

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)