Narrative outline

ALL IRB submission must include a written narrative of the project. Below is an outline of the basic information that must be included in each narrative.

All pages in this summary should be: numbered, PI initials and dated with the date of submission in the footer on the left bottom corner. (Example: Page 1, tkm, 8-10-2015) The footer in the bottom right hand corner should contain the title of the project.

1. Background
   a. Brief Overview of the research project
   b. Purpose of the project
      i. It’s importance and why the need to do it
         1. Improve program
         2. Develop guidelines
         3. Identify standards
      ii. Who will benefit from the project: only ND, nationwide
   c. Any other background information

2. Methodology
   a. Description of procedures for data collection.
      i. Must include how data will be collected, any forms needed, how population is to be identified, and include any perceived risk to the participants, whether risk to health or confidentiality.
      ii. If using an existing data set include methodology used to create the data set.
   b. Include reasons for, if any, the need to use confidential data. Additionally, if confidential data is used initially to create a linked data set, and then removed, describe how this will be done.
   c. The anticipated number of subjects enrolled; if data set, the number of participants.
   d. The analysis used in the study.
   e. Include any secondary or anticipated modifications to the protocol (ie additional steps taken to increase enrollment efforts).
   f. Include how you will collect informed consent, if you do not plan to obtain consent, explain why you feel this is not necessary.

3. Security
   a. Data storage and handling
   b. Where data will be stored, maintained, and efforts used to maintain data security (firewalls, passwords, etc).
   c. Include if the data will be stored on any mobile drives such as thumb drives or external hard drives.
   d. If project includes obtaining an existing de-identified data base, you must include a statement regarding the need/necessity to attempt to identify individuals in the data set.
   e. Who, besides yourself, will have access to the raw data files and why they need access.

4. Release of Information
   a. Identify if and how the information from this study will be shared
      i. News release, newsletters, online, internal document only
      ii. Published in a journal/publication/conference presentations
   b. Identify any anticipated concerns/complaints you may receive about the study.

5. Conclusions
   a. Include any final survey instruments, consent forms, release of information statements
   b. Include any documents reviewed by another institution’s IRB (if applicable)