**Quality Improvement Project IRB Template**

1. Title:
2. Project Leader:

Department/University:

Address:

Email:

Phone:

Protecting Human Research Participants: (you will need to upload your NIH certificate and your preceptor’s)

**Project Details:**

1. Which of the following is the primary purpose for undertaking this QI project?

(Select quality improvement in the local environment.)

1. In what facility will this QI project take place? (Upload approval letter from host facility or letter of commitment from administrative representative of the facility that indicates intent of facility to participate in and host this project).
2. Projected start date: / Projected end date: (one year from start date)
3. Problem description:
4. Available knowledge (bullet points with applicable research):
5. Purpose of the project including measurement criteria:
6. Will any protected health information (PHI) be accessed by ANY member of this QI team?

No If no, proceed to #10

Yes If yes, complete the remainder of the items in question 9.

**Elements of Protected Health Information (PHI) to be accessed (check all that apply)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Names |  | Web URLs |
|  | Email addresses |  | IP Addresses |
|  | Social Security numbers  |  | Account numbers |
|  | Medical Records numbers |  | Biometric ID's, including finger and voice prints |
|  | Fax numbers |  | Full face photographic images & comparable images |
|  | Health Plan beneficiary numbers |  | All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, & their equivalent geocodes, except for the initial 3 digits of a zip code if, according to the current publicly available data from the Census Bureau |
|  | Vehicle ID & serial numbers, license plate numbers |  | All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older |
|  | Device identifiers & serial numbers |  | Any other unique identifying number, characteristic, or code, except as permitted in section immediately above |

Describe why this project cannot be completed without accessing PHI or gaining consent of the subject to whom PHI belongs (patient).

Describe your plan to protect the identifiers from improper use and disclosure.

PI Assurance:

As the project leader, I hereby assure that the Protected Health Information will not be used or disclosed to any person or entity, except as required by law, for authorized oversight of the project.

Describe alternates/limitations to project design if access of PHI is not granted.

Upload verification of HIPPA education for you and your committee members.

1. Methods: Please provide a detailed summary of your proposed project, including consenting processes and all other procedure elements.
2. Measures. Please list outcome measures. Include a description of how the data will be obtained and evaluated.
3. Please list process measures. Include a description of how the data will be obtained and evaluated.
4. Please list balancing measures (if applicable.) Include a description of how the data will be obtained and evaluated.
5. Are there any costs to the subjects for participating in this project (including emotional, physical, inconvenience, or monetary costs)? If yes, describe all costs to subjects.
6. Why do you think this project is quality improvement and not research?
7. Signatures
	* Student signature
	* Capstone chair’s name
	* List Capstone Committee
8. Upload files: You must submit all form to be used in the project, including education, audit and data collection forms.