

 (Web Link)	National Biobank Consortium of Taiwan Standard Operating Procedure		No.: NBCT SOP-003
	Title: Confidentiality and Conflict of Interest Avoidance		Version/Total Pages: 1.1 / 9 pages
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Table of Contents

1. Purpose:.....	2
2. Basis.....	2
3. Scope.....	2
4. Confidentiality	2
5. Conflict of Interest Avoidance	3
6. Attachments	4
Attachment 1: Confidentiality Agreement for Committee Members and Experts (Non-Members)	4
Attachment 2: Staff Confidentiality Undertaking	5
Attachment 3: Scientific Review Committee Member Conflict of Interest Recusal Undertaking	6
Attachment 4: Review Panel Conflict of Interest Recusal Undertaking.....	10

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1. Purpose:

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 confidentiality and conflict-of-interest avoidance. Scientific Review Committee members of the National Biobank Consortium of Taiwan (hereinafter referred to as “Scientific Review Committee members”), and Review Panel members of the National Biobank Consortium of Taiwan (hereinafter referred to as “Review Panel members”), who review and oversee matters relating to the management of the biobank, shall conduct their review independently and shall not be improperly influenced by their affiliated research institution, principal investigators, or clients.

2. Basis

1. Human Biobank Management Act, Article 19: “Members of the establishing entity and their stakeholders shall recuse themselves from matters involving a conflict of interest.”
2. Human Subjects Research Act.

3. Scope

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

4. Confidentiality

1. Scientific Review Committee members, Review Panel members, and relevant Integration Platform administrative staff shall sign a confidentiality agreement at the time of their appointment.
2. Should Scientific Review Committee members, Review Panel members, or relevant Integration Platform administrative staff violate the principle of confidentiality or conflict-of-interest avoidance, their appointment or employment shall be terminated.

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5. Conflict of Interest Avoidance

1. During project review, Scientific Review Committee members and Integration Platform Review Panel members shall disclose any related conflicts of interest.
2. Scientific Review Committee members and Review Panel members who fall under any of the following circumstances shall immediately recuse themselves and may not participate in the review:
 - (1) The principal investigator, co-investigator, or client of the research project under review is the member themselves, their spouse, or a relative within the third degree of kinship.
 - (2) The principal investigator or co-investigator of the research project under review and the member are co-investigators of another research project that is being applied for or is ongoing.
 - (3) The research project under review is an integrated project or a sub-project thereof, and the member is the principal investigator or co-investigator of that integrated project or sub-project.
 - (4) The member has an employment relationship with the company commissioning the research project under review.
 - (5) The principal investigator of the research project under review is a master's or doctoral student the member has supervised within the past three years, or is a postdoctoral researcher of the member.
 - (6) The principal investigator or client of the research project under review has, within the past three years, served as the member's master's or doctoral thesis or research project advisor.
 - (7) There is concrete evidence sufficient to establish a risk of bias.
 - (8) Any other circumstance in which the Integration Platform Review Panel has resolved that recusal is required.

6. Attachments

Attachment 1: Confidentiality Agreement for Committee Members and Experts (Non-Members)



National Biobank Consortium of Taiwan Confidentiality Agreement

1. To protect the personal privacy, safety, and well-being of participants, and to safeguard the rights and interests of researchers and their related information submitted for review, the undersigned agrees to sign this Confidentiality Agreement.
2. For purposes of this Confidentiality Agreement, the term “undersigned” includes National Biobank Consortium of Taiwan Review Panel members, Scientific Review Committee members, consulting experts, site visit personnel, visiting personnel, meeting attendees, and other related personnel.
3. The undersigned has a duty of confidentiality with respect to the review-related content and case discussions of the National Biobank Consortium of Taiwan (hereinafter referred to as the “Integration Platform”), and may not, without cause, disclose or use such information for the undersigned's own purposes, or provide it to others for use.
4. The undersigned has a duty of confidentiality with respect to any data provided by the Integration Platform that the undersigned comes to know or possess, and may not disclose, inform others of, deliver, transfer to others, or publish externally such data.

The undersigned has carefully read and agrees to comply with the contents of this Agreement, and, should the undersigned violate it, agrees to accept the Integration Platform's disposition without objection.

To:

National Biobank Consortium of Taiwan

Undersigned: _____

Address: _____

Republic of China (ROC) _____ Year _____ Month _____ Day

Title (please check one):

- ☐ Integration Platform Review Panel Member
- ☐ Scientific Review Committee Member
- ☐ Consulting Expert
- ☐ Site Visit Personnel
- ☐ Visiting Personnel
- ☐ Meeting Attendee
- ☐ Cancer Precision Medicine Clinical Panel Member
- ☐ Other

National Biobank Consortium of Taiwan Project Staff Confidentiality Undertaking

I, the undersigned, _____ have participated in the National Biobank Consortium of Taiwan project work since the Republic of China (ROC) _____ Year _____ Month _____ Day. I undertake to keep in absolute confidence, and not disclose to any outside party, the personal data of research participants that I come to know in the course of my duties, including: ID number, medical record number, name, date of birth, telephone number, residential address, and other personal information. Should any violation occur that results in harm to the rights or interests of the individual concerned, I agree to bear legal responsibility accordingly, and this obligation shall continue to apply even after I leave my position.

Attachment 2: Staff
Confidentiality Undertaking

To:		
National Health Research Institutes Institutional Review Board		
Name of Institution:		
Undersigned:	(Seal)	
Address:		
ID Number:		
Republic of China (ROC)	Year	Month
	Day	

Attachment 3: Scientific Review Committee Member Conflict of Interest Recusal Undertaking

National Biobank Consortium of Taiwan Scientific Review Committee Member

Conflict of Interest Recusal Undertaking

Recusal Required	Recusal Not Required	Case Number	Principal Investigator	Project Title

Undersigned _____ (hereinafter referred to as “Party B”), serving in the scientific review of applications to the National Biobank Consortium of Taiwan (hereinafter “Party A,” referred to as the “Integration Platform”), is willing to comply with the principle of conflict-of-interest recusal in review, with respect to the data accessed in the course of review.

Reason for Recusal:

- ☐ The principal investigator, co-investigator, or client of the research project under review is the member themselves, their spouse, or a relative within the third degree of kinship.
- ☐ The principal investigator or co-investigator of the research project under review and the member are co-investigators of another research project that is being applied for or is ongoing.
- ☐ The research project under review is an integrated project or a sub-project thereof, and the member is the principal investigator or co-investigator of that integrated project or sub-project.
- ☐ The member has an employment relationship with the company commissioning the research project under review.
- ☐ The principal investigator or co-investigator of the research project under review is a master's or doctoral student the member has supervised within the past three years, or is a postdoctoral researcher of the member.
- ☐ The principal investigator or co-investigator of the research project under review has, within the past three years, served as the member's master's or doctoral thesis

or research project advisor.

- ☐ The principal investigator or co-investigator of the research project under review is a colleague of the member in the same department, division, or institute.

To:

National Biobank Consortium of Taiwan

Undersigned

Name: (Signature/Seal)

Republic of China (ROC) Year Month Day

Project Review Conflict-of-Interest Avoidance Principles

1. A review committee member shall recuse themselves from reviewing any research project application in which they are involved in their primary role/position or have a related interest.
2. During project review, members shall disclose any related conflicts of interest.
3. Pursuant to Article 5 of the Ministry of Health and Welfare's "Human Biobank Management Act," review personnel shall recuse themselves whenever recusal is necessary.
4. National Biobank Consortium of Taiwan Conflict-of-Interest Avoidance Rules
 - (1) To protect official confidentiality and the rights and interests of the applicant institution, Party B shall bear a duty of confidentiality with respect to the content of any data accessed during review.
 - (2) Party B agrees not to privately collect any information, and not to disclose, copy, transfer, reuse, or deliver the aforementioned information to any third party.
 - (3) The confidentiality obligation for the data of this case is not limited by the completion (closure) of the project work, nor by different work locations or times. Party B shall not disclose or transfer to a third party any data it holds or comes to know; should any disclosure or delivery to others occur, Party B agrees to bear the relevant legal liability.
 - (4) Should Party B violate the provisions of this Confidentiality Undertaking and thereby cause damage or liability to Party A or a third party, Party B agrees to unconditionally bear full responsibility, including but not limited to all costs and damages arising from any resulting litigation involving Party A or a third party. Should a third party make a claim or bring litigation against Party A, Party B agrees, upon Party A's written notice, to fully cooperate in providing the relevant information.
 - (5) A member shall not participate in review under any of the following circumstances:
 1. The principal investigator, co-investigator, or client of the research project under review is the member themselves, their spouse, or a relative within the third degree of kinship.
 2. The principal investigator or co-investigator of the research project under review and the member are co-investigators of another research project that is being applied for or is ongoing.

3. The research project under review is an integrated project or a sub-project thereof, and the member is the principal investigator or co-investigator of that integrated project or sub-project.
4. The member has an employment relationship with the client of the human-subjects research project.
5. The principal investigator of the research project under review, or co-investigator, is a master's or doctoral student the member has supervised within the past three years, or is a postdoctoral researcher of the member.
6. The principal investigator of the research project under review, or co-investigator, has, within the past three years, served as the member's master's or doctoral thesis or research project advisor.

Attachment 4: Review Panel Conflict of Interest Recusal Undertaking

National Biobank Consortium of Taiwan Review Panel

Conflict of Interest Recusal Undertaking

Recusal Required	Recusal Not Required	Case Number	Principal Investigator	Project Title

Undersigned _____ (hereinafter referred to as “Party B”), serving in the review of applications to the National Biobank Consortium of Taiwan (hereinafter “Party A,” referred to as the “Integration Platform”), is willing to comply with the principle of conflict-of-interest recusal in review, with respect to the data accessed in the course of review.

Reason for Recusal:

- ☐ The principal investigator, co-investigator, or client of the research project under review is the member themselves, their spouse, or a relative within the third degree of kinship.
- ☐ The principal investigator or co-investigator of the research project under review and the member are co-investigators of another research project that is being applied for or is ongoing.
- ☐ The research project under review is an integrated project or a sub-project thereof, and the member is the principal investigator or co-investigator of that integrated project or sub-project.
- ☐ The member has an employment relationship with the company commissioning the research project under review.
- ☐ The principal investigator or co-investigator of the research project under review is a master's or doctoral student the member has supervised within the past three years, or is a postdoctoral researcher of the member.
- ☐ The principal investigator or co-investigator of the research project under review has, within the past three years, served as the member's master's or doctoral thesis or research project advisor.
- ☐ The principal investigator or co-investigator of the research project under review is a colleague of the member in the same department, division, or institute.

To:

National Biobank Consortium of Taiwan

Undersigned

Name: (Signature/Seal)

Republic of China (ROC) Year Month Day

Project Review Conflict-of-Interest Avoidance Principles

1. Members of this Panel shall recuse themselves from reviewing any research project application in which they are involved in their primary role/position or have a related interest.
2. During project review, members shall disclose any related conflicts of interest.
3. Pursuant to Article 5 of the Ministry of Health and Welfare's "Human Biobank Management Act," review personnel shall recuse themselves whenever recusal is necessary.
4. National Biobank Consortium of Taiwan Conflict-of-Interest Avoidance Rules
 - (1) To protect official confidentiality and the rights and interests of the applicant institution, Party B shall bear a duty of confidentiality with respect to the content of any data accessed during review.
 - (2) Party B agrees not to privately collect any information, and not to disclose, copy, transfer, reuse, or deliver the aforementioned information to any third party.
 - (3) The confidentiality obligation for the data of this case is not limited by the completion (closure) of the project work, nor by different work locations or times. Party B shall not disclose or transfer to a third party any data it holds or comes to know; should any disclosure or delivery to others occur, Party B agrees to bear the relevant legal liability.
 - (4) Should Party B violate the provisions of this Confidentiality Undertaking and thereby cause damage or liability to Party A or a third party, Party B agrees to unconditionally bear full responsibility, including but not limited to all costs and damages arising from any resulting litigation involving Party A or a third party. Should a third party make a claim or bring litigation against Party A, Party B agrees, upon Party A's written notice, to fully cooperate in providing the relevant information.
 - (5) A member shall not participate in review under any of the following circumstances:
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 2. The principal investigator or co-investigator of the research project under review and the member are co-investigators of another research project that is being applied for or is ongoing.
 3. The research project under review is an integrated project or a sub-project thereof, and the

member is the principal investigator or co-investigator of that integrated project or sub-project.

4. The member has an employment relationship with the client of the human-subjects research project.
5. The principal investigator of the research project under review, or co-investigator, is a master's or doctoral student the member has supervised within the past three years, or is a postdoctoral researcher of the member.
6. The principal investigator of the research project under review, or co-investigator, has, within the past three years, served as the member's master's or doctoral thesis or research project advisor.