Human Subjects Research Process Flow Chart for IRB
Part 1 – Does PIPL Apply to data collection?

1. Does the Protocol involve human subjects located in the PRC?
   - Yes: 1a
     - If protocol involves PI/SPI collected from human subjects in the PRC, the PIPL may apply depending on how the data is obtained and handled.
   - No: 2

2. Does the protocol involve PI or SPI collected or stored in the PRC?
   - Yes: 3
     - Is the information being collected anonymously so the identity of the research subject cannot be determined directly or indirectly?
       - Yes: 3a, 4a
         - PIPL does not apply to anonymous data
       - No: 4
         - Will data be fully anonymized prior to being obtained by NU investigator?
           - Yes: 5
             - Will data be deidentified?
               - Yes: 6
                 - Will anyone at NU have the key to decode the data?
                   - Yes: 6a
                     - If anyone at NU has access to the key then information is not considered anonymous under PIPL.
                   - No: 5
                 - No: 6b
                   - If no one at NU has access to the key or any way to decode the data then the PIPL may not apply. NU should have a DHA in place indicating that data provider will never provide NU with key and that the NU researcher will not try to decode the data.
               - No: 4
             - No: 5
           - No: 4
         - No: 4
   - No: 2

3. Is the information being collected anonymously so the identity of the research subject cannot be determined directly or indirectly?
   - Yes: 3a, 4a
     - PIPL does not apply to anonymous data
   - No: 4
     - Will data be fully anonymized prior to being obtained by NU investigator?
       - Yes: 5
         - Will data be deidentified?
           - Yes: 6
             - Will anyone at NU have the key to decode the data?
               - Yes: 6a
                 - If anyone at NU has access to the key then information is not considered anonymous under PIPL.
               - No: 5
             - No: 6b
               - If no one at NU has access to the key or any way to decode the data then the PIPL may not apply. NU should have a DHA in place indicating that data provider will never provide NU with key and that the NU researcher will not try to decode the data.
           - No: 5
         - No: 5
       - No: 4
     - No: 4

4. Will data be fully anonymized prior to being obtained by NU investigator?
   - Yes: 5
     - Will data be deidentified?
       - Yes: 6
         - Will anyone at NU have the key to decode the data?
           - Yes: 6a
             - If anyone at NU has access to the key then information is not considered anonymous under PIPL.
           - No: 5
         - No: 6b
           - If no one at NU has access to the key or any way to decode the data then the PIPL may not apply. NU should have a DHA in place indicating that data provider will never provide NU with key and that the NU researcher will not try to decode the data.
       - No: 5
     - No: 5
   - No: 4

5. Will data be deidentified?
   - Yes: 6
     - Will anyone at NU have the key to decode the data?
       - Yes: 6a
         - If anyone at NU has access to the key then information is not considered anonymous under PIPL.
       - No: 5
     - No: 6b
       - If no one at NU has access to the key or any way to decode the data then the PIPL may not apply. NU should have a DHA in place indicating that data provider will never provide NU with key and that the NU researcher will not try to decode the data.
   - No: 5

6. Will anyone at NU have the key to decode the data?
   - Yes: 6a
     - If anyone at NU has access to the key then information is not considered anonymous under PIPL.
   - No: 6b
     - If no one at NU has access to the key or any way to decode the data then the PIPL may not apply. NU should have a DHA in place indicating that data provider will never provide NU with key and that the NU researcher will not try to decode the data.

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PIPL WILL APPLY

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7. Does the protocol involve the re-use/new use of previously collected PRC PI/SPI?
   - Yes: 8
     - Did original consent cover the new/re-use?
       - Yes: 8b
         - All research subjects would need to be notified and reconsented
       - No: 8a
         - Unless there are other handling changes no need to notify/reconsent
   - No: 8b
     - All research subjects would need to be notified and reconsented

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8. Did original consent cover the new/re-use?
   - Yes: 8b
     - All research subjects would need to be notified and reconsented
   - No: 8a
     - Unless there are other handling changes no need to notify/reconsent

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