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| **NCT Number**: | NCT05130788 |
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NYU Langone Health

# Research Subject Informed Consent Form

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| **Title of Study:** | WeChat Quit Coach Pilot Study (s20-01959) |
| **Principal Investigator:** | Nan Jiang, PhD<br>Department of Population Health<br>NYU Grossman School of Medicine<br>180 Madison Ave, Rm #17-54, New York, NY 10016<br>(646) 501-3553 |
| **Emergency Contact:** | Nan Jiang, PhD<br>(646) 501-3553 |

## 1. About volunteering for this research study

You are invited to take part in a research study. Your participation is voluntary. People who agree to take part in research studies are called “subjects”. This word is used throughout this consent form. Before you can make your decision, you need to know what the study is about, possible risks and benefits, and what you will do in this study. You may decide to discuss this study and this form with your family or friends. If you have any questions about the study or this form, please ask me. If you decide to take part in this study, you must sign this form. We will give you a copy of this form for your record.

## 2. What is the purpose of this study?

We would like to develop and assess if a social media-based text messaging easy to use and effective in helping with smoking cessation among Chinese immigrant smokers in New York City (NYC). We will be mainly focusing on WeChat as a social media in the study. You are invited to participate in the second part of the study. In this part we test whether the social media text messaging is possible to do and how well it works to help people to quit smoking. We use WeChat platform for the purpose of an intervention.

## 3. How long will I be in the study? How many other people will be in the study?

A total of 60 smokers will participate in the Aim 2 of this study. The study includes an in-person survey at enrollment, a 6-week WeChat smoking cessation intervention, a phone survey at the end of the intervention, a phone survey 6 months post-enrollment, and a biochemical confirmation test (i.e., exhaled carbon monoxide test) if you quit, and a post-test in-person interview (for 30 out of the 60 participants). Each survey will take less than 10 minutes. The WeChat cessation intervention will take 6 weeks (less than 1 minute per day). The biochemical confirmation test will take less than 1 minute. The in-depth interview will take less than 60 minutes.

## 4. What will I be asked to do in the study?

You will be randomly assigned (like a flip of a coin) to one of the two groups:
**Group A** – intervention group. You will join a WeChat private group consisting of 4-10 smokers, a smoking cessation coach, and a research assistant. The group will receive a text message about smoking and quitting at a fixed time every day (e.g., 8:00 am). The group will also receive a small question for group discussion. You can respond to the group discussion question any time during the

day. Responding to the questions will take less than 1 minute. You can interact with group members by commenting on their responses. You can ask your questions about smoking and quitting either in group (so everyone in the group will see your questions) or directly to the coach (so only the coach will see your questions). Our coach will answer your questions from 9:00 am − 9:00 pm 7 days a week. If you do not respond to group questions for 3 consecutive days, the research assistant will contact you and remind you to join group discussions. You can withdraw from the study at any time by texting "withdraw" to the research assistant through WeChat. It is important that you do not share any health information about yourself.

**Group B** – control group. You will receive a leaflet with information about existing smoking cessation programs that focus on Chinese American smokers. You can withdraw from the study at any time by texting "withdraw" to our research assistant.

You cannot choose which group to join, because the allocation is random, like rolling a dice.

You will be offered a 4-week supple of nicotine patches and/or lozenge with an instruction sheet, no matter which group you are assigned to. Nicotine patches and lozenge are FDA approved smoking cessation medications. It is completely your decision to use or not to use them. If you want to use the medications, we will mail the patches and/or lozenge to you or deliver in person. If you do not want to use them, let us know and you will not receive the medications from us.

You will complete 3 surveys in this study. One will be conducted at enrollment, one right after the 6-week intervention, and the last one at 6 months post-enrollment. Each survey will take less than 10 minutes, and will be administered by our research assistant (RA). At each follow-up, if you quit smoking, you will be invited to participate in an exhaled carbon monoxide test to confirm that you have quit. The RA will conduct the test at a public venue (e.g., café shop) that you select. The test is non-invasive and we will use a Smokerlyzer® monitor to conduct the test. Specifically, you will first inhale and hold breath for about 15 seconds, then blow slowly into the mouthpiece of the monitor, aiming to empty lungs completely. The test will take less than 1 minute, and you can see the measure of the amount of CO in your breath immediately. This is a way to biochemically validate your smoking status.

After the intervention (at 6-week follow-up), 30 participants will be selected to take part in an in-depth interview in person interview. The interview aims to explore your insights and experience with the WeChat intervention. If you are selected for the interview, you will attend a 60-minute in-person interview which will be conducted by Dr. Nan Jiang, the Principal Investigator of the study. We will audio record the interview in order to capture all of your insights. We will only do so with your permission. If you do not wish to be audio recorded, it will not be possible for you to be in the interview. We will not call your name during the interview so the information you share with us will remain anonymous.

We will use these recording for data analysis purpose. All recordings will be immediately downloaded and stored in a password-protected computer at NYU. Once transcribed and entered into a password-protected data analysis program, the recordings will be deleted from the computer and digital recorders. Only authorized researchers (including the Principal Investigator and the research assistant) have access to the data. There will be no document linking your name or any other personal identity information to the data.

Data collected and/or used for the purposes of this research will not be used or distributed for future research studies.

## 5. What are the possible risks or discomforts?

**Risk of Study**

**Use of the WeChat platform** (for intervention participants only): Please be advised that we will send you text messages through WeChat, because our smoking cessation intervention will eventually be carried out via the WeChat platform. Sending messages over an application like WeChat is an unsecure and unencrypted form of communication and there is a potential risk of disclosing information to an individual who is not authorized to receive it (unauthorized disclosure). You should not respond to the WeChat messages in a manner that provides or discloses any Protected Health Information (PHI). We will ask your permission to use the WeChat platform during the 6 weeks when we carry out the intervention. After the intervention, we will immediately remove you from our WeChat contact. If you do not wish to use WeChat, it will not be possible for you to be in this study.

We have rules for attending the WeChat private group (Group A), and we reserve the right to remove those who do not comply with the rules.

- Please do not defame, attack, or disparage others when you make a comment. Profanity, obscene content, and personal attacks will not be tolerated.
- To keep our dialogue on topic, we don't accept any comment that appears to be commercial or that could otherwise be viewed as spam.
- You should not respond to WeChat messages in a manner that provides or discloses any Protected Health Information. Please do not post confidential or proprietary information. As a safety precaution, do not post your name, address, phone number, email address, or health information on social media platforms.
- To protect your confidentiality, we will create a study ID, a unique identifier, for each participant. Please use your study ID as the alias name in our WeChat private group. If you want to change your WeChat username for any reasons (e.g., username contains personal identification information), our research assistant will help you change your WeChat username prior to the start of the intervention.
- Please realize your posts are public; nothing is truly private. Think about your comments before you post your contents. Remember that anything you share via social media including in WeChat, even within a closed private group, may become public and live on in perpetuity.

This study will use WeChat, a mobile application, to gather information for the researchers as part of this study. WeChat is provided by Tencent Ltd., a Chinese multinational technology conglomerate holding company, and there are terms of use that Tencent requires of all users. You will need to review Tencent's terms of use and privacy agreement. Tencent may retain some of the data collected through the WeChat platform, even after the study ends. If you do not want this data collection to continue by Tencent after the study ends, you will need to discontinue the use of WeChat. The research team can help explain how to do this.

**Privacy and confidentiality:** We are committed to protect your privacy and maintain confidentiality. In this study, we will not collect your personal identifying information or PHI. To maintain your data confidential, we will create a unique study ID for you and use this study ID instead of your name in all study activities. Your personal information and survey data will be stored on a password-protected secure computer at NYU Grossman School of Medicine. Only authorized researchers have access to the data. There will be no document linking your name or other identifying information to your data. Thus, there will be no way to identify individual participants.

If you agree to participate in this study, you are giving us permission to collect and analyze your data (non-personal identifying information and non-PHI). We will protect your data confidential. If you decide not to verbally agree to allow us to collect or analyze your data, you cannot be in this study.

**Risks of Nicotine Replacement Therapy:** Possible side effects of the nicotine patch include skin irritation (redness, mild itching or burning) at patch application sites, nausea, dizziness, headache, dry mouth, diarrhea, nervousness or restlessness, vivid dreams or other sleep disturbances, and irritability. Possible side effects of nicotine lozenge include warm or tingling sensation in the mouth, dizziness, nausea, headache, irritability, insomnia, and increased salivation. If you experience severe side effects, stop using the patch and lozenge immediately and call your doctor.

**Other Risks:** You may feel uncomfortable to answer some of the group discussion questions during the intervention or answer some questions in the post-intervention interview. However, you can refuse to answer any question that makes you feel uncomfortable.

The research may involve risks that are currently unforeseeable.

## 6. What if new information becomes available?

During the course of this study, we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

## 7. What are the possible benefits of the study?

We hope that information from this study will help improve our social media platform smoking cessation intervention. You may or may not get any direct benefit from participation in the study.

## 8. What other choices do I have if I do not participate?

Your participation is completely voluntary. You can refuse to participate or withdraw anytime during the interview with no penalty.

## 9. Will I be paid for being in this study?

You will be paid $20 in a pre-loaded debit card on the completion of each survey (3 surveys in total) and each CO test. If you are selected for the post-intervention interview, you will be paid $50 in a pre-loaded debit card on the completion of the interview.

## 10. Will I have to pay for anything?

You will not be charged for anything in this study.

## 11. When is the study over? Can I leave the Study before it ends?

The WeChat Quit Coach program will take 6 weeks. The final follow-up phone survey will be 6 months post-enrollment. You can withdraw anytime during the study with no penalty.

## 12. How will you protect my confidentiality?

We will NOT collect your medical or personal identification information during the study. Your written consent will be kept in locked folders in a secure computer at NYU Grossman School of Medicine. Only authorized researchers (including the Principal Investigator and the research assistant) will have access to the files. No personal identification information (e.g., name, WeChat username) will be recorded or included in the transcripts. All recordings will be immediately downloaded and stored in a password-

protected computer. Once transcribed and entered into a password-protected data analysis program, the recordings will be deleted from the computer and digital recorders. There will be no document linking your name or any other personal identity information to the data.

**Certificate of Confidentiality**

To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you. Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight. The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research information, including lab results, X-rays, MRIs, information about the investigational drug used in this study, may be included in your NYU Langone Health electronic medical record.

## 13. HIPAA Authorization

As noted in the privacy and confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

**What information may be used or shared with others in connection with this study?**

All information in your research record for this study may be used and shared with those individuals listed in this section.

**Who may use and share information in connection with this study?**

The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator and the research assistant who is responsible for the support or oversight of the study.
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

**What if I do not want to give permission to use and share my information for this study?**
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

**Can I change my mind and withdraw permission to use or share my information?**
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

**How long may my information be used or shared?**
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

## 14. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies, including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research

studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of doctors, nurses, non-scientists, and people from the community

## 15. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

**When you sign this form**, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. You will receive a copy of this e-Consent by mail or through email, per your preference.

| Name of Subject (Print) | Signature of Subject | Date |
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| Name of Person Obtaining Consent (Print) | Signature of Person Obtaining Consent |
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