or governmental guidelines thereof, or (v) the law of any other jurisdiction as may apply.

Applicant shall be the owner of any animals used hereunder at all times and it shall obtain the approval/license/certificate for all activities involving animals from the appropriate Ethics Committee or regulatory authority. <u>Ethics Committee</u> shall mean the ethical committee responsible for overseeing animal care and use, which may include, but is not limited to, the Institutional Animal Care and Use Committee (IACUC) for US companies, an Ethics Committee on Animal Experiments (ECAE), and/or Animal Welfare Body for European companies.

Applicant shall not initiate any activity involving live animals unless the protocol used for the activity has been reviewed and approved by Applicant's Ethics Committee. A copy of such approval decision shall be provided to Janssen upon request.

When live animals are to be used in conjunction with the activity, the Applicant agrees to treat such animals humanely and use only humane and appropriate methods of euthanasia such as those described in the American Veterinary Medical Association (AVMA) guidelines on euthanasia, those established under the EU legislation on the protection of animals used for scientific purposes, or those established under the laws of any other jurisdiction as may apply. The Applicant's failure to abide by these requirements in connection with the delivery of animal related service shall be deemed a material breach and be grounds for Janssen's termination of this agreement.

Applicant represents and warrants that it understands that the Janssen expects its external service Applicants to follow the same standards as described in the J&J Policy on The Humane Care & Use of Animals, which is included in Attachment 1 attached.

If Applicant is AAALAC accredited.

Applicant represents and warrants that the facility where the activities involving animals are being conducted is AAALAC accredited. Applicant shall maintain its accredited status for the facilities listed within the agreement for the duration of the Research Agreement. Applicant shall immediately notify Janssen if a facility's AAALAC accreditation is not continuously maintained for any reason. Janssen (or Janssen's authorized representative) may inspect the facility where the activities involving animals are being conducted and review Applicant's animal care and use program. Applicant will cooperate with Janssen (or Janssen's authorized representative) during inspection and review.

If Applicant is not AAALAC accredited.

If the facility where the activities involving live animals are intended to be conducted is not currently accredited by AAALAC, Applicant will permit Janssen (or Janssen's authorized representative) access to the facility where the activities are intended to be conducted in order to evaluate the Applicant's animal care and use program. Applicant will cooperate with Janssen (or Janssen's authorized representative) during the evaluation and review.

Reporting

The Applicant agrees to provide a report with animal usage information to Janssen as requested, but no less than once annually. Such report should include all live animals which have been entered into the respective study(ies)/activities in the prior year, and at a minimum will contain at least the name and reference number of the protocol, animal species, number of animals used, start and end date, and the Applicant's contact person. An example of the reporting document is included in Attachment 2 attached. Additional information may be requested as agreed upon by the parties.

ACKNOWLEDGED AND AGREED

By: ______ Name:

Organization: Title:

ATTACHMENT 1

Johnson & Johnson Policy on the Humane Care & Use of Animals

Johnson & Johnson have a responsibility to ensure the ethical and humane treatment of animals that are used to advance patient safety and well-being. The care and use of laboratory animals in biomedical procedures is highly regulated. In general, the regulations govern procurement, housing, feeding, veterinary care, research project review, and require both internal and external inspections. Our companies have clear, well-developed policies and guidelines in place that mandate and drive the ethical and humane treatment of the animals we use, and that promote the use of non-animal alternatives whenever possible. We support and participate in efforts to obtain regulatory acceptance of any alternative testing methods. Our standards for animal care and use meet or exceed all applicable local, state and national laws and regulations.

Our corporation is committed to the "3R" Principles

- •• Replacement Using alternative non-animal systems in place of live animal utilization whenever possible
- •• Reduction Using the minimum number of animals possible to achieve maximum information without compromising animal welfare
- •• Refinement Continually modifying procedures to limit the discomfort and distress to animals

Institutional Animal Care and Use Committee (IACUC)/Ethical Review

•• Proposed Animal studies must be reviewed and approved by an IACUC or equivalent Ethical Committee.

Personnel Training – Competency

•• Personnel involved with the care and use of animals must be educated, trained, and/or qualified in the principles of animal welfare and compliance to help ensure quality science and animal well-being.

Sourcing Animals & Tissue

•• Live animals, preferably bred and raised specifically for research, and animal tissue used in research and teaching shall be obtained only from appropriate sources.

•• Euthanasia: Only humane and appropriate methods of euthanasia will be used, such as those described in the American Veterinary Medical Association (AVMA) guidelines on euthanasia and those established under the EU legislation on the protection of animals used for scientific purposes.

Teaching & Education

• Live animals shall only be used when actual participation by the trainee is required to learn a medical or surgical procedure (including proper product usage) where alternate models have been deemed inadequate for the purpose.
• We are committed to continually seek ways to refine training requirements that yield additional reductions in the use of animals in testing.

Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC)

- •• We require that all Johnson & Johnson Animal facilities be AAALAC accredited.
- •• Newly acquired non-accredited companies are expected to apply for accreditation

External Service Applicants

•• Johnson & Johnson expects the standards for animal care & use for external service Applicants to follow the same standards as described in this document.

Standards for animal care and use will meet or exceed all applicable local, state and national laws and regulations.

♦ Johnson & Johnson preference is to work with external service Applicants that are AAALAC accredited. In cases where non-accredited external service Applicant use is justified, established Johnson & Johnson procedures must be followed and complied with to assure that such facilities meet Johnson & Johnson standards.

Cosmetics

•• The Johnson & Johnson Family of Consumer Companies does not test cosmetic products or ingredients on animals and we do not ask others to test on our behalf, except in those cases where testing is required by law or government regulations.

ATTACHMENT 2

Institution/CRO	Contractor's	1&I Op	181	Protocol /	Protocol /	Species	# of	Study /	Study /
Name, Location,	Contact	со	Contact	Study ID	Study Title		Animals	Activity	Activity
Country								Start	Town data
								date	Term date
								uate	

附件 E

Notification and Consent Regarding Collection, Processing and Use of Personal Information

Notification

In order to collect, process, and use your personal information which you have provided or will provide (hereinafter referred to as "the Personal Information"), based on the reason that you are participating in "ITRI-Janssen Joint Grant Call 2020", SPONSORS would like to inform you about the following matters:

- A. Purposes for collection: Industry-Academy Cooperation Management
- B. Classification of the Personal Information: Type for identifying individuals. (For the principal researcher of the Proposal which will be submitted to the Event, "details about your other family members", and "Professional and Technical Personnel Management" may be needed according to Exhibit A.)
- C. Time period of the use of the Personal Information: until the purposes for collecting the information no longer exists.
- D. Areas of use of the Personal Information: The territory of the ROC and SPONSORS's overseas locations and offices.
- E. Users of the Personal Information: SPONSORS as well as government agencies and nongovernment agencies that have or will have business relations with SPONSORS.
- F. Way of the use of the Personal Information: Under the condition that there is no excess of the scope of the purposes for which the Personal Information was collected, the Personal Information may be used on the Internet, in e-mail, in documents, in facsimiles, and in other lawful ways.
- G. You may exercise the following rights by raising written request(s):
- 1. any inquiry and request for a review of the Personal Information;
- 2. any request to make duplications of the Personal Information;
- 3. any request to supplement or correct the Personal Information;
- 4. any request to discontinue collection, processing or use of the Personal Information; and
- 5. any request to delete the Personal Information.
- H. If you do not sign this Notification and Consent Regarding Collection, Processing and Use of Personal Information, SPONSORS may not be able to contact with you.
- I. SPONSORS will keep your Personal Information confidential and in proper custody in accordance with the relevant laws and regulations of the ROC.

Consent

I have read and understood the Notification set forth above, and hereby agree that SPONSORS may, within the scope of and in conformity with the contents of said Notification, collect, process and use the Personal Information. This consent may be expressed in the way of an electronic document.

The Party:

Name : Address : ID Number : Date :