Human Subjects Research Process Flow Chart

1) Does the protocol involve human subjects located in the People’s Republic of China (PRC)?
   a. YES – The PIPL may apply depending on how the data is being collected and handled.

2) Does the protocol involve Personal Information (PI) or Sensitive Personal Information (SPI) data collected or stored in the PRC?
   a. YES – PIPL will apply

3) Is the information being collected anonymously so the identity of the research subject cannot be determined directly or indirectly?
   a. YES – PIPL does not apply

4) Will data be fully anonymized prior to being obtained by the NU investigator?
   a. YES - PIPL does not apply

5) Will data be de-identified?
   a. If no, PIPL does apply

6) If data is de-identified, will anyone at the university have the key?
   a. If anyone at the university has access to the key, then the information is not considered anonymous and the PIPL does apply.
   b. If university does not have the key and cannot decode the data, then PIPL may not apply (with some conditions).

7) Does the protocol involve new/re-use of previously collected PRC data?

8) If new/reuse of PRC data, did the original consent cover the new use?
   a. If yes, unless other handling changes are made, no need to reconsent.
   b. If no, will need to re-consent subjects to use data.

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DATA HANDLING (Collection, Transfer, Sharing, Storage, Access, etc.)

It is important that the protocol and the consent document(s) clearly delineate everyone who will handle the PI/SPI (by name), contact information for recipients, purpose, and method of processing the PI/SPI, type of PI/SPI (Data elements) and how data subjects can exercise their rights.

9) What kind of data is being collected? Minors, Sensitive Personal Information (SPI), etc, determine the type of data elements that will be collected, how much data, one time or longitudinal study, etc. Address in protocol and informed consent.

10) Who is collecting the data? University collaborator, third party, or university itself?
    a. Need to determine all parties involved and the relationship of the parties
    i. Primary information handler – for example, the university is conducting the study by having people located in the PRC access a university website to take an online survey.
    ii. Entrusted Party – for example, university is working for a PRC university who is conducting a study and university is working as a subcontractor to process some part of the research under the direction of the PRC university.
    iii. Joint Handler – for example, university is working in collaboration with a PRC university, together they are jointly directing the study and each are doing their own thing with the data being collected.
This information should be included in the protocol and informed consent.

11) Will data be transferred out of the PRC? If yes:
   a. Who is transferring it?
   b. Who is receiving data?
   c. What is being done with data at university?
   d. How will it be stored and for how long?

   This information should be included in the protocol and informed consent.

12) Will university share any of the PRC data with others outside the university?
   a. If yes, they will need to be disclosed in the informed consent, protocol, and a Data
      Handling Agreement (DHA) should be executed between NU and the other outside entity.

13) Are there any 3rd party service providers, software involved in the handling, storage? (Box,
    Sharepoint, AWS, Qualtrics).
   a. If yes, is there a PIPL compliant Data Handling Agreement (DHA) in place?

   This information should be included in the protocol and informed consent.

**Informed Consent: Elements for PIPL compliance**

1) The protocol and consent should include a complete listing of everyone who will have access to
   subject’s Personal Information (PI) and/or Sensitive Personal Information (SPI). This should name
   the specific research team members who will have access and for what purpose.
   In addition, the consent and protocol should include other university units that might have access
   based on their role at the university.

2) Describe the purpose of the handling activity (if not already spelled out in main consent) and why it
   needs to be done. Provide the legal basis that it is being collected under PIPL (typically consent)
   and that consent can be withdrawn at any time.

3) Explain that data will be transferred out of the PRC and where it will go (e.g., university servers,
   third party storage services, etc).

4) Describe security and retention processes – will data be de-identified, how long will it be retained,
   how it will be destroyed. Refer to university and specific school’s policies regarding security,
   retention.

5) If study will handle SPI, then explain what SPI is and that it will be protected.

6) Explicit affirmative consent must be obtained for the handling (collection, use, processing,
   retention, sharing) of the data.

7) If transferring out of PRC, separate affirmative agreement (question or statement) must be
   obtained for the transfer out of PRC.

8) How to withdraw consent – typically an email address (e.g., privacy@university.edu, which is
   managed for right to withdraw.

9) Specify what other rights subjects have.

10) Contact information for all foreign recipients of PI/SPI.

*Information from above should also be included consistently in the protocol, as applicable.

**OTHER CONSIDERATIONS:** There are other applicable laws that may apply if there are biological
samples being shipped (Export Controls), if the PI/SPI is considered ‘Human Genetic Resource’
information, and for publishing collaborative research between China and non-China university

Regulation of the People’s Republic of China on the Administration of Human Genetic Resources – Effective
7/1/19
i. This regulation covers “materials of human genetic resources” meaning genetic materials such as organs, tissues and cells which contain human genomes, genes and other genetic substances, and “information on human genetic resources” meaning information materials such as data generated from the utilization of materials of human genetic resources.

ii. Article 22 “The scientific research conducted through international cooperation by using China’s human genetic resources shall meet the following conditions, and both parties to cooperation shall jointly file an application, which shall be subject to approval by the science and technology administrative department of the State Council.”


iii. Pursuant to Article 14 of the Measures for the Management of Scientific Data, "When paper authors are required to submit corresponding scientific data outside China when writing and publishing papers on foreign academic journals by utilizing the scientific data formed by government budgetary funding, they shall submit the scientific data to their employers for unified management before the publication of the papers."