

# **ITRI 2022 Grant Call in Collaboration with Janssen**

## ➤ **Sponsors : Janssen Biotech, Inc. (Janssen)**

### **Industrial Technology Research Institute (ITRI)**

## ➤ **Program Objectives and Description**

The purpose of the “ITRI 2022 Grant Call in Collaboration with Janssen Biotech, Inc. (Janssen)” (the “Grant Call”) as co-funded (or co-sponsored) by Janssen is to solicit proposals of integrating breakthrough science with commercial innovations to effectively intercept disease prior to onset and to catalyze a new paradigm in healthcare.

Sharing joint interest to advance life science research and development activities in Taiwan, ITRI, with the support of Ministry of Economic Affairs of Taiwan, will implement this call for proposal in collaboration with Janssen. This Grant Call presents a great opportunity for Taiwan's research institutes, enterprises, hospitals, and schools to collaborate with world-class enterprises, and add value to existing technological innovations within Taiwan's biomedical industry. ITRI, in collaboration with Janssen, aims to collectively select proposals to receive funding up to an aggregate of one million U.S. dollars (US\$1,000,000) for each proposal/Applicant.

## ➤ **Applicant Eligibility**

Applicants herein should be companies, foundations, universities, institutions of higher learning (including ITRI's laboratories), hospitals, or other corporations, which are established and existing under the laws of the Republic of China (Taiwan). Please note that all Applicants must complete the healthcare compliance screening questionnaire attached hereto as Exhibit A and shall be subject to healthcare compliance screening for eligibility to receive funding.

## ➤ **Timetable ( Current tentative schedule )**

|                                       |                                  |
|---------------------------------------|----------------------------------|
| Proposal Summary Submission Deadline  | June 17 <sup>th</sup> , 2022     |
| First Selection Notification          | August 2 <sup>nd</sup> , 2022    |
| Detailed Proposal Submission Deadline | TBC                              |
| Final Selection Notification          | October 7 <sup>th</sup> , 2022   |
| Research Agreement Execution          | December 31 <sup>st</sup> , 2022 |

## ➤ **Grant Call details can be found at <https://jti.itri.org.tw/index.aspx>**

## ➤ Focus Areas

The Sponsors are seeking proposals that address one of the following Therapeutic Areas and have potential in resolving any one of the below problems:

### 1. WWDA

#### I. Algorithms for CT-based risk classification of Renal Cell Carcinoma lesions

CT or MRI play an important role in preoperative renal mass evaluation to differentiate renal malignancy from common benign entities like renal cysts. Basic radiographic characteristics are used today to help characterize renal masses, however distinguishing between renal malignancy from benign lesions remain difficult with current radiographic techniques. Harnessing of existing radiographic imaging data to better differentiate malignant from benign masses could improve upon standard of care today. We seek relevant algorithms for imaging-based classification that could be easily applied in a clinical setting.

#### II. Urine or blood-based biomarkers for Renal Cell Carcinoma malignancy or risk of recurrence post surgery

Basic radiographic characteristics are most commonly used today to help characterize renal masses. However, distinguishing between renal malignancy from benign lesions remain difficult with current radiographic techniques. Assessing risk of recurrence is also important and done by mainly by histopathology that requires invasive biopsy. There is a need for less invasive or non-invasive diagnostic biomarkers for discrimination of benign and malignant renal masses or stratifying patients based on risk of recurrence.

### 2. Neuroscience

#### I. Neurodegenerative & Neurological Diseases

Alzheimer's Disease, Parkinson's Disease, Amyotrophic Lateral Sclerosis (ALS), as well as Myasthenia Gravis & Multiple Sclerosis

##### i) Disease Areas & Solutions

##### DISEASE-MODIFYING ACTIVITY

Agents in preclinical stage or later should have preclinical validated in-vivo, test-of-concept data.

Targets driven by human genetics, including:

- Neuroimmune pathways
- Differentiated modulators of  $\alpha$ -synuclein spread and clearance
- Differentiated modulators of tau pathobiology
- Compounds that promote synaptic resilience
- Modulators of ApoE4 pathology

Validated mechanisms that slow or halt the progression of multiple sclerosis (preferably with clinical evidence)

New therapeutic treatment modalities for neurodegenerative diseases, including gene therapy, and RNA modulation

##### ii) Platforms

##### BIOMARKERS AND DIAGNOSTICS

- Prognostic, diagnostic, and disease progression biomarkers
- Diagnostic imaging agents, including imaging of disease pathology, structural and

functional MRI

- Improved cerebrospinal fluid (CSF) and blood biomarker assays

## **II. Neuropsychiatric Disorders**

Mood Disorders & Schizophrenia

### **i) Depression & Treatment-Resistant Depression**

Novel therapeutic agents that have fast onset of action, good safety and tolerability profiles, and that address common comorbidities (e.g., anxiety, insomnia, and substance abuse):

- Neuroactive cytokines
- Molecules that positively impact synaptic plasticity and cellular resilience
- Differentiated modulators of glutamatergic signaling

### **ii) Bipolar Disorder**

Novel therapeutic agents that provide rapid improvement in bipolar depression and in suicidal patients, and that produce long-term stabilization of mood and prevent recurrences

## **III Other Areas of Interest**

Our neuroscience team is also scouting for data science and analytic approaches that drive insights into patient subtypes, phenotypes and biology, patient journeys, and real-world data.

Janssen is also pursuing digital health software and therapeutics that enable clinical development or commercially deployable solutions that augment our portfolio of neuropsychiatric diseases, neurodegenerative diseases, and neurological disorders.

## **2. Data Science**

### **I. Digital Health**

Digital health platforms are expanding in coverage and capabilities and similarly, digital health data is growing rapidly through these platforms and associated technologies. While the growth has been tremendous, the integration of digital health into processes for pharmaceutical R&D is still a rapidly developing space. Topics of interest here include digital patient data, digital health platforms for patient recruitment, follow-up, and trial retention.

### **II. Real World Data**

Real world data is becoming increasingly acceptable for regulatory submissions and evidence generation. Coverage, access to, and quality of data sources has been varied in different geographic regions, complicating the utilization of RWD in various countries. For Asia Pacific countries in particular, topics of interest include longitudinal RWD with documented regulatory use, AI/ML based risk factor identification, and linked datasets across multiple health systems.

### **III. Computer Vision – algorithm development and deployment**

The application of computer vision to medical images of various types (e.g., radiology, digital histopathology) holds the potential to revolutionize the treatment of patients by enhancing diagnosis, monitoring, identifying new patient segments, and better matching patients to therapy. Topics of interest include approaches that use Asia Pacific data to develop algorithms in the areas of Immunology, Neuroscience, Oncology, as well as approaches for deploying these algorithms in real-world care settings.

## ➤ **Proposal Documents:**

Proposals will be reviewed in two stages. For the first stage, applicants should download the [Proposal Summary](#) template from our website and submit by June 17<sup>th</sup>. In the second stage, the applicants who have been shortlisted through the First Selection Notification should submit the [Detailed Proposal](#) package by the time and date requested by JTI Office.

### **A. First Stage:**

Please complete and submit the following Proposal Summary package to [jtioffice@itri.org.tw](mailto:jtioffice@itri.org.tw) prior to 17:00 by June 17th, 2022.

1. [Proposal Summary](#)(Executive Summary Template): the template can be downloaded from here as well: <https://jti.itri.org.tw/index.aspx>
2. Executed “Notification and Consent Regarding Collection, Processing and Use of Personal Information” in the form attached hereto as Exhibit E by the principal researcher.
3. Executed “Confirmation of Intellectual Property Policy Notification & Statement of Non-Confidentiality”.

### **B. Second Stage:**

Applicants who have received the First Selection Notification should prepare and submit the Detailed Proposal package to [jtioffice@itri.org.tw](mailto:jtioffice@itri.org.tw) prior to the time and date requested by JTI Office. The Detailed Proposal should be titled “ITRI 2022 Grant Call in Collaboration with Janssen” and should include the following information: Applicant’s name, research proposal title, contact person, principal researcher and his/her position. Please include the following attachments in your Detailed Proposal package.

1. [Detailed Proposal](#): include items such as Budget Table (including administration fee/Indirect costs, manpower arrangement, etc.) and Milestones – please download and fill out the Detailed Proposal template which can also be found here: <https://jti.itri.org.tw/index.aspx> ;
2. Completed Healthcare Compliance Due Diligence questionnaire set forth in Exhibit A;
3. An affirmative or negative confirmation as to whether Applicant agrees to the material terms and conditions of the Research Agreement set forth in Exhibit B. For the avoidance of doubt, a negative confirmation of the material terms and conditions of the Research Agreement will still be reviewed by the Sponsors;
4. Executed Statement Against Corrupt Practices in the form attached hereto as Exhibit C;
5. Executed Statement of Compliance with Federal Animal Welfare Regulations in the form attached hereto as Exhibit D.
6. Executed “Notification and Consent Regarding Collection, Processing and Use of Personal Information” in the form attached hereto as Exhibit E by each team member.
7. If such Applicant is a company, or the research institutions funded by MOEA (Taiwan’s Ministry of Economic Affairs), please also submit the Detailed Proposal by MOEA’s template.

## ➤ **Review Process**

1. The Proposal Summary package will be reviewed by a committee organized by the Sponsors (the “Committee”) according to the Application Instructions (please find Application Instructions in “Other References” at <https://jti.itri.org.tw/index.aspx>).
2. Applicants who enter final selection (receiving the First Selection Notification) will give an oral presentation in front of the Committee and provide the aforesaid Detailed Proposal package according to the date and the time requested by the Committee. The date of oral presentation will depend on the review schedule. Please prepare for presentation upon notification. Final Selected Proposal will be notified in writing including the approved amount of funding by the decision of the Committee.
3. If Applicants are the companies, industries, or the research institutions funded by MOEA, Applicants, based on the request of the MOEA, also shall submit the aforesaid MOEA Detailed Proposal and shall receive the grant notification from MOEA. If Applicants are the universities or other academic research institutions funded by MOST (Taiwan’s Ministry of Science and Technology), it’s also necessary for Applicants to get the grant notification of funds from MOST or other funds applied by itself.
4. Within 90 days after receiving the Final Selection Notification, Applicant should sign Research Agreement which shall incorporate the terms substantially set forth in Exhibits B to D with ITRI and Janssen.
5. The initial installment of funds will be disbursed by the Sponsors following the fully execution of the Research Agreement.

## ➤ **Ownership of Program Technology**

The ownership, title to the new IP under the Research Agreement shall be jointly owned by Janssen and Applicant. The share of Joint IP owned by Janssen and Applicant hereunder is subject to the ratio, 50% and 50% with equal rights (“Joint IP”), benefits, and liabilities. (Please see Exhibits B Terms Sheet for Research Agreement and License Option)

## ➤ **Other Specifications**

1. Proposals contemplated to be funded by the Sponsors need to be completed within thirty-six (36) months from the date of funding;
2. Applicant may not obtain any other funding to conduct the Selected Proposal without each Sponsor’s consent.
3. Research funding provided herein should be used exclusively for the Selected Proposal (overhead/indirect costs must not exceed 10% of the total cost of Selected Proposal).
4. There should not be any confidential information included in the Proposals. Applicant acknowledges that i) each Sponsor and its affiliates have wide access to ideas, concept, approach, format, designs, protocols, methodologies and other or other respects (collectively, "Ideas"), and those new Ideas are constantly being submitted to it or being developed by their own employees; ii) many Ideas may be competitive with, similar to, or identical to content in the Proposal(s) from Applicant; iii) Applicant will not be entitled to any compensation as a result of each Sponsor and its affiliates’ development or use of any such Ideas that has been made without the use of such information with respect to this Proposal(s).

5. Except as otherwise provided in its Proposal and received by the Committee, Applicant may not engage any subcontractors or collaborators without each Sponsor's consent.
6. Applicant should obtain and maintain adequate insurance to cover any liability arising from its conduct of the Selected Proposal.
7. 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 Selected Proposal, or if principal researcher was replaced without each Sponsor's consent.
8. Applicant shall be responsible for any costs and expenses arising from participating in the Grant Call.
9. Proposals will be reviewed by the Committee at the Committee's sole discretion. Sponsors, their affiliates and their respective employees, agents, directors, officers, representatives, contractors, independent consultants, or any other associates, shall not be liable for any Applicant's remedies, damages, penalties, losses, expenses, fees, costs or liabilities of any kind or nature whatsoever, in connection with Applicant's participation in the Event, except to the extent required by applicable laws.
10. Any and all taxes, duties, levies, and fees imposed by any government authority in connection with this Grant Call shall be borne by Applicant itself.
11. Applicant of Selected Proposal shall set up a separate account (the "Separate Account") to manage the use of all research funding. Applicant agrees to permit any authorized representative appointed by Sponsor(s) to carry out an audit of the Separate Account.
12. Applicant agrees to cooperate with ITRI to abide by all the applicable law of Ministry of Economic Affairs, or Ministry of Science and Technology of Republic of China (Taiwan), including but not limited to Regulation Governing the Approval of Investment or Technical Cooperation in Mainland China.
13. Sponsors will need to collect, process, and use Applicant's personal information, including names, office address and other contact information, which may be provided to Sponsors' affiliates and their respective employees, agents, representatives, contractors, independent consultants, and other associates. Sponsors will comply with the provisions of the Personal Data Protection Act ("PDPA") Taiwan, where ITRI acts as a data controller in the processing of personal data in this Event.
14. 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.
15. The validity, construction, and performance of this Grant Call is governed by the laws of the Republic of China (Taiwan). All claims brought by an Applicant against the Sponsors in connection with the Grant Call or its subject matter that are not resolved by the Sponsors and Applicant through negotiations shall be submitted to the Hsinchu District Court of the Republic of China (Taiwan). For the avoidance of doubt, the terms of the Research Agreement shall govern all relevant disputes arising under such Research Agreement.
16. In the event any detail herein is modified, Sponsors should disclose it on the website <https://jti.itri.org.tw/index.aspx>, without further notice.

➤ **Contact Information**

Fong-Ching Lee (李鳳卿) /Administrator

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TEL: 886+3+5919142

Industrial Technology Research Institute/ Janssen Taiwan Initiative Office

工業技術研究院/ JTI 計畫辦公室

E-Mail : jtioffice@itri.org.tw

ADDRESS: Rm.236, Bldg.53, No. 195, Sec. 4, Chung Hsing Rd., Chutung, Hsinchu, Taiwan  
31057, R.O.C.

# Exhibit 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 Grant Call.
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 Grant Co-funding as an employee of a government-linked entity or a corporate entity?**

Government-linked Entity. Please go to Section G.

Corporate Entity. Please go to Section C.

**SECTION G – For Participants from Government-linked Entities**



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

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

|  |   |
|--|---|
| <p><b>7a. Do any HCPs own options to obtain shares in your company?</b></p>  | <p><input type="checkbox"/> Yes. Please go to 7b.</p> <p><input type="checkbox"/> No. Please go to 8a.</p>  |
| <p><b>7b. If so, please provide the names of these HCPs and details of their economic interest and position with your company.</b></p> <p><b>i. Is the HCP licensed and practicing?</b></p> <p><b>ii. Area of practice</b></p> <p><b>iii. % ownership of company</b></p> <p><b>iv. Current affiliations (e.g., hospitals, universities, ACOs, formulary committees, procurement committees, product review committees, product advisory committees, Boards, etc.)</b></p> <p><b>v. Does the HCP have any prior or current relationships with J&amp;J or any J&amp;J subsidiary? (e.g., a paid speaker or consultant to any J&amp;J products, engaged in J&amp;J company sponsored research, engaged in a clinical study funded by a J&amp;J Company, etc.)</b></p> <p><b>vi. Will the HCP be involved in this research proposal/project?</b></p> | <p>Name:</p> <p>Position in Company:</p> <p>HCP License: <input type="checkbox"/> Past<br/><input type="checkbox"/> Current</p> <p>Is the HCP currently practicing? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Area of Practice:</p> <p>Company Ownership: %</p> <p>Current Affiliations:</p> <p>Does the HCP have any influence on the use, recommendation, procurement or approval of J&amp;J products?</p> <p><input type="checkbox"/> Yes. Please provide details.</p> <p><input type="checkbox"/> No</p> <p>Prior relationships with J&amp;J:</p> <p>Current relationship with J&amp;J (including J&amp;J subsidiaries):</p> <p>Involved with research proposal/project?<br/><input type="checkbox"/> Yes <input type="checkbox"/> No</p> |

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

**8b. If so, please provide the names of these HCPs and details of their economic interest and position with your company.**

- i. Is the HCP licensed and practicing?**
- ii. Area of practice**
- iii. % ownership of company**
- iv. Current affiliations (e.g., hospitals, universities, ACOs, formulary committees, procurement committees, product review committees, product advisory committees, Boards, etc.)**
- v. Does the HCP have any influence on the use, recommendation, procurement or approval of J&J products?**
- vi. Does the HCP have any prior or current relationships with J&J or any J&J subsidiary? (e.g., a paid speaker or consultant to any J&J products, engaged in J&J company sponsored research, engaged in a clinical study funded by a J&J Company, etc.)**
- vii. Will the HCP be involved in this research proposal/project?**

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.  
 No  
  
Prior relationships with J&J:  
  
Current relationship with J&J (including J&J subsidiaries):  
  
Involved with research proposal/project?  
 Yes  No

Name:  
Position in Company:  
HCP License:  Past  
 Current  
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 9a.

**9a. Are any key personnel (Board members, Officers of the Company, key employees) an HCP?**

Yes. Please go to 9b.

No. Please go to 10a.

|  |   |
|--|---|
| <p><b>9b. If so, please provide the names of these HCPs and details of their economic interest and position with your company.</b></p> <ul style="list-style-type: none"> <li><b>i. Is the HCP licensed and practicing?</b></li> <li><b>ii. Area of practice</b></li> <li><b>iii. % ownership of company</b></li> <li><b>iv. Current affiliations (e.g., hospitals, universities, ACOs, formulary committees, procurement committees, product review committees, product advisory committees, Boards, etc.)</b></li> <li><b>v. Does the HCP have any influence on the use, recommendation, procurement or approval of J&amp;J products?</b></li> </ul> | <p>Name:</p> <p>Position in Company:</p> <p>HCP License: <input type="checkbox"/> Past<br/> <input type="checkbox"/> Current</p> <p>Is the HCP currently practicing? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Area of Practice:</p> <p>Company Ownership: %</p> <p>Current Affiliations:</p> <p>Does the HCP have any influence on the use, recommendation, procurement or approval of J&amp;J products?</p> <p><input type="checkbox"/> Yes. Please provide details.</p> <p><input type="checkbox"/> No</p> <p>Prior relationships with J&amp;J:</p> <p>Current relationship with J&amp;J (including J&amp;J subsidiaries):</p> <p>Involved with research proposal/project?<br/> <input type="checkbox"/> Yes <input type="checkbox"/> No</p> |
|--|---|

|  |  |
|--|--|
| <p><b>vi. Does the HCP have any prior or current relationships with J&amp;J or any J&amp;J subsidiary? (e.g., a paid speaker or consultant to any J&amp;J products, engaged in J&amp;J company sponsored research, engaged in a clinical study funded by a J&amp;J Company, etc.)</b></p> <p><b>vii. Will the HCP be involved in this research proposal/project?</b></p> | <p>Name:<br/> Position in Company:<br/> HCP License: <input type="checkbox"/> Past<br/> <input type="checkbox"/> Current<br/> Is the HCP currently practicing? <input type="checkbox"/> Yes <input type="checkbox"/> No<br/> Area of Practice:<br/> Company Ownership: %<br/> Current Affiliations:</p> <p>Does the HCP have any influence on the use, recommendation, procurement or approval of J&amp;J products?<br/> <input type="checkbox"/> Yes. Please provide details.<br/> <input type="checkbox"/> No</p> <p>Prior relationships with J&amp;J:<br/> Current relationship with J&amp;J (including J&amp;J subsidiaries):<br/> Involved with research proposal/project?<br/> <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Please go to 10a.</p> |
| <p><b>10a. Are your company owners, partners, shareholders, or key decision makers a Government Official or affiliated with a Government Official?</b></p>   | <p><input type="checkbox"/> Yes. Please go to 10b.<br/> <input type="checkbox"/> No. Please go to 11a.</p>   |
| <p><b>10b. If 'Yes', please provide name(s) and the individual's(s') position(s).</b></p>  | <p>Name:<br/> Position:<br/> Government Institution/Agency:</p> <hr/> <p>Name:<br/> Position:<br/> Government Institution/Agency:</p> <p>Please go to 11a.</p>   |
| <p><b>11a. Are your company owners, partners, shareholders, key decision makers currently working for a government-owned or a government-linked institution (e.g., a public hospital) which is or could potentially be a J&amp;J customer? Note: This includes providing advisory, consulting or part-time services.</b></p>   | <p><input type="checkbox"/> Yes. Please go to 11b.<br/> <input type="checkbox"/> No. Please go to 12a.</p>   |



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| <b>11b. If ‘Yes’, please provide name of the government-owned or government-linked institution(s).</b>   | Please go to 12a.  |
| <b>12a. Are any of the family members of the owners, principals, or board members of your company or your parent company employees of J&amp;J?</b> | <input type="checkbox"/> Yes. Please go to 12b.<br><input type="checkbox"/> No |
| <b>12b. If ‘Yes’, please provide details.</b>  | Name:<br>Relationship:   |

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| <b>COMPLETED BY</b> |  |
| <b>Signature</b>    |  |
| <b>Name</b>         |  |
| <b>Date</b>         |  |

# Exhibit 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 [Johnson & Johnson entity] (“**JB**I”) 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.

|                         |   |
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| <b>Parties</b>          | <ul style="list-style-type: none"><li>• [JBI]</li><li>• [ITRI]</li><li>• Applicant (“<b>Institution</b>”)</li></ul>   |
| <b>Research Program</b> | <ul style="list-style-type: none"><li>• Institution will conduct the research in accordance with the timelines, milestones, and deliverables set forth in the mutually agreed upon research program.</li><li>• 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.</li><li>• Research funding will be provided in accordance with an agreed-upon budget and payment schedule and will be used exclusively for the research.</li><li>• Institution may not obtain any other funding to conduct the research without each Sponsor’s consent.</li><li>• Except as otherwise provided in its proposals received by selection committee, Institution may not engage any subcontractors or collaborators without each Sponsor’s consent.</li></ul> |

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|  | <ul style="list-style-type: none"> <li>• Institution will obtain and maintain adequate insurance to cover any liability arising from its conduct of the research.</li> <li>• 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.</li> </ul>   |
| <b>Principal Investigator</b>          | <ul style="list-style-type: none"> <li>• Institution will designate a principal investigator to conduct and directly supervise the research program.</li> <li>• 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.</li> </ul>   |
| <b>Research Agreement</b>              |  |
| <b>Ownership of Program Technology</b> | <ul style="list-style-type: none"> <li>• The ownership, title to the new IP under this Agreement shall be jointly owned by Janssen and Institution. The share of Joint IP owns by Janssen and Institution is subject to the ratio, 50% and 50% , with equal rights, benefits, and liabilities. Each party shall be free to use, sell, license or otherwise transfer any Joint IP without accounting to the other party and without the other party's consent.</li> <li>• Janssen and Institution shall jointly file and prosecute patent applications for all Joint IP in the name of both parties, and shall jointly maintain any patents issued thereon, at their joint expense. If one party wishes to file, prosecute and/or maintain a patent application or patent claiming any Joint IP in a country and the other party declines to participate, then the first party can file, prosecute and/or maintain that patent application or patent in its own name, at its own expense, and the declining party shall have no further rights thereto. In such event, the declining party, at no charge, shall promptly assign all of its rights in and to the corresponding patent application to the other party, and shall execute such documents and perform such other acts as may be necessary or reasonably requested to permit the other party to file, prosecute and/or maintain such patent applications in a timely and complete manner. If neither party is interested in paying the related fee(s) to secure or maintain patent rights within the notice period of time, such application or patent shall be deemed to be abandoned by such parties. For each Institution's Invention made under this Research program and for which patent application(s) are filed, the Sponsors</li> </ul> |

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|  | <p>shall be entitled to a non-exclusive, non-transferable, royalty-free license to use them.</p>  |
| <p><b>JBI Right of First Negotiation and Trailing Right of First Refusal</b></p> | <ul style="list-style-type: none"> <li>• 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 “<b>Data Package</b>”, and also called as “<b>Licensed Technology</b>” hereunder). 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.</li> <li>• <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 (“<b>ROFN Exercise Period</b>”), 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 (“<b>License</b>”) (such option, the “<b>JBI Option</b>”). 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 Period by delivery of written notice to Institution (“<b>Exercise Notice</b>”), 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 “<b>Exclusive Negotiation Period</b>”) to enter into a License with the Institution. <ul style="list-style-type: none"> <li>o 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</li> </ul> </li> </ul> |

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.

- o “Transaction” shall mean any transaction (i) which 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.

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|                           | <p><u>Right of Last Refusal.</u> For a period of one hundred eighty(180) calendar days following the expiration of the Exclusive Negotiation Period (the “<b>Tail Period</b>” and, the last date of such period, the “<b>Expiration Date</b>”), the Institution shall not consummate or agree to consummate a Transaction with any other party (a “<b>Third Party</b>”) without first giving prompt notice thereof to JBI in writing (the “<b>Proposed Transaction Notice</b>”) (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</p> |
|                           | <p>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 “<b>Negotiation Period</b>”). Notwithstanding the foregoing, upon the Expiration Date all rights relating to this Right of Last Refusal shall terminate and any Proposed Transaction Notice period or Negotiation Period, 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.</p> <ul style="list-style-type: none"> <li>• 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.</li> </ul>           |
| <p><b>Termination</b></p> | <ul style="list-style-type: none"> <li>• 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.</li> </ul>  |

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| <p><b>Governing Law/Dispute Resolution</b></p>  | <ul style="list-style-type: none"> <li>• The Research Agreement will be governed by the laws of the State of New York.</li> <li>• The parties will resolve any dispute arising out of or in connection with this Research Agreement, including any question regarding its existence, validity or termination, shall be referred to and finally resolved by arbitration administered by the Singapore International Arbitration Centre (“SIAC”) in accordance with the Arbitration Rules of the Singapore International Arbitration Centre ("SIAC Rules") for the time being in force, which rules are deemed to be incorporated by reference in this clause. The seat of the arbitration shall be Singapore. The Tribunal shall consist of one arbitrator. The language of the arbitration shall be English.</li> </ul> |
| <p><b>License</b></p>                           |   |
|   | <ul style="list-style-type: none"> <li>• 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.</li> <li>• JBI and Institution will each appoint an alliance manager to be the point of contact and to coordinate between the parties.</li> </ul>   |
| <p><b>Development and Commercialization</b></p> | <ul style="list-style-type: none"> <li>• JBI will, in its sole discretion, determine whether to develop and commercialize the Licensed Technology and related products.</li> </ul>  |

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|   | <ul style="list-style-type: none"> <li>• JBI will be solely responsible for all decisions regarding the development, manufacturing, and commercialization of the Licensed Technology and related products.</li> <li>• 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.</li> <li>• 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.</li> <li>• Institution will have customary audit rights.</li> <li>• Institution will provide customary representations and warranties regarding the Licensed Technology, including non-infringement.</li> </ul> |
| <p><b>Ownership of Technology Developed Under the Exclusive License</b></p> | <ul style="list-style-type: none"> <li>• 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 responsible for filing, prosecuting, and maintaining any patent rights.</li> </ul>  |
| <p><b>Business Acknowledgment.</b></p>                                      | <ul style="list-style-type: none"> <li>• Business Acknowledgement. Institution acknowledges that each Sponsor and its affiliates have wide access to ideas, concept, approach, format, designs, protocols, methodologies and other or other respects (collectively, "Ideas"), and those new Ideas are constantly being submitted to it or being developed by their own employees; ii) many Ideas may be competitive with, similar to, or identical to content in the Research Program from Institution; iii) Institution will not be entitled to any compensation as a result of each Sponsor and its affiliates' development or use of any such Ideas that has been made without the use of such Information with respect to this Research Program, or may come to JBI, ITRI, or its affiliates, from other sources.</li> </ul>   |



**ACKNOWLEDGED AND AGREED**

By: \_\_\_\_\_

Name:

Organization:

Title:

# Exhibit C

## Statement Against Corrupt Practices

### Compliance with Anti-Corruption Laws

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

- (i) 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;
  - c. 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**

By: \_\_\_\_\_

Name:

Organization:

Title:

# Exhibit 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. Ethics Committee 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**

| <b>Institution/CRO<br/>Name, Location,<br/>Country</b> | <b>Contractor's<br/>Contact</b> | <b>J&amp;J<br/>Op CO</b> | <b>J&amp;J<br/>Contact</b> | <b>Protocol /<br/>Study ID</b> | <b>Protocol /<br/>Study Title</b> | <b>Species</b> | <b># of<br/>Animals</b> | <b>Study /<br/>Activity<br/><br/>Start<br/>date</b> | <b>Study /<br/>Activity<br/><br/>Term date</b> |
|--|---------------------------------|--------------------------|----------------------------|--------------------------------|-----------------------------------|----------------|-------------------------|---|--|
|  |                                 |                          |                            |                                |                                   |                |                         |   |  |
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# Exhibit 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 2022”, 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 non-government 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 :