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1. Purpose

The National Biobank Consortium of Taiwan (NBCT) Integration Platform (hereinafter, the "Integration Platform") integrates domestic human biobanks in the cloud, including biospecimens, data, and associated information (hereinafter, "Integration Platform Specimen Data"), and makes them available for application by medical, clinical, industry, and other biomedical researchers nationwide. The goal is to rapidly assemble the largest possible pool of research participants that is nationally representative of patients and the general public, and to make effective use of their biospecimens and data, thereby advancing Taiwan's biomedical and biotechnology research and benefiting the public.

2. Basis

1. Human Biobank Management Act.
2. Human Research Act.
3. Establishment Guidelines for the NBCT Integration Platform Review Panel (Attachment 1).

3. Scope

This Standard Operating Procedure applies to all domestic and international applicants from industry, academia, research institutions, and the medical community who apply to the Integration Platform for specimens or data for biomedical research purposes.

4. Division of Responsibilities

1. Integration Platform Central Office (hereinafter, the "Central Office"):
   Accepts applications and compiles related materials; handles the administrative processing of administrative review, scientific review, and Review Panel pre-review; provides consultation and guidance on related matters; and convenes review meetings.

2. Integration Platform Review Panel (hereinafter, the "Review Panel"):
   (1) Drafting the Integration Platform application review process and related application forms and institutional documents.
   (2) Pre-review of and recommendations on Integration Platform specimen and data applications.
   (3) Monitoring and evaluating the performance of approved Integration Platform applications.
   (4) Other Integration Platform-related consultation matters.

3. Human biobanks participating in the Integration Platform (hereinafter, "Platform Biobank(s)"):
   (1) Accepting applications referred by the Integration Platform, conducting administrative verification, compiling related materials, and reporting the results of specimen/data matching.
   (2) For applications referred by the Integration Platform that have completed Review Panel pre-review, conducting dispensing review in accordance with each institution's own review procedures.

5. Operating Procedures

5.1 Central Office Review Process

5.1.1 Administrative Review

The applicant shall log on to the Integration Platform website (xxxxx) and complete the upload of all required application documents in accordance with the regulations, or send the electronic files of the application form and specimen request list to the Central Office. Administrative staff shall verify that the application documents are complete; if any documents are missing, the applicant shall be notified by email to submit the missing items. The case shall then be assigned a case number and scheduled for scientific review.

5.1.2 Scientific Review

1. Within 3 days of receiving the complete application materials, the Central Office shall report them to the Director of the Central Office, who shall authorize the Executive Director to select five Scientific Review Committee Members for the application (one expert in public health epidemiology or statistical analysis, two experts in basic biomedical research, and two experts in clinical medicine). Scientific Review Committee Members shall complete their online review on the Integration Platform website within 7 days. After compiling the review comments, the Central Office administrative staff shall notify the applicant of the scientific review comments by email (with all Scientific Review Committee Members copied via BCC).
2. Within 14 days of receiving the review comments, the applicant shall send the revised full set of application materials (including the response-to-comments form) to the Central Office. The Central Office shall notify the original review committee members by email to respond online on the Integration Platform website, and the review committee members shall send their comments to the Central Office within 3 days. If the applicant wishes to request an extension, the request must be submitted within 10 days of receiving the review comments; the extension shall not exceed 14 days and may be requested only once. If no response is received by the deadline, the case shall be withdrawn automatically.

5.1.3 Matching and Dispensing

Within 7 days of completing the scientific review, the Central Office shall carry out matching and dispensing based on the registered holdings of each Platform Biobank.

1. The Central Office shall email the complete electronic application file (including the compiled scientific review comments) to each Platform Biobank holding specimens/data suitable for dispensing.
2. Each Platform Biobank shall reply to the Central Office by email with the results of its inventory check within 14 days of receiving the notification.
3. After matching is complete, if the matched quantity is less than the applicant's request, the Central Office shall notify the applicant by email within 7 days as to whether the applicant agrees to a revision. The applicant shall reply by email within 7 days of receiving the notification as to whether the application content will be revised.
4. Based on the applicant's reply, the Central Office shall confirm the quantity and content of the specimens/data to be matched and dispensed.

5.1.4 Review Panel Review

1. Written Review

(1) The Central Office shall report the application materials, including the scientific review and completed matching, to the Convener of the Review Panel. The Convener shall authorize the Executive Director of the Central Office to select four committee members for the application (comprising one government representative or subject-matter expert, one expert in information security management and biostatistics, one legal expert, and one social worker or public-interest representative) to conduct an online review on the Integration Platform website. Committee members shall submit their review comments within 10 days. After compiling the review comments, administrative staff shall notify the applicant in writing of the comments for revision and response.

(2) The applicant shall return the revised full set of electronic materials to the Central Office within 7 days; failure to respond by the deadline shall be treated as a withdrawal of the application. The Central Office shall send the revised documents to the original review committee members, who shall return their comments to the Central Office within 3 days.

(3) If, after two rounds of the applicant's responses to the committee members' comments, an original review committee member still recommends against approval, the case shall be referred to a Review Panel meeting for discussion.

(4) For applications approved through written review, within 7 days the Convener of the Review Panel shall issue a letter, through the Central Office, notifying each successfully matched Platform Biobank of the pre-review result and providing all application documents, so that dispensing review may proceed.

2. Meeting Review

(1) During written review, if after two rounds of the applicant's responses to review comments an original review committee member still recommends against approval, the case shall be referred to a Review Panel meeting (which may be held by videoconference) for discussion. The applicant may attend to provide an explanation.

(2) At the review meeting, resolutions shall be adopted by a majority vote of the committee members present.

(3) For applications approved at the review meeting, the Central Office shall forward the application documents and the Review Panel's review result to the Institutional Review Board (IRB) of each biobank institution suitable for dispensing, for further review.

(4) For applications not approved at the review meeting, the Central Office shall notify the applicant, who may file an appeal within 14 days of receiving the notification. If no appeal is filed within this period, the decision not to approve shall become final.

(5) Cases for which an appeal has been filed shall be placed on the agenda of the next review meeting. Only one appeal per case is permitted.

5.2 Platform Biobank Review Process

1. The Central Office shall email the complete electronic application file (including the compiled scientific review comments), after the scientific review has been completed, to each Platform Biobank holding specimens/data suitable for dispensing.
2. Upon receiving an application referred by the Central Office, each Platform Biobank shall conduct an administrative verification and check whether it holds specimens suitable for dispensing.
3. Each Platform Biobank shall reply to the Central Office by email with the results of its specimen/data inventory check within 14 days of receiving the notification.
4. After confirming the final requested quantities with the applicant, the Central Office shall promptly notify the Platform Biobank(s) holding suitable specimens/data for dispensing so that preparations can be made.
5. After the Integration Platform Review Panel completes its pre-review, an official letter shall be issued to each successfully matched Platform Biobank stating the Review Panel's review result for the application, and all application documents shall be provided by email.
6. After receiving the Review Panel's review result and the related application documents from the Central Office, each Platform Biobank shall conduct its review in accordance with its own institutional dispensing review procedures. Once the review is complete, the Platform Biobank shall send a letter to the Central Office with the review result for the case, at which point the review process is confirmed complete.
7. If unforeseen circumstances prevent a Platform Biobank from dispensing in accordance with the original letter, the Central Office shall be notified as early as possible so that appropriate measures can be taken.

5.3 Preparatory Procedures for Dispensing of Applications

1. After receiving the review reply letters from the Platform Biobanks, the Central Office shall confirm the number of cases and quantity of specimens available for dispensing and draft the Use Consent Form for the application (see Attachment 4), specifying the approved number of cases and quantities.
2. The Central Office shall send the Use Consent Form to the applicant for signature, which must also be signed and sealed by the responsible officer of the applicant's institution.
3. When sending the Use Consent Form, the Central Office shall simultaneously notify each Platform Biobank associated with the application to prepare the specimens for dispensing, along with the content and format of the clinical information to accompany the dispensed specimens.
4. After the applicant submits the signed and sealed Use Consent Form, the Central Office shall provide a scanned electronic copy to the Platform Biobank(s) associated with the application for their records, and shall issue a payment notice requesting the applicant to begin payment.
5. The Central Office shall assign serial numbers to the specimens (or data) for the application in the order in which the Platform Biobanks' approval reply letters were received, with the Platform Biobank that replied first placed first. The numbering convention is NB-[Application No.]-[Specimen Serial No.].
6. The Central Office shall notify the Platform Biobank(s) associated with the application of the assigned serial numbers.
7. After the applicant completes payment, the Central Office shall notify the Platform Biobank(s) associated with the application to prepare for dispensing.
8. The specimen and data processing fees collected by the Central Office shall be disbursed quarterly, based on the verified number of specimen cases provided by each dispensing institution, into that institution's designated account.

6. Attachments

Attachment 1: Establishment Guidelines for the NBCT Review Panel

109-08-25

1. The Ministry of Health and Welfare (hereinafter, the "Ministry") has established the "National Biobank Consortium of Taiwan Integration Platform Review Panel" (hereinafter, the "Review Panel") to carry out the review and management of human biological data application cases under the "Project to Establish the National Biobank Consortium of Taiwan Integration Platform" (hereinafter, the "Integration Platform").

2. The duties of the Review Panel are as follows:
   (1) Drafting the Integration Platform application review process and related application forms and institutional documents.
   (2) Review of Integration Platform specimen and data applications.
   (3) Monitoring and evaluating the performance of approved Integration Platform applications.
   (4) Other Integration Platform-related consultation matters.

3. The Review Panel shall consist of seventeen to twenty members, one of whom shall serve as Convener, a position held by the Principal Investigator of the "National Biobank Consortium of Taiwan Integration Platform Central Administrative Office Operation Project" (hereinafter, the "Commissioned Project") entrusted by the Ministry. The Ministry shall additionally appoint one Deputy Convener, and the remaining members shall be appointed or assigned by the Ministry from experts in the following fields. Members of either gender shall constitute no less than one-third of the total number of members:
   (1) Government representatives and subject-matter experts.
   (2) Legal experts.
   (3) Experts in information security management and biostatistics.
   (4) Social workers and public-interest representatives/experts.

4. Review Panel members shall serve one-year terms and may be reappointed depending on the project schedule upon expiration of their terms.

5. If a vacancy arises during a member's term for any reason, a replacement member shall be appointed; the replacement member's term shall run through the end of the original term.

6. The Review Panel may convene meetings as needed. The Convener shall preside as chair; if the Convener is unable to attend, the Deputy Convener shall preside in the Convener's place; if neither is able to attend, the Convener shall designate a member to preside. Resolutions require the approval of a majority of the members present; in the event of a tie, the chair shall decide.

7. Experts or representatives from relevant fields or organizations may be invited to attend Review Panel meetings as needed.

8. The Convener, Deputy Convener, and members of the Review Panel shall serve without compensation; provided, however, that experts who are not Ministry staff and are not personnel under the Commissioned Project (i.e., those not already receiving compensation charged to personnel expenses) may be paid attendance and transportation allowances in accordance with applicable regulations.

Attachment 2: Scientific Committee Review Form

National Biobank Consortium of Taiwan (NBCT)

	(NBCT No.)

Title of this Application	**Chinese:** **English :**		
Applicant Organization		**Department**	
Principal Investigator		**Title**	
Requested Biosamples	☐ **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** ☐ **Urine _____μl per case, ____ patients** ☐ **others, see special request**		
Decision	**☐ Agree to provide biosamples** **☐ Do not agree to provide biosamples (please specify reason)** **☐ Conditional approval (please specify request)**		

As specimens are precious, committee members are asked to carefully evaluate the requested specimen quantities as well, for reference by the Institutional Review Board.

1. Is the number of requested cases appropriate? Yes☐

☐No, recommended number of cases _____ Please explain: _____

2. Is the requested specimen quantity per case appropriate? Yes☐

☐No, recommended quantity _____ Please explain: _____

3. Is the scientific basis sufficient? Yes☐

☐No, please explain: _____

Attachment 3: Review Panel Assessment Form

National Biobank Consortium of Taiwan (NBCT)

	(NBCT

Title of the project	**Chinese:** **English :**		
Affiliation	**Chinese：** **English：**	**Department**	**Chinese：** **English：**
Principal Investigator	**Chinese：** **English：**	**Job Title**	**Chinese：** **English：**
(Biosample types)	☐ **Blood DNA: _____ μg per case, _____ patients** ☐ **Blood RNA: _____ 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 per case, ____ patients** ☐ **Serum _____μl per case, ____ patients** ☐ **plasma _____μl per case, ____ patients** ☐ **Buffy coat _____μl per case, ____ patients**		
Decision	☐ **Recommend Approval** ☐ **Recommend Approval with Revisions** ☐ **Recommend Disapproval.**		

Application Type: ☐ New Application ☐ Amendment Application (Original approved No.: (NBCT No.) Reason for amendment: ☐ Additional information requested / ☐ Other: please explain		
Review Criteria	Compliance	Review Comments

		(Does the applicant need to provide further explanation?)
(1) Does the research purpose help advance medical development and promote public health and welfare?	☐ Yes ☐ No (please note in Review Comments)	
(2) Is the research scientifically reasonable and feasible, and not contrary to social ethics or public morals?	☐ Yes ☐ No (please note in Review Comments)	
(3) Is the scientific basis sufficient?	☐ Yes ☐ No (please note in Review Comments)	
(4) Does the applicant have appropriate measures in place for the protection of specimens/data and information security?	☐ Yes ☐ No (please note in Review Comments)	
(5) Is the applicant's proposed use of the biospecimens and data reasonable?	☐ Yes ☐ No (please note in Review Comments)	
(6) Is the number of requested cases appropriate?	☐ Yes ☐ No; recommended number of cases (please note in Review Comments)	
(7) Is the requested specimen quantity per case appropriate?	☐ Yes ☐ No; recommended quantity (please note in Review Comments)	
(8) Is there potential future commercial benefit, and if so, has a commercial benefit-sharing plan been clearly described?	☐ This data will be used solely for academic research; no commercial benefit is currently anticipated ☐ There is commercial benefit, and the commercial benefit-sharing plan has been	

	clearly described ☐ There is commercial benefit, but the benefit-sharing plan has not been clearly described (please note in Review Comments)	
(9) Does the IRB protocol state that the source of specimens includes the National Biobank Consortium of Taiwan Integration Platform?	☐ Yes ☐ No (please note in Review Comments) ☐ Not applicable	
Assigned Institution:		
Overall Comments:		

Review Committee Member's Signature: _____ Date: _____

Attachment 4: Integration Platform Use Consent Form

109-07-24

I, the undersigned (the "Consenting Party"), _____ , employed at (institution name)_____ , in order to conduct research on (research topic)_____, intend to apply to the National Biobank Consortium of Taiwan Integration Platform (hereinafter, the "Integration Platform") for the biospecimens, data, or information under its management (hereinafter, "Integration Platform Biospecimen Data") for use in the above research. I hereby agree (undertake) to comply with the Integration Platform's following requirements:

Integration Platform Biospecimen Data Requested:

1. I understand that the Integration Platform Biospecimen Data provided is for biomedical research purposes only, and that its use shall comply with the "Human Biobank Management Act" and related regulations. I agree to bear sole responsibility for any loss, claim, injury, or liability arising from the use, storage, or handling of the Integration Platform Biospecimen Data. The Integration Platform shall bear no legal liability whatsoever.
2. I agree to pay the application processing fee in accordance with the published fee schedule and shall not unilaterally cancel the application. The Integration Platform Biospecimen Data shall be provided only after payment has been made.
3. I, together with other participating research personnel, staff, project representatives, and related personnel at co-research institutions, shall exercise the duty of care of a good custodian with respect to the safekeeping of the Integration Platform Biospecimen Data. When using or publishing research results derived from the Integration Platform Biospecimen Data, all applicable laws and confidentiality/privacy obligations must be observed, and there shall be no infringement of personal privacy or other violation of ethical standards.
4. I understand that, at the time of application, the expected research outcomes, including whether any derivative benefits will arise, must be considered. If I apply for intellectual property rights, I shall notify the Integration Platform within 20 days of filing the application. If any commercial benefit arises from the Integration

Platform Biospecimen Data, I shall proceed in accordance with the Ministry of Health and Welfare's "Regulations on the Sharing of Commercial Benefits from Human Biobanks."

I understand that if the applicant's funding source is from industry, it shall be deemed at the time of application that commercial benefit already exists.

5. I shall, upon completion of the project, submit the IRB closure report to the Integration Platform for its records. After publishing research results obtained through use of the Integration Platform Biospecimen Data, I shall notify the Integration Platform within 30 days.
6. After the project is completed, 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 proof of IRB approval for the new project. Upon approval by the Integration Platform, I may continue to use the remaining specimens. The Integration Platform may, when necessary, conduct a security audit of my use of the Integration Platform Biospecimen Data and require me to provide a written explanation.
7. I agree that, pursuant to Article 15 of the "Human Biobank Management Act," biospecimens, other than their derivatives, shall not be exported outside Taiwan. If I need to engage in international transmission or export of the aforementioned derivatives, I shall obtain approval from the competent authority in accordance with the "Review Criteria for International Transmission of Human Biobank Data or Export of Biospecimen Derivatives."
8. I agree that, when publishing papers, I shall indicate the source of the data in the "Acknowledgment" section or other appropriate section using the following text; otherwise, I agree to accept a two-year suspension of eligibility to reapply: "The biospecimen data used in this material were obtained through the National Biobank Consortium of Taiwan Integration Platform 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 paper 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 de-identified) for our research. "National Biobank Consortium of Taiwan" is supported by grants from Ministry of Health and Welfare and National Health Research Institutes, Taiwan."

9. If I violate all or part of this Consent Form or applicable laws and regulations, the Integration Platform may set a reasonable period for correction; if the violation is not corrected by the deadline, the Integration Platform may rescind or terminate this agreement and seek damages. Any Integration Platform Biospecimen Data I have obtained shall be destroyed as instructed by the Integration Platform. The Integration Platform may publicize the fact of my violation and shall not accept any application from me for a period of two years.
10. In the event of any dispute, controversy, or disagreement arising out of or related to this Consent Form or a violation thereof, both parties agree to first negotiate in good faith. If negotiation is unsuccessful and litigation ensues, both parties agree that the Taiwan Taipei District Court shall have jurisdiction as the court of first instance.
11. Any matters not addressed in this Consent Form shall be governed by the interpretation of the "Human Biobank Management Act" and other applicable laws and regulations; the same shall apply if such laws and regulations are subsequently amended.

I have reviewed all the terms of this Consent Form within a reasonable period of time, and hereby undertake and sign below:

Institutional Representative:
(Signature or Seal)

Consenting Party: (Signature or Seal)

Mailing Address:
Telephone:

R. O. C. Year _____ Month _____ Day _____