APPLICATION FORM FOR ACCESS TO IMPACT BIOBANK

1.0 Objective

The objectives of the IMPACT Biobank are to provide a basis for future research on pregnancy and newborn health.

To support these objectives, the IMPACT consent for Future Research on Stored Biological Samples obtained from Participants is broad enough to support a range of research on fetal growth, pregnancy and the health of mothers and their children. Biobanking is an optional part of the IMPACT study. Participants may decide not to participate in the optional biobanking research and still participate in the main study

Some of the future research may include testing on genes related to viruses. No hereditary testing will occur. Researchers also may be interested in the way that genes affect health and disease, or how the body responds to treatment.

The criteria for granting access include: feasibility, scientific value, minimal risk, availability of specimens, contribution to the IMPACT Research Study, and public health importance to Canadians.

The IMPACT Biobank operates on a cost-recovery basis. The fees to access the IMPACT Biobank are determined by the IMPACT Biobank Manager and will be used to cover the operating costs of the IMPACT Biobank as well as its maintenance over 30 years. The IMPACT Biobank does not allow access by insurers or employers.

2.0 Definitions

Applicant (referred to as "Applicant"): Researcher seeking access to the IMPACT Biobank, for a proposed project, identified hereafter as "Applicant". Generally the Principal Investigator of the proposed project. There may be one Co-Applicant, identified hereafter as "Applicant 2", who will share the responsibility of the Biobank Project.

Biobank Manager: Mrs. Jessica Pudwell, or her duly appointed replacement.

Biobank Project: A research study that involves access to the Material in the IMPACT Biobank. The following would be considered Biobank Projects: (1) any request to access the data stored in the IMPACT Biobank by an individual who was not a Co-Investigator on the studies in which the data were collected; (2) any proposal to link data in the IMPACT Biobank with other datasets; (3) any proposal to analyse any specimens stored in the IMPACT Biobank; (4) any proposal not led by the IMPACT Study Co-Principal Investigators that entails contact with Participants.

Co-authors: For the purpose of a Reanalysis Study, a group of authors that published the original report based on IMPACT Biobank data to address a specific research question that the Applicants are proposing to reanalyse in a Reanalysis Study.

Conflict of Interest: any situation in which financial or other personal considerations may compromise, or have the appearance of compromising a researcher's professional judgment in conducting or reporting research.

Data Pooling: A method of combining similar Individual-level Data from multiple sources or studies into a single dataset, with the sole purpose of increasing the sample size for statistical analyses. This does not lead to the creation of derived variables at the individual level.

End-Users: All individuals identified in **Schedule B** who will have access to the Material. Access is limited to those who require it in order to meet the objectives of the Biobank Project.

IMPACT Biobank: A collection of data, and biological and environmental specimens obtained in the course of the IMPACT Research Platform Studies that have been stored for future research with the consent of Participants.

IMPACT Biobank Management Committee (referred to as "**IMBC**"): A duly constituted committee with the composition set forth as described in the IMPACT Biobank Management Policy that is responsible for the strategic direction of the IMPACT Biobank.

IMPACT Biobank Management Policy (referred to as "**Management Policy**"): A policy that defines the organisational structure and governance of the IMPACT Biobank, as well as policies and procedures for management of the data and specimens stored in the IMPACT Biobank.

IMPACT Data: Information about Participants, whether grouped or at the Individual-level, that includes but is not limited to that derived or obtained from questionnaires, images, clinical tests, medical chart abstractions, physical exams, linkage to external ecological datasets (e.g., ambient air pollution, municipal drinking water analysis), linkage to external Individual-level Data sources for IMPACT Participants, and the laboratory results from analysis of their specimens.

Individual-level data: Information at the level of individual participants.

Individual-level Data Linkage: A method that brings information or records on an identified individual from external data source(s) to be linked to information on the same individual from IMPACT, to create a new richer dataset for IMPACT Participants. Depending on the data sharing policies of the external data source(s), this may lead to the creation of new or derived variables for IMPACT Participants, to be added to the IMPACT Biobank.

Material: Data and specimens stored in the IMPACT Biobank. Examples of specimens include blood, urine, hair, cord blood and meconium. Examples of data include that generated from questionnaires to the Participants, laboratory test results, clinical tests, Ecological Data Linkages, Biobank Projects, and Derived Variables.

Reanalysis Study: A IMPACT Biobank Project that aims at repeating analysis of Biobank data to answer a question previously addressed using the same data, to confirm or refute prior findings. It involves analysing the data using a statistical methodological approach and/or a laboratory method that is substantially different from the original work. The IMPACT Biobank Management Committee expects the reanalysis to be conducted by a qualified team without any preconceived agenda or bias.

Research Question (referred to as "**RQ**"): An answerable inquiry into a specific concern or issue that is the first step in developing a research project.

Research Question Form (referred to as "**RQ Form**"): A form completed by IMPACT Research Platform Studies Investigators or their Trainees which identifies the proposed Research Question, the Research Team, the data sources, keywords associated with the Research Question, the Data Analysis Plan and whether consultation has taken place with the relevant Theme Leader(s).

Research Team Members: All investigators (including the Designated Principal Investigators/Applicants on the Research Question), staff, colleagues and Trainees who will be involved in analysing IMPACT Data or reviewing results based on this analysis, whether individual-level or grouped, to address the approved Research Question. These members are listed in **Schedule B**.

Secure Server: A server that encrypts information sent and received over a network.

Trainee: An undergraduate, graduate or post-doctoral student, resident or fellow supervised by a IMPACT Research Platform Studies Investigator.

3.0 Process for Applying to Access the IMPACT Biobank

1: The **Applicant** submits a **preliminary application** (Step 1).

2: The **IMBC reviews** the preliminary application and provides **comments to the Applicant**.

3: If needed, the **Applicant revises the preliminary application**, in response to the IMBC comments.

4: If the IMBC approves the *preliminary application*:

a) the Biobank Manager provides a **provisional support letter**, including the cost estimate for the project;
Note: no ballpark figures can be provided before the review of the preliminary application.

5: Once funding has been secured, the **Applicant submits a full application** (Step 2).

6: The **IMBC reviews** the full application and, based on its merit, either:
a) approves the proposed project as submitted;
b) asks for clarifications and/or revisions, prior to approving, or
c) refuses the proposed project, providing reasons.

7: If the IMBC approves the *full application*:

a) the Biobank Manager provides a **letter of provisional support**, confirming the **availability of the requested specimens**, the **cost estimate**, and that no **scientific advances have** occurred that would impact the need for the proposed work;

8: The Applicant **submits an ethics application** to his/her institution (Step 3).

9: Once approved by the ethics board, the **Applicant and all Team Members** complete and sign the **IMPACT Biobank End-User Acknowledgement for Biobank Applicants**.

10: An **inter-institutional agreement** is signed between Queen's University and the Applicant's institution.

11: The Biobank Manager sends the requested **data and specimens**.

12: To modify an approved project, including request for additional data, the Applicant must submit an Amendment Form and obtain approval of the IMBC and the REBs (if needed) prior to implementing these changes.

Step 1: PRELIMINARY APPLICATION

Important: this form is edited regularly. Before completing, contact the Biobank Manager to get the up to date version of this form and the selection tools.

A. Description of the proposed project

1. Title:

2. Applicant:

Family (last) name:	
Given (first) name and initial:	
Title, institution, department:	
Mailing address:	
Work and cell phone numbers:	
Email address:	
Role in the project:	
Will work with Individual-level Data? (y/n)	

Applicant 2 (if applicable – to be confirmed with the Biobank Manager):

Family (last) name:	
Given (first) name and initial:	
Title, institution, department:	
Mailing address:	
Work and cell phone numbers:	
Email address:	
Role in the project:	
Will work with Individual-level Data? (y/n)	

3. **List of Team Members**:

Name	Position	Institution	Role on RQ *(e.g. data analysis, content expert, review of grouped data, statistical analysis, co-authorship of IMPACT communications)*	Will work with Individual-level Data? (y/n)	Work location (city, country)	Trainee (y/n)	Degree sought

Add lines as needed

Step 1: PRELIMINARY APPLICATION

4. **Project description** (1,500 words maximum)

Introduction and rationale:	
Main objectives:	
Hypotheses:	
Predictors or risk factors:	
Outcomes:	
Other covariate information of interest:	
Public health significance:	
Rationale for selecting the IMPACT Biobank, as opposed to other sources, to answer the research question:	

5. Data selection

CRF Data ☐
Lab test results ☐

6. Population of interest

Specify how the IMPACT cohort population is well suited to address the project objectives:	

7. Statistical analyses (1,500 words maximum)

Describe in detail the proposed methods of statistical analyses:	
Name of Applicant or Team Member who designed and is leading the statistical analyses:	
Provide sample size/power calculations for the major outcomes of interest, if available (the IMBC may request more detail):	

8. Limitations of proposed project (maximum 500 words)**:**

Any covariates that would be useful, but were not collected in IMPACT studies?	
Analysis of interest that is not feasible, and why:	

9. Specify how you found out about the IMPACT Biobank:

Continued next page.

Step 1: PRELIMINARY APPLICATION

10. Will IMPACT Data be linked to external data? **Yes ☐** **No ☐**

If yes, specify:

The **type(s)** of linkage:	**I**ndividual-level linkage ☐
The **purpose** of the linkage:	
The **external variables** that will be linked to the IMPACT Data:	
The **source database(s)**:	
The **IMPACT variables** to which they will be linked:	
The **new variables** that will be derived from the linkage: (note: these variables will be added to the IMPACT datasets at the end of this Biobank Project)	

11. Will IMPACT Data be pooled with external data? **Yes ☐** **No ☐**

If yes, specify:

The **purpose** of the pooling:	
The **external variables** that will be pooled with the IMPACT Data:	
The **source database(s)**:	
The **name of the study**:	
The name of the **researcher(s) responsible** for the **study**:	
The **IMPACT variables** to which they will be pooled:	

12. Contribution of the proposed project to the IMPACT Biobank objectives:

13. Has funding been secured for this project? **Yes ☐** **No ☐**

If yes, specify the funding source:	
If no, specify the funding sources that have been or will be applied to and the anticipated decision date:	

14. List the abbreviations used in the application:

15. List of references cited in application:

Step 1: PRELIMINARY APPLICATION

B. Details on requested specimens and proposed lab tests

Are IMPACT Biobank specimens being requested? **Yes ☐** **No ☐**

- If no, go to Section C.
- If yes:
  - Complete **Appendix 1** at the end of this document.

C. Restrictions on use of the IMPACT data and specimens

Working with IMPACT Data

1. The **Individual-level Data** are confidential, and their use is **subject to strict rules**:
   - Individual-level Data must be kept at all times on **a secure server** protected by a firewall **within a public Canadian institution** such as a university or hospital.
   - Individual-level Data **can never leave Canada**.
     - The IMPACT Biobank does not provide VPN access. If an Applicant or Team Member plans to work with Individual-level Data from outside Canada, one of the Canadian Applicants or Team Members must establish a **VPN access** to his/her **institution's secure server**.
     - Special permissions may be granted for a sub-group of **non-sensitive information** that could not lead to indirect identification of a participant, considered on a **case by case basis**.
2. Results that could **lead to identification of a IMPACT participant** cannot be published.
3. Any **new data generated** as part of the Biobank Project will be added to the IMPACT Biobank.

Working from outside of Canada

Does any of the Applicants or Team Members plan to work with **Individual-level Data from outside Canada**? **Yes ☐** **No ☐**

- If yes, specify:

Name(s):	
Canadian institution where the server would be located:	
Canadian Applicant or Team Member who would be responsible for setting up the access:	

Working with IMPACT specimens

1. Access to specimens requested is **not guaranteed until the full application is approved**.
2. If the volume provided is greater than requested, the **leftover portion must be returned** to the IMPACT Biobank.
3. The **Applicant covers the shipment costs** for the delivery of the samples to the laboratory conducting the analyses and for the return of leftovers to the Biobank.
4. IMPACT samples **cannot be used for validating** a lab method. **Repeat analyses** are **not allowed**.

Applicants' acknowledgement of the restrictions on use of the IMPACT data and specimens

- ☐ I acknowledge that **I have read and understand the restrictions** on use of the IMPACT Data and specimens.
- ☐ I acknowledge that **any changes** will be communicated without delay to the Biobank Manager.
- ☐ I acknowledge that all the **Team Members** will work in compliance with the above listed conditions.

Name of Applicant: _____ **Signature:** _____ **Date:** _____

Name of Applicant: _____ **Signature:** _____ **Date:** _____

Step 1: PRELIMINARY APPLICATION

D. Applicants acknowledgement of the Biobank Management policies

- I acknowledge that I **have read and agree to comply** with the KT and Management policies.

Name of Applicant: _____ **Signature:** _____ **Date:** _____

Name of Applicant: _____ **Signature:** _____ **Date:** _____

E. Applicants' declaration

- **By signing below, I declare** that all information provided in this preliminary application is **complete and correct**.

Name of Applicant: _____ **Signature:** _____ **Date:** _____

Name of Applicant: _____ **Signature:** _____ **Date:** _____

F. List of documents to be provided to IMPACT Biobank Manager

Email the following documents **to jessica.pudwell@queensu.ca**

☐ Completed **Preliminary application**

☐ Completed **Appendix 1**

☐ Completed **Appendix 2 for each Applicant and Team Member**

☐ Funding approval(s), if available

☐ Scanned copy of the signature pages (if e-signatures not available)

SUPPORT FOLDER

☐ Up-to-date condensed CV of the Applicants and all Team Members, with publications and research funded from the past 5 years

IMBC's DECISION on PRELIMINARY APPLICATION

Comments by IMBC members on proposed Preliminary application:

Preliminary Application approved by IMBC: ☐ **Preliminary Application rejected by IMBC:** ☐

Date of decision letter:

Overlap verification

Does this Preliminary Application overlap with a past or existing RQ led by other IMPACT Research Study Investigators?

Yes ☐ No ☐

If yes:

- Specify the **IMPACT Research Study Investigators and topics**:
- **Date the information email** was sent to the above listed investigators:

Notes:

Internal reference numbers:

Step 2: FULL APPLICATION

Complete the FULL APPLICATION, using the approved Preliminary Application document provided by the Biobank Manager.

A. Overview of the Revised Preliminary Application

1. **Was the content of the Step 1: Preliminary Application revised?** **Yes ☐** **No ☐**
   - If no, go to Section B.
   - If yes:
     - Edit the Step 1: Preliminary Application, using the track changes feature.
     - Summarize the changes and why they were made:

2. **Was the list of Applicants or Team Members modified?** **Yes ☐** **No ☐**
   - If no, go to next section.
   - If yes:
     - Does any of the new Applicants or Team Members need to access individual-level data from outside Canada? **Yes ☐** **No ☐**
       - If yes, make sure the changes were made in Section C of the Preliminary Application.

3. **Was Appendix 1 modified?** **Yes ☐** **No ☐**
   - If no, go to next question.
   - If yes:
     - Edit the Appendix 1 at the end of this document, using the track changes feature.
     - Describe the changes:

Step 2: FULL APPLICATION

B. Description of the proposed project

4. Plain language summary

Provide a short, plain language (grade 8) description of the project suitable for the general public in no more than 250 words, avoiding scientific jargon. (note: this information may be used in publications such as IMPACT newsletter, IMPACT website)	

5. **Scientific abstract** (350 words maximum)

6. **Knowledge transfer plan** (i.e., dissemination plan)

Describe all planned knowledge transfer activities, including plans to present and publish the results:	

7. **Status of research ethics board review(s)**

8. Was a scientific peer review conducted on the proposed project? Yes ☐ No ☐

- If yes, **provide a copy** of the review and your responses.
- If no, explain why:

9. **Provide dates for projected timeline**

Starting lab analysis (yyyy/mm):	Ending lab analysis (yyyy/mm):
Starting data analysis (yyyy/mm)	Ending data analysis (yyyy/mm)
Last publication (yyyy/mm):	
Specify if any time restriction (e.g. funding timelines, student expected graduation, post-doc term):	

NOTE: every effort is made to best accommodate the projected timeline, without guarantee.

10. New data to be added to the IMPACT Biobank

Describe what kinds of variables/data will be generated by the project (e.g., results of lab analysis, derived variables, any variables created from linkage with non-IMPACT datasets):	
Specify the format of the data that will be returned to the Biobank (e.g. CSV, XLSX):	
Specify the expected date (yyyy/mm):	

11. **Are there any conflicts of interest to declare**? **Yes ☐ No ☐**

- If yes, specify:

Step 2: FULL APPLICATION

C. List of documents to be provided to IMPACT Biobank Manager

Email the following documents **to IMPACT.project@recherche-ste-justine.qc.ca**

MAIN FOLDER

☐ Completed **Full application**, with changes to Preliminary application visible

☐ **Appendix 1**, if changes were made after approval of Preliminary application (tracked changes)

☐ Completed **Appendix 2 for each Applicant and Team Member**, if changes were made after approval of Preliminary application (tracked changes)

☐ Funding approval(s)

☐ Scanned copy of the signature pages (if e-signatures not available)

SUPPORT FOLDER

☐ Scientific peer review and responses, if available

Step 2: FULL APPLICATION

SIGNATURE PAGE for FULL APPLICATION to the IMPACT BIOBANK

Applicant

By signing below, I declare that all information provided in this application is complete and correct.

_____ _____ _____

Name of Applicant **Signature** **Date**

Institutional Representative

_____ _____

Name of Authorized Person **Title of Authorized Person**

_____ _____ _____

Signature **Location** **Date**

_____

Institution

Applicant 2

By signing below, I declare that all information provided in this application is complete and correct.

_____ _____ _____

Name of Applicant **Signature** **Date**

Institutional Representative 2

_____ _____

Name of Authorized Person **Title of Authorized Person**

_____ _____ _____

Signature **Location** **Date**

_____

Institution

IMBC's DECISION on FULL APPLICATION

Full Application approved by IMBC: ☐ **Full Application rejected by IMBC:** ☐

Date of decision letter:

Does this Full Application overlap with a past or existing RQ led by other IMPACT Research Platform Studies Investigators?
Yes ☐ No ☐

If yes:

- Specify the **IMPACT Research Study Investigators and topics**:
- **Date the information email** was sent to the above listed investigators:

Notes:

If approved, internal reference numbers: BBK-____ / RQ-____

Step 3: FINAL STEPS

A. Ethics Approvals

Requirements

If the Full Application is approved, the Applicant must submit the project to Queen's University's REB as well as his/her institution's research ethics boards (REBs).

Applicant's REB

1. Once Queen's University's REB has approved the project, the Applicant prepares the submission bundle for his/her institution's REB
    a. The Applicant sends the REB bundle to the Biobank Manager, for review
2. Once approved by the Biobank Manager, the Applicant submits the bundle to his/her institution's REB
3. Once approved by his/her institution's REB, the Applicant provides the approval letter to the Biobank Manager
    - If the review from his/her institution's REB led to modifications of the Biobank application, the Applicant:
        - Shares the REB response with the Biobank Manager
        - Completes a "Biobank full application amendment" document
        - Edits the Biobank application and/or selection tools accordingly
        - Submits the documents to the Biobank Manager
        - Once the modifications have been approved by the IMBC, submits an amendment with these modifications to Queen's REB
        - When modifications have been approved by Queen's REB, sends the approval letter to the Biobank Manager

Step 3: FINAL STEPS

B. End-User Acknowledgement

Once the project has been approved by the 2 REBs:

1. The Applicant and the Team Members must complete and sign the IMPACT Biobank End-User Acknowledgement for Biobank Applicants.
2. If biospecimens were requested, the laboratory representative and staff will need to sign Schedule G.

C. Inter-Institutional Agreement

The Queen's University contract officer will submit a draft agreement to the Applicant Institution's officer, which will be signed by both institutions research directors and the Applicants.

Applicants' declaration

- **By signing below, I declare** that I understand the final steps required before obtaining access to the requested Material.

Name of Applicant: _____ **Signature:** _____ **Date:** _____

Name of Applicant: _____ **Signature:** _____ **Date:** _____

FINAL CONFIRMATIONS by the Biobank Manager

- **Queen's University REB approval obtained:** ☐ **Date:** _____
- **The Applicant institution's REB approval obtained:** ☐ **Date:** _____
- **End-User Acknowledgement completed:** ☐ **Date:** _____
- **Inter-Institutional Agreement fully executed:** ☐ **Date:** _____

Appendix 1: Detailed information on the proposed lab tests

Complete a page for each selected specimen

Specimen #1

Specify the type and time point: _____

1. Details on proposed lab tests

Test names	**Minimum required volume** *for each test*	**Volume unit** *(e.g. mL, mcL, g)*	**Lab method**	**Selected lab** *(name of lab, name of lab representative, city, province or state)*	**Method already validated?** *(y/n)*	**If validated, specify LOD** *(with unit)*

Add lines as needed

Important reminder:
1. Repeat analyses are not allowed.
2. IMPACT samples cannot be used for validating a lab method.

2. Rationale

Why did you select the above listed lab(s)?	
If a lab method is not yet validated, specify the expected timeline:	
Specify any benchmarks of success for the proposed tests:	
What potential problems may arise from these lab analyses?	

Add pages if requesting more than one specimen

Appendix 2: Declaration of conflicts of interest

Every Applicant and Team Member must complete and sign this Appendix.

Name of Applicant or Team Member: _____

DEFINITION OF CONFLICTS OF INTEREST

Any situations in which financial or other personal considerations may compromise, or have the appearance of compromising a researcher's professional judgment in conducting or reporting research.

1- CONSULTING ACTIVITIES

Financial interest includes:

- Anything of monetary value (salary, consulting fees, gifts, stocks, equity or other ownership interests)
- Intellectual property rights (patents, copyrights, royalties).

Gifts include, but are not limited to:

- Articles of value such as cash, personal loans, donations or property.
- Offers of travel, accommodation, meals, entertainment, equipment or other special considerations.
- Offers of products or services related to the staff member's profession field or discipline.

Did you engage in consulting activities over the past 36 months? Yes ☐ No ☐

If yes, complete the following for each activity:

Description of Consulting Activity:	
Company/Organization:	
Financial benefits:	
Gifts:	
Time Commitment (day/hour):	

Add tables as needed

Did an external organization in which you or a family member have an employment relationship, consulting arrangement and/or a financial interest, contribute a donation or gift that directly benefited your research activities? Yes ☐ No ☐

If yes, specify:

2- INTELLECTUAL PROPERTY

Intellectual property: inventions (whether or not patentable) technology, technical information, know -how, trademarks, official marks, industrial designs, and literary and artistic works, and includes, but is not limited to, formulae, computer software and hardware, drawings, graphics, designs, concepts, ideas, apparatus, processes, materials including cell lines, antibodies and other tangible research property and device.

Did you develop intellectual property that you licensed to an external organization in which you or a family member has an employment or consulting arrangement and/or a financial interest? Yes ☐ No ☐

If yes, specify:

3- GRANTS/CONTRACTS WHICH BENEFIT A COMPANY

Were you awarded a grant or contract on which you are the investigator, either solely or in collaboration with others, which could benefit a company in which you or a family member has an employment relationship, consulting arrangement and/or financial interest? Yes ☐ No ☐

If yes, specify:

4- INDIRECT BENEFITS AND SECONDARY INTERESTS

Secondary interests: the desire to obtain and publish research findings that support friends and colleagues, or advocate for strongly held social or political points of view.

Do you have any secondary interests or could you benefit indirectly from a reanalysis of these research findings? Yes ☐ No ☐

If yes, specify:

Signature of Applicant or Team Member: _____ Date: _____

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- Offers of travel, accommodation, meals, entertainment, equipment or other special considerations.
- Offers of products or services related to the staff member's profession field or discipline.

Did you engage in consulting activities over the past 36 months? Yes ☐ No ☐

If yes, complete the following for each activity:

Description of Consulting Activity:	
Company/Organization:	
Financial benefits:	
Gifts:	
Time Commitment (day/hour):	

Add tables as needed

Did an external organization in which you or a family member have an employment relationship, consulting arrangement and/or a financial interest, contribute a donation or gift that directly benefited your research activities? Yes ☐ No ☐

If yes, specify:

2- INTELLECTUAL PROPERTY

Intellectual property: inventions (whether or not patentable) technology, technical information, know -how, trademarks, official marks, industrial designs, and literary and artistic works, and includes, but is not limited to, formulae, computer software and hardware, drawings, graphics, designs, concepts, ideas, apparatus, processes, materials including cell lines, antibodies and other tangible research property and device.

Did you develop intellectual property that you licensed to an external organization in which you or a family member has an employment or consulting arrangement and/or a financial interest? Yes ☐ No ☐

If yes, specify:

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Were you awarded a grant or contract on which you are the investigator, either solely or in collaboration with others, which could benefit a company in which you or a family member has an employment relationship, consulting arrangement and/or financial interest? Yes ☐ No ☐

If yes, specify:

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Do you have any secondary interests or could you benefit indirectly from a reanalysis of these research findings? Yes ☐ No ☐

If yes, specify:

Signature of Applicant or Team Member: _____ Date: _____

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- Articles of value such as cash, personal loans, donations or property.
- Offers of travel, accommodation, meals, entertainment, equipment or other special considerations.
- Offers of products or services related to the staff member's profession field or discipline.

Did you engage in consulting activities over the past 36 months? Yes ☐ No ☐

If yes, complete the following for each activity:

Description of Consulting Activity:	
Company/Organization:	
Financial benefits:	
Gifts:	
Time Commitment (day/hour):	

Add tables as needed

Did an external organization in which you or a family member have an employment relationship, consulting arrangement and/or a financial interest, contribute a donation or gift that directly benefited your research activities? Yes ☐ No ☐

If yes, specify:

2- INTELLECTUAL PROPERTY

Intellectual property: inventions (whether or not patentable) technology, technical information, know -how, trademarks, official marks, industrial designs, and literary and artistic works, and includes, but is not limited to, formulae, computer software and hardware, drawings, graphics, designs, concepts, ideas, apparatus, processes, materials including cell lines, antibodies and other tangible research property and device.

Did you develop intellectual property that you licensed to an external organization in which you or a family member has an employment or consulting arrangement and/or a financial interest? Yes ☐ No ☐

If yes, specify:

3- GRANTS/CONTRACTS WHICH BENEFIT A COMPANY

Were you awarded a grant or contract on which you are the investigator, either solely or in collaboration with others, which could benefit a company in which you or a family member has an employment relationship, consulting arrangement and/or financial interest? Yes ☐ No ☐

If yes, specify:

4- INDIRECT BENEFITS AND SECONDARY INTERESTS

Secondary interests: the desire to obtain and publish research findings that support friends and colleagues, or advocate for strongly held social or political points of view.

Do you have any secondary interests or could you benefit indirectly from a reanalysis of these research findings? Yes ☐ No ☐

If yes, specify:

Signature of Applicant or Team Member: _____ Date: _____

Add pages as needed