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1.0	Central Office	110-07-14	Ministry of Health and Welfare	110-07-20
1.1	Central Office	114-09-16	Ministry of Health and Welfare	114-12-01

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1. Purpose

The “National Biobank Consortium of Taiwan” (hereinafter referred to as the “Integration Platform”) primarily integrates domestic human biobanks — their data, biospecimens, and related information (hereinafter referred to as “Integration Platform biospecimen data”) — through a cloud-based system, and makes them available for application and use by medical, clinical, industry, and related biomedical research investigators nationwide. The aim is to rapidly assemble the largest possible pool of research participants — patients or members of the general public — that is representative of the whole country, and to make effective use of their biospecimens or data, thereby advancing Taiwan's biomedical and biotechnology research achievements for the benefit of the nation.

2. Basis

1.Human Biobank Management Act.
2.Human Subjects Research Act.

3. Scope

This SOP applies to all applicants — domestic and international, from academia, industry, research institutions, and the medical community — who apply to the Integration Platform for biospecimens or data for biomedical research purposes.

4. Eligibility for Application

Institutions eligible to apply to this Integration Platform for biospecimens or data are limited to: public or private research institutions recognized by the competent authority; full-time faculty members and attending physicians at regional teaching hospitals or above; researchers eligible to apply for National Science and Technology Council (NSTC) projects; and legally established domestic or foreign companies with experience in biological science research. Applicants must submit documentation verifying their eligibility at the time of application.

5. Available Biospecimens and Data for Application

The data that the Integration Platform may provide, according to an applicant's needs, is limited to de-identified basic clinical data, biospecimens, and related information. By law,

biospecimens themselves may not be provided to institutions overseas; export of derivatives of biospecimens abroad requires prior approval from the competent authority. The Integration Platform shall ensure that its manner of providing data raises no concern of violating personal data protection or other applicable laws and regulations.

6. Application Documents

(1) **Application Form:**

Applicants shall complete the application form in the format specified by the Integration Platform. Its content shall include: (1) the institution's name and the name of the principal investigator (PI) of the research project; (2) the title of the research project; (3) the source of research funding; (4) the status of medical research ethics review; (5) undertakings; (6) the specific aims/hypothesis of this research; (7) the content and quantity of biospecimens or data requested from the Integration Platform; (8) the statistical justification for the types and quantities of biospecimens or data requested; (9) a brief description of the technical approach of this research; (10) the clinical background data and survival/outcome data required; (11) management of biospecimens, data, and information, including measures to protect participants' privacy during and after the course of the research; (12) the expected outcomes of the research: a brief description of the expected outcomes, including whether the research outcomes will give rise to any derivative benefits, and, if so, the plan for sharing such benefits. (Attachment 1)

(2) **Biosample Request List** (Attachment 2)

(3) **Other Related Documents:**

1. proof of approval of research funding
2. company registration documents and other related materials for industry applicants;
3. the IRB (Institutional Review Board) approval certificate for the research project, or proof of submission for IRB review.

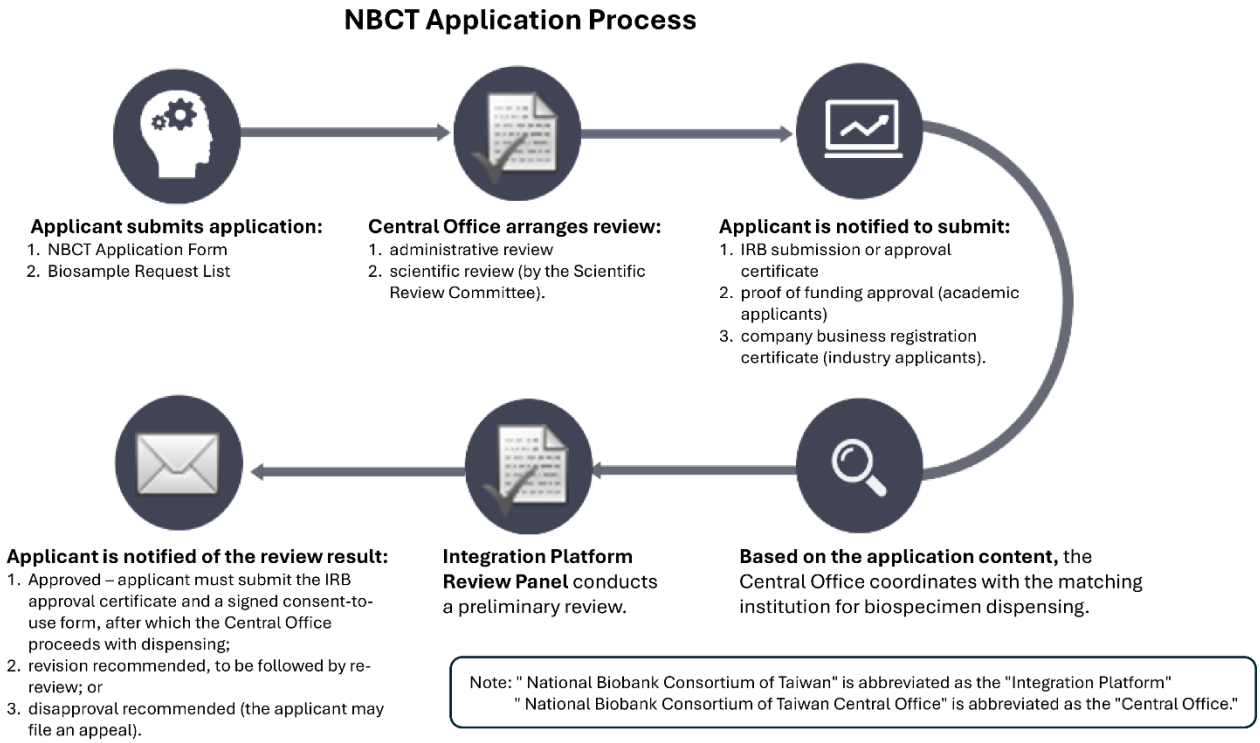
7. Conflict of Interest Avoidance

To maintain fairness in the review of applications for the use of data, all personnel involved in the review process shall comply with the principle of conflict-of-interest avoidance.

8. Information Disclosure

The names of all researchers and institutions applying to the Integration Platform, together with their research topics, will be published on the Integration Platform's website.

9. Application Flowchart



10. Attachments

Attachment 1:

NBCT application 111-03-28 v2

National Biobank Consortium of Taiwan (NBCT)
Application Form

	NBCT No.

Project Title **Title of the project**	**Chinese** **English**		
Affiliation **Affiliation**	**Chinese** **English**	**Department** **Department**	**Chinese** **English**
Principal Investigator **Principal Investigator**	**Chinese** **English**	**Job Title** **Job Title**	**Chinese** **English**
Telephone No. **Telephone No.**		**Fax No.** **Fax No.**	
E-mail Address **E-mail Address**			
Mailing Address **Mailing Address**	**Chinese** **English**		
Project Contact Person **Contact Person**		**Job Title** **Job Title**	
Telephone No. **Telephone No.**		**Fax No.** **Fax No.**	
E-mail Address **E-mail Address**			
Source of Research Funding **Funding Source**	**Is research funding from industry: □ No, □ Yes (see Note *2 below)** **(Funding sources from Industry: □ No，□ Yes)**		
Medical Research Ethics Review	**□ Not yet submitted for review** **□ Already submitted an application to the Human Subjects Research Ethics Committee, with proof of submission attached.** **Name of Ethics Committee:** **□ Review completed (Approval No.:), with approval certificate attached.**		

Undertakings:

(1)**I understand that the Integration Platform biospecimen data provided is for biomedical research purposes only, and that its use must comply with the "Human Biobank Management Act" and its related regulations. I agree to independently bear any loss, claim, injury, or liability arising from my use, storage, or handling of the Integration Platform biospecimen data. The Integration Platform shall bear no legal liability whatsoever.**

(2)**The research content and the quantity of biospecimens requested in this application form are consistent with the content of the protocol submitted to, and approved by, the IRB.**

(3)**I agree to pay the processing fee for this application in accordance with the published fee schedule, and may not unilaterally cancel the application. Integration Platform biospecimen data will be provided only after payment of the fee.**

(4)**I, together with other currently employed researchers, staff, project representatives, and the aforementioned personnel of co-research institutions, shall, with respect to Integration Platform biospecimen data, exercise the duty of care of a good administrator in its safekeeping. When using or publishing research results derived from Integration Platform biospecimen data, we must comply with applicable laws and regulations and confidentiality and privacy obligations, and must not infringe upon personal privacy or otherwise violate ethical norms.**

(5)**I understand that, when applying for a project, I am required to state whether the expected research outcomes will give rise to any derivative benefits. Should I apply for intellectual property rights, I will notify the Integration Platform within 20 days of that application. If commercial-application benefits are derived from Integration Platform biospecimen data, I will proceed in accordance with the "Ministry of Health and Welfare Directions for Benefit-Sharing from the Commercial Application of Human Biobanks." I understand that where an applicant's funding source is industry, the applicant is deemed, at the time of application, to already have commercial-application benefits.**

(6)**Upon completion of the project, I shall submit the IRB closure report to the Integration Platform for its records; after any research results obtained using Integration Platform biospecimen data are published, I shall notify the Integration Platform within 30 days.**

(7)**After completion of the project, any remaining Integration Platform biospecimens shall, in principle, be destroyed. If further use is required, I agree to submit a new application to the Integration Platform for a new project, together with that new project's medical research ethics committee approval; once approved by the Integration Platform's review, I may then continue to use the remaining biospecimens. The Integration Platform may, when necessary, conduct a security audit of my use of Integration Platform biospecimen data and require me to provide a written explanation.**

(8)**I agree that, pursuant to Article 15 of the "Human Biobank Management Act," biospecimens — other than their derivatives — may not be exported outside the territory. Should I need to engage in international transfer, or export of the aforementioned derivatives, I shall obtain approval from the competent authority in accordance with the "Review Criteria for International Transfer of Human Biobank Data or Export of Biospecimen Derivatives."**

(9)**I agree that, when publishing papers, I shall, in the "Acknowledgment" section or another appropriate section, cite the source of the data using the following wording; otherwise I agree to accept disqualification from re-applying for a period of two years: "The biospecimen data used in this research were obtained through the National Biobank Consortium of Taiwan and its cooperating institutions. Funding was provided by the Ministry of Health and Welfare and the National Health Research Institutes. Any interpretations or conclusions in this article do not**

represent the position of the Ministry of Health and Welfare, or the National Health Research Institutes."Or: "We would like to thank The National Biobank Consortium of Taiwan and its cooperative institutions for providing the biological specimen and related clinical data (all are deidentified) for our research. "National Biobank Consortium of Taiwan" is supported by grants from Ministry of Health and Welfare and National Health Research Institutes, Taiwan."

Please note: 1. After you receive the notice of approval, you must submit: I. the Medical Research Ethics Committee (IRB) approval certificate; II. the consent-to-use form approved by the head of your institution; and III. proof of payment (payment made in accordance with the Integration Platform's published fee schedule for specimen and data processing) before biospecimens can be collected. The above consent-to-use form is retained on file by the Central Office.

***2. If your funding is from industry, fees will be charged according to the industry fee schedule. For questions, please call (037-206166, ext. 33327, 33332).**

3. Please attach a brief CV of the principal investigator when submitting the application.

Principal Investigator's Signature: _____ Date: _____

(1) **Specific Aims/Hypothesis of the Proposed Research (Specific Aims/hypothesis of the proposed research):**(Please briefly describe the specific aims, background, and hypothesis of this research. It is preferable to provide some preliminary results to support the necessity of this application. This section should not exceed two pages; please write in Chinese, or provide a 200-word Chinese abstract, so that ethics committee members without a biomedical background can understand it.)

(2) **Progress Report (Progress Report):**
Note: Applicants who have previously used biospecimens or data provided by this Platform are required to fill out this item (applicants who have used biosamples or data from NBCT need to fill out this item

(3) **The Content and Quantity of Biospecimens or Data Requested from the Integration Platform (he approximate numbers of cases required, and the biospecimen types and amount)**

i. (Please describe the content of the biospecimens or data being requested from the Integration Platform, including diagnosis and the type and quantity of biospecimens.)
ii. Example 1: Hepatocellular carcinoma, 30 cases, paired tumor and non-tumor RNA 10 ug each
iii. Example 2: Lung adenocarcinoma, 50 cases, 10 blank paraffin block sections of tumor tissue each
iv. Example 3: Breast cancer, triple-negative, 30 cases, paired tumor and non-tumor DNA, 5 ug
v. Example 4: COVID-19 genetic/medical data, 200 cases
vi. Example 5: Complete liver cancer medical data, 6,000 cases, for linkage with a national database(After completing this section, please delete the above example text):

(4) **Statistical Justification for the Types and Quantities of Biospecimens or Data Requested (Statistical justification for the numbers and types of samples requested):**

(5) **A Brief Description of the Technical Approach of This Research (A brief description of the technical approach):**(Please briefly describe the technical methods that will be used to study these biospecimens.)

(6) **Clinical Data, Epidemiological Data, Genetic Data, and Outcome/Follow-up Data Required (Clinical, epidemiological, genetic, and/or outcome data)**(Please specify which clinical data related to the biospecimens you require from the Integration Platform.)

Basic clinical data can be found by consulting the NBCT website:
https://nbct.nhri.org.tw/docDetail.aspx?uid=10117&pid=22&docid=10131&rn=23545

(7) **Management of Biospecimens, Data, and Information: including measures to protect participants' privacy during and after the course of the research.**

Example:

□ The specimen storage cabinet is locked

(□ the key is kept by a designated person □ it is a combination lock, and the code is known only to authorized personnel)

□ Access to the biospecimens is restricted to the principal investigator and researchers in their laboratory

□ Paper records are kept in a locked cabinet, with the key held by a designated person; personnel other than those involved in executing the project cannot access the data

□ Electronic files are protected by an access-control mechanism; personnel other than those involved in executing the project, cannot access the data

□ Data are strictly controlled, and copying or leakage is prohibited

(8) **Expected Research Outcomes: Briefly describe the expected outcomes of the research, and state whether the research outcomes will give rise to any derivative benefits, and, if so, the plan for sharing such benefits.**

Example:

1. Example with no derivative commercial benefit:

The expected research outcome is to infer that Protein A may help activate certain favorable genes during the process of liver regeneration; this research is not currently expected to give rise to any patent or other commercial benefit.

2. Example with derivative commercial benefit:

i. A patent will be applied for in the future, or there is a clear commercial benefit (please complete the commercial benefit-sharing plan)

ii. Use of this data may generate commercial benefit, but this is difficult to estimate specifically; Party B is willing to provide advance benefit-sharing payments to the relevant specific group. The benefit-sharing amount is_____ , and the recipient(s) of the benefit-sharing is/are_____.

Attachment 2:

NBCT biosample list 110-06-22 v2

National Biobank Consortium of Taiwan (NBCT)
Biosample Request List

			(NBCT No.)
Project Title **Title of the project**	**Chinese** **English**		
Affiliation **Affiliation**	**Chinese** **English**	**Department** **Department**	**Chinese** **English**
Principal Investigator **Principal Investigator**	**Chinese** **English**	**Job Title** **Job Title**	**Chinese** **English**
Mailing Address **Mailing Address**	**Chinese** **English**		
Telephone No. **Telephone No.**		**Fax No.** **Fax No.**	
E-mail Address **E-mail Address**			
Biosample Type **Biosample types**	☐ **Blood DNA: _____ µg per case, _____ patients** ☐ **Tumor Tissue DNA: _____ µg per case, _____ patients** ☐ **Paired Non-tumor Tissue DNA: _____µg per case, _____ patients** ☐ **Tumor Tissue RNA: _____ µg per case, _____ patients** ☐ **Paired Non-tumor Tissue RNA: _____ µg per case, _____ patients** ☐ **Tumor Tissue for protein extraction: one piece (>200ug) , _____ patients** ☐ **Paired Non-tumor Tissue for protein extraction: one piece (>200ug),_____ patients** ☐ **Unstained Paraffin sections : _____ slides per case, _____ patients** ☐ **Unstained tissue array Paraffin Sections : _____slides, _____ patients** ☐ **Serum : _____µl per case, ____ patients** ☐ **Plasma : _____µl per case, ____ patients** ☐ **Buffy coat : _____µl per case, ____ patients** ☐ **Bone marrow: _____µl per case, ____ patients** ☐ **Spinal fluid: _____µl per case, ____ patients** ☐ **Pleural effusion DNA: _____µg per case, ____ patients** ☐ **Ascites DNA: _____µg per case, ____ patients** ☐ **others, see special request**		
Special Request: **For tumor tissue RNA or DNA, the minimal tumor percentage requirement is: _____%** **For tumor paraffin sections, the minimal tumor percentage requirement is: _____%** **For DNA quality: do you need to check Qubit concentration:_____ (an additional fee applies)** **For RNA quality: do you need to check RIN : ____, The cut off value is:_____ (an additional fee applies)**			

Note: Currently, DNA and RNA concentration is checked by NanoDrop. RNA quality is checked by electrophoresis (gel electrophoresis)