BGU | BAKKE GRADUATE UNIVERSITY

2021-22

Institutional Review Board Policies & Procedures

Bakke Graduate University
strengthens leaders who steward resources
with and for vulnerable people and places,
by means of contextual, Christian-based education
innovatively delivered throughout the urban world.

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Some sections of this manual were adapted with permission from the IRB Handbook of Azusa Pacific University in Azusa, California

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The information contained in pages 1 through 25 of this document is required by BGU's accreditation association, TRACS. The "Core Appendices" is a separate document that provides much more detail about the topics lightly touched on in this first section about BGU, which can be found by going to BGU's online library in Populi or

https://www.bgu.edu/students/handbooks-catalogs/

WHO IS BGU?

History

Originally founded in 1990 under the name Northwest Graduate School of the Ministry (NWGS), Bakke Graduate University (hereinafter BGU or "the university") provides graduate level leadership education focusing on rigorous academics, immediately practical application, and involving a global constituency of faculty and students. BGU is accredited through the Transnational Association of Christian Colleges and Schools (TRACS) and is fully recognized by the US Department of Education. BGU has earned a strong reputation within academic Christian service, and business organizations.

During the last fifteen years, BGU has journeyed from its founding identity as a one-church based educational organization faithfully serving the Northwest United States to its current role as the school of choice for international urban leaders on five continents. This network was originally assembled as young leaders under the urban track of the Lausanne movement in the 1980s and was called the Lausanne Urban Associates. As Lausanne ended this initiative in the late 1980s, these same leaders and more were reassembled by Dr. Ray Bakke through the International Urban Associates (IUA). Now, this growing, global, urban network of leaders has acknowledged and responded to a strong need for a unifying educational experience that prepares and equips them for transformational work in a global world. BGU's strategic plan outlines the ways in which it is responding to this educational opportunity for expanded excellence in the sphere of Christian service while charting a path of outstanding stewardship and solid business practices. (See BGU Core Appendices-*Appendix 1* for a more detailed history of BGU, which can be found by going to BGU's online library in Populi or https://www.bgu.edu/students/handbooks-catalogs/.)

Mission Statement

BGU's mission statement is as follows:

> Bakke Graduate University strengthens leaders who steward resources with and for vulnerable people and places, by means of contextual, Christian-based education innovatively delivered throughout the urban world.

Accreditation

Bakke Graduate University is a member of the Transnational Association of Christian Colleges and Schools (TRACS) having been awarded Reaffirmed Status as a Category III and IV

Institution by the TRACS Accreditation Commission on April 21, 2020; this status is effective for a period of ten years (Licensed until April 2030). TRACS is recognized by the United States Department of Education (USDE), the Council for Higher Education Accreditation (CHEA) and the International Network for Quality Assurance Agencies in Higher Education (INQAAHE).

Transnational Association of
Christian Colleges and Schools (TRACS)
15935 Forest Road, Forest, VA 24551
Phone: 434-525-9539; Fax: 434-525-9538
info@tracs.org; www.tracs.org

Government Agency Approvals

Selected academic programs of study at BGU are approved by the Texas Higher Education Coordinating Board for enrollment of those eligible to receive benefits under Title 38 and Title 10, U.S. Code. Veterans of United States armed services organizations should contact the Student Finance Coordinator to ensure proper documentation is presented and information is adequately communicated to the Veteran Affairs Office. Students participating in joint degrees that are the result of an agreement between BGU and an international school are not eligible for Veteran benefits.

Faith Statement

BGU was founded as a non-denominational Christian university. Doctrinally, the institution stands for the fundamentals of the faith as taught in the Christian Scriptures and handed down through the centuries by the Church. Consistent with this purpose, the faculty and directors of BGU acknowledge the creeds of the early church and the confessions of the Protestant communions to which they severally belong. BGU explicitly affirms the classic ecumenical creeds, the Nicene Creed, the Apostles' Creed, and, the more recent evangelical confession known as the Lausanne Covenant (BGU Core Appendices-*Appendix 2*, hereinafter referred to as "the Statement of Faith"). The Board of Directors, full-time faculty and staff as well as students are invited annually to affirm BGU's Statement of Faith.

Vision

BGU looks beyond itself to embody the commonly-held vision of an international network. BGU serves and is served by a large international network of urban leaders, and its vision is shaped by these networks and partners. The vision of BGU includes the following key components (for full descriptions, see BGU Core Appendices-*Appendix 3*):

1. Served by and Serving Emerging and Experienced Transformational Leaders
2. Proclaiming the Whole Gospel, through the Whole Church, to the Whole World
3. Kingdom Sharing
4. Bible-based Perspective and Values Education
5. Accessibility to Life-Long Learning for Global Christian Leaders
6. Web-based Educational Services

Institutional Objectives

The institutional objectives for BGU are as follows (for a full description of each, see BGU Core Appendices-*Appendix 4*):

1. **Spiritual Formation**: This university will help a student have increased trust in God, while dynamically developing and stewarding its partnerships and networks.
2. **Perspective**: Shifts in worldview, mindset, new ways of seeing themselves and God, will result as the BGU 8 perspectives are integrated in students' lives and outreach/influence.
3. **Knowledge**: Prophetically disruptive and ethically sound knowledge is needed to accomplish Spiritual Formation and Perspective Transformation.
4. **Skills**: Hands-on leadership-related skills are taught, demonstrated and evaluated throughout BGU's academic and non-academic services to students.
5. **Application**: BGU students apply their learning in their life and work during their studies and after they graduate, while expanding their own partnerships and networks and becoming increasingly Christ-like.

Overall Objectives

The overall objectives for all BGU's programs (for full description, see BGU Core Appendices-*Appendix 5*):

1. Deliver Practical Ministry Instruction
2. Deliver Biblically-Based Curricula
3. Provide a Faculty Composed of Successful Global Practitioners
4. Deliver through an Adult Learning Educational Approach
5. Instill in Students a Recognition of the Diversity of the Church
6. Provide Leadership Training to Build the Local Church within a Global Perspective
7. Instill in Students the Reality of Globalization

Educational Values & Philosophy of Engagement

The educational values and philosophy of BGU form the guidelines of how BGU will develop courses, form networks, select students, faculty, and staff, while pursuing its unique approach to graduate education. BGU is a community formed around spiritual reflection, authentic relationships, and sacrificial service. It is an accredited higher educational institution committed to developing incarnational servant leaders who are intentional instruments of God in their communities and workplaces. BGU collaborates with an emerging global network of organizations, churches, and schools to develop transformational leaders who seek peace in their cities worldwide. For a complete list of these values, see BGU Core Appendices-*Appendix 6*.

Core Values

BGU's Core values are as follows (for full details, see BGU Core Appendices-*Appendix 7*):

1. Passion
2. Celebration

3. Respect
4. Integrity
5. Community

Ministry & Educational Philosophy

Practical Ministry Philosophy Based on Mentoring

The courses of Bakke Graduate University (BGU) are taught by seasoned instructors who are academically qualified and currently engaged in practicing what they teach. The instruction provided in the classroom is based on principles of *"modeling"* and *"mentoring."* As in other professional fields, such as law or medicine, Christian practitioners who are being trained for Christian leadership benefit from practicing *"mentors"* who teach not only from a textbook but from a life of experiences. BGU's instructors have proven track records in leading effective ministries or professions, and therefore teach from a practical as well as from an academic viewpoint. The doctoral and master's degrees are designed so that Christian practitioners will accomplish significant academic growth while grounded in very real practice. The goal of BGU is to stretch, challenge and equip its students to be transformational leaders in the global context.

Academic Program Based on Biblical Foundations

The educational philosophy of BGU emphasizes the equipping of individuals for effective ministry as well as providing a sound biblical framework within which all service must take place. *All courses are taught from a biblical perspective and are Christ-centered*. The Bible is recognized as the primary and authoritative Christian text for all Christian faith and practice. Therefore, the various forms of ministry taught at BGU are defined and evaluated according to biblical descriptions. It is also recognized that all Christian service occurs within a specific cultural environment. Therefore, the content of the curricula is continually evaluated and adjusted to ensure that biblically-defined leadership principles are applied in forms which are culturally relevant to society.

The educational philosophy of BGU also focuses on the nature of the church and the formation of a biblical self-identity for pastors and professional leaders. The curriculum assumes that the Great Commission of Matthew 28:19-20 and the Great Commandment of Matthew 22:35-40 are the standards by which all service is to be measured.

Health & Security

BGU strives to ensure the health and safety of its staff, faculty, and students according to and beyond relevant state and federal requirements. BGU Core Appendices-*Appendix 8* provides a list of emergency procedures that are applicable in its Dallas, Texas, office and classrooms.

Community Standards of Conduct

BGU's desire is to create an environment that is restorative and redemptive. Therefore, with the help of the Holy Spirit, Board members, students, administrators, faculty and staff strive to live lives that reflect the Kingdom values expressed in the Community Standards of Conduct. However, violations of the expressed principles and policies described in this document and in the Lausanne Covenant may result in disciplinary action up to and including dismissal or termination. These standards include:

1. Statement on Academic Freedom
2. Statement on Academic Integrity
3. Statement on Christian Conduct
4. Statement on Non-Discrimination
5. Statement on Harassment
6. Statement on Respect for People and Property
7. Statement on Substance Abuse

For a detailed description of these standards, please see BGU Core Appendices-*Appendix 9*.

Complaint Procedures

The Texas Higher Education Coordinating Board (THECB) adopted rules codified under Title 19 of the Texas Administrative Code, Sections 1.110 – 1.120, on October 25, 2012. These rules create a student complaint procedure to comply with the U.S. Department of Education's "Program Integrity" regulations, which require each state to have a student complaint procedure in order for public and private higher education institutions to be eligible for federal Title IV funds. In December 2011, the Office of Attorney General of Texas issued an opinion stating that THECB has authority under Texas Education Code Section 61.031 to promulgate procedures for handling student complaints concerning higher education institutions. For details about this procedure, please see BGU Core Appendices-*Appendix 10*.

Fraud, Abuse, & Accurate Representation

BGU is committed to maintaining an educational entity that is not involved in any form of fraud or abuse, and will not support practices or procedures that are designed to deceive students or falsify information to students. BGU proactively investigates and resolves all complaints and other reports or findings that raise suspicion of fraud and/or abuse. Such cases and findings are reported to external regulatory and law enforcement agencies as required by law and contract. Following receipt of the complaint/fraud and abuse referral, the process for dealing with complaints is explained in BGU Core Appendices-*Appendix 10*. BGU is committed to accurately represent itself to the public in all of its publications, its website, its classrooms, and any communications with others.

Academic Services

BGU Website

BGU's website contains a section devoted to Student Resources which include:

- Downloadable documents (https://www.bgu.edu/students/downloadable-documents/).
- Handbooks & Catalogs (https://www.bgu.edu/students/handbooks-catalogs/).
- Graduation Information (https://www.bgu.edu/students/graduation-information/).

- Title IX Information (https://bgu.edu/students/student-resources/standards-of-conduct-clery/title-ix)
- Standards of Conduct/Clery (https://bgu.edu/students/student-resources/standards-of-conduct-clery)

Orientation

BGU has created an Orientation Packet for every incoming student. In addition to links to welcoming videos from the BGU President, Academic Dean, Registrar, and program directors, this packet contains numerous instructional videos for assistance in writing, formatting papers, etc. In addition, BGU provides synchronous orientation sessions each term regarding online learning and resources that are recorded and made available to all students. Each faculty, at the beginning of a course, also provides an introductory synchronous course orientation session that is recorded and made available to all students enrolled in the course. (See BGU Core Appendices-*Appendix 11* for the Orientation Packet.)

Writing Assistance

BGU has purchased Unicheck, a plagiarism checker that has been incorporated into Populi. When documents are uploaded into the online classroom, Unicheck will immediately show quoted materials that have not use quotation marks or proper citations.

BGU also has created a free writing certificate "course" that can assist students in learning to write academically (especially important for students for whom English is a second language). To register for this free course, students can contact BGU's eLearning Team. Students are also provided with numerous writing resources through the Writing Center.

Library/Learning Resources

BGU offers its students a variety of alternatives for accessing books and research materials for courses and as preparation for their final projects. The onsite Library that is located at BGU's Dallas Office contains over 4,000 volumes. There is a collection of dissertations and theses produced by BGU graduating students and there are also other research resources available to students. The library collection is cataloged and indexed and a searchable database can be accessed on any of the computers provided in the library. The computers are also available in BGU's Dallas Office for student use to gain access to online search engines and for internet research.

BGU's main online library of over 5,000 volumes is made available to every student regardless of location in an online format. This library contains a rich collection of research guides and resources, and eBooks for social sciences, business, and theology. The Online Library is overseen by a MLS Librarian, Jennifer Roman (Jennifer.Roman@bgu.edu) who is available to assist students with in-depth research, search strategies, referral, and reference questions. The Online Library also provides guidance on academic writing, citation styles, and paper formatting, and provides a portal for students to express feedback and contribute suggestions on additional resources for the Online Library. Students also have off-campus access to the ProQuest® databases, which include ProQuest Religion, the ProQuest Business Research Library and the ProQuest Newsstand of national newspapers including the Christian Science Monitor. The ProQuest Databases can be found in the Research Guide section of the Online Library. For a

nominal fee, students can register with the Society of Christian Scholars (www.scshub.net) and have access to the EBSCO Religion and Social Sciences Library.

Online Mentoring

BGU's Online Mentoring allows students the opportunity to meet with an academic advisor/mentor in group and individual settings to discuss their degree roadmap and enjoy prayer, counseling, coaching, and ongoing encouragement using either phone, Skype, Zoom, or other video technology.

BGU Online Helpdesk

BGU's Helpdesk is available to all students for easy access to Frequently-Asked Questions as well as access to technical support staff for questions, consultations, tutorials, and feedback. The Helpdesk is available Monday through Saturday, honoring Sunday as a Sabbath day.

Office of the Registrar

The Registrar's Office arranges course schedules, receives and processes student admission applications and course registrations, and maintains a repository of academic records. Students should contact the Registrar for official and un-official transcripts, registration information, financial account questions, issues concerning grades, and any other inquiries related to student records. Appointments may be scheduled for advisement on course schedules, class registration, etc., by contacting the Registrar via email at Registrar@bgu.edu.

Counseling and Advising Appointments

Upon admission, each student is assigned a specific advisor. The role of the advisor is to guide the student to make the best academic choices for the development of his/her degree and to ensure the student's best integration and growth with BGU. It is the advisor's responsibility to contact his/her advisee at least once a month. Students are required to keep appointments with that advisor throughout the course of their degree programs. To schedule an advising appointment, students may contact BGU at (214) 329-4447, or via email. For students who are unable to attend an appointment in person, a phone/Skype appointment will be scheduled. In addition to the Program Director of the student, the Director of Student Services (Ms. Kafi Carrasco) and Director of Spiritual Formation (Dr. Nita Kotiuga), the following staff and/or faculty members are also available for advising appointments:

Doctoral Degree Students	
Prospective Students:	Kafi Carrasco (ext. 122; Kafi.Carrasco@bgu.edu)
Admission Procedures:	Kafi Carrasco (ext. 122; Kafi.Carrasco@bgu.edu)
General Academic Questions:	Martine Audeoud (ext. 135; Martine.Audeoud@bgu.edu)
General Academic Advisor:	Martine Audeoud (ext. 135; Martine.Audeoud@bgu.edu)
Doctoral Final Project:	Bill Payne (ext. 137; Bill.Payne@bgu.edu)
Master's Degree Students	
Prospective Students:	Kafi Carrasco (ext. 122; Kafi.Carrasco@bgu.edu)
Admission Procedures:	Kafi Carrasco (ext. 122; Kafi.Carrasco@bgu.edu)
General Academic Questions:	Martine Audeoud (ext. 135; Martine.Audeoud@bgu.edu)
General Academic Advisor:	Martine Audeoud (ext. 135; Martine.Audeoud@bgu.edu)
Master's Final Project	Yvonne McKenzie (ext. 134; Yvonne.McKenzie@bgu.edu)
Capstone Project (EMBA)	Lynn Jackson (Lynn.Jackson@bgu.edu)

Admission Policies

Admissions Standards

BGU graduate programs have a unique focus on global urban leadership realities. The university is committed to the equipping of transformational leaders in business or various forms of Christian service. BGU not only seeks to strengthen those who come with traditional academic qualifications but also those who lead effective transformational organizations and who have a proven record of leadership without a traditional academic background. In many settings, both internationally and nationally, leaders have not had adequate access to educational opportunities. Non-Western and non-formal qualitative learning is given considerable value at BGU. Based on these convictions, BGU encourages transformational leaders worldwide to apply for its graduate programs. Each applicant will be evaluated on his/her merit and will receive a recommendation from the Academic Dean, in consultation with the Academic Cabinet, regarding the most appropriate academic program. Students who are re-entering a BGU program after having gone away for several years need to fill the Special Program Extension Request sheet with new PLCs that will be presented to and approved by the AC. For specific standards, please see BGU Core Appendices-*Appendix 12*.

Student Status Classifications

The status of students at BGU are classified under various classifications, ranging from full-time, to part-time, auditors, and educational experiences. For a complete list and definition of each, please see BGU Core Appendices-*Appendix 13*.

Transfer Credit Policy

If students have accumulated credits from other academic institutions that they believe may be applicable to their BGU degree, they may petition the Academic Dean at the time of admission for transfer of those credits (advanced standing). The Academic Dean, in consultation with the Academic Cabinet, may approve a transfer of a maximum of 50% of the total required credits in the degree program. For the complete process, please refer to BGU Core Appendices-*Appendix 14*.

Admission Requirements & Procedures

Admission to any of the master's programs or doctoral programs at BGU is based on a selection process conducted by the Academic Dean, in consultation with the Academic Cabinet. The Academic Cabinet reviews each application thoroughly to determine the applicant's qualifications, as well as compatibility of the university programs to the applicant's educational goals. The applicant will then be approved by the Academic Dean, in consultation with the Academic Cabinet after all required application materials have been received by the university. For the step-by-step process, please refer to BGU Core Appendices-*Appendix 15*.

Personal Learning Community

BGU attributes much of its students' educational success to what is called the "Personal Learning Community" (or PLC). Students create a PLC by identifying three to five individuals who agree to support the student during the course of his/her studies. The admissions process includes the requirement that a minimum of three PLC members must be identified, each of whom shall submit a completed PLC Agreement to BGU before an applicant will be considered for acceptance. The PLC can be close friends, co-workers, pastors, spouse, children, etc., each of

whom will be asked to read assignments, provide periodic evaluations, and assist the student in staying accountable to completing their degree. For a description of the specific requirements of the PLC, see BGU Core Appendices-*Appendix 16*.

English Language Proficiency

Each student must demonstrate English-proficiency by: (1) showing that English is his/her native language, or (2) by having successfully completed an undergraduate or graduate school program in which English is the primary method of instruction, or (3) exhibiting sufficient English-language capabilities to succeed in the classroom and in BGU programs as measured by a score of not less than 80 on the internet-based TOEFL or TOEFL-equivalent exams taken within the last five years. As an alternative to the TOEFL, BGU will accept the IELTS (International English Language Testing System) if a student has scored 6.5 or better, or a copy of the certificate that is awarded at the completion of the Total Immersion Program (TIP). Applicants who can fulfill the qualifications may submit a TOEFL Waiver Request with their application.

Students who are taking the TOEFL test should use BGU's code number of **0709** so BGU will receive the final score directly from the testing agency. For on-line information about TOEFL testing locations and practice tests go to www.ets.org/toefl.

Minimum Technology Requirements

Since *every* BGU course includes participation via the internet, the minimum requirements for participating in courses for both students and professors include:

1. For email attachments: with dial-up connection a 1MB file can take 10 minutes to download.
2. For rich content web pages: dial up (54KB) will be able to load but it will take a while. If document contains a number of embedded images and media, 512KB will be sufficient.
3. For Audio Steaming: at least 128 KB for Web Conferencing (video with low resolution/quality options): 900KB for two-person video session, higher for more participants. For better quality: 3.5 MB-10 MB for streaming video.
4. For student to be fully visible and audibly present in online interactions/classes: the use of a webcam and good microphone speakers is recommended.

International Students

The term "international student" is used at BGU to denote both internationals who attend courses in the United States on visas, as well as those who are legal, permanent residents of the United States. BGU is not authorized to issue visa documents for the F-1 Student Visa.

Admission as Special Student

An applicant who does not meet the admission requirements of an individual degree is admitted under "Special Student Status" (SSS). Persons who are interested in applying to a degree program under SSS are asked to complete the online application and to provide official or unofficial transcripts and a current CV or resume to the Admissions Office for preliminary review. The applicant is also asked to fill out an equivalency worksheet if they have not graduated with the requisite degree. This worksheet will assist the Academic Dean in determining whether the courses and work previously completed are of a sufficient quality and quantity to be considered for SSS before the applicant is presented to the Academic Cabinet. The Academic Dean will recommend the path of either a degree completion program elsewhere or

admission under SSS. The Academic Dean's recommendation of potential eligibility is required in order to be permitted to continue the SSS application process. BGU allows a maximum of 15% of its student body to be classified as SSS. In the event an applicant requires admission under SSS and BGU already has reached the 15% maximum of its enrollment designated as SSS, the applicant will be required to wait one or two terms until an opening occurs before being admitted.

Students under SSS who do not maintain Satisfactory Academic Progress (SAP) or who do not complete any courses for a period of one year or more will be automatically withdrawn. Students admitted under SSS will be required to take a minimum of two 4-credit (or 3-credit for MA) courses per year and maintain a 3.0 GPA. If the student is unable to take two courses per year, they will be placed on a leave of absence and removed from SSS. If and when they return to active student status and there are no SSS slots available, the student will be placed on a waiting list and will only be allowed to take courses once they are reinstated to SSS. Once the student has successfully completed two courses, they will be removed from SSS. For more details, see BGU Core Appendices-*Appendix 17*.

Admission with a Degree-Completion Program

Qualified applicants who are studying in a BGU-approved degree-completion program at the bachelor-degree level and who have one year or less remaining in that program may apply for a BGU master's degree program. Applicants may be accepted "pending bachelor's degree completion." Upon acceptance, students will then be eligible to take up to two courses prior to the Registrar's receipt of their final official transcripts.

Special Needs Policy

The Americans with Disabilities Act (ADA) of 1990 and Section 504 of the Rehabilitation Act of 1973 mandate equal opportunities for students to participate in or benefit from the services offered by BGU. As such, BGU endeavors to respond to the special needs of students with disabilities. Ramps and elevators provide access to BGU's Dallas, Texas, offices and classrooms. Special efforts are made to schedule classes in facilities that are accessible, and parking places are reserved in all campus parking areas.

A qualified individual under the ADA must have a physical or mental impairment which substantially limits one or more major life activities. Major life activities involve caring for oneself, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working.

A qualified student with a disability must meet the academic and technical standards required for admission or participation in an education program or activity. It is the responsibility of the student to make his/her needs known in a timely manner to the Director of Student Services of BGU. Reviewing and granting accommodation for special needs can take up to eight weeks, so students should ensure timely processing of his/her needs by communicating in writing the type of accommodations as soon as possible.

Students reading in English for whom English is a second language (ESL) may read or write 25% slower than what is required of English-speaking students. Students who are reading or writing in Chinese should calculate that 10 pages of English are equal to seven pages of Chinese.

Financial Policies

Tuition and Fees

BGU seeks to provide excellence in education, while keeping costs as reasonable as possible. Student tuition and fees cover only a portion of the total operating costs of the university. The charges listed are effective as of July 1, 2020, and are subject to change without notice. Tuition and fees will change periodically and students are *required to pay the rates in effect at the time each course is held*. It is incumbent upon the student to verify current rates. All amounts are quoted in US Dollars. Check BGU's website for Administrative Fee for specific classes, which varies for each course. For a list of all tuition and fees, see BGU Core Appendices-*Appendix 18*.

Course Registration

Course tuition and fees are due 14 days prior to the first day of the on-line portion of the course. Students who have not made payment or arranged for a payment plan will have a "Financial Lock" added to their account until the above-mentioned arrangements are made with BGU's Financial Department. Students will not be allowed to take classes unless their accounts are paid in full or they have a payment plan in place on which they are current. The Administrative Fee is due at the same time as tuition except for city immersion courses. The Onsite Administrative Fees for city immersion courses are due six weeks prior to the onsite portion of the course and are, for the most part, non-refundable.

Those who attend a city immersion but fail to complete all assignments by agreed-upon deadlines will forfeit all tuition and fees. If the course tuition was not yet paid in full, the student's account will be assessed for all course tuition and fees, if applicable.

Refund Policy

Courses require considerable advance preparation and expense by the university based on student registrations and deposits. Therefore, the following refund policies are enforced, based upon when a student withdraws from a course in relation to the course starting date. For the full refund policy, see BGU Core Appendices-*Appendix 19*.

Course Extensions

A student may apply for a 1-month extension due to extenuating circumstances as long as 80% of the coursework has already been completed. The extension request must be signed by the POR and submitted to the Registrar's Office. If the student is unable to complete the work by the 1-month extension due date, the student may submit a special extension request for extenuating circumstances for five more months (for a maximum of six months from the original due date). Whether or not the student has filed a request for extension, the student account will automatically be charged $50 per month starting the second month of the extension taken. The student may not start another course until all work from past courses are completed.

Financial Aid

BGU understands the financial stress that can result from the pursuit of graduate-level education. To help ease that burden, BGU has sought to identify various financial aid opportunities for qualified students wishing to attend BGU, but who do not have the financial resources to do so. BGU's hope is that these resources and financial aid packages will help you move forward with your educational goals. For more details about financial aid, see BGU Core

Appendices-*Appendix 20*. For information about Title IV funding, see BGU Core Appendices-*Appendix 21*.

Financial Appeals Process

If a student feels that his/her situation warrants an exception to the financial policies or regulations, he or she is encouraged to file a written appeal to the Registrar for consideration by the Academic Dean, in consultation with the Academic Cabinet. The Office of the Registrar will be responsible for investigating the circumstances of the appeal and making a report to the Academic Dean for final resolution at the next Cabinet meeting.

Academic Policies

Identity Verification in Distance Learning

BGU's identity verification policy applies to all credit-bearing distance education courses or programs offered by BGU, beginning with the application for admission and continuing through to a student's graduation, transfer, or withdrawal from study. The purpose of this policy is to ensure that BGU operates in compliance with the provisions of the United States Federal Higher Education Opportunity Act (HEOA) concerning the verification of student identity in distance education.

The HEOA requires that institutions offering distance education courses or programs have processes in place to ensure that the student registering for a course is the same student who participates in the course or receives course credit. For more details, see BGU Core Appendices-*Appendix 22*.

Student's Right to Know Act

The Student Right-to-Know Act, passed by Congress in 1990, requires for institutions eligible for Title IV funding, under the Higher Education Act of 1965, to calculate completion or graduation rates of certificate- or degree-seeking, full-time students entering that institution, and to disclose these rates to current and prospective students. Since Bakke Graduate University (BGU) is an institution that participates in a Title IV program it is required to disclose graduation/completion rates of all students by race/ethnicity, gender and by sport (not applicable), and the average completion or graduation rate for the four most recent years. To read more about the Student Right-to-Know Act, please visit the National Center for Education Statistics website at http://nces.ed.gov and see BGU Core Appendices-*Appendix 23* for the updated version of BGU's graduation rates.

Student Privacy (FERPA)

The Family Educational Rights and Privacy Act (FERPA) is a federal law that protects the privacy of personally identifiable information contained in a student's educational record. FERPA applies to all schools that receive funds under various programs from the U.S. Department of Education. See BGU Core Appendices-*Appendix 24.*

Correspondence Courses

The Federal definition of correspondence education is "education provided through one or more courses by an institution under which the institution provides instructional materials by mail or electronic transmission, including examinations on the materials, to students who are separated from the instructor; interaction between the instructor and the student is limited, is not regular and substantive, and is primarily initiated by the student; correspondence courses are typically self-paced; and correspondence education is not distance education." No correspondence courses are available to BGU students other than the independent and directed studies mentioned above.

Online Courses/Distance Education

The Federal definition of Distance Education is "education that uses one or more of the technologies listed to deliver instruction to students who are separated from the instructor and to support regular and substantive interaction between the students and the instructor, either synchronously or asynchronously. The technologies may include the internet; one-way and two-way transmissions through open broadcast, closed circuit, cable, microwave, broadband lines, fiber optics, satellite, or wireless communications devices; audio conferencing; or video cassettes, DVDs, and CD-ROMS, if used in a course in conjunction with any of the technologies listed above."

All of BGU's courses include an online component and most courses are completely online. The Populi online software is BGU's Learning Management System (LMS). The minimum requirement for BGU's courses is a computer and reliable access to the Internet, which is the same requirement for all courses for all students. Students register for online courses just as they register for hybrid courses in Populi. The student will be required to participate in both synchronous and asynchronous class interactions, which include online discussions, real-time virtual classroom sessions, readings, and other requirements which, if not fulfilled, will result in a lower grade, as described in the syllabus for each course. Students and professors are required to be in direct and substantive communication on a weekly basis throughout the course.

Independent or Directed Studies

Students may include a maximum twelve credits of Independent or Directed Studies courses in their program. Any exception to this policy must be approved by the Academic Dean, in consultation with the Academic Cabinet. An Independent Study is defined as a course that the student designs with the assistance of a supervisor. A Directed Study generally includes the student's participation in a seminar or conference and regular scheduled interaction with the professor. See BGU Core Appendices-*Appendix 25* for details.

Changing Course Credits

A student can only be allowed to increase or decrease the number of credits for a course upon review and agreement of the Academic Dean. A student can only double a course's credits twice in the course of a program.

Course Requirements

BGU's degree programs include fully online courses as well as hybrid courses that combine online components with face-to-face urban immersions, local cohorts and mentors. Urban immersions are held in various large cities on five continents and all travel expenses are

the responsibility of the student. BGU has strict attendance policies, reading, assignments, and projects. For a full description of these requirements, see BGU Core Appendices-*Appendix 26.*

Grading Policies

Course grades are submitted by the instructor to the Registrar's Office approximately two to four weeks following the date the students submit their projects. Final grades are based upon the course syllabus. Any grade below a 2.67 or B- will not be considered passing. Students must maintain an overall minimum 3.00 GPA to graduate. Students receiving a low course grade may invoke a one-time opportunity to resubmit their assignments. The student must then re-submit the revised project or assignments within 30 days of receiving the final grade and pay an additional $100 to have the work re-graded. After the re-submission, the grade may be changed at the discretion of the course instructor or academic dean if warranted by an improved project and/or assignment. Grade points are calculated by multiplying the grade numerical value by the number of credit hours for a class. Grade Point Average (GPA) is calculated by dividing the total grade points by the total accumulated credit hours. (See BGU Core Appendices-*Appendix 27* the Grading Scale.)

Grading Rubrics

BGU has designed grading rubrics that shall be used by all professors in determining the grades for all student projects, online interaction, journals, etc. Rubrics are loaded into every course in Populi, BGU's LMS, under "Files." To see those rubrics in BGU's online library, go to: https://bgu.populiweb.com/library/resource.php?resourceID=11175577

Credit Hour Definition

The Federal definition of a credit hour is as follows: "A credit hour for Federal purposes is an institutionally established equivalency that reasonably approximates some minimum amount of student work reflective of the amount of worked expected in a Carnegie unit: key phrases being 'institutionally established,' 'equivalency,' 'reasonable approximate,' and 'minimum amount.'" For graduate-level work, one credit hour for BGU students is defined by the academic work consisting of professor instructions, reading assignments, group projects, class presentations, and independent project work and is equivalent to a minimum of 45 hours of work. Each degree program defines how many credit hours are needed to earn the degree.

Satisfactory Academic Progress (SAP)

All students must meet the following standards of academic achievement to be classified as students in Good Standing. The qualitative standard requires the student to achieve and maintain a minimum overall or cumulative grade point average of 3.0 for the entirety of the program. The quantitative standard requires all students to complete their program of study within the normal time frame for completing the program. For details about how BGU determines SAP, academic probation, and dismissal, see BGU Core Appendices-*Appendix 29.*

Degree Program Duration and Time Limits

A maximum of seven (7) years and minimum of three (3) years will be allowed to complete a BGU degree. The time limit will begin on the student's acceptance date. An extension may be granted, at the discretion of the Academic Dean, in consultation with the Academic Cabinet, if the student demonstrates steady progress toward degree completion and

has a legitimate need for more time. Extensions must be requested in writing to the Registrar's Office explaining the extenuating circumstances and providing a projected completion date.

Withdrawal from the University

The following will result in a student being moved to withdrawn status: failing to request extensions for homework that is more than six months overdue, being inactive for more than 12 months and have not responded to any BGU communications, or requesting withdrawal. Students requesting a withdrawal should submit an Exit Interview to the Registrar's Office and the Academic Dean or the Registrar will seek to hold a face-to-face exit interview with that student (to obtain this document go to https://www.bgu.edu/students/downloadable-documents/). Maintaining an outstanding balance for over a year without contacting BGU to set up a payment plan will also result in the student's withdrawal. Prior to a withdrawal for financial reasons, at least three attempts to contact the student about the pending action will be made, over a period of at least two months.

Reinstatement of Withdrawn Students

A maximum of seven (7) years and minimum of three (3) years will be allowed to complete the doctoral programs (DMin, DTL, and PhD). A maximum of six (6) years and, except for transfer students, a minimum of two (2) years will be allowed to complete the master's programs (MATL). The time limit will begin on the student's acceptance date.

Students who want to be reinstated after having been withdrawn or inactive for over a year and less than 7 years will need to petition the Academic Dean's office for approval and will need to update their personal data and PLC contact information. If the student has attended any other institution(s) during his/her absence, arrangements must be made for an official transcript (showing good standing) to be sent from each institution to the Office of Admissions (see Transfer policy above). Exceptions and appeals may be made to the Academic Dean, in consultation with the Academic Cabinet.

Degree Extension

BGU, in accordance with standard academic procedures, requires that a student complete his/her program within seven years, including all coursework and final projects, from the date on which the student enrolled for his or her first course. Any student who has not completed the degree within the 7-year limitation may appeal to the Academic Dean, in consultation with the Academic Cabinet, to be allowed to exceed the limitation by filling out a Degree Extension Request (to obtain this document go to https://www.bgu.edu/students/downloadable-documents/). This document includes a short statement about why the student was unable to complete the program within the 7-year limit as well as a plan for completion within a relatively short period of time, which will need to be approved by the Academic Cabinet.

Dissertation Advisory Team

BGU's Director of Final Projects coordinates a Dissertation Advisory Team. The purpose of that team is to review dissertation proposals, review the congruence of expertise between proposed dissertation supervisors and second readers and the theme of a given dissertation, as well as to review any academic issue pertaining the dissertation writing process. It reports to the Academic Cabinet on a monthly basis.

Graduation Policy

BGU academic curriculum and course calendar is designed for June Graduation, but, BGU students have the option of December Graduation (first Monday of December) or June Graduation (first Saturday of June). However, a joint commencement ceremony is only held once a year during the June Graduation. All graduating students (December or June Graduation) are encouraged to attend and to invite their friends and family to celebrate their accomplishment during the June commencement service. See further graduation and candidacy requirements listed under each degree program.

All charges assessed to the student's account, e.g., course tuition, graduation fees, library fees, Dissertation, Doctoral Final Project, or Master's Final Project fees, etc., must be paid in full before a degree will be issued. The deadline to submit all required course work, final projects, and payment of all dues for the December graduation is September 30 and the deadline to submit all required course work, final projects, and payment of all outstanding dues for the June graduation is April 15 (or before an oral review can be scheduled, whichever comes first).

The Catalog in effect at the time of a student's matriculation shall determine the complete requirements for graduation. The Final Project Handbook that was in effect when the student took the research course will contain the requirements by which that student must abide when writing his/her dissertation. Any exceptions to this policy or special cases will be handled by the Academic Dean in consultation with the Academic Cabinet.

Audit Registration Policy

Auditing students, spouses of students, and alumni may register for courses up to six (6) weeks before the first day of the professor-led class session/immersion portion of a course, *depending upon space availability.*

BGU'S Social Media Policy & Disclaimer

Bakke Graduate University encourages interaction among users on BGU's social media sites but is not responsible for the content of others published on any official BGU websites, pages, or affiliates. This is including, but not limited to, Facebook, Twitter, YouTube, LinkedIn, Wikipedia, Foursquare, Google+, Instagram, Pinterest and all other social media websites listed here or not listed. For details about BGU's policy, please see BGU Core Appendices-*Appendix 30.*

Bakke Graduate University thanks you in advance for your contributions to the university's social media pages, and for your compliance and assistance in creating a safe and vibrant online community. BGU abides by the European General Data Protection Regulations (EGDPR) (https://gdpr-info.eu/) in its communications. Any questions or concerns should be emailed to info@bgu.edu.

Student Records

The Family Educational Rights and Privacy Act of 1974 (FERPA) provides generally that: 1) students shall have the right of access to their educational records; and 2) educational institutions shall not release educational records to non-school employees without the consent of the student (or former student). With few exceptions, which are provided by law, students may see any of their educational records upon written request to the Registrar. For more details, see BGU Core Appendices-*Appendix 31.*

Transcripts

All transcript requests must be authorized in person or in writing and must include the student's full name, Social Security number (US taxpayers only), date of birth, dates of attendance at BGU, the complete name and address of the office or person to whom the transcript is to be sent, and the signed authorization to release the transcript. There is a $5.00 charge for every transcript issued. A minimum of *four days'* notice is required when requesting copies of official transcripts. A Transcript Request can be downloaded from the BGU website (www.bgu.edu/students/downloadable-documents).

Institutional Review Board

Bakke Graduate University (BGU) requires the conduct of ethical practices in relation to all research related to human subjects. BGU has adopted the guidelines outlined in the Code of Federal Regulations Title 45 (Public Welfare), Part 46 (Protection of Human Subjects). This document is available at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

Before collecting data related to specific types of research with human subjects, all students, faculty, project supervisors, and other staff members must obtain approval from the BGU Institutional Review Board (IRB) when required by the guidelines established in Federal regulations § 45 CFR 46 and described in the *BGU Institutional Review Board Policy and Procedure Manual* (available on the BGU website). Engaging in research with human subjects without IRB approval when required has serious ethical implications and violates university and Federal policies. Some categories of research that will probably require approval of the IRB include the following:

1. Research involving interaction with children
2. Research involving prisoners
3. Research that involves deception or withholding of information from subjects
4. Research that involves intense physical exercise
5. Research that may cause emotional distress or discomfort greater that what would be expected in daily life

The IRB team coordinator reports to the Academic Cabinet on a monthly basis. For more information on the types of research requiring IRB approval, visit the BGU website.

Referral Policy

Current BGU students may earn tuition credit by referring a new student to BGU. For the guidelines and the complete policy, see BGU Core Appendices-*Appendix 56*.

Academic Programs: Description, Requirements & Outcomes

Bakke Graduate University currently offers five U.S. Accredited Academic Programs. Students in all five programs are invited to attend courses with those in other degrees, thus providing them with the additional advantage of experiencing BGU's unique geographic,

cultural, and organizationally diverse relationships. BGU degrees provide theological, operational, and personal skill sets for entry into the most diverse range of world realities, from a call and ministry with those in abject poverty to a call and ministry with those in the corridors of the powerful. All five programs engage the unique niche areas of expertise in the BGU network of students, alumni, and faculty. For a list of the areas of expertise for each of these individuals, see BGU Core Appendices-*Appendix 32*.

Master of Arts in Transformational Leadership (MATL)

The Master of Arts in Transformational Leadership (MATL) degree is designed especially for urban ministry leaders who desire greater expertise and skill in leading transformation in cities or for leaders of start-up organizations or small to medium-sized existing organizations, who need practical skills in leading teams and organizations. Students can specialize in personal leadership development or dig deeper in the core topic areas of relief, development or advocacy. Students can also access a unique set of theological core courses designed for leaders working with younger populations in global urban centers. Through Elective and Capstone courses, this degree is designed to contribute to the student's unique personal and organizational needs. For the program outcomes, see BGU Core Appendices-*Appendix 33*, and for the program outline, see BGU Core Appendices-*Appendix 34*.

Executive Master of Business Administration (EMBA)

Bakke Graduate University offers an accredited, values-driven Executive Master of Business Administration (EMBA) degree for working adults that takes into account the worldwide marketplace trends and the need for organizations that are both socially responsible and profitable in today's global contexts. This degree is designed to provide the student with the knowledge, perspective, models, mentors, relationships, and skills to address their work, their calling, and the whole of their life in an integrated manner. Leaders enrolled in this EMBA can be involved in for-profit, non-profit organizations (NGO) or governmental organizations. The EMBA is a hybrid program that includes both online and face-to-face courses and immersions into global best business practices. Students are exposed to cross-cultural, internationally-oriented faculty, case-studies, historic, and emerging trends in the various fields of substantive, advanced business study. Students will also have opportunities to travel as part of their education to see first-hand the application of these skill sets and principles. The BGU EMBA is unique as every topic is taught from the perspective of social, spiritual, economic and environmental transformation of students' own lives, their organizations, cities and industry sectors. BGU's EMBA graduates are prepared to integrate their work, character and calling to make a positive difference in their career and impact. For the program outcomes, see BGU Core Appendices-*Appendix 35*, and for the program outline, see BGU Core Appendices-*Appendix 36*.

Doctor of Ministry (DMin)

BGU's Doctor of Ministry (DMin) is a ministry degree program designed to enhance the leadership skills of individuals engaged in Christian ministry. BGU's DMin program is unique in many ways. We are not recruiting lone rangers into this program, but ministry leaders. The DMin is distinct from the PhD or ThD in that its primary focus is on implementing and strengthening effective ministry rather than preparing the participant for research or teaching in purely academic arenas. BGU follows the medical model of preparing doctors for surgery in the operating room. At BGU the cities are the labs, and practitioners are professors. Although the DMin is not designed as simply a research degree, in recent years many seminary educators have

chosen the DMin degree to enhance their ability to provide training relevant to practical issues in Christian ministry.

Those who pursue a DMin with BGU will obtain a doctoral education in the discipline of ministry to provide global transformation throughout the world. Students who have graduated with a DMin from BGU have utilized their degrees to:

- Plant global churches
- Develop and engage missional ministries throughout the world
- Pastor churches globally implementing ministries to transform lives and communities
- Develop faith-based non-profits
- Develop global mentoring ministries to disciple global communities
- Leadership development that has a global impact in the church and the community
- Develop ministries that assist individuals who are oppressed and abused to provide liberation and transformation

For the program outcomes, see BGU Core Appendices-*Appendix 37*, and for the program outline, see BGU Core Appendices-*Appendix 38*.

Doctor of Transformational Leadership (DTL)

The Doctor of Transformational Leadership (DTL) is designed for leaders in organizations that are focused on urban relief, development or advocacy, economic, political, social or cultural influence, from a Christian perspective. These organizations can be non-profit, for-profit or government entities. BGU asks every student to write every assignment, including the Dissertation, in ways that benefit his/her sending organization. The DTL is distinct from the PhD or the EdD in that its primary focus is on implementing and strengthening effective organizational practices rather than preparing the participant for research or teaching in purely academic arenas. Once the student has completed his/her degree both the organization and the student will have been strengthened. For the program outcomes, see BGU Core Appendices-*Appendix 39*, and for the program outline, see BGU Core Appendices-*Appendix 40*.

Doctor of Philosophy (PhD) in Innovative Urban Leadership

The PhD in Innovative Urban Leadership is designed to equip scholar-practitioners and thought leaders to innovate in the urban context. Leaders will accomplish this goal as they build on demonstrated leadership practice and research skills to exemplify sustainable and regenerative leadership grounded in collaboration, community, and context. For the program outcomes, see BGU Core Appendices-Appendix *51*. For the Program Outline, see BGU Core Appendices-*Appendix 52*.

Degree Completion Requirements

For the details of each degree's completion requirements, see BGU Core Appendices-*Appendix 41*.

High Honors

The designation of "High Honors" will be given to graduates, and designated on their diploma, when they have graduated with high honors in light of having attained an overall GPA of 4.0 or higher to attest to the high quality of his or her work.

Academic Calendar

To see the current academic calendar, refer to BGU Core Appendices-*Appendix 42*.

Staff and Faculty

See the following appendices for a complete list of BGU's administrative staff (BGU Core Appendices-*Appendix 43*), adjunct faculty (BGU Core Appendices-*Appendix 44*), resource faculty (BGU Core Appendices-*Appendix 45*), Board of Directors (BGU Core Appendices-*Appendix 46*), Board of Regents (BGU Core Appendices-*Appendix 47*), and all staff (BGU Core Appendices-*Appendix 48*).

Academic Cabinet

The Chief Academic Officer is responsible for decisions affecting the academic integrity and effectiveness of the University and will delegate portions of this responsibility to the appropriate individual staff and faculty leaders. The Academic Cabinet serves as a standing advice process entity to support this effort. The Academic Cabinet advises regarding student acceptance and scheduling of courses, appointing of faculty, maintenance of all BGU academic documents such as the catalog, handbooks, curriculum, and syllabi.

Bakke Graduate University reserves the right, but is not obligated, to remove comments or posts that are racist, sexist, abusive, profane, violent, obscene or spam; that advocate illegal activity, include falsehoods, contain commercial solicitations, are wildly off-topic, or cannot be translated to English using free online tools; that libel, incite, threaten or make ad hominem attacks on BGU students, employees, guests or others. BGU also reserves the right to remove comments or posts that are deemed negative or offensive by the page's administrators. Violators will be banned from the page.

Office of the Registrar

The Registrar's Office arranges course schedules, receives and processes student admission applications and course registrations, and maintains a repository of academic records. Students should contact the Registrar for official and un-official transcripts, registration information, financial account questions, issues concerning grades, and any other inquiries related to student records. Appointments may be scheduled for advisement on course schedules, class registration, etc., by contacting the Associate Registrar, Julia Burk, via email at Julia.Burk@bgu.edu or calling the BGU office at 214-329-4447 ext. 120.

Certificates

Intensive Certificates

Intensive Certificates are opportunities for life-long learners to glean from what BGU has to offer without the commitment to a full graduate-level degree. For more information on certificates, please see BGU Core Appendices – *Appendix 53*.

II. INSTITUTIONAL REVIEW BOARD POLICIES

Bakke Graduate University (BGU) encourages the conduct of ethical practices in relation to all research related to human subjects. BGU has adopted the U.S. human research requirements outlined in the Code of Federal Regulations Title 45 (Public Welfare), Part 46 (Protection of Human Subjects). This document is available at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html and referred to in this manual as § 45 CFR 46. This policy manual provides guidance for the BGU Institutional Review Board (IRB) as well as faculty and students. Several modifications were made to the federal standards in 2018, and those revisions are reflected in this version of the 2021-22 IRB policy manual. One major revision relates to revised definitions of vulnerable populations. Also, updated policies allow many BGU human research projects to be approved by an *expedited IRB review* which can be done by one or more IRB members rather requiring a full review by the IRB.

Before collecting research data related to human subjects, all students, faculty, project supervisors, and other staff members must obtain some level of approval from the BGU Institutional Review Board (IRB) if required by criteria established in the Federal Code federal defined in § 45 CFR 46 and described in this policy manual. Engaging in research with human subjects without appropriate IRB approval when required has serious ethical implications and violates university and federal policies. Questions regarding when BGU IRB approval is required may be directed to the IRB Coordinator at IRBCoordinator@bgu.edu.

The National Research Act was passed in 1974 and established the Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission published the *Belmont Report* in 1979 which established the ethical basis for the regulations outlined in § 45 CFR 46. The *Belmont Report* describes the following internationally recognized ethical principles.

> ***Respect for persons*** "incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents; and second, that persons with diminished autonomy are entitled to protection" [thus, the need to obtain informed consent].
>
> ***Beneficence*** entails treating persons "in an ethical manner not only by respecting their decisions, but also by making efforts to secure their well-being. Two general rules: (1) do no harm; and (2) protect from harm by maximizing anticipated results and minimizing possible risks of harm."
>
> ***Justice*** requires that the "benefits and burdens of research be distributed fairly" [thus, the principle of justice is applied in the selection of research subjects].

For more information on these ethical principles, please refer *to Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* at: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

A. Definitions

Federal regulations define *research* as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (§ 45 CFR. 46.102 [l]). These regulations define a h*uman subject* as "a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information" (§ 45 CFR 46.101[e]).

A project or study is considered to be research if it: 1) is conducted with the intention of drawing conclusions that have some general applicability to populations or situations other than the one being studied ("generalizable knowledge"), and 2) uses a commonly accepted qualitative or quantitative method. More specifically, generalizable knowledge is information based on results or findings that are expected 1) to be reproducible, and 2) to apply broadly with the expectation of predictable outcomes.

B. Levels of Review

If a project meets the criteria of being both "research" and with "human subjects" as noted above, it will require at least what is called an *expediated review* by one or members of the IRB (see § 45 CFR 46.110). Many BGU dissertation proposal can receive an IRB approval through an expedited review. The need for some level of IRB review is not determined by whether the researcher intends to present or publish the study outcomes, since publishing the results of a project does not by itself classify the study as one that is generalizable. However, in some cases, the intent to publish can be used as one criteria for determining whether the project meets the above definition of "research."

Opportunity samples, pilot studies, and preliminary studies designed to help the researcher refine data collection procedures, instruments, or research design, require the same scrutiny as full-scale research projects. They are therefore subject to some level of IRB review.

Research involving the secondary analysis of existing data (e.g., public de-identified data) does not require review when it does not meet the definition of research with human subjects noted above. Also, the secondary use of data may qualify for Exempt Status under the federal regulations if the initial dataset is identifiable and if it would not be possible for the researcher to identify the subjects. In some cases, secondary use of data may warrant expedited or full board review (see the Categories of Review in Section III of this policy manual).

Studies initiated with the primary intent of improving institutional practice (sometimes labeled outcome studies or program assessment) are considered "quality improvement" activities and are typically not classified as research. However, some program evaluation projects may fall into the definition of research based on design and intent to generalize outside of the local area.

Studies conducted by faculty with their own students would not typically lead to generalizable outcomes and would not normally fall under the category of research to be reviewed by the IRB. Professors that choose to do research with their own university students should be aware that they will need to mitigate the inherent potential for bias built into that methodology.

If human subjects are involved in a study which does not meet the definition of "research," they must be protected using the same level of care as if IRB review had taken place. For example, the researcher must always obtain permission from participants and disclose any risks to them before collecting data. Please consult with a member of the IRB for additional guidance (also see Appendix E for the IRB Approval Decision Charts, especially Chart 1, item 5).

C. Online Training for Human Subject Research

There is online training available on regulations regarding human subject research. Students may set up an account through the National Institute of Health (NIH) and register for a seven-module course. The login information is available at Lesson 1: When HHS Regulations Apply | HHS.gov

III. BGU INSTITUTIONAL REVIEW BOARD COMPOSITION AND FUNCTIONS

A. Membership and Meetings

In regards to the membership of the BGU IRB, the following federal policies apply (see § 45 CFR 46.107).

1. Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.
2. Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.
3. Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
4. Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
5. No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
6. An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB (§ 45 CFR 46.107[d]).

In addition, at least two alternate faculty members will be appointed to assure adequate representation for any review beyond an expedited review. Members are appointed by the Academic Dean and confirmed by the Academic Cabinet. Use of online conferences is acceptable for any convened meetings of the IRB.

B. General Functions of the IRB

All research requiring review according to federal policy § 45 CFR 46 will be subject to at least an *expedited review* by an IRB, which may be conducted by one or more IRB members. BGU research projects such as dissertations, theses, coursework, and the like are subject to some level of IRB review. In terms of coursework, all BGU faculty should have a basic understanding of the type of content needed IRB review. All proposals for dissertations and other forms of final projects will be reviewed and approved by one of the dissertation advisory teams and reported to the Academic Cabinet (AC). The advisory teams will determine the research proposals that need IRB attention. As previously indicated, many BGU human research projects can be approved through an expedited review involving one or more IRB members. Human research requiring more than an expedited review will be discussed at a convened meeting of the IRB and must receive approval of a majority of those members attending the meeting (§ 45 CFR 46.108). Convened meetings may be conducted using online conferencing programs IRB applications, meetings, documents, and minutes are confidential.

C. IRB Recordkeeping requirements

The IRB will prepare and maintain accurate documentation of all IRB activities, based on the following federal regulations, and will include the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
2. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
3. Records of continuing review activities.
4. Copies of all correspondence between the IRB and the investigators.
5. A list of IRB members in the same detail as described in §46.103(b)(3).
6. Written procedures for the IRB in the same detail as described in §46.103(b)(4) and §46.103(b)(5).
7. Statements of significant new findings provided to subjects, as required by §46.116(b)(5).

The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner. (§45 CFR 46.111)

IV. FACTORS CONSIDERED IN IRB REVIEWS

A. Evaluation of IRB Review Level

Several factors are considered in evaluating the level of IRB review to be required for research projects (see *The Belmont Report* for more details on these issues).

Benefit - Federal regulations charge the IRB with determining that research benefits outweigh research risks. Benefit can be defined as value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge.

Risk - Risk can be defined as the magnitude of the potential harm or discomfort and the probability of the harm or discomfort occurring. For purposes of protecting human subjects in research projects, risk includes:

1. Violation of privacy
2. Violation of confidentiality
3. Questions that the participant may consider sensitive
4. Possible emotional distress or physical injury
5. Invasive procedures

Minimal Risk - The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Benefit vs. Risk - The "Common Rule" developed and agreed upon by various federal agencies instructs Institutional Review Boards to ensure that "risks to subjects are minimized" and "risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may be reasonably expected to result".

Vulnerable populations - Vulnerable populations are individuals or groups who may be vulnerable to coercion or undue influence such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged person. The US Department of Health and Human Services regulations mandate special protections for vulnerable research participants.

Sensitive topics - Any research protocol that involves solicitation of information from human subjects that could reasonably cause harm to the participant if the data were not kept confidential is considered sensitive topic research. Causing embarrassment is the minimum threshold for determining whether research harm is foreseeable and thus sensitive.

Privacy - Privacy is defined as having control over extent, timing and circumstances of sharing oneself with others. Please be attentive to threats to participants' privacy. An acceptable practice is to distribute invitations to a broad population and ask for persons to self-identify as meeting

more narrow criteria. An option for some sensitive interview research is to offer the participant the opportunity to review publication drafts for unintended markers of identity.

Confidentiality - Confidentiality pertains to the treatment of information an individual has disclosed in a relationship of trust and with the expectation that it will not, without permission, be divulged to others in ways that are inconsistent with the understanding of the original disclosure. Researchers ordinarily use information participants have disclosed or provided voluntarily (i.e., with their informed consent) for research purposes.

B. General Criteria for IRB Approvals

A completed Application for IRB Review form (Appendix A) must be submitted before any level of IRB review can be implemented. Procedural guidelines for completing the application are provided in Appendix D. For summaries of criteria used by the IRB approval process, see the IRB Initial Review Form (Appendix C) and the IRB Decision Charts (Appendix E). The IRB must ensure that the following requirements are satisfied based on descriptions in the Federal Code section entitled Criteria for IRB Approval of Research (§ 45 CFR 46.111).

1. Risks to participants are minimized by using procedures consistent with sound research design that do not unnecessarily expose participants to risk.
2. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and to the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those that may result from the research, as distinguished from those participants would receive even if not participating.
3. Selection of participants is equitable. The IRB should consider the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly mindful of the special problems of research involving participants who may be vulnerable to coercion or undue influence such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged person.
4. Informed consent is sought, and will be obtained, from each prospective participant or the participant's legally authorized representative in accordance with, and to the extent required by § 45 CFR 46.116.
5. Informed consent is appropriately documented in accordance with, and to the extent required by § 45 CFR 46.117.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
7. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
8. Additional safeguards have been included in the research methodology to protect the rights and welfare of the participants, especially when some or all of the participants are likely to be vulnerable to coercion or undue influence such as children, prisoners,

individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

The IRB has the authority to approve, require modifications (in order to secure approval), or not approve all research activities. The IRB will notify the researcher in writing of its decision to approve or not approve the proposed research or of modifications required to secure IRB approval. If the proposed research is not approved, the IRB will include in its written notification a statement of the reasons for its decision and give the researcher an opportunity to reapply. When the IRB requests substantive clarifications or modifications of protocol or informed consent documents from the researcher, IRB approval of the proposed research must be deferred, pending subsequent review by the IRB.

C. IRB Criteria for Research with Children

The IRB will often approve research involving children if the board determines:

1. there is no greater than minimal risk,
2. adequate provisions have been made for soliciting the assent of the children, and
3. permission has been obtained from their parents or guardians (See § 45 CFR 46.404).

If the IRB determines research involving children may involve greater than minimal risk, they may approve the project if the board considers:

1. the risk is justified by the anticipated benefit to the subjects,
2. the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by any other available alternatives, and
3. the requirements for assent and permission have been met. (See § 45 CFR 46.405)

If the children are not likely to directly benefit from the study, the IRB may still approve the research if the board considers:

1. the risk represents a minor increase over minimal risk,
2. the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual psychological, social or educational situations,
3. the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or treatment of the subject's disorder or condition, and
4. the requirements for assent and permission have been met. (see § 45 CFR 46.406)

Any other research with children that does not meet the above requirements may be approved under special circumstances defined in § 45 CFR 46.407.

D. Suspension or Termination of IRB Approval

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported within two business days to the investigator, faculty supervisor (if a student is involved), Department Chair and Dean, Provost, and any pertinent governing institution (such as a funding agency or the Office of Human Research Protection). As a response to complaints, pressing concerns, or evidence of harm to subjects, the RIO or IRB Chair may suspend a study. If necessary, the RIO may, with one or more IRB members, initiate an investigation. Every investigator will be given the opportunity to respond to the concerns. The convened IRB must vote on any action of suspension or termination upon completion of an investigation.

E. Request for Revision or Addition to Approved Research

Researchers who will in any way modify their research protocol or personnel which has been previously submitted to and approved by the IRB must submit a report to the IRB requesting revisions of additions review. Deviations from this approved protocol may result in termination of approval by the IRB.

F. Renewals for Continuing Research

After the initial approval, all studies must undergo continuing review by the IRB to ensure that the risk-benefit relationship of the research remains acceptable, the informed consent process and documents are still appropriate, and the enrollment of subjects has been equitable. By federal regulation, the maximum period between these IRB reviews is one year. The researcher is responsible for applying for continuing review in a timely manner to ensure IRB approval is continuous.

Therefore, researchers must submit an annual renewal request for their continuing research three weeks prior to the anniversary date of the original approval. Depending on the degree of risk involved, more frequent reporting may be requested by the IRB (see § 45 CFR 46.109.e). If a study is not re-approved before the study's expiration date, the research study is automatically suspended.

G. Closure Report of Research Study

A closure report must be submitted after all data collection and de-identification is complete, and PRIOR to the one-year anniversary date of your approval. IRB applications from researchers who are delinquent on closure reports from previous research will be delayed until closure reports are filed. The Closure Report form can be found at https://apu.my.irbmanager.com

H. Leaving Bakke Graduate University

Researchers must contact the IRB as soon as they are aware of an impending departure from BGU. They must file a closure report before their departure. The BGU IRB will no longer cover

a researcher once he or she leaves the institution even if that person remains a member of the research team. In that situation, a study revision would be required indicating the researcher's new role and, if "engaged in research," the researcher must obtain IRB approval from his/her new institution.

V. REVIEW PROCESS CATEGORIES

A. Exempt Status

Some studies on human subjects may be exempt from the need for an extensive review by the IRB. Exempt research proposals are submitted to the IRB Coordinator and then reviewed for protection of human subjects by a member of the Institutional Review Board.

Qualifications for Exempt Status

The federal policy § 45 CFR 46 lists the following conditions for exempt status of research:

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 of 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 human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human 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 educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) 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. (§ 45 CFR 46)

The IRB has the final authority in determining if a research project may be considered as qualifying for exempt status.

Research that Cannot Qualify for Exempt Status

Research that cannot qualify for exempt status includes:

1. Research involving interaction with children
2. Research involving prisoners
3. Research that involves deception or withholding of information from subjects
4. Research that involves intense physical exercise
5. Research that may cause emotional distress or discomfort greater that what would be expected in daily life (see Appendix E for IRB Approval Decision Charts, specifically to Charts 2-7.)
6. Research that involves vulnerable participants and previously defined.

B. Expedited Review

Expedited review procedures may be carried out by one or more IRB members for research that is not considered high risk to the research participants (§ 45 CFR 46.110).

IRB Criteria for Evaluating Expedited Research

Criteria for IRB approval through an expedited review include the following.

1. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.
2. Risks to subjects are reasonable in relation to the anticipated benefits, if any, to subjects and the importance of the knowledge that may be reasonably expected to result.
3. Selection of the subjects is equitable.
4. Informed consent is received from each research participant.
5. Informed consent is appropriately documented.
6. The research plan makes adequate provision to ensure the safety of subjects.
7. Adequate provisions are made to protect the privacy of subjects and to maintain the confidentiality of data. (Criteria is adapted from § 45 CFR 46.110)

Research that Generally Requires an IRB Expedited Review

The following categories generally require at least an IRB expedited review (for further explanation, see http://www.hhs.gov/ohrp under expedited review).

1. Illegal or punishable conduct, including use of alcohol, drugs, or other addictive products
2. Information that could damage an individual's financial standing, employability, or reputation
3. Information (usually in medical records) that could lead to social stigmatization or discrimination
4. Psychological well-being or mental health, including physical or mental abuse
5. Sexual orientation, attitudes, preferences, or practices
6. Incest, rape, date rape, or sexual molestation
7. Genetic information
8. Religious orientation or views – Religion is just one example of a sensitive topic. As with all sensitive topics, the broader principle is whether or not there is a potential for harm if the data were revealed. Identifying religious orientation on a research project would not typically be considered a sensitive topic at BGU. However, it should be noted that there are many possible scenarios where religious research could be potentially harmful to the participant if confidential data were revealed.
9. Veteran or wartime experiences
10. Topics that may be perceived as sensitive or injurious by participants
11. Immigration status

C. Full Board Review

Research that involves more than minimal risk requires a full IRB review. Determination for a full IRB review will be based on an expedited review by one or more IRB members. As previously indicated, higher risk situations may typically involve research with participants vulnerable to coercion or undue influence such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged person. Research that involves asking questions about sensitive topics may also require a full IRB review. Sensitive inquiries would involve solicitation of information from human subjects that could reasonably cause harm to the participant if the data were not kept confidential. Causing embarrassment is the minimum threshold for determining whether research harm is foreseeable and thus sensitive. Examples of sensitive topics that could potentially cause harm to participants, depending on the context, include, but are not limited to, the following:

1. Illegal or punishable conduct, including use of alcohol, drugs, or other addictive products
2. Information that could damage an individual's financial standing, employability, or reputation

3. Information (usually in medical records) that could lead to social stigmatization or discrimination
4. Psychological well-being or mental health, including physical or mental abuse
5. Sexual orientation, attitudes, preferences, or practices
6. Incest, rape, date rape, or sexual molestation
7. Genetic information
8. Veteran or wartime experiences
9. Immigration status
10. Religious orientation or views are topics that could potentially cause harm if the data were revealed within some oppressive social contexts. Identifying religious orientation in a research project would not typically be considered a sensitive topic at BGU. However, it should be noted that there are many possible scenarios where religious research could be potentially harmful to the participant if confidential data were revealed.

Full IRB reviews are required when the probability and magnitude of harm or discomfort anticipated in the research are greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (§ 45 CFR 46). Invasive procedures, possible emotional distress, and the potential for lack of confidentiality, for example, are considered greater than minimal risk. In order to be approved by the Board, such risks must be addressed.

VI. INFORMED CONSENT

Based on federal regulations regarding research (see definitions in Section I of this manual), people may not be involved as a human subjects in the research unless legally effective informed consent has been obtained from the subject(s) or the subject's legally authorized representative (see § 45 CFR 46.116).

A. Specific Content of Informed Consent Form

The Informed Consent will contain the following information:

1. statement that the study involves research;
2. explanation of the purpose of the research, an invitation to participate and explanation of why the participant was selected, and the expected duration of the participant's participation;
3. description of procedures to be followed and identification of which procedures are investigational and which might be provided as standard care to the participant in another setting. Use of research methods such as randomization and placebo controls should be explained;
4. statement of any financial or other means of sponsorship for the research;

5. description of any foreseeable risks or discomforts to the participant, an estimate of their likelihood, and a description of what steps will be taken to prevent or minimize them; as well as acknowledgment of potentially unforeseeable risks;
6. description of any benefits to the participant or to others that may reasonably be expected from the research, and an estimate of their likelihood;
7. disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous to the participant;
8. statement describing to what extent records will be kept confidential, including examples of who may have access to research records such as hospital personnel, the FDA, and drug sponsors;
9. explanation and description of any compensation and any medical treatments that are available if participants are injured through participation; where further information can be obtained, and whom to contact in the event of research-related injury;
10. explanation of whom to contact for answers to questions about the research and the research participant's rights including the name and phone number of the Principal Investigator (PI);
11. statement informing the subject that inquiries regarding the nature of the research, his/her rights as a subject, or any other aspect of the research as it relates to his/her participation as a subject can be directed to the Research Integrity Officer at BGU;
12. statement that research is voluntary and that refusal to participate or a decision to withdraw at any time will involve no penalty or loss of benefits to which the participant is otherwise entitled;
13. statement that if a participant declines to continue, any data gathered to that point may be part of data analysis;
14. statement indicating that the participant is making a decision whether or not to participate, and that his/her signature indicates that he/she has decided to participate having read and discussed the information presented;
15. statement outlining the nature of subject remuneration (if any). Remuneration should be described as a “token of appreciation” for participating subjects. Care should be taken to ensure that remuneration is appropriate to the scope and context of the project. Excessive remuneration may be viewed as potentially coercive;
16. authorization for Use of Private Health Information - if personal information considered “Protected Health Information” is used in the study; and
17. signature of the researcher after explaining the research to the participant and when they are satisfied the participant fully understands. It is not appropriate for the researcher to sign in advance or to use a stamped signature.

See Appendix B for a sample Informed Consent Form.

B. Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus) if the subject is or may become pregnant which are currently unforeseeable,
2. anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. any additional costs to the subject that may result from participation in the research;
4. consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
6. approximate number of subjects involved in the study (§ § 45 CFR 46.116).

C. Documentation of Informed Consent

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds any of the following to be true.

1. The only record linking the subjects and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

See Decision Trees at http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html, Charts 10 and 11.

Except as provided in in the waiver criteria shown above, informed consent shall be documented by the use of a written consent form approved by the IRB or by use of an electronic consent form for electronic surveys (see Appendix B for sample Informed Consent Form). The written consent forms must be signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

Except as provided in the waiver criteria shown above, of this section, the consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent required by § 45 CFR 46.116 above. This form may be read to the subject or the subject's legally

authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

2. A short, written consent document stating that the elements of informed consent required by § 45 CFR 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. See § 45 CFR 46.117 for additional related regulations.

See Appendix B for a sample Informed Consent Form.

D. Assent Form for Research with Children

The IRB shall determine that adequate provisions are made for soliciting the assent of children participating in research when, in the judgment of the IRB, the children are capable of providing assent. Children 12-17 years of age must give their written assent to participate in research. The IRB may determine that children younger than 12 years of age must give their assent for a particular research project.

E. Deception and Incomplete Disclosure

In certain circumstances, the use of deception or incomplete disclosure in research are acceptable and important techniques, though these approaches place special responsibilities both on the researcher and on the IRB. In these cases, the IRB requests additional information from researchers and will review those proposals carefully. Whereas deception occurs when research subjects are deliberately given false information about some aspect of the research, incomplete disclosure results when the true nature or purpose of the research is withheld. It is therefore the provision of erroneous information (deception) or the omission of information (incomplete disclosure) which creates a circumstance warranting special consideration for the protection of those human subjects.

Requirements when Incomplete Disclosure is Intentionally Used in Research

In all cases of deception or incomplete disclosure, the following guidelines apply:

1. The research must involve no more than minimal risk to participants
2. The waiver or alteration of the informed consent may not adversely affect the rights and welfare of the participants
3. The research could not practicably be carried out without the alteration or waiver
4. At the appropriate time, participants will be provided with additional pertinent information regarding participation
5. Participants must be given the right to withdraw their participation once they are made fully aware of the study's purpose

IRB Application Content for Use of Deception or Incomplete Disclosure

IRB applications proposing to use deception or incomplete disclosure should include the following information:

1. clear explanation of why deception or incomplete disclosure is justified and whether alternative methods could achieve the same research goals,
2. indication of whether deception or incomplete disclosure may affect a participant's willingness to participate in research,
3. identification of any elements of the Informed Consent the researcher is requesting to waive,
4. explanation of how and when you will inform participants of intended incomplete disclosures in the research process with a copy of the debriefing statement and the debriefing script (the informed consent document must include the fact that the information provided to the subject is incomplete and that they will be debriefed after research procedures are completed, and
5. indication that deception or incomplete disclosure is likely to cause the subjects discomfort before or after debriefing them and how that risk will be minimized.

The debriefing of participants is required at an appropriate point in time. Such a debriefing must include a full explanation of the research question and hypothesis, the procedures used for the study, and why deception was necessary. In no case can the debriefing cause more harm than the deception or incomplete disclosure.

In its review, the IRB must consider factors in addition to the scientific value of the research and the efficacy of alternative procedures. They will also need to confirm that the deception does not extend to influence the participants' willingness to participate, and that any experimentally induced harm may be removed through debriefing. Further, the IRB will consider whether the researcher is equipped to manage emotional reactions that may occur during debriefing, and whether the proposed deception could facilitate unwanted and inappropriate invasions of privacy.

Deception or incomplete disclosure cannot be approved if non-deceptive alternatives are available, if human subjects would likely not participate if the true purpose of the study were known to them, and if it places participants at significant risk of any type.

VII. OTHER REQUIREMENTS FOR RESEARCHERS

A. Integrity of Research

BGU values honesty and integrity of research and is dedicated to ensuring the credibility and trustworthiness of the research conducted by our research community, to protecting this community from unsubstantiated allegations of research misconduct, and to upholding the university's high standards for research activity. Misconduct in research represents a breach of the policies of BGU, the standards expected by our sponsors, and the expectations of scholarly communities for accuracy, validity, and integrity in research. It is therefore the policy of BGU to inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged research misconduct. Further, it is also the policy to comply in a timely manner with sponsor requirements for reporting cases of possible research misconduct when sponsored project funds are involved. Each allegation of research misconduct will be responded to in a thorough, competent, objective, and fair manner. An Annual Report on Possible Research Misconduct is

filed with the Office of Research Integrity (in the U.S. Department of Health and Human Services) by the Academic Dean of Coordinator of the IRB.

B. Privacy and Confidentiality

Privacy is defined as having control over extent, timing and circumstances of sharing oneself with others. Please be attentive to threats to participants' privacy. An acceptable practice is to distribute invitations to a broad population and ask for persons to self-identify as meeting more narrow criteria. An option for some sensitive interview research is to offer the participant the opportunity to review publication drafts for unintended markers of identity.

Confidentiality pertains to the treatment of information an individual has disclosed in a relationship of trust and with the expectation that it will not, without permission, be divulged to others in ways that are inconsistent with the understanding of the original disclosure. Researchers ordinarily use information participants have disclosed or provided voluntarily (i.e., with their informed consent) for research purposes. In most research, ensuring confidentiality can occur by following these routine practices.

1. Substitute codes for identifiers or encrypting identifiable data.
2. Store informed consent documents and de-identified research data in separate secure locations.
3. Use random numbers to identify research records (Social Security and student ID numbers are not acceptable).
4. Remove face sheets (containing identifiers such as names and addresses) from survey instruments containing data
5. Properly dispose of computer sheets and other papers.
6. Limit access to identifiable data.
7. Educate the research staff on the importance of confidentiality.
8. Store paper records in locked cabinets or assigning security codes to computerized records.

C. Conflict of Interest

BGU's policies regarding Conflicts of Interest are consistent with federal requirements for research and best practices in academia (see various BGU policy manuals). A statement regarding Conflict of Interest will be included on all applications submitted to the IRB.

Faculty, administrators, and all personnel associated with BGU commit themselves to the pursuit of research in accordance with the highest standards of integrity and in compliance with legal, professional, ethical and other requirements that promote objectivity and protect against financial conflicts of interest in research. BGU will identify possible conflicts of interest in research, whether apparent or real, and provide mechanisms for their management, reduction or elimination in compliance with federal and state law as well as any relevant policies of entities funding research at the university.

The success of BGU depends upon the integrity of the research and the researchers as well as the public's confidence in them. Conflicts of interest in research strike at the heart of BGU's integrity. In pursuit of its mission as a private institution of higher education, BGU seeks excellence in the quality of its research, in the teaching and education it provides to its students, and in the service it provides to the broader community. This knowledge transfer inevitably leads to increasingly close relationships between universities and those with financial capital in the private sector. The benefits that potentially accrue from this proximity are accompanied by real or apparent risks that economic interests might compromise academic research by influencing an investigator's judgment about the design, conduct, reporting, or management of research, and, in the case of research involving human subjects, imperil the safety of participants.

Faculty assuming the responsibility for the design, conduct or reporting of research have a special obligation to avoid bias or the appearance of bias in the conduct of these studies. Any possible conflict of interest must be formally disclosed to the institution. Questions about the Conflict of Interest policies may be directed to the Academic Dean.

D. Recording Data

In recording data, the researcher must properly care for records in a systematic manner to avoid problems if someone asks about or questions the work. Hard-copy evidence should be entered into a bound notebook so that there is no question later about the date and content of data collected. Any changes to data must be noted, indicating date and reasons for the change.

Electronic data should be validated to in regards to date and circumstances in regards to when it was recorded. It is easy to change dates on computers and thereby alter the date a particular file seems to have been created. Electronically collected data must be validated in some manner to show it has not been changed.

Responsible handling of data must begin with proper storage and protection from accidental damage, loss or theft:

1. Lab notebooks should be stored in a safe place.
2. Computer files should be backed up and the backup data saved in a secure place that is physically removed from the original data.
3. Samples should be appropriately saved so that they will not degrade over time.

Data should be retained for a reasonable period of time to allow other researchers to check results or to use the data for other purposes. There is, however, no common definition of a reasonable period of time.

The National institute for Health (NIH) generally requires that data be retained for 3 years following the submission of the closure report. Some government programs require retention for up to 7 years. BGU requires that data be kept for 3 years after the closure report unless a longer retention is required by a specific agency.

E. International and Cross-Cultural Research

All human subject research conducted internationally or across cultures must adequately protect the rights and welfare of the research subjects. Researchers must provide evidence that research projects and translated documents are sensitive to participants' local research context, particularly culture and language. These protocols should be categorized (i.e., expedited, full board) using the same risk/benefit considerations applied to any other research project. In addition to obtaining IRB approval, the researcher must provide evidence that research projects and translated documents are sensitive to participant context and inclusive of culture and language. The first choice for documenting sensitivity to participant context is IRB review in the participants' country of residence. As an alternative, researchers may seek written documentation of sensitivity to local research context from persons who meet three criteria, namely (1) indigenous to the participant culture, (2) a resident of the research area for two of the last ten years, and (3) presently serving as an official of a local government or local academic institution.

International and cross-cultural research proposals requiring translated documents should include contact information/scripts and informed consent. The researcher can demonstrate accuracy and sensitivity of translated documents through back translation by persons indigenous to the participant culture and fluent in participant language. The researcher can translate documents but cannot serve as back translator of documents employed in his/her research. Local consulates may have personnel that meet IRB criteria that can assist with verifying that the planned research is culturally sensitive and/or with translations.

The International Compilation of Human Research Standards provides a resource of laws, regulations, and guidelines that govern human subject research as well as the standards from a number of international and regional organizations. These are listed by country and can be found here: https://www.hhs.gov/ohrp/international/compilation-human-research-standards/ .

F. External Research Review Process

IRB Involvement in External Research

All requests from researchers outside of BGU to involve BGU faculty, staff, and students for their research with human subjects should be sent to the IRB Coordinator who will assist the researcher in understanding the BGU specific review process for such requests. If the proposal is deemed to be "non-engaged research," the researcher should submit a copy of his/her IRB application from his/her home institution, if one exists. If the proposal is deemed to be "engaged research," the researcher must submit a completed BGU IRB application. This step is necessary, even if the research was classified as "exempt" at another institution. The IRB application should, whenever possible, identify a sponsor at BGU -- someone at the department chair or director level. The external researcher's proposal and supporting materials are forwarded to the BGU IRB.

The Academic Dean will also review the proposal for external research to consider factors including the timing of the project related to other planned research projects, whether such information has recently been collected at BGU, and the purpose and potential benefit of the research project. Based on the review, the Academic Dean will determine whether the proposed research is approved. The Academic Dean will notify the researcher of the approval or denial,

noting any conditions in the case of approval, and will direct the external researcher to contact person for the BGU IRB. In the case of "engaged" research with human subjects, the next step is IRB review and approval. The IRB Coordinator will then direct the researcher to the on-line application process.

Institutional Authorization Agreement

An institutional authorization agreement (IAA) is a formal, written document that provides a mechanism for BGU to accept authority to review and approve research conducted elsewhere, or for BGU to cede that authority to another entity. An IAA is a joint review arrangement that facilitates collaboration on research of human subjects, enabling collaborating institutions to rely on a single IRB (an "IRB of Record") for review and for some or all aspects of continuing oversight of the research, in order avoid a duplication of efforts. The IRB must approve the arrangement. .

If a researcher at BGU collaborates on a project with another institution and his/her involvement is limited to data analysis of research collected by collaborating investigators at the other institution, then the other institution may agree to serve as the IRB of record for the project and BGU can cede authority. Likewise, if the BGU researcher fully collaborates with another institution on a project and the IRB at the other institution is better-prepared to review the research, then that institution may agree to serve as the IRB of record for the project and BGU ,may cede authority.

Researchers may request an IAA, but generally the agreement is initiated by the IRB and require approval of the appropriate officials at each institution. Factors to be considered include:

1. ensuring quality and thoroughness of protocol review;
2. local context issues;
3. institutional liability;
4. complexity of shared control and accountability;
5. costs of delegating or accepting review; and
6. relationship to the outside organization.

The IRB will determine eligibility for an IAA and will recommend the terms of such an agreement. For becoming the IRB-of-Record, considerations include, for example, the time and resources required to accept the review, BGU's expertise for initial and continuing review, and the willingness of the other institution to monitor compliance, review adverse events and to handle complaints. For ceding authority to another institution, considerations include the impracticability of an BGU IRB review, the appropriateness of the other IRB to review the protocol, and the proposed arrangements for that institution to monitor and oversee the research.

As part of the IAA or in a separate document, the parties must establish and clearly document roles and responsibilities, the IRB of record for a protocol, communication channels, etc. Research may not commence until the IAA is fully executed. Because establishing an IAA requires thorough review, it should not be considered as a time-saving effort; indeed, some agreements take several weeks to negotiate, rendering a full board review more expedient.

G. Guidelines for Projects after IRB Approval

Once a project has been approved by the IRB, researchers must adhere to the approved protocol and follow any additional IRB instructions. The continuing responsibilities include:

1. enrolling only those subjects that meet IRB approved inclusion and exclusion criteria;
2. properly obtaining and documenting informed consent;
3. obtaining prior approval for any deviation from the approved protocol;
4. keeping accurate records; and
5. promptly reporting to the IRB any unanticipated problems involving risks to subjects or others, including adverse events, noncompliance, and protocol deviations

Research approved by the IRB may be monitored for compliance.

H. Reporting Unanticipated Problems and Protocol Deviations

Researchers are required to report to the IRB all unanticipated problems and adverse events, as well as protocol changes and deviations. It is the expectation of the IRB that all approved protocol procedures are being followed without alteration unless the IRB has been informed of a protocol change or deviation either by reporting an unanticipated problem or adverse event by seeking a protocol revision.

Unanticipated problems involving risks to subjects or others refers to a problem, event, or information that is not expected, given the nature of the research procedures and the subject population being studied, and which suggests that the research places subjects or others at a greater risk of harm or discomfort related to the research than was anticipated at the time IRB approval was conferred. Specifically, "unanticipated problems" are those that meet all three of the following criteria:

1. *Unexpected* (in terms of nature, specificity, severity, or frequency) given the research procedures described in the protocol-related documents and the characteristics of the subject population being studied.
2. *Related or possibly related* to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).
3. *Suggests that the research places subjects or others at a greater risk of harm* (including physical, psychological, economic, legal, or social harm) than was anticipated at the time IRB approval was conferred.

An adverse event is defined as an untoward or unfavorable occurrence in a human subject which may or may not be related to the subject's participation in the research.

A serious adverse event is one which results in death, is life-threatening, requires hospitalization, results in a significant disability/incapacity, or any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed.

The timeframe for reporting unanticipated events is as follows:

1. Serious adverse events must be reported to the IRB or to the RIO within 24 hours of the occurrence of the event.
2. Other unanticipated problems or protocol changes and deviations that meet the three criteria above must be reported to the IRB within 5 days of the occurrence of the event.
3. All other events or adverse events that do not meet these reporting criteria, including unanticipated protocol changes and deviations, must be submitted within one week of the investigator becoming aware of the problem.

If unanticipated problems occur during research, the Principal Investigator must report the following to the Chair of the APU Institutional Review Board:

1. Research number as assigned by the IRB, title of approved research project
2. A detailed description of the adverse event, incident, experience, or outcome
3. An explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem, and
4. A description of any recommended changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem

The report must be submitted in writing to the IRB Chair, who will promptly present the report to the IRB. If the IRB Chair is the Principal Investigator making the report under this policy, the report shall be presented directly to the Research Integrity Officer who will present the report to the IRB.

The IRB, the Chair or designee will review the report to consider whether the event impacts the risk/benefit ratio and whether that warrants a reconsideration of the approval of the study, modifications to the study, revisions to the continuing review timetable, suspension of the study, or other action required due to safety concerns. The IRB has the authority to require, as a condition of continued approval by the IRB, submission of more detailed information by the researcher or sponsor about any adverse event or unanticipated problem occurring in a research protocol. The IRB Coordinator will brief the Academic Dean concerning all reports.

For serious adverse events, the IRB Coordinator or designee has the authority and responsibility to make immediate changes to the study, as noted above, and will refer the issue to the full IRB as soon as is feasible for additional consideration. Only a full IRB can make a determination to take no action on a serious adverse event.

All BGU faculty and staff must promptly report to a member of the BGU IRB any of the following occurrences when required by law:

1. Unanticipated problems involving risks to subjects and others
2. Serious or continuing noncompliance with requirements or determinations of the IRB
3. Suspension or termination of IRB approval of non-exempt human subject research.

For further guidance, the researcher is encouraged to review the Department of Health and Human Services Guidance on Reviewing and Reporting Unanticipated Problems Involving Risk to Subject or Others and Adverse Events at http://www.hhs.gov/ohrp/policy/advevntguid.html.

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APPENDICES

Appendix A
Application for IRB Review

Request for Approval of Research with Human Participants
In Social and Behavioral Research
Institutional Review Board for Research with Humans
Bakke Graduate University
8515 Greenville Ave.
Dallas, TX 75243-7039
Email: IRBcoordinator@bgu.edu

Bakke Graduate University (BGU) and Federal policies require that each project involving studies of humans be reviewed to consider 1) the rights and welfare of the individuals involved; 2) the appropriateness of the methods used to secure informed consent; and 3) the risk and potential benefits of the investigation. All research proposals should be reviewed by the IRB Coordinator to determine if further review is required by the full IRB committee. The levels of review and their associated criteria are available in the current edition of the BGU IRB Policy and Procedures Manual, which is available on request to the IRB Coordinator. **Research involving human subjects may not be initiated prior to formal, written approval by the appropriate committee or person.**

The information on the following pages is necessary for review by the IRB. Please prepare a document that provides the information indicated. Answer each item thoroughly, and put N/A for those that do not apply. Label each piece of information by section letter (A – G), item number (1, 2, etc.), and the boldface headers for each item. **Proposals lacking information will be returned without review**. Attach this cover sheet to your document.

Submit the completed document to the BGU IRB Coordinator using the email address shown above. Please keep a copy of all material you submit because it will remain on file with the school and not be returned to you. You will be notified by letter or email of the committee's decision.

1/9/09

A. Identifying Information

1. **Date**
2. **Principal Researcher -**– name, address, phone number, and e-mail address.
3. **Co-researchers (if any)** – name, address, phone number, and e-mail address.
4. **Project Title**
5. **Key Words** – For classification purposes, give two or three key words that describe or categorize this research.
6. **Inclusive Dates of Project** – Indicate the beginning and ending dates for data collection and reporting of the results.
7. **Final Project Supervisor** – name (indicate if the supervisor is a BGU faculty member – if not, provide address, phone number, and email address.
8. **Funding Agency (if any)** – organization name, contact person's name, address, phone number, agency-assigned grant number or other identifier
9. **Investigational Agents** – If the research involves the use of any drugs or experimental substances, give the IND or IDE number assigned by the FDA and the expiration date.

B. Participants

1. **Type of Participants** – Indicate if the project will involve only adults or other age categories of people. Adults are considered those 18 and older who are of normal cognitive functioning. Any other groups (mentally disabled, emotionally disturbed, senile, special minorities) must be identified.
2. **Institutional Affiliation** – If participants are affiliated with some organization or institution through which they will be recruited, i.e., schools, prisons, hospitals, human services organizations, etc., please identity
3. **Approximate Number of Participants –** Indicate the approximate number of people from who data will be collected in some manner.
4. **How Participants are Chosen** – Indicate specifically how participants will be selected for the project such as random selection, criteria-based selection, review of records, referrals, classes, referrals, canvassing, etc. If records are used, indicate who gave approval for use of records.
5. **How Participants are Contacted** – Indicate how you will contact and recruit participants such as by ads, email, telephone, letters, etc.
6. **Inducements** – Describe what, if any, inducements before or rewards after the study will be offered.
7. **Monetary Charges** – If participants will be charged for any research-related procedure, please describe.

C. Informed Consent

Submit an Informed Consent Form with this application (see sample in Appendix B of the IRB Policy and Procedures Manual or available online at the BGU website). For research with minors or with vulnerable populations, consent from parents or guardians is required in most cases.

D. Summary of Project Focus and Research Design

1. **Project Focus** – Summarize the problem and purpose statements of the study

2. **Research Design** – Indicate exactly how data will be collected from participants. Include when and where the data will be collected. Attach copies of invitation letters if participants are sent any. Describe exactly what will be done to and for the participants. Include when and where the data will be collected (attach copies of permission letters if participants are being recruited and/or tested in a field location), what instructions will be given to the participants (attach a copy if the instructions are written out for the researcher and/or the participants to read), precisely how and when the informed consent will be requested, what tasks the participants will perform (attach a copy of all verbal and/or visual materials to be used), and how the participants will be debriefed regarding the purpose of the study.

E. Confidentiality

Specify steps that will be taken to ensure the confidentiality of the information collected. Please include information on who will have access to the data, where the data will be securely kept, and other steps you will take to protect the information. Also, please note that confidentiality also extends to the reporting of the data in written papers or presentations. Data should not be reported in a way that violates participants' confidentiality. If data will become part of a participant's permanent record or if some third party will be informed of anyone's participation in the study, explain exactly why this is necessary. If video or audiotaping is used, specify when and how the tapes will be destroyed.

E. Risks

Use the following chart to evaluate the level of risk to participants involved in your project. For items that apply to your project, indicate what precautions will be taken to minimize risk to the participants (use the Notes box or attach a separate sheet). If, in the course of review, the committee finds evidence of possible risk that is not addressed, the proposal will be rejected, and a re-submittal will be required.

Potential Risks	**Yes**	**No**	**Notes**
Will research involve any possible **invasion of privacy** of the participants or their families, including the review of personal information or records?			
Will research involve administration of any **physical stimulus** other than sensory stimuli associated with normal classroom situations and/or daily life?			
Will research involve any **deprivation** of physiological requirements such as nutrition or sleep, **manipulation** of psychological and/or			

social variables, e.g., sensory deprivation, social isolation, psychological stresses, etc.			
Will research involve any **deception** in which full informed consent cannot be obtained before the study begins? In these cases, the protocol must include a statement of why the deception is necessary and how participants will be debriefed upon completion of the study. Informed consent is *not* waived when deception is used; it must be obtained after the data are gathered but before analysis is performed.			
Will research involve asking participants anything regarding **sensitive information** that they may consider to be personal or sensitive in content?			
Will research involve the presentation of any materials which participants might find to be **offensive, threatening,** or **degrading**?			
Will research involve any **physical exertion** beyond normal classroom and daily life situations			
Will research involve any **vulnerable populations** including children under the age of 18, pregnant women, prisoners, wards, and other "vulnerable populations," such as mentally or physically disabled persons and economically or educationally disadvantaged persons (see Federal Code, 45 CFR 46 for definitions of vulnerable populations).			

G. Signatures

Type the following paragraph at the end of the proposal and have all investigators and the research advisor (if applicable) sign and date below it.

"I certify that the information furnished concerning the procedures to be taken for the protection of human participants is correct. I will seek and obtain prior approval for any substantive modification in the proposal and will report promptly any unexpected or otherwise significant adverse effects in the course of this study."

Appendix B
Participant Consent Form

Participant Consent Form
Institutional Review Board for Research with Humans
Bakke Graduate University
8515 Greenville Ave.
Dallas, TX 75243-7039
800-935-4723
Email: *IRBcoordinator@bgu.edu*

(**Note to** researchers: Please use this form as a model for your Participant Consent Form, which must be distributed to all of your research participants.)

You are being asked to take part in a research study related to Bakke Graduate University on the topic of _____. Please read this form carefully and ask any questions you may have before agreeing to take part in the study. You must be at least 18 years old and _____ (indicate any other requirements for participants in this study).

What we will ask you to do: If you agree to be in this study, ***someone on the research team*** will conduct an interview with you ***and/or ask you participate in a questionnaire***. The interview ***and or questionnaire*** will include questions about

_____
_____

If an interview is conducted, it will require approximately _____(time) to complete. With your permission, we would also like to tape-record the interview.

Risks and benefits: There is the risk that you may find some of the questions to be sensitive in nature. [Note: For studies posing no specific risks, use the IRB standard minimal risk statement, "I do not anticipate any risks to you participating in this study other than those encountered in day-to-day life."] There are no benefits to you other than what you may learn from the study

Compensation: You will earn no compensation participating in this study.

Your answers will be confidential. The records of this study will be kept private. Publicly available reports will not include any information that will make it possible to identify you. Research records will be kept in a restricted or 'locked' file, where only the researchers will have access to the records. If ***an*** interview ***is audio recorded, the research team will*** destroy the tape after it has been transcribed, which we anticipate will be within two months of its taping.

Taking part is voluntary: Taking part in this study is completely voluntary. You may skip any questions that you do not want to answer. If you decide not to take part or to skip some of the questions, it will not affect your current or future relationship with BGU. If you decide to take part, you are free to withdraw at any time.

If you have questions: The researchers conducting this study are _____ and _____, and they can be contacted at _____.

Please ask the researcher(s) any questions you have before signing this form. If you have questions later, you may contact any of the researcher indicated above.

If you have questions or concerns regarding your rights as a subject of this study or other question that you would like to discuss with a representative from Bakke Graduate University, you may send an email to the Coordinator of BGU Institutional Review Board or you can call the school (see contact information at top of this form). You can also use a phone call to report your concerns or complaints anonymously if you so desire. You may also see information on Bakke Graduate University at the school website at www.bgu.edu. You will be given a copy of this form to keep for your records.

Statement of Consent: I have read the above information and have received answers to any questions I asked. I consent to take part in the study.

Your Signature _____ Date _____

Your Name (printed) _____

In addition to agreeing to participate, I also consent to having the interview tape-recorded.

Your Signature _____ Date _____

Signature of person obtaining consent _____ Date _____

Printed name of person obtaining consent _____ Date _____

NOTE: The researcher will keep this consent form for at least three years beyond the end of the study. The title of the study should appear at the top of every page.

Appendix C
IRB Initial Review Form

Review Requirement	Applicable Questions to Consider	Yes	No
1. The proposed research design is sound and will not unnecessarily expose subjects to risk.	a. Is the hypothesis clearly stated?		
	b. Is the research design appropriate?		
	c. Will the research contribute to generalized knowledge and be worth the risk?		
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of knowledge that may reasonably be expected to results.	What does the IRB consider Level of risk to be? __High __Medium __Low __Other	N/A	N/A
	What does researcher considered level of risk to be? __High __Medium __Low __Other	N/A	N/A
	Does the IRB consider there to be prospect of direct research benefit to subjects, excluding any financial compensation?		
3. Subject selection is equitable	a. Are participants clearly identified (such as men, women, children, ill-heath individuals, etc.)?		
	b. Are the subjects appropriate for the defined research methodology?		
4. Safeguards required for subjects likely to be vulnerable to coercion or undue influence.	Are appropriate safeguards in place for vulnerable subjects such as pregnant women, socially or economically disadvantaged, those with impaired decision-making abilities, etc.?		
5. Informed consent is obtained from research subjects or their legally authorized representative.	a. Does the Informed Consent form include all information based on the sample BGU Consent form?		
	b. Is the Informed Consent form clear to subjects?		
	c. Is it clear as to who will be responsible to obtain the informed consent?		
	d. If appropriate, is there a procedure for assent of children and their parents/guardians?		
	e. Is there a request for the IRB to waive or alter any informed consent requirements?		
6. Subject privacy is maximized.	a. Does the methodology minimize risks to subjects?		
	b. Do the circumstances of the project warrant an observation team to ensure safety of participants?		
7. Subject privacy and confidentiality are maximized.	a. Will personally-identifiable research data be protected from inappropriate access or use to the highest degree possible?		
	b. Are all special privacy and confidentiality issues properly address such as medical records, financial records, etc.?		
8. Other	Are there other issues that need to b addressed? (Add attached sheets as necessary)		

__Exempt __ Approved __Make Changes & Resubmit __Reject

Appendix D
Checklist for Application for IRB Review

Checklist for Bakke Graduate University IRB Application for IRB Review

Please ensure all items are completed prior to submission. Failure to submit all required material may lead to the application being sent back to you without review and will delay formal review and the start of your final project.

_____ 1. I have fully completed all required areas on the Application for IRB Review or indicated N/A for any areas that do not apply to my project.

_____ 2. In the dissertation proposal submitted to the IRB with my application, I have included in the appendix, or within the chapters, samples of items such as advertisements, solicitation letters, questionnaires, tests, interview questions, solicitation letters, advertisements, detailed research protocol, and supporting documents as needed.

_____ 3. If I am collecting data from members of an organization (school, business, university other than Bethel, prison, etc.), I have received prior written permission from the proper administration of that organization and have attached it as an appendix or appendices to my application.

_____ 4. If I am collecting information from a protected class, such as children, I have prepared a separate informed consent for those who are legally responsible for consent.

_____ 5. The informed consent document I have prepared includes all the necessary fields as outlined in the sample BGU Informed Consent Form. This form is free from jargon or technical terms or when those terms are used an appropriate non-technical definition is included.

_____ 6. I have described any risks to the participants in the both the IRB application AND the informed consent document.

_____ 7. I have described how I will attempt to mitigate the risk to participants in the IRB application materials.

_____ 8. I have addressed how I will keep participant information both private and confidential during my project.

_____ 9. I have explained any potential risks to privacy and confidentiality in the informed consent as well how I will work to minimize these risks.

_____ 10. My application includes a summary of the research process and procedures that is written for a general audience. That is, any jargon or technical terms are clearly explained.

Appendix E
IRB Approval Decision Charts

The following decision charts are produced by the U.S. Department of Health and Human Services, Office for Human Research Protections (http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html)

Chart 1: Is an Activity Research Involving Human Subjects?

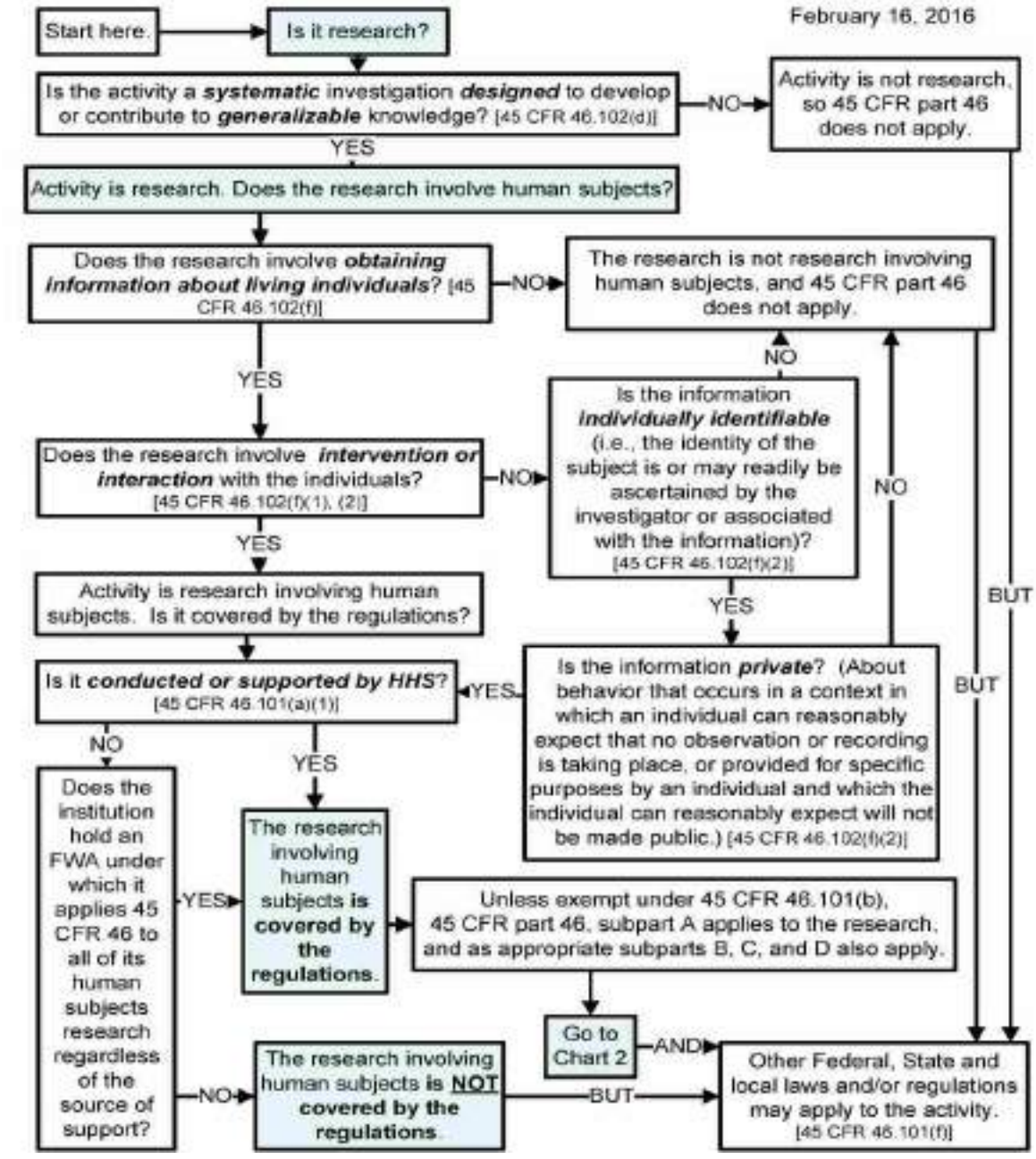


Chart 2: Is the Human Subjects Research Eligible for Exemption?

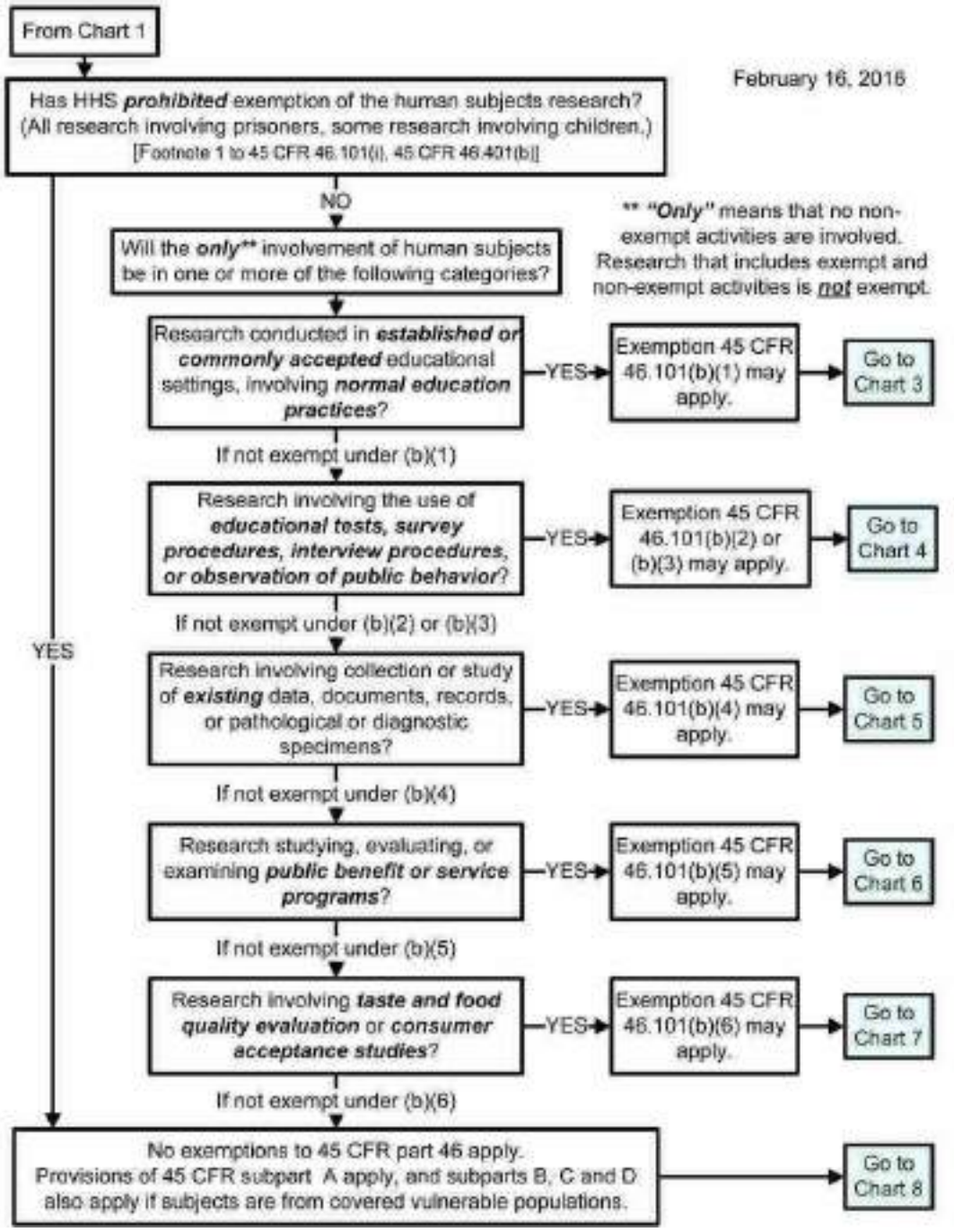
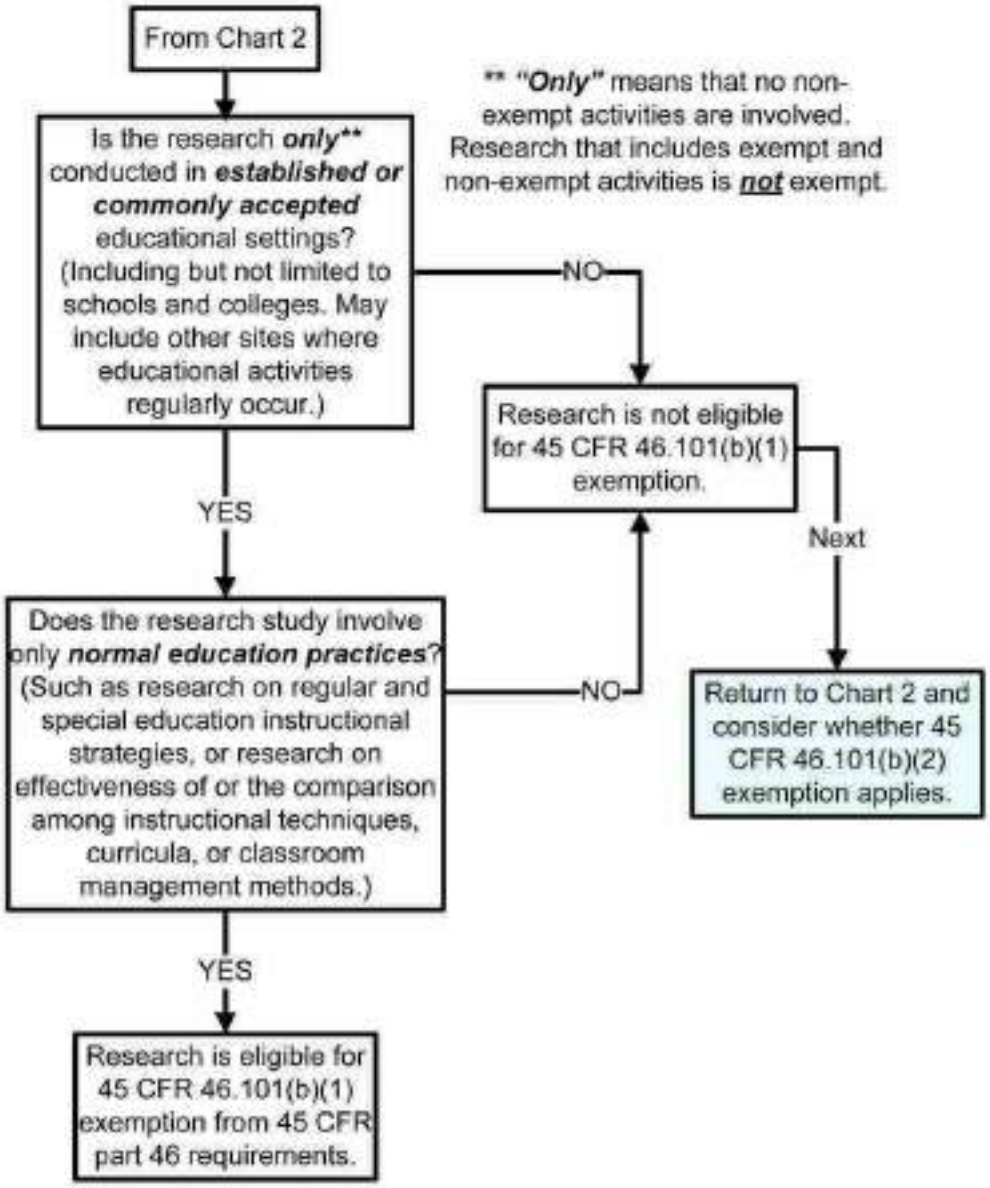


Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?



February 16, 20126

Chart 4: Does exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

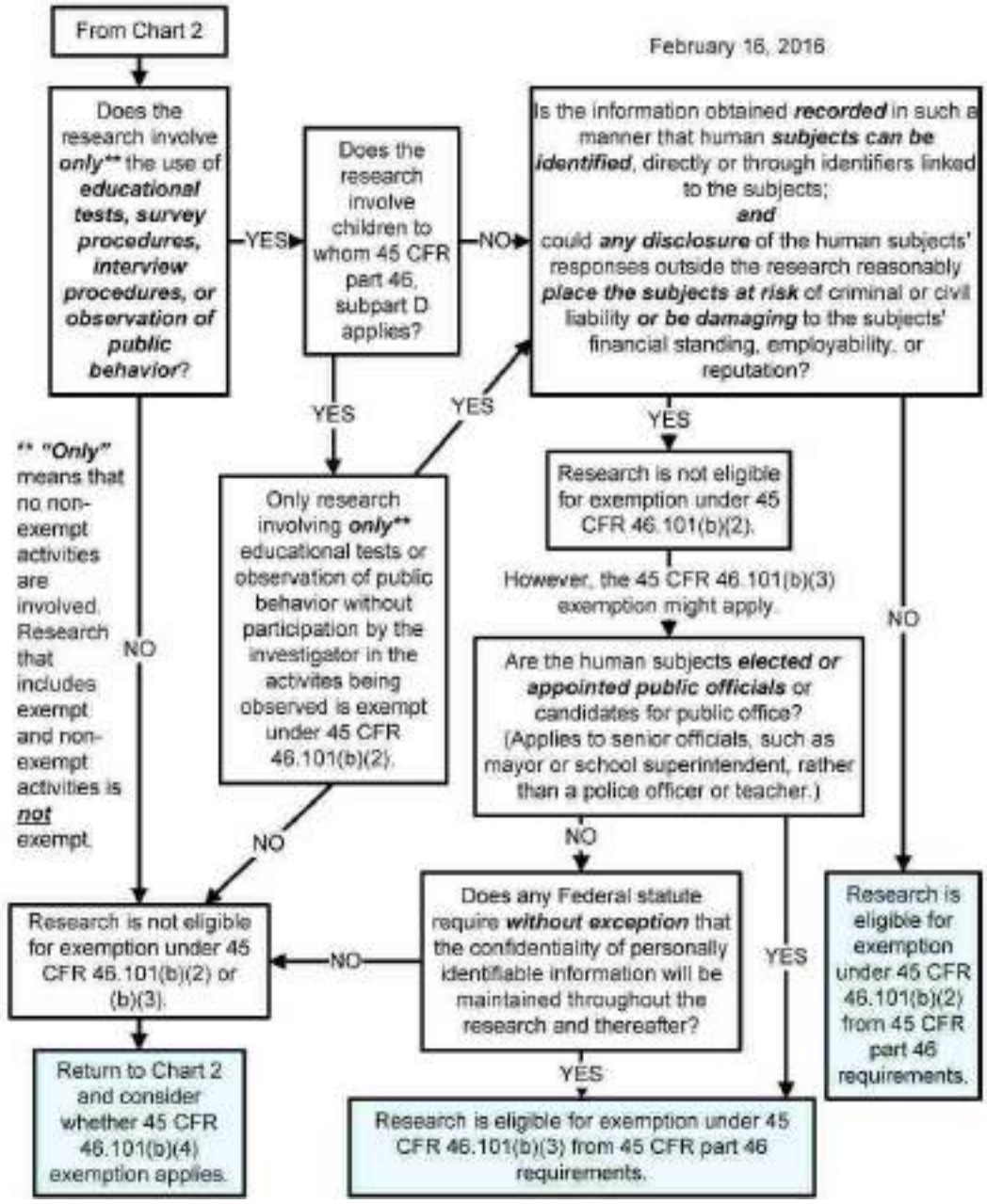
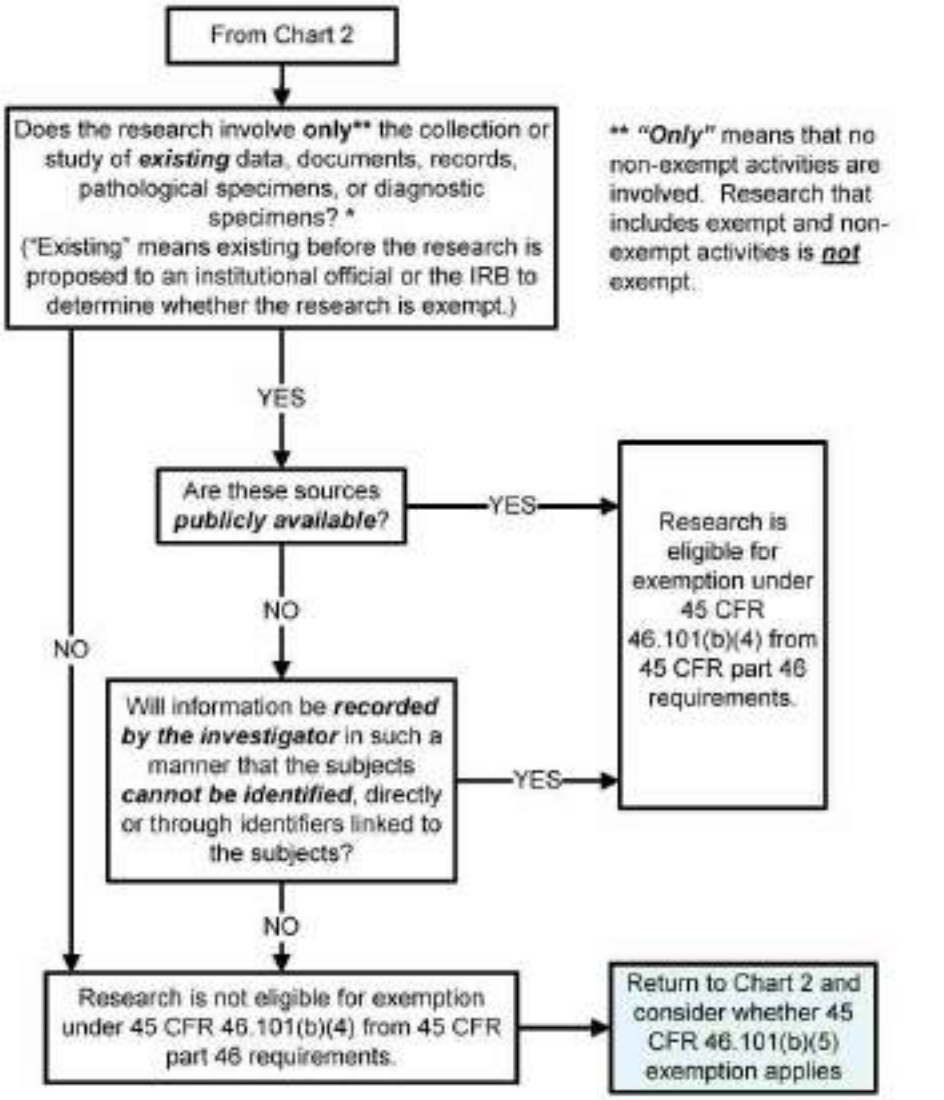


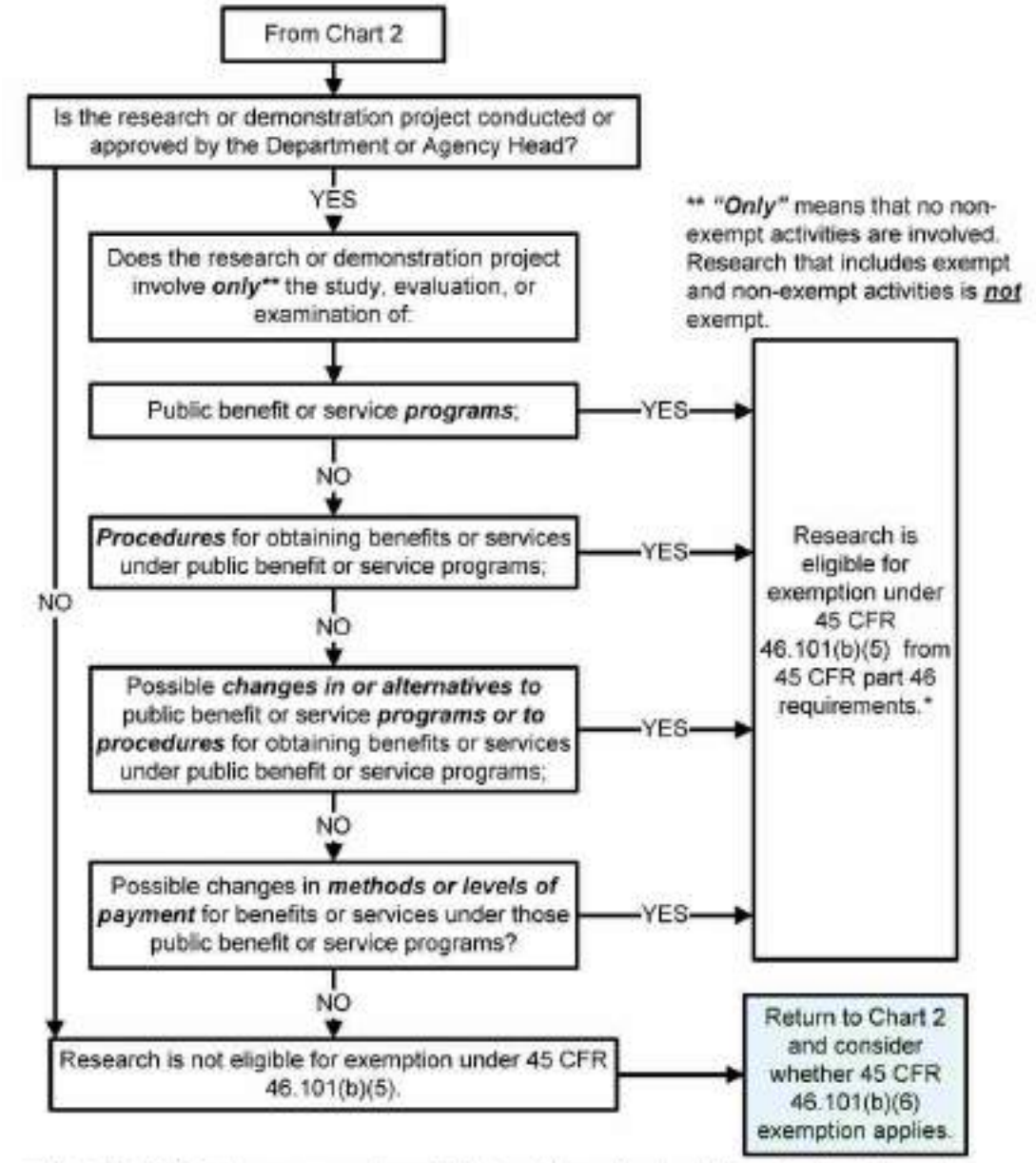
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data, Documents, Records and Specimens) Apply?



* Note: See **OHRP** guidance on research use of stored data or tissues and on stem cells at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-research-involving-stem-cells/index.html, and on coded data or specimens at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html for further information on those topics.

February 16, 2016

Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?



* Note: See OHRP guidance on exemptions at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/exemptions-for-public-benefit-and-service-programs/index.html for further description of requirements for this exemption.

February 16, 2016

Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?

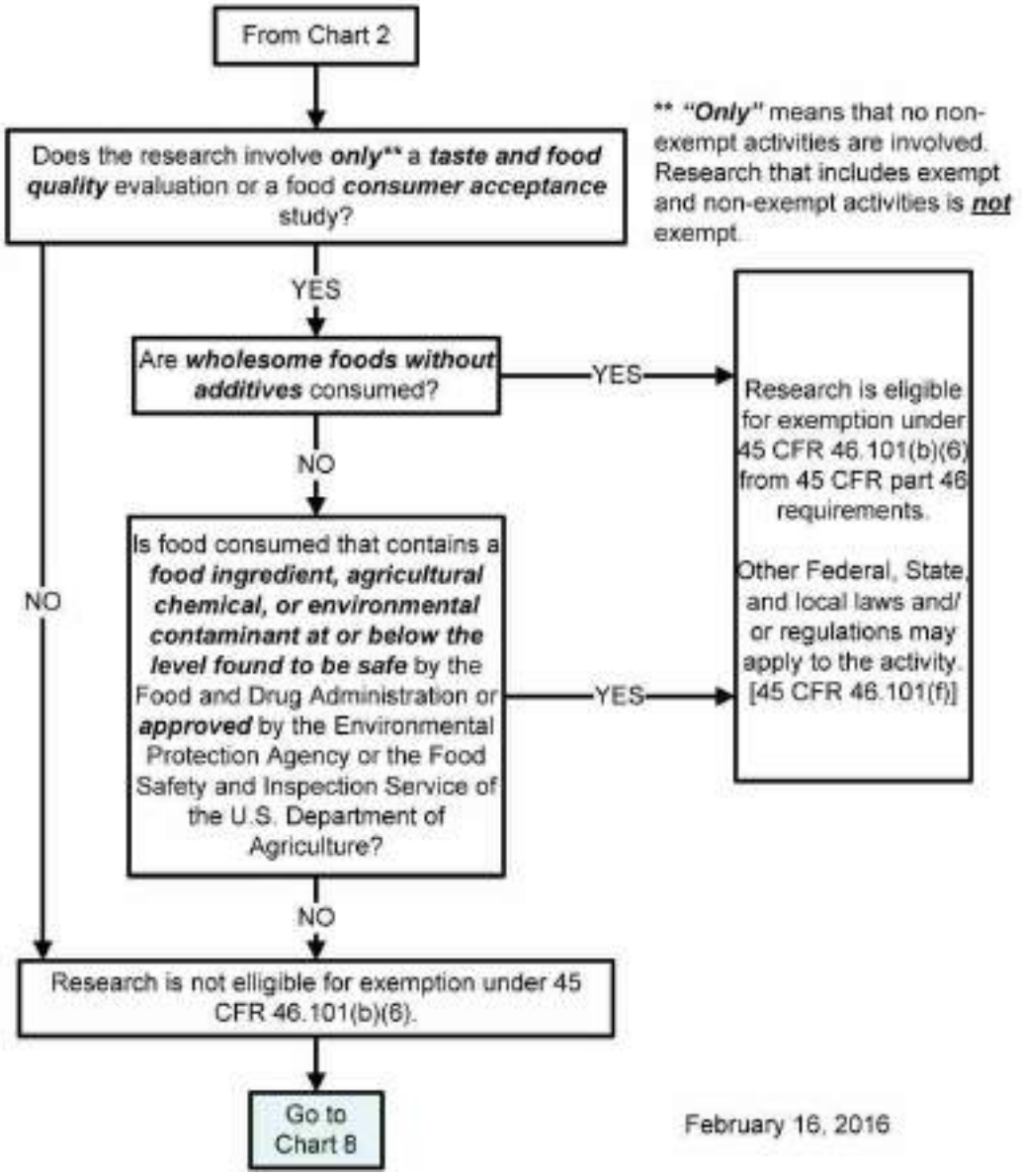


Chart 8: May the IRB Review Be Done by Expedited Procedures?

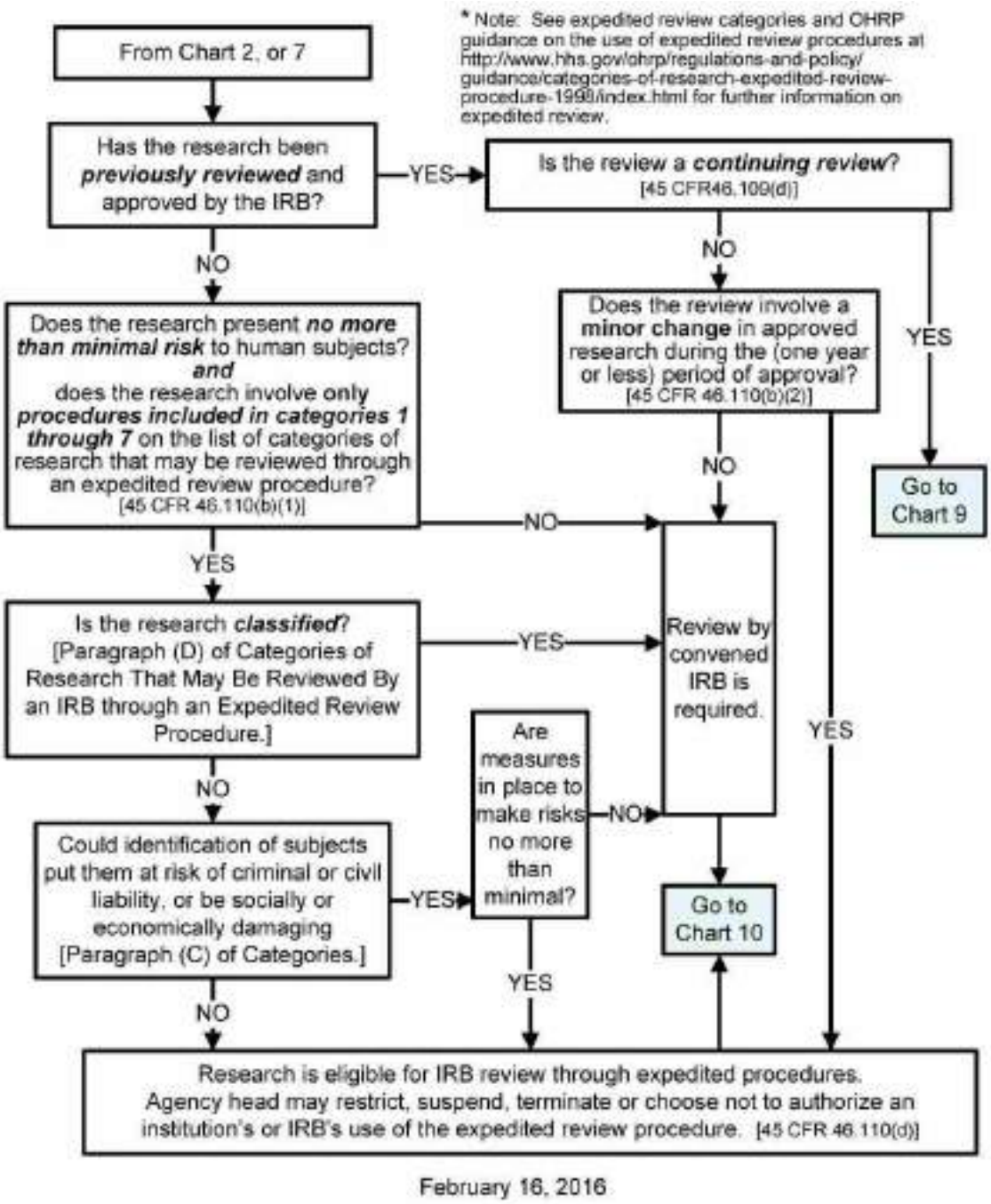


Chart 9: May the IRB Continuing Review Be Done by Expedited Procedures?

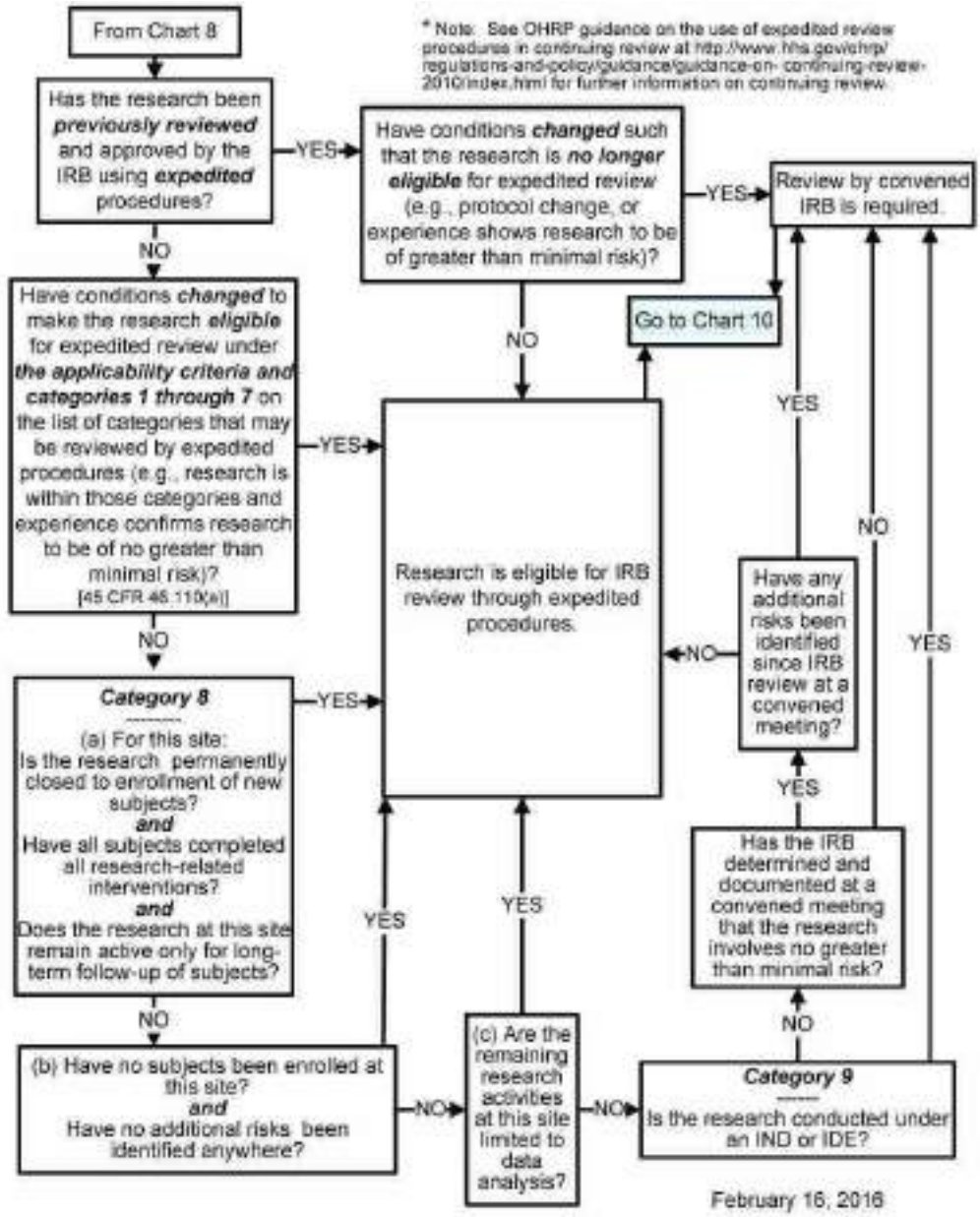


Chart 10: May Informed Consent Be Waived or Consent Elements Be Altered under 45 CFR 46.116(d)?

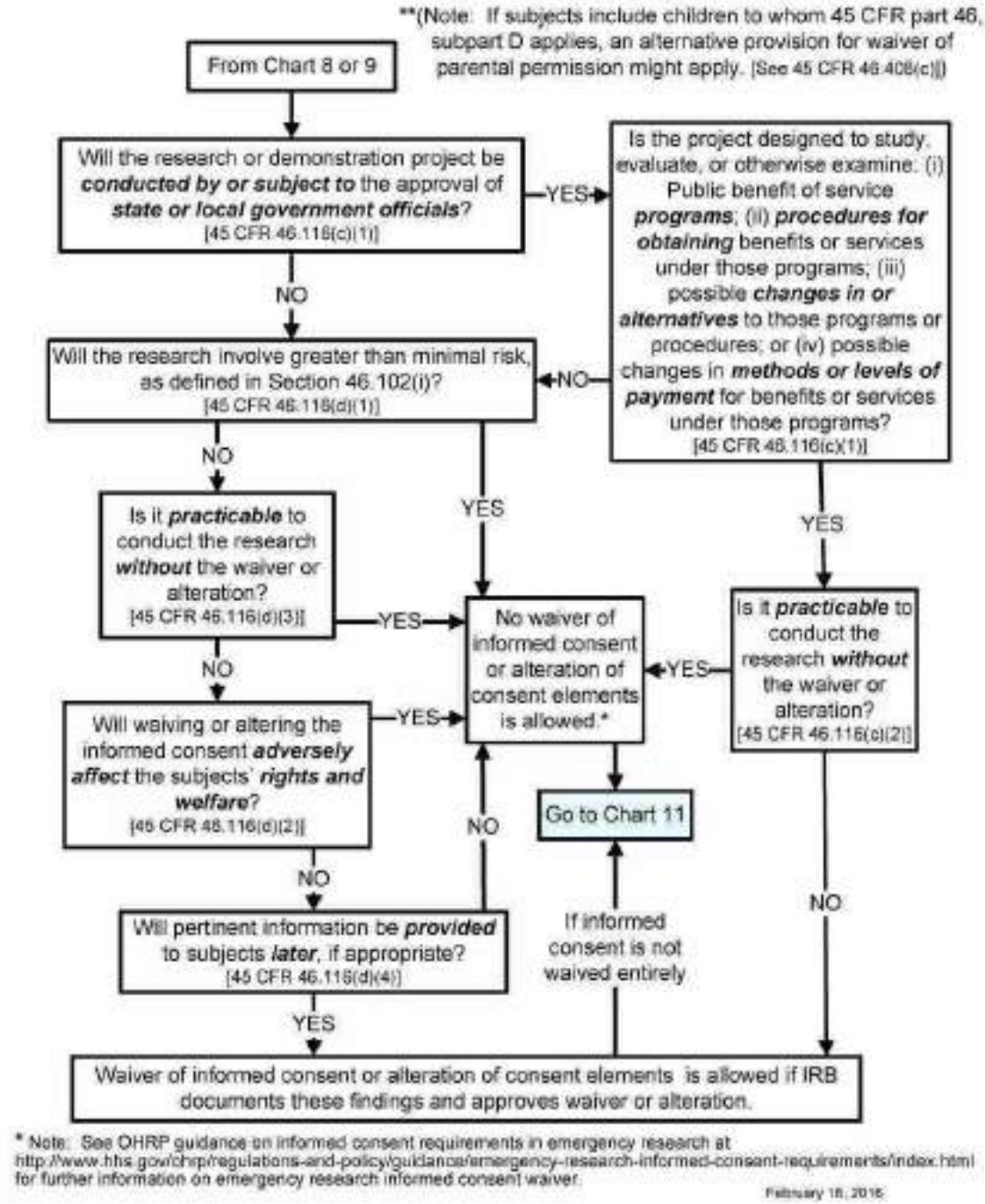


Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?