**QUALITY IMPROVEMENT/ QUALITY ASSURANCE (QI/QA) PROJECT**

*You should allow approximately 2 weeks for the review of QI/QA projects.*

**DATE:**

**NAME:**

**PROJECT STUDY TITLE:**

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| According to the federal definition, **research** means a **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**. Quality improvement and quality assurance projects do not fall within this definition.  Complete this form for projects that meet the following criteria:   * Are focused on improving the outcomes or processes at an organization or other entity (and do not contribute to generalizable knowledge).   AND   * Involve interactions to obtain information about people and/or accessing or collecting individually identifiable and private information about living individuals.   ***Private information*** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record information). Private information must be individually identifiable.  *Individually identifiable* includes where the identity of the subject is or may be ascertained by the researcher or associated with the information.  Note that IRB submissions are not needed for projects that ONLY involve publicly-available data, data in public records, or datasets with no identifying information.  For more information, see the IRB website, specifically the FAQ on data that has been stripped of identifying information. |

**DIRECTIONS**:

This form is to be submitted to the Gonzaga Institutional Review Board (IRB) *before* the initiation of a project that will be completed as part of an undergraduate or graduate program. Some faculty, staff or administration may submit this form prior to conducting QI/QA projects as well. See the FAQs for more guidance.

The information you provide on this form and the materials you submit will be evaluated to verify that the project does not meet the federal definition of research and that participants are treated in accordance with the principles of the Belmont Report.

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| **SECTION I: LOCATION OF ACTIVITIES** |
| 1. Specify all sites involved.  Gonzaga -- Within your department or division (If this is the only site, skip to Section II.)  Gonzaga – Outside of your department or division. Please specify:  Outside of Gonzaga Please specify:  If your project is conducted outside of your department or division at Gonzaga, attach one of the following with your IRB submission:   * + A letter or email from the outside department, organization or agency stating what the project entails and how the project will help improve agency processes or outcomes.   Or   * + Determination from another IRB that the project is Quality Improvement/Quality Assurance (QI/QA). * *For example, nurses working in hospitals may be required to have their projects reviewed by a local IRB. When an IRB has determined a project to be QI/QA, no additional letter is needed to verify that the project is QI/QA.*   2. If the project is to be conducted in an outside organization or agency, determine the policy or procedures for permission to conduct your project and/or use data in a written product (e.g., dissertation/thesis/capstone).  Explain how you have met the local requirements to obtain pemission to conduct the project and/or use data in a written product: |

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| **SECTION II: DATA COLLECTION** |
| **1. What type of project is being conducted?** Check any of the following that apply:  Needs analysis (i.e., gathering and analyzing data to identify areas for organizational improvement)  Quality assurance/ Program evaluation (i.e., gathering and analyzing data to determine the effectiveness of a program that was previously implemented)  Quality improvement/ Process improvement (e.g., gathering and analyzing data about the impact of an educational intervention or an implementation intervention)  Other:  For each box checked above, explain how this project is designed to help an organization or agency improve its outcomes or processes:  **2.  Will you manipulate or interact with individuals to collect data (i.e., prospective collection of data/specimens)?**  Yes  No    A. Which stakeholder groups do you plan to interact with? Specify any pertinent eligibility criteria for each stakeholder group (e.g., years worked, etc.):  B. For each stakeholder group, answer the following questions:  i. How will potential participants be identified and recruited? If surveys are to be  emailed, specify how emails will be obtained, stored securely, and then disposed of:    *Attach recruitment materials, emails, flyers, etc.*    ii. How will participants be fully informed of this study prior to their participation  (through the use of an informed consent form, study information sheet, letter, etc.):        *Attach Information Sheet or Informed Consent form, if applicable. Note that the Informed Consent in QI or QA may state that everyone will participate in the activities but that individuals can choose whether to allow their data to be analyzed for the project.*   * *For example, in a school setting, all students would be expected to complete all the learning activities, but parental consent would be requested for the data to be analyzed for a graduate project, etc.*   iii. Explain the procedures that will be used to collect data. Indicate whether these procedures would be conducted as part of standard of care, regardless of the project.  *Attach all surveys, instruments, interview questions, etc.*  iv. Explain how subject privacy will be protected while data is being collected. For example, if interviewing, where will the interview be conducted?  **3. Will you access and analyze existing *data/ specimens* (e.g., archived academic, medical or personnel records)?**  Yes  No (*Skip to Section III and answer the additional questions.)*  If yes, answer parts A through F below for each stakeholder group:  *Note that the responsible PI on the cover sheet is tasked with ensuring that privacy regulations (e.g., HIPAA, FERPA) are followed in this study.*   1. Will a Data Use Agreement be executed to conduct this study? If yes, explain the process you are in to establish the Data Use Agreement      a   *Also be sure all the answers below match the agreement. The responsible PI must ensure that data are used in accordance with the Data Use Agreement in place, as stated above.*   1. State the eligibility criteria for the records that will be included for each stakeholder group (e.g., age range, gender, language spoken, etc.). 2. Specify the number of records being secured for purposes of the project: 3. List the variables to be extracted from the records and included in the data sets: 4. Will the *data/ specimens be coded* such that a link exists that could allow the source of the data/ specimens to be re-identified (i.e., key available to decipher the code)?   N/A The provider of the data/ specimens will remove the code before sending the data/specimens to the researcher. (***Skip to question 3)***  Yes, provide details that describe how the data are coded, by whom, and how the key is to be stored (if applicable).  *Include any applicable documentation of agreements (e.g., if the holder of the key and the investigator have documented that the release of the key would be prohibited until the individuals are deceased, this document could be attached)*  No, the data/specimens will be identifiable. (Answer part F below.)   1. Describe the safety measures in place for securing identifiable data (e.g. kept electronically in HIPAA-compliant secured servers, hard copies kept in PI files under lock and key.) Identify any and all persons with access to said data. |

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| **SECTION III: ADDITIONAL QUESTIONS** |
| **1. Will you be audio or video recording?**  No Proceed to next question.  Yes Complete items A and B below.   1. How do you plan to protect the confidentiality of the audio or video recordings: will they contain subject names or images; where will they be kept; who will have access; will they be archived and if so, how; might they be used for secondary uses, and when will they be destroyed?   *Be sure the informed consent document provides the same information to the participants and allows them to explicitly agree to the process of recording and also to any additional use of the video or audio files.*  *Also ensure the recordings could not be used for evaluative purposes of employees or students.*   1. Could the information obtained or recorded about subjects place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, or reputation?   No Proceed to next question.  Yes This study does not meet the criteria for a QI/QA project. *Please submit an application for Non-Exempt research.*  **2. Will subjects be paid for participation in the study (e.g. monetary, meals, free services, gifts, course credit, including extra credit)?**  No Proceed to next question.  Yes Complete items a. and b. below.   1. Explain the payment arrangements (e.g. amount and timing of payment and the proposed method of disbursement). NOTE: Payments must accrue and not be contingent upon completion of the study. However, a small payment (bonus) for completion of the study may be acceptable if it is found to not be persuasive for the subjects to remain in the study.        1. Justify the proposed payment arrangements described in part A above. (e.g., how this proposed payment arrangement is not considered to be coercive).   **3. Will you include individuals in the following groups in your research?** (Select all that apply. For each selection, explain preventative measures that you will take to prevent exploitation and/or coercion)  Individuals with diminished autonomy (e.g. children, people with limited ability to make decisions)  Subordinates to the investigators (e.g., employees or students whose boss or teacher are conducting a study in their own setting)  Speakers of a foreign language (e.g., individuals who could not complete the research tasks in English)  Other vulnerable subjects. Please specify:  For each group selected above, please explain how they will be protected:  None of the above  **4. Will personally identifiable information be collected in your research?** (i.e., emails or data linked to an identifier like a patient number or a physical address)  No Proceed to next question.  Yes Complete parts A and B below*.*  A. Explain how identifiable information will be kept confidential after it has been collected.  B. Explain how long the data will be stored after it has been collected (this should be a  minimum of 3 years; longer if required by the project’s funding source federal  regulations).      **5. How will data be analyzed?**  Explain the methods by which data will be analyzed to achieve project aims.  *Be sure the information in the protocol provides details that show how these analyses can be carried out. For example, if you state that you are going to conduct a dependent t test, be sure the reviewer can see how you will link the pre and post test information for each subject.*  **6. Are there any features of your participants, the setting, or your project that introduce potential risks that haven’t been addressed yet on this form?** Potentials risks may include psychological, social, legal, physical, etc.  No Proceed to the Submision Checklist  Yes Complete items A and B below.  A. Explain how will you help to minimize potential risks that individuals may be exposed to while participating in the project.  B. Explain how you have determined that the risk in this study is no more than the participants would encounter in a typical day. |

**SUBMISSION CHECKLIST:**

* COVER SHEET—Faculty or Student version as appropriate (with all signatures/approvals)
* THIS FORM—With detailed answers that are cohesive throughout
* Emails/Letter(s) of permission – with information about how the project will help improve the processes or outcomes for the site
* ALL INSTRUMENTS used in the project:
  + Informed Consent (and/or Assent) documents **OR** an information sheet about the project
  + Recruitment script and/or other materials needed for the study
  + Additional information about the intervention, if an intervention is involved

**SUBMISSION INSTRUCTIONS:**

You can submit your protocol by going to [www.gonzaga.edu/irb](http://www.gonzaga.edu/irb) and clicking on the Submission Process tab. Go to “Submit Your Study Materials.” This link takes you to the IRB SharePoint site where you fill out the required information and attach all your study materials.