

GONZAGA UNIVERSITY

Policy and Procedures* For the Protection of Human Subjects in Research

Part I: Policy

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 Report¹ of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and the Nuremberg Code². The three Belmont Principles have been summarized by the Office for Human Research Protection (OHRP), National Institutes of Health (NIH), as follows³:

"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."

* <http://www.gonzaga.edu/Campus-Resources/Offices-and-Services-A-Z/Academic-Vice-President/Institutional-Review-Board/>

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 Governmental Regulations and Policies to All Research

The following policy statements, definitions and procedures are in accord with the federally mandated requirements of 45CFR46 (*Code of Federal Regulations*) and constitute the basis of the University's Single Project Assurances filed as required with the Office for Human Research Protection (OHRP) of the Department of Health and Human Services (DHHS). *In the case of conflict between regulations of the funding or regulatory agency and DHHS, the more restrictive regulations 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 research involving human beings as subjects who are being investigated for any purpose other than solely for the benefit of the subject as an individual, shall be approved by the University's 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 research activity which involves human subjects, 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, and whether it involves minimal risk or more than minimal risk. **This includes course-related research projects, unless the instructor has obtained an exemption from the IRB.**

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.

2. Ultimately the responsibility for maintaining ethical standards and protecting human rights rests with the individual researcher (and in the case of Gonzaga students, their faculty research advisor). Responsibility for compliance with regulations rests with the Academic Vice President (AVP). The IRB is required as an added measure of reassurance and as a local resource for the interpretation of ethical guidelines. Any research involving human subjects must have associated with it a Responsible Project Investigator who is a qualified faculty member or a qualified staff member, and who will monitor and be liable for the conduct of the research.

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

5. Human subjects approval granted by the IRB are good for one year from the date of approval, unless substantial modification of the approved protocol has required a new review. Approval of exempt protocols, including exemptions for course-related research projects, is valid for five years from the date of approval, provided there is no modification of the originally approved study procedures.

6. "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 45CFR46.112)

7. In addition to compliance with federal and University procedures contained herein, projects involving human subjects whose protection is the responsibility of an agency other than Gonzaga University will also be subject to that agency's procedures.

C. Statement of Policy

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

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.

Any payment or other incentive provided to subjects should not be large enough to constitute excessive 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] No interventional biological research involving pregnant women or fetuses will be conducted at Gonzaga University.

(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 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 research involving human subjects, confidentiality of identifiable information is presumed and *must* be maintained unless the investigator obtains the express permission of the subject and/or parent/guardian 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 paper or electronic 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 project investigator and his or 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 their express written permission.

(e) Use of stored data or information, which were originally obtained for different purposes and which involves identifiable subjects, 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 subjects 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 research involving human subjects, 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. Categories of Review and Exemptions to Review

Research using human subjects can be divided into three review categories: Exempt, Expedited Review, and Full IRB Review.

1. Exempt Research

Based on applicable federal regulations and/or provisions of the University's Policy and Procedures, *investigators whose research involves human subjects will not make the final determination of exemption. Exemption 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 qualify for exemption. Exercise of such oversight will rarely be necessary. The requirements of sponsoring agencies, unexpected problems, 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 and does not include one of the 12 exceptions to the exemptions. (45CFR46.101(b), 1-6)

(a) 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.

(b) 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.

(c) 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.

(d) 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.

(e) 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.

(f) 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.⁷
 - Will the child participate in a survey?
 - Will the child be interviewed?
 - Will the investigator manipulate the environment or interact with the child as part of the data gathering?

Note: 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 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.
- If blood or body fluids will be drawn.

2. Non-Exempt Research

Non-exempt research is subject to one of two levels of review, either Expedited Review or Full IRB Review.

(a) Expedited Review

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 45CFR46.110 and 21CFR56.110. 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.

The 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.

IRBs 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 IRB review.

Research Categories

The following list of research activities (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 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 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. (Federal Register CFR 63:FR60364; Nov. 9, 1998; revised from CFR 46:8392; Jan. 26, 1981)

(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

All research not exempted 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 (see Decision Matrix).

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

This office shall be the administrative unit responsible for coordinating all reviews of research conducted with human subjects. The Director of Sponsored Research and Programs (SRP) shall be a member of the Institutional Review Board and shall be the Authorized Institutional Official whose responsibility is to ensure that the University will effectively fulfill its research oversight function.

The Sponsored Research and Programs office will be the office of record to prepare and maintain adequate documentation of IRB activities. Such documentation must include copies of all applications, research proposals reviewed, results, minutes of IRB meetings, records or continuing review activities, copies of all correspondence between the IRB and investigators, and statements of significant new findings provided to subjects.
[45CFR46.116(b)(5)]

2. The Institutional Review Board

The IRB will consist of a minimum of **seven** members. The IRB will try to select members from departments in the University that regularly conduct research that involves human subjects. In addition, departments that occasionally conduct or have the potential to conduct research that involves human subjects may be invited to provide a member as appropriate to their current interest. The Chair will be chosen from the IRB members. The chosen representative of Sponsored Research and Programs, as the Authorized Institutional Official, shall be a voting member of the IRB. Further, in accordance with federal policy requirements [45CFR46.107] , 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 the AVP, as well as kept with the IRB's records.
[45CFR46.103(b)(3) and § .115(a)(5)] Any changes in IRB membership must be reported to OHRP and AVP.

The responsibilities of the IRB shall be to review all research involving human subjects that is not exempt, 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 exempt research, the IRB will regularly notify the approval of such exemptions to the Academic Vice President.

(b) In the case of expedited review, the Chair of the IRB will review all applications along with one or more members as necessary from the IRB, each of whom in turn will serve in this reviewer capacity for a one month tenure. 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.

(c) In the case of full Board review, the IRB will hold an open meeting at least once per month as needed, to review all research neither exempt nor expedited. At such meetings a majority of the members of the IRB must be present, including at least one member whose primary concerns are in nonscientific areas. 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 proposals. 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.

Part II: Procedures

A. Submission of Proposals

Written approval from the IRB *must* be received by the investigator *before* the research is begun.

1. Exempt Research. The investigator should complete the Application for Exemption (available on the IRB webpage) and submit a copy to the IRB (through the office of the Academic Vice President). 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 subjects. Approval of exempt protocols is valid for five years from the date of approval, barring any changes in the originally approved study procedures.

2. Non-Exempt Research. The investigator must complete the Application for IRB Review (available from the chair of the IRB or IRB webpage) with relevant attachments and submit the required number of copies to the chair of the IRB.

(a) In the case of full IRB review, one hard copy and an electronic copy of this complete form with relevant attachments should be submitted to the chair of the IRB two weeks prior to the next scheduled open meeting of the University IRB. Principal investigators may attend the IRB meeting to respond to questions raised by the Board members.

(b) In the case of request for IRB expedited review, one hard copy and an electronic copy of this complete form with relevant attachments should be submitted sufficiently in advance of the desired date to begin research that the IRB reviewers have a reasonable length of time to respond to the proposal and, if deemed necessary, submit it to full IRB review.

(c) Human subjects approvals granted by the IRB are good for one year from the date of approval.

Both investigators and reviewing bodies will endeavor in good faith to submit and respond to proposals in a timely manner so that research, that would otherwise be approved, shall not be jeopardized by the administrative constraints of the process. Exempt and expedited reviews at the IRB level should normally take less than a week. Full IRB reviews will take longer and are dependent on the meeting schedule of the IRB.

B. Changes in Protocols

1. If, subsequent to initial approval, a research protocol requires minor changes, the chair of the IRB should be notified of those changes prior to their implementation.

2. Any major departures from the original proposal must be approved by the appropriate review process before the protocol may be altered. An application for Change of Protocol must be submitted to the IRB for any change in the protocol (change of protocol available on the IRB webpage). The Chair of the IRB will determine whether or not the research must then be resubmitted for approval.

C. Annual Renewals

If research is to continue, with no substantial changes, beyond the term for which it has been approved, an application for Renewal of Approval (available from the IRB webpage) must be obtained prior to continuation of the project.

D. Records Retention, Inspection and Copying

1. 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 by FDA are generally 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 majority (18 years 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.

Attachments:

Human Subjects Regulations Decision Charts

<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>

Application for IRB Review, Application for Change of Protocol, Application for Exemption, and Application for Renewal of Approval are all available on the Gonzaga University IRB webpage at:

<http://www.gonzaga.edu/Campus-Resources/Offices-and-Services-A-Z/Academic-Vice-President/Institutional-Review-Board/>