GONZAGA UNIVERSITY IRB
POLICY AND PROCEDURES FOR HUMAN RESEARCH
PART I: POLICY

The purpose of this document is to outline the policies, procedures, regulatory terms and conditions of conducting research with human subjects, human data or human anatomical substances (except commercially purchased substances) at Gonzaga University.

It is the policy of Gonzaga University to adhere to the generally accepted ethical and professional standards for the protection of human subjects in research that are formulated in The Belmont Report[1] of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and the Nuremberg Code[2]. The three Belmont Principles have been summarized by the Office for Human Research Protection (OHRP), National Institutes of Health (NIH), as follows[3]:

"*Respect for Persons* involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy...Required by the moral principle of respect for persons, informed consent contains three elements: information, comprehension, and voluntariness...Institutional Review Boards should be especially sensitive to these factors when particularly vulnerable subjects are involved."

"*Beneficence* entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks or harm...The Report recommends the Institutional Review Board's (IRB) insistence upon precise answers to direct questions. The IRB should: (1) determine the 'validity of the presuppositions of the research,' (2) distinguish the 'nature, probability, and magnitude of risk...with as much clarity as possible,' and (3) 'determine whether the investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.'"

"*Justice* requires that the benefits and burdens of research be distributed fairly...The principles of justice mandates that the selection of research subjects must be the result of fair selection procedures and must also result in fair selection outcomes. The 'justness' of subject selection relates both to the subject as an individual and to the subject as a member of social, racial, sexual, or ethnic groups."

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[1] *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, DHEW Publication No. (OS) 78-0012 (1978).

[2] *Trials of War Criminals Before the Nuremberg Military Tribunals.* Superintendent of Documents. U.S. Government Printing Office, Washington, D.C. (1947).

[3] *Protecting Human Research Subject: Institutional Review Board Guidebook.* National Institutes of Health, Office of Extramural Research, Office for Protection from Research Risks. Superintendent of Documents. U.S. Government Printing Office, Washington, D.C. (1993), pp. xxi-xxiii.

A. Applicability of Regulations, Standards and Policies to All Research

The following policy statements, definitions and procedures are in accord with the federally mandated requirements of 45CFR46 (but not limited to), and constitute the basis of the University's Federalwide Assurance (FWA) filed as required with the Office for Human Research Protection (OHRP) of the Department of Health and Human Services (DHHS). Moreover, research standards are guided by the standards set forth by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP). In the case of conflict between regulations of the funding or regulatory agency, and/or the Gonzaga University IRB, the more restrictive requirements shall prevail.

In compliance with federal regulations governing federally-funded research, and in consideration of the liability assumed by the University when faculty, students, and employees conduct research, all human research, including that which is being conducted for any purpose other than solely for the benefit of the subject as an individual, shall be approved by the Gonzaga University Institutional Review Board (IRB) and reviewed at the appropriate level, following the established procedures presented below.

B. Responsibility, Jurisdiction and the Institutional Review Board

1. University policy and procedures apply to any human research activity, whether such research is undertaken on a large or small scale, whether it is preliminary or fully designed, whether it is student or faculty research, whether it is funded or non-funded[4], and whether it involves minimal risk or more than minimal risk.

2. Ultimately the responsibility for maintaining ethical standards and protecting human rights rests with the individual researcher (and in the case of Gonzaga students, his/her faculty research advisor). Responsibility for compliance with regulations rests with the Academic Vice President (AVP). The IRB is required as a measure of reassurance and as a local resource for the interpretation of ethical and regulatory guidelines. Any human research must have associated with it a responsible Principal Investigator (PI) who is a qualified faculty member or a qualified staff member, and who will monitor and be liable for the conduct of the research along with the protocol PI.

3. Engaging in human research without IRB approval puts the researcher at risk and is a violation of University, federal, and state policies. Regardless of investigator intent, unapproved human research places those subjects at an unacceptable risk.

4. Written approval from the IRB must be received before initiation of subject recruitment or initiation of procedures that involve human subjects, human data or human anatomical substances.

[4] Funded research is defined as research supported either by internal or external sources. This includes studies that do not have support but that use data generated by a funded study. Non-funded research is defined as research that is conducted without internal or external funding support.

5. Human research approvals granted by the IRB are good for six months to one year from the date of approval (as indicated on the Gonzaga IRB approval or determination letter), unless substantial modification of the approved protocol requires an additional review.
6. Approval of Exempt protocols do not expire unless there are additions or changes in the Study Staff (i.e. PI/PIs/Co-PIs), significant changes to the design, and/or potential increased risk to subjects.
7. "The IRB has the authority to approve, require modification in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy. Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the University. However, those officials may not approve research if it has been disapproved by the IRB." (Federal Policy 45 CFR 46.112)
8. In addition to compliance with federal and University procedures contained herein, projects involving human subjects, whose protection is also the responsibility of an agency other than Gonzaga University, will be subject to that agency's requirements as well.

C. Statement of Policy[5]

1. Informed Consent

Informed consent includes three essential elements: voluntariness, disclosure, and comprehension.

(a) Voluntariness. Participation of human subjects in research governed by this policy must be voluntary. The consent of authorized representatives is usually required, in accordance with application statutes and regulations, for subjects who have diminished capacity to consent, as well as that of the subject if practical. Such persons include minors, the mentally retarded, individuals with limited civil freedom, fetuses, or children.

The methods used for approaching subjects and securing their participation should be designed carefully to protect the privacy of the subjects and should be reasonable in terms of their condition or circumstances.

No coercion, explicit or implicit, should be used to obtain or maintain cooperation. Where the professional-client or faculty-student relationship is converted into an investigator-subject relationship, special care must be taken to ensure that the subject feels completely free to decline to participate. Where access to subjects is gained through cooperating institutions or individuals, care should be taken not to abridge prior commitments made to the subjects about the confidentiality or other terms of the primary relationship.

[5] The following definitions and statements are in accordance with those set forth in federal regulations, and in the guidelines of the OHRP.

Any payment made to subjects should not be large enough to constitute excessive [or undue] inducement for participation of the subjects.

Standards for the use of pregnant women and of fetuses in research exceed those of other categories of subjects. Pregnant women and fetuses may not be used as research subjects unless studies of animals and non-pregnant individuals have been completed, unless the study is to meet the health needs of the woman and fetus, and the risk to each is minimal. A fetus *in utero* may be used for research only if: (1) the purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means. No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity. [45CFR46.208(a) and 45CFR46.206]

(b) Disclosure. Disclosure generally includes: the research procedures; their general purposes, risks, and anticipated benefits; alternative procedures where therapy is involved; and a statement offering the subject the opportunity to ask questions and to withdraw without negative consequences at any time from the research. The extent and nature of information should be such that persons, knowing that the procedures are neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, subjects should understand clearly the range of risk and the voluntary nature of participation. For research involving more than minimal risk, it is necessary to provide an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. [45CFR46.116(a)(6)]

In some research, fully informing the subject would invalidate the research. In such cases, it may be necessary to withhold (conceal) information from the subject. However, information should not be withheld if withholding it would affect a reasonable person's decision to participate or damage his or her subsequent self-esteem. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

(c) Comprehension. The third element in informed consent is comprehension. The manner and context in which information is conveyed is as important as the information itself. Consideration must be given to the subject's ability to understand the language and

terminology used as well as the subject's physical and mental state. Investigators are responsible for ascertaining that the subject has comprehended the information.

2. Confidentiality of Data

In all human research, confidentiality of identifiable information is presumed and must be maintained unless the investigator obtains the express permission of the subject to do otherwise.

The University recognizes the rights of the subjects to be protected against injury or illegal invasions of their privacy and their interests as members of a free society in preserving their dignity. The more sensitive the material, the greater the care that must be exercised in obtaining, handling, and storing data. Ordinarily, the following requirements must be met, subject only to their applicability to the particular activity.

(a) Questionnaires, inventories, interview schedules, and other data-gathering instruments and procedures should be carefully designed to limit the personal information to be acquired to that which is absolutely essential to the activity.

(b) Data that include information which would reveal a subject's identity should be stored in files accessible only to the PI and his/her authorized staff or representative.

(c) As early as feasible, the data should be handled in coded form, i.e., the subject's name and information that would reveal his or her identity should be removed. Plans and a schedule for the ultimate disposition or indefinite retention of the data must be approved by the IRB.

(d) The identity of subjects must not be released except with his/her express written permission.

(e) Use of stored data or information, which were originally obtained for different purposes and which involves identifiable persons, requires examination of the risk involved, a determination of whether the new use is within the scope of the original consent or whether obtaining additional consent is necessary and feasible, and provision for the preservation of anonymity of the subjects.

Data that are part of the public domain are not covered by the foregoing restrictions. (For research requiring prior review, the material submitted for review must specify the provisions for maintaining the confidentiality of data and/or preserving the anonymity of subjects.)

3. Classification of Risk and Required Safeguards

A subject is at risk if he or she may be exposed to the possibility of injury, including physical, psychological, or social injury as a consequence of participating as a subject in the research,

development, or related activity. These potential injuries must depart from the established and accepted methods necessary to meet the subject's needs or increase the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service. A subject may be a risk when an investigator uses stored data or information obtained for purposes other than the investigator's research.

For the purposes of safeguarding the human identifiable information or data, and ensuring that these safeguards are continuously provided, two classifications of risks are introduced.

(a) Minimal Risk. The risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(b) More Than Minimal Risk. The anticipated risks in the proposed research exceed, either in probability or magnitude, those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

In classifying human research, the investigator and those who review the proposed use of subjects should follow the principles and procedures of this document in arriving at a carefully reasoned decision.

D. Research Categories and Research Review Methods

Research using human subjects can be divided into research categories (a reflection of risk) and review methods.

1. Exempt Research (may go through Expedited Review)

Exempt research is human research, per federal regulations. However, it is exempt from IRB oversight (beyond its Exempt Determination by the IRB). Based on applicable federal regulations and/or provisions of the University's Policy and Procedures, investigators will not make the final determination of Exemption for human research. A study protocol Exemption Determination requires the approval of the IRB.

The IRB reserves the right to require review of specific research activities or classes of research activities even though they may qualify for Exemption. The requirements of sponsoring agencies, unexpected problems, previous investigator noncompliance and the need to evaluate experiences with Exemption categories might trigger such review.

Categories of Exempt research are established by federal regulations and cannot be amended. Research may be exempt from review if it meets one or more of the following six federal grounds for Exemption[6] *and does not include one of the 12 exceptions to the Exemptions.*

45CFR46.101(b)(1-6)

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   (i) research on regular and special education instructional strategies, or
   (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use the educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless
   (i) information obtained is recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; and
   (ii) any disclosure of the subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph (b) of this section, if:
   (i) the human subjects are elected or appointed public officials or candidates for public office; or
   (ii) federal statute(s) requires without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
   (i) public benefit or service programs;
   (ii) procedures for obtaining benefits or services under those programs;
   (iii) possible changes in or alternatives to those programs or procedures; or
   (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies,

(i) if wholesome foods without additives are consumed or

(ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Based on both federal policy and/or University policy, exempt status may not be granted for research in the preceding six categories if any of the following conditions applies:

Exceptions to Granting Exempt Status

- If any of the subjects are children as defined by state law.[6] Will the child participate in a survey (Exempt Category 45CFR46.101(b)(2))?
  - Will the child be interviewed?
  - Will the investigator manipulate the environment or interact with the child as part of the data gathering?
- If any of the subjects are confined in a correctional or detention facility.
- If pregnancy is a prerequisite for serving as a subject.
- If fetuses in utero are subjects in this research.
- If any subjects are presumed not to be legally competent.
- If personal records (medical, academic, etc.) are used without written consent.
- If data from subjects (responses, information, specimens, etc.) are directly or indirectly identifiable.
- If data are damaging to subjects' financial standing, employability or reputation.
- If material obtained at autopsy is to be used in the research.
- If subjects are to be asked sensitive questions about personal feelings, behavior, interactions, or sexual experiences.
- If alcohol or any other drugs will be ingested.

[6] Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. If subjects have the legal status of emancipated minors, or are mature minors, i.e., they may legally be treated as adult for certain purposes, they may be exempt from the restrictions applicable to children.

- If blood or body fluids will be drawn.

2. Research Review Methods by the IRB

Research is subject to either: **Expedited Review** or **Full IRB Review**.

(a) Expedited Review
(Exempt and Minimal Risk Non-Exempt)

Research activities that **(1)** present no more than minimal risk to human subjects, and **(2)** involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The categories in this list apply regardless of the age of subjects, except as noted.

he expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

The expedited review procedure may not be used for classified research involving human subjects.

IRB's are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply, regardless of the type of *review*--expedited or convened--utilized by the IRB.

Categories one (1) through seven (7) pertain to both initial and continuing review.

The following list of research activities[7] (carried out through standard methods) may be reviewed through expedited review procedures as long as the research contains minimal risk to the subjects, does not address sensitive issues, and does not use subjects who are not competent to give consent. This list is based on federal regulations so that additions to and extrapolation from the list by the IRB are not

[7] Federal Register CFR 63:FR60364; Nov. 9, 1998 (revised from CFR 46:8392; Jan. 26, 1981) the risks or decreases the acceptability of the risks associated with the use of the

appropriate. If there is external funding, projects shall comply with the review requirements set forth in this document. In the case of expedited review, the investigator will not begin the research until informed that the IRB will not conduct a full review of the project.

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption (IDE) application (21CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than two times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than two times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist by nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding

procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). [Note: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. 45CFR46.101(b)(4). This listing refers only to research that is not exempt.]

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. [Note: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. 45CFR46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.]

(8) Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a

convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

(b) Full IRB Review
(Minimal Risk Non-Exempt, Greater Than Minimal Risk Non-Exempt and Non-Exempt Pediatric/Minor Research)

All research not Exempt, or eligible for expedited review, shall be reviewed by the full IRB; this includes all research that involves more than minimal risk to the subjects, addresses sensitive issues, uses subjects who are not competent to give consent, and/or is required by a funding source to undergo full IRB review.

E. Reviewing Bodies

There are two administrative units that may participate in the several levels of the review process: Office of the Academic Vice President and the Institutional Review Board (IRB).

1. Office of the Academic Vice President (AVP)

(a) This office shall be the administrative unit responsible for all human research offices and activities.

(b) The AVP office will be the office of record to direct the maintenance of adequate IRB activities (including an over-arching IRB management office to be named). The IRB documentation must include (but is not limited to): copies of all applications, research protocols, minutes of IRB meetings, records and/or continuing review activities, copies of all correspondence between the IRB and investigators, and statements of significant new findings provided to subjects.[9]

2. The Gonzaga University Institutional Review Board (GU IRB)

The IRB will consist of a minimum of five members. Each department in the University that regularly conducts human research shall provide a member. In addition, departments that occasionally conduct or have the potential to conduct research that involves human research may be invited to provide a member as appropriate to their current interest. The Chair will be chosen from the IRB members. Further, in accordance with federal policy requirements[10], the IRB should include one or more individuals who are knowledgeable about and experienced in working with vulnerable categories of subjects; at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas; and must include at least one member who is not otherwise affiliated with the University and who is not part of the immediate family of a person who is affiliated with the University. The IRB may invite individuals with special expertise not available on the IRB to assist in the review of specific issues; these individuals may not vote. No IRB member may participate in the review of any project in which the member has a conflicting interest, except to provide

information requested by the IRB. A list of current IRB members must be submitted to OHRP and also kept with the IRB's records.[11] Any changes in IRB membership must be reported to OHRP.

The responsibilities of the IRB shall be to review all human, as defined above, either by a full Board review or as an expedited review and to notify investigators in writing of its decision to approve or disapprove of the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the proposed research activity is disapproved, the IRB shall include in its written notification a statement of the reasons and provide the investigator an opportunity to respond in person or in writing.

(a) In the case of expedited review, the Chair of the IRB (or a Designee Of The Chair) will review all study protocol applications along with one or more members as necessary from the IRB. The expedited review procedure may result only in one of three decisions: approval, approval contingent upon minor changes, or referral to the full IRB for further consideration. Expedited procedure reviewers may not disapprove research.

(b) In the case of full Board review, the IRB will hold an open meeting at least once per month to review all research as needed. At such meetings a majority of the members of the IRB must be present, including at least one member whose primary expertise is not in a scientific area. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. The IRB may approve, disapprove, or ask for further modification/clarification of all research protocols. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by the University President, but the President may not approve the research if it has been disapproved by the IRB.

[9] 45CFR46.116(b)(5)
[10] 45CFR46.107
[11] 45CFR46.103(b)(3) and §.115(a)(5)

GONZAGA UNIVERSITY IRB
POLICY AND PROCEDURES FOR HUMAN RESEARCH
PART II: PROCEDURES

A. Submission of Human Research Protocols

Written approval from the IRB must be received by the investigator before the human research activities can begin.

1. Exempt Research

The investigator should complete the Application for Exemption (available on the Gonzaga IRB website page) and submit a copy to the. This should be done in a timely manner prior to the start of research and before initiation of subject recruitment or initiation of any procedures that involve human data, substances or subjects.

2. Non-Exempt Research.

The investigator must complete the IRB Cover Sheet and Protocol (available on the Gonzaga IRB website page) with relevant attachments, consent forms, etc., and submit electronically to the Gonzaga IRB via: IRBSubmission@gonzaga.edu.

(a) In the case of full IRB review, copies of the complete study forms with relevant attachments should be submitted four to six weeks prior to the next scheduled open meeting of the IRB. Principal investigators may be asked to attend the IRB meeting to respond to questions raised by the Board members. The PI will be notified at least two weeks in advance of their requested attendance, which he/she can do in person or via teleconference.

(b) In the case of request for IRB expedited review, a copy of the complete study forms with relevant attachments should be submitted four to six weeks prior to the desired date to commence research, in order to ensure that the IRB reviewers have a reasonable length of time review the protocol, and if deemed necessary, submit it to full IRB review.

(c) Human research approvals granted by the IRB are good for six months to one year from the date of approval (as indicated on the Gonzaga IRB approval or determination letter), unless substantial modification of the approved protocol requires an additional review.

Both investigators and reviewing bodies will endeavor in good faith to submit and respond to protocols in a timely manner so that research, that would otherwise be approved, shall not be jeopardized by the administrative constraints of the process. Exempt/Expedited

reviews at the IRB level should normally take less than two weeks. Full IRB reviews will take longer and are dependent on the meeting schedule of the IRB.

B. Gonzaga University IRB Reporting and Compliance Requirements

1. NOTICE OF IRB APPROVAL AND CONDITIONS

The PI must conduct this study in accordance with the description and information provided in the approved protocol, associated documents and IRB approval/determination letter.

2. APPROVAL PERIOD AND EXPIRATION DATE

The updated approval period for this note the expiration date. If the approval lapses, the PI may not conduct work on this study until appropriate approval has been reestablished, except as necessary to eliminate apparent immediate hazards to research subjects or others. Should the latter occur, the PI must notify the IRB as soon as possible. **The PI cannot use any data collected during a period of lapsed approval.**

Suspensions, holds (voluntary or involuntary) or terminations of this research by the institution, investigator, sponsor or any regulatory agencies should be reported immediately to the IRB.

3. APPROVED STUDY DOCUMENTS

The PI must use approved versions of recruitment materials, protocol forms and informed consent forms (ICFs). Approved materials should be dated the same date as the approval letter. This is in accordance with 45 CFR 46.111, IRB practice and processes to ensure accuracy and federal compliance.

4. RENEWAL/TERMINATION

Up to two months prior to the expiration date, the PI should submit a continuing review or study termination application either to renew or terminate the study. Failure to allow sufficient time for IRB review may result in a lapse of appropriate approval.

5. AMENDMENTS

All proposed changes to the study (e.g., personnel, procedures, or documents), must be approved in advance by the IRB through the amendment process, except as necessary to eliminate apparent immediate hazards to research subjects or others. Should the latter occur, the PI must notify the IRB Office as soon as possible, i.e. report a protocol deviation or violation.

6. ADVERSE EVENTS (AEs)

The PI must continue to inform the IRB of all unanticipated events, adverse events (AEs), and other reportable information and occurrences. These include but are not limited to events and/or information that may have physical, psychological, social, legal, or economic impact on the research subjects, research staff or others.

Investigators and research staff are responsible for reporting information concerning the approved research to the IRB in a timely fashion, and not implementing any changes to the

research without IRB approval of the change via an amendment submission. When changes are necessary to eliminate apparent immediate hazards to the subject, implement the change and report it via an amendment submission within (5-10 business days) days after the action is taken. This includes all information with the potential to impact the risk or benefit assessments of the research.

7. OTHER REPORTING REQUIREMENTS

Knowledge of any pending compliance inspection/visit by the Office for Human Research Protections, (OHRP), FDA, other government agency concerning this research; the issuance of inspection reports, FDA Form 483, warning letters, actions taken by any regulatory agencies including legal or medical actions; and any instances of serious or continuing noncompliance with the regulations or requirements must be reported immediately to the IRB.

8. GONZAGA IRB VISITS

The Gonzaga IRB can conduct investigator visits as part of its responsibility for research compliance oversight. Accurate and complete study records must be maintained and made available to representatives of the IRB as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.

C. Records Retention, Inspection and Copying

1. Research Records Retention

In accordance with the provisions under DHHS regulations, the University keeps and maintains systems of records and documentation (i.e., minutes, correspondence, approved consent documents, et al.) of IRB activities. IRB records relative to research funded by federal agencies or regulated federal offices are required to be retained for at least three years after completion of the research.

It is generally recommended that IRB and academic research records pertaining to children as subjects be kept for seven years after the children reach the age of majoring (18 in Washington) and for records pertaining to in vitro studies of pregnant women (25 years).

2. Inspection and Copying

The IRB records under federally-funded or regulated projects shall be accessible for inspection and copying by authorized representatives of DHHS/FDA and the federal sponsor at reasonable times and in a reasonable manner. In the case of projects funded by non-federal sponsors, IRB records shall be retained and be accessible for inspection and copying by the sponsor in accordance with applicable law and University policy.

D. Research Ethics & Compliance Audits

1. Gonzaga IRB Research Compliance Program (Audits)

The Research Compliance Program (RCP) is responsible for internal auditing of human research studies to monitor research compliance. The RCP helps assure that all research studies utilizing human subjects and/or human derived materials comply with federal, state and institutional regulations and policies to protect research subjects, the university and the research team.

GU requires ways to assure that there are procedures that monitor compliance with human research protection standards. Conducting study compliance assessments provides a way for meeting this requirement. The assessments are used to improve the quality of human research subject's protections program and to increase the awareness of regulatory compliance. The compliance reviews are intended to be proactive, non-punitive and focused on educating PIs and research staff of their ethical and regulatory responsibilities.

2. The Research Compliance Program (Audits) consists of

1) Routine Regulatory Audits ("not for cause" audits, e.g. QI audits, PI invitation audits)
2) GU IRB Internal Audits (quality control and process improvement)
3) Directed Audits ("for cause" audits)

Goals

- To ensure subject safety, verify accurate data collection, identify problem areas, and take corrective action when necessary.
- This process includes verifying eligibility and protocol and regulatory compliance according to GU policy, as well as the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) Regulations and Guidelines.
- To work closely with members of the GU community to improve the overall quality and standards of research, and to facilitate the application and approval process.

Audits are conducted in parallel, in as much as is possible, to the standards of the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) for accreditation preparation.

Audits are audits conducted, supervised, or verified by the Gonzaga University's IRB point of contact.

An "active" study is a study approved by and under continuing oversight from the GU Institutional Review Board (IRB), regardless of whether the study is "open" or "closed" to enrollment.

A "completed" study is a study for which oversight by the GU IRB has been concluded.

The informed consent document (ICF) audit requirement refers to the research ICFs required under federal regulation. Regardless of how research protocols and parts of research protocols are tracked or labeled by an IRB, "sub-studies" also constitute research that requires specific IRB approval of the "sub-study" protocol and informed consent, and RECOs are required to audit those sub-studies, and ICFs as described above.

Informed Consent (IC) Audits

Informed consent audits of all active human research studies performed require a confirmation of the approval status by the IRB, as well as a review of subjects' signed Informed Consent Forms (ICFs). All ICFs must be current IRB-approved versions and contain subject and PI signatures**.**

(a) Studies to be audited. All human research studies active at any time during the reporting period must receive an informed consent audit, regardless of whether any ICFs were required or signed during the reporting period.

(b) IRB Exempt studies. The informed consent audit requirement includes human studies determined to be Exempt from IRB oversight. The audit requirement for Exempt human research is fulfilled by verifying consent methods used in Exempt research, such as information sheets, written consent PI scripts, etc.

(c) Studies overseen by the IRB with no ICFs signed during this period.
If an active human study that has no ICFs signed during the period being audited, the audit requirement is fulfilled by confirming the current IRB-approved version, and subject and PI signatures. The reason there are no ICFs to audit should be noted. This may be because informed consent was waived by the IRB, or the *documentation* of informed consent was waived by the IRB, or because ICFs were approved but no subjects were consented during the period being audited. The auditor should also note whether continuing review of the study occurred as required GU IRB policy.

(d) ICFs to be audited.

i. Initial audits of studies must include all ICFs obtained since study initiation. Studies initiated during this period must have an informed consent audit during this period even if no subjects have yet been consented.
ii. Audits of studies that were audited previously must include all ICFs obtained since the previous audit.

(e) Records that will need to be reviewed may include but not be limited to regulatory files, versions of approved ICFs, individuals authorized to obtain consent, and subject lists.

Protocol Audits

Regulatory audits of human research studies should be performed at least every 3 years (i.e., triennially) for active non-Exempt studies that remain open. *Initial* audits should be no later than 3 years from initial approval.

(a) Audits required. Any active human research studies overseen by the IRB can receive at least one audit by the GU IRB point of contact. Auditors are allowed to add additional audit elements as needed, as long as audits include at a minimum all information on the GU audit tool.

(b) Records Reviewed. Records that will need to be reviewed may include, but not be limited to, case records, IRB files, the PI records, research team training records, and other research records.

(c) Circumstances where audits are not required. Regulatory audits of the following studies overseen by the IRB are not required, even at study closure:

i. Chart Review Studies. Once a protocol has had at least one regulatory audit, additional regulatory audits are not required for studies solely involving chart reviews.

ii. Studies in Data Analysis and/or Long-Term Follow up. Once a protocol has had at least one regulatory audit, additional regulatory audits are not required for studies that satisfy (i) or (ii) below:

a. Where 1) the research is permanently closed to the enrollment of new subjects; and 2) all subjects have completed all research-related interventions; and 3) the research remains active only for long-term follow-up of subjects; or
b. The remaining research activities are limited to data analysis.

(d) Abbreviated audits. If a human research study is opened and completed without enrolling any subjects, and before any audit is done, then the requirement for an audit may be satisfied in an abbreviated fashion by reviewing administrative data only.