Participant Information Sheet and Informed Consent Form

Project Title: **Women Rise, Families Thrive: Advancing Women's Health and Fertility Awareness through Ovarian Reserve Assessment in Hong Kong**"

Principal Investigator (PI) Information

- **Name:** Professor MING WAI KIT (MD)
- **Title:** Associate Professor, Department of infectious disease and Public Health and Associate Director, Institute for Global Governance and Innovation (IGGI)
- **Institution:** City University of Hong Kong
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Invitation to Participate

We sincerely invite you to participate in a research project. Before you make your decision, it is crucial to understand the purpose of this study and what it involves. Please take the time to read the following information carefully and discuss it with others if needed. If anything is unclear or if you would like more information, please feel free to ask us. Thank you for your valuable time.

Collaborating Organizations: This study is hosted by the City University of Hong Kong and jointly conducted with the Hong Kong Fertility Foundation (HKFF).

Study Description

Purpose

This study aims to understand the ovarian health status of working women in Hong Kong. We intend to measure a hormone in the blood called Anti-Müllerian Hormone (AMH), which reflects a woman's ovarian reserve (egg supply). By collecting relevant data from women aged 25 to 38, we hope to further understand how the ovarian reserve of local women changes with age. As many women nowadays choose to have children later in life, this knowledge is of critical importance, and we hope to provide scientific evidence for Hong Kong women to support better fertility awareness and health planning.

Procedures

If you agree to participate, the following procedures will be conducted during your **Research Visit** to the City University of Hong Kong or HKFF:

1. **Informed Consent and Confirmation:** The researchers will receive you, explain the study details again, and answer any questions you may have. Once you fully understand, you will be

asked to sign an informed consent form. They will also confirm your final eligibility for this study.

2. **Questionnaire:** Following this, you will need to fill out a short, anonymous questionnaire. The questionnaire will ask for basic background information (such as age) and some general health questions. It will take approximately 35–40 minutes to complete on a paper form or a tablet.
3. **Randomization:** All participants will be randomly allocated into one of the following two major categories, with each category comprising 50% of the participants.

Category 1: Ovarian Reserve Assessment Group (50% of participants)

Participants allocated to this category will receive a professional ovarian reserve assessment (AMH blood test), and will be further randomized into two groups based on the report interpretation method:

- **Group A — AI Interactive Interpretation Group:** Receives AMH test results with personalized report interpretation and explanation provided by an AI system.
- **Group B — Static Report Group:** Receives AMH test results accompanied by a standard static PDF report for reference.

Participant Benefits for this Category:

This study provides the following free professional testing services for participants in this category:

- **Clinical Report:** Test results will be presented in both ng/mL and pmol/L, two international standard units, for easy reference by participants and their medical teams.

Participation Steps (Ovarian Reserve Assessment Group):

- Complete a baseline questionnaire regarding fertility intentions.
- Go to the designated testing center to provide a blood sample, and obtain your exclusive report upon completion of the test.
- Obtain the AMH test report (AI-interpreted or static PDF).
- Complete a follow-up questionnaire 4 weeks later.

Category 2: Fertility Education Group (50% of participants)

Participants allocated to this category will not undergo a blood test but will receive fertility health education instead, and will be further randomized into two groups based on the educational method:

- **Group A — AI-Guided Education Group:** Receives personalized fertility health education guidance through an AI interactive system.
- **Group B — Standard Booklet Education Group:** Reads a standard fertility health webpage as an educational reference.

Participation Steps (Fertility Education Group):

- Complete a baseline questionnaire.
- Receive fertility education (AI-guided or standard booklet).
- Complete a follow-up questionnaire 4 weeks later.

Physical / Psychological Capacity Assessment Tools

This study does not involve any formal assessment or testing of your physical, psychological, or cognitive capacities. The only procedure is a routine blood draw. This study does not recruit vulnerable subjects (e.g., minors, individuals with cognitive impairments).

Photography, Video Recording / Audio Recording

Photography, video recording, or audio recording **will not be used** at any stage of this study. Your participation will not be recorded in any media format.

Time Commitment / Cooperation Required

The time you need to invest is limited to **two visits**.

- **The first visit** is expected to take about **60 to 90 minutes**, which includes the informed consent process, filling out the questionnaire (35–40 minutes) for **Category 1and 2,** and undergoing the blood draw or taking approximately 30 minutes for **Category 1**
- **The second visit** is expected to take about **20 minutes** to **collect the AMH test results** and complete the **follow-up questionnaire**. Participants in the **Fertility Education Group** only need to complete the **follow-up questionnaire**.

Risks and Benefits

(i) Potential Risks / Discomforts and Mitigation Measures:

The risks of participating in this study are very low.

- **Physical discomfort from blood draw:** The primary foreseeable discomfort is brief pain, a stinging sensation, and possible mild bruising (hematoma) at the needle insertion site during the single blood sample collection.
    - *Mitigation Measures:* This procedure will be performed by trained and experienced phlebotomists using disposable sterile equipment to ensure safety and hygiene. Pressure will be applied after the blood draw to stop bleeding and minimize bruising. This is a routine, low-risk clinical procedure.
- **Psychological or emotional distress:** Receiving and interpreting AMH test results may cause

anxiety, worry, or concern regarding one's current or future fertility.

  - *Mitigation Measures:* We will proactively manage this risk through the following measures:
    - *Pre-test counseling:* During the informed consent process, staff will clearly explain that AMH is only one indicator of ovarian reserve and does not represent absolute fertility or the probability of natural conception. It is merely a reflection of the current status, not a definitive prediction.
    - *Structured post-test explanation:* Test results will be communicated by researchers who will provide standardized, objective, and non-alarmist explanations in plain language, putting both the substantial and non-substantial meanings of the values into context.

- **Risk of privacy breach:** The risk of unauthorized access to personal health data is extremely low.
  - *Mitigation Measures:* All data will be strictly protected. Personal identifying information will be separated from the research data immediately upon collection and replaced with a unique research code. All electronic data will be encrypted and password-protected; paper documents will be stored in locked cabinets. Access is restricted solely to authorized researchers. This study fully complies with the Personal Data (Privacy) Ordinance of Hong Kong.

Channels for Seeking Assistance: If participants experience any ongoing concern or distress regarding the study procedures or results, they are encouraged to contact:

1. The Principal Investigator, Professor Wing Wai Kit (contact details provided above), to address any research-related concerns.
2. The external support services listed on the attached resource page.

(ii) Potential Benefits:

- **Benefits to the participants:**
  - *Personal Health Information:* Participants will receive their personal AMH test results and explanations free of charge. This provides objective, personalized information not easily obtained in routine check-ups, empowering them with knowledge about their reproductive health for personal consideration or future discussions with healthcare providers.
  - *Contribution to Personal and Public Awareness:* Participants will be part of a pioneering effort to improve fertility knowledge among women in Hong Kong.
- **Benefits to others and society:**

- *Establishing Local Scientific Evidence:* Participants' anonymous data will contribute to establishing the first comprehensive local database of ovarian reserve in a key demographic population in Hong Kong. This is a significant step toward evidence-based women's healthcare in the region.
- *Informing Public Health and Policy:* The study findings will directly inform the formulation of more effective public health strategies, fertility awareness campaigns, and supportive social policies aimed at addressing Hong Kong's low fertility rate and supporting well-informed family planning.
- *Advancing Scientific Knowledge:* The findings will be shared with the medical and scientific communities through academic publications, thereby enhancing the general understanding of ovarian health trends in urban populations.

Important Note: This study is an observational study. The AMH test is for informational and research purposes only. Participation in this study does not constitute a medical diagnosis or fertility treatment, nor does it guarantee any specific health outcomes. It provides data and knowledge, not clinical intervention.

Participation Remuneration / Payment

No financial compensation, remuneration, or monetary rewards will be provided for participating in this study.

However, participants will receive the Anti-Müllerian Hormone (AMH) blood test and relevant clinical interpretations **free of charge**. The cost of the test, which is normally borne by the individual in routine clinical settings, is fully sponsored and funded by the research grant hosting this study.

This arrangement complies with academic research ethics guidelines to ensure that participation is voluntary and not unduly influenced by financial interests. The primary benefits of participation are obtaining personal health information and contributing to socially valuable research, as detailed in the "Potential Benefits" section.

Participants' Rights — Participation and Withdrawal

Your participation in this study is entirely voluntary. You are under no obligation to participate, and your decision will not affect your current or future relationship with the City University of Hong Kong, the Hong Kong Fertility Foundation, or any other collaborating organizations.

You have the right to withdraw from this study at any time and for any reason, without any penalty and without the need to provide any explanation.

Privacy and Confidentiality

We assure you that all information collected for this study will be used solely for research purposes. Your identity and personal data will be treated with the strictest confidentiality. Unless your prior explicit permission is obtained, or disclosure is required by law (such as a court order), your name and any other information that could identify you will never be disclosed to anyone outside the immediate research team.

How We Maintain Your Confidentiality Rights: We employ a multi-step process to protect your privacy:

- **Coding / De-identification:** At the start of your participation, you will be assigned a unique research code (e.g., WRFT001). All research data collected from you (including your questionnaire responses and AMH test results) will be labeled and stored using this code instead of your name.
- **Data Separation:** A document linking your name and contact details with your unique research code will be created solely for administrative and communication purposes (e.g., contacting you to provide results). This "key master file" will be stored separately and securely from your research data.
- **Access Permissions:** Access to the identifiable "key master file" and the coded research data will be strictly limited to authorized members of the CityU research team and authorized clinical staff from the Hong Kong Fertility Foundation (HKFF) directly involved in this study. All personnel with access have undergone training in data confidentiality.

Data Processing by Service Providers: Part of the research involves collaboration with an external service provider:

- **Organization Name:** Hong Kong Fertility Foundation (HKFF).
- **Maintenance of Confidentiality:** CityU's ethical standards must be adhered to during the conduct of this study. HKFF will only receive the minimum identifiable information required to perform its clinical functions (such as name and appointment details) and will share your AMH results with the research team using only your unique research code.

Data Ownership, Retention, and Access:

- **Ownership:** For the purpose of this collaborative research, the collected research data (coded questionnaires and AMH results) are jointly owned by the City University of Hong Kong and the Hong Kong Fertility Foundation.
- **Retention Plan:** In accordance with CityU's standard data retention policy and the requirements of the funding body, all research data will be retained for seven (7) years after the completion of the study, after which it will be securely destroyed.

- **Data Access Requests:** After the publication of the primary research results, other researchers may submit a written request to the Principal Investigator to perform a secondary analysis on the anonymized research dataset. Such requests will be reviewed by the research team on a case-by-case basis and must comply with ethical and data protection regulations.

Disclosure of Information to Other Parties: Your identifiable information will not be disclosed to any other party, including the research sponsor (Merck Pharmaceutical (Hong Kong) Limited). Only aggregated, anonymous group results will be published in academic journals, reports, or presented at conferences. It is impossible to identify any individual from these published results.

Confidentiality in Group Settings: This study does not involve focus groups or any settings where participants would meet or share information with each other.

Access to Research Results: The results of this study will be analyzed and reported only as group results. Upon completion of the study, a plain-language summary of the overall group results will be made available to the public and interested participants. If you wish to obtain a copy of this summary, you may contact the Principal Investigator, Professor Ming Wai Kit, after **December 31, 2026**, using the contact details provided.

Questions and Inquiries

If you have any questions, concerns, or wish to obtain further information about this study at any time, you may contact the following persons:

- **Professor MING WAI KIT (MD)**

  Associate Director (Medical Research and Governance Innovation) Institute for Global Governance and Innovation (IGGI)

  Associate Professor (Public Health) / City University of Hong Kong

  Email: Wkming2@cityu.hk

- **ZHOU YUXIN**

  PhD Candidate City University of Hong Kong

  Email: Yuxizhou9-c@my.cityu.edu.hk

Informed Consent

I have read the above research information statement and understand the aforementioned procedures and other details.

I **AGREE / DO NOT AGREE** to participate in the research project titled "Project Title: **Women Rise, Families Thrive: Advancing Women's Health and Fertility Awareness through Ovarian Reserve Assessment in Hong Kong**".

(Please delete as inappropriate)

(The items included in the table below are optional. Please delete as inappropriate.)

I agree to:	**Yes**	**No**
• Audio recording during this study*.	Yes	No
• Video recording during this study*.	Yes	No
• Photography during this study*.	Yes	No
• The use of audio/video recordings/files and photographs generated from this study for (describe the intended use of the tapes/files/data)*.	Yes	No
• Recording of online activities during this study.	Yes	No
• My identity being disclosed in written materials (and/or other media, please specify) generated from this study.	Yes	No

I undertake to: Sign the "Agreement for Use of Photography, Audio/Video Recording" filled out by the participant. The template can be downloaded from the following webpage: https://www.cityu.edu.hk/ro/studentlan/dlHuman.htm

Participant Signature: _____

Participant Name (Block Letters): _____

Date: _____