INSTITUTIONAL REVIEW BOARD
Glossary of Terms

Anonymous	An individual's participation in a research project can be described as anonymous if it is impossible to know whether that individual participated in the study. For example, participation in an online survey would be considered anonymous if that survey could not be linked in any way to the individual.
Approval Date:	The approval date is the first date that research can be performed. The approval date is reflected on the Princeton IRB approval letter. A revision letter aka conditionally approved letter is not the approval letter.
Approval period	The period in which the study can be conducted
Assent	"Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. This means the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way.
Assurance	A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved
Authorized Institutional Official	An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research.
Autonomy	Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others.
Belmont Report	A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.
Beneficence	An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.
Benefit	A valued or desired outcome; an advantage.
Biologic	Any therapeutic serum, toxin, anti-toxin, or analogous microbial product applicable to the prevention, treatment, or cure of diseases or injuries. Biologics include vaccines, blood and blood products, cellular and gene therapy products, tissue and tissue products, and allergenics.
Children	Children, or minors, are individuals under 18 years of age regardless of the jurisdiction in which the research is performed.
Clinical Trial	A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. Note that the FDA uses a different definition.

Cognitively Impaired	Individuals having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.
Compensation	Payment for participation in research or for medical care provided to subjects as a result of being injured in research
Competence	Capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (See also: Incompetence, Incapacity.)
Confidential	When participation is confidential, the research team knows that a particular individual has participated in the research, but the team members are obligated not to disclose that information to others outside the research team, except as clearly noted in the consent document.
Confidentiality	Confidentiality refers to subjects' data and the study safeguards that will protect the data.
Congruency Review	The process to ensure that the information in the grant is congruent with the information in the application. The IRB will not perform grant congruency unless the IRB, in its discretion, decides that performing a grant congruency would be appropriate for the study.
Consent	See: Informed Consent.
Continuing Review	One mechanism by which the IRB periodically reviews the conduct of research. Continuing review is distinct from Post-Approval Monitoring (please see that definition elsewhere in the glossary).
Contribute	To result in.
Data and Safety Monitoring Board	A group of individuals that reviews study data on a regular basis to ensure subject safety. Also known as a Data Monitoring Committees (DMC) or a Data and Safety Monitoring Committee (DSMC).
Debriefing	Giving subjects previously undisclosed information about the research project following completion of their participation in research.
Declaration of Helsinki	A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries.
Designed	The purpose of an activity that is realized via an investigator's observable behaviors.
Develop	To form the basis for a future contribution, such as a pilot study.
DHHS	U.S. Department of Health and Human Services, one of the IRB regulators
Drug	A drug is defined as: A substance recognized by an official pharmacopoeia or formulary. A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. A substance (other than food) intended to affect the structure or any function of the body. A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device. Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)

Embryo	Early stages of a developing organism, broadly used to refer to stages immediately following fertilization of an egg through implantation and very early pregnancy (i.e., from conception to the eighth week of pregnancy). (See also: Fetus.)
Equitable	Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed
Exempt	Categories of research that are exempt from federal oversight. However, exempt studies are still human subjects research and must be submitted to the IRB for an exempt determination. Investigators are not authorized to make this determination. The ethical guidelines of the Belmont Report and Princeton IRB policies still apply to exempt human subjects research.
Expedited Review	Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research
Expiration date	The first date that the protocol is no longer approved. The date after the end date of the approval period.
FDA	Food and Drug Administration, one of the IRB regulators
Fetal Material	The placenta, amniotic fluid, fetal membranes, and umbilical cord.
Fetus	The product of conception from the time of implantation until delivery. If the delivered or expelled fetus is viable, it is designated an infant. The term "fetus" generally refers to later phases of development; the term "embryo" is usually used for earlier phases of development. (See also: Embryo.)
Full Board Review	Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting
Generalizable	Widely applicable or universally applicable
Grant	Financial support provided for research study designed and proposed by the principal investigator(s).
Guardian	An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.
Human Subjects	A living individual about whom an investigator (whether professional or student) conducting research: obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens OR obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Note that if your proposed research activity involves a drug, device, or biologic, other regulations and definitions may apply. Please contact the IRB for further clarification.

Human Subjects Research Not Engaged	An activity that is human subjects research, but the Princeton investigator's role does not engage Princeton University in the research. If the Princeton investigator's role does not engage Princeton University in the research, Princeton IRB review is not applicable. Please see Princeton University IRB SOP 208: "Collaborations with other researchers, institutions, and organizations" for more details.
Identifiable Private Information	Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. Examples of identifiers include names, social security numbers, medical record numbers, OR any code that permits the data to be linked to individually identifiable living individuals.
Identifiable Biospecimen	An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
Incapacity	Refers to a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence. (See also: Incompetence.)
Incompetence	Inability to manage one's own affairs. Often used as a synonym for incapacity. (See also: Incapacity.)
Informed Consent	A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. . An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.
Institution	Any public or private entity or agency (including federal, state, and local agencies).
Institutional Review Board (IRB)	A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.
IRB Authorization Agreement (IAA)	IAAs, also called Reliance Agreements, are Agreements entered into between two institutions in which one IRB agrees to serve as the Reviewing IRB (or IRB of record) and one IRB agrees to serve as the Relying IRB. Please see Princeton University IRB SOP 208: "Collaborations with other researchers, institutions, and organizations" for more details.
Institutionalized	Confined, either voluntarily or involuntarily (e.g., a hospital, prison, or nursing home).
Interaction	Interaction includes communication or interpersonal contact between investigator and subject.
Intervention	Intervention includes physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.
Investigation	A searching inquiry for facts; a detailed or careful examination.

Justice	An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.
Knowledge	Truth, facts, information.
Lead investigator	In multi-site studies, the lead investigator is the person who manages the research study at all sites and is responsible for the conduct of the study at all sites.
Legally Authorized Representative	An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures involved in the research.
Medical Device	A diagnostic or therapeutic article that does not achieve any of its principal intended purposes through chemical action within or on the body. The FDA defines "devices" very broadly. For example, devices include, but are not limited to, diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic pins or other orthopedic equipment.
Mentally Disabled	See: Cognitively Impaired.
Minimal Risk	"Minimal risk" is defined as 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.
Minors	Individuals under 18 years of age, regardless of the jurisdiction in which the research is performed.
Modification	A change to an approved study. Modifications must not be implemented without IRB approval.
Multi-site	A multi-site study is one in which non-Princeton research personnel work at a university or organization that has an IRB. For example, a study in which the procedures are done at Princeton University and another university is a multi-site study. In contrast, a study in which the procedures are done in Peretsman-Scully Hall of Princeton and Green Hall of Princeton is not a multi-site study. A study in which the procedures are done in Peretsman-Scully Hall of Princeton and Shadybrook Elementary School is not a multi-site study. Note that multi-site studies involving human subjects research funded by the federal government must decide upon a single Institutional Review Board ("sIRB"). Please contact the IRB office if you have questions.
Nonaffiliated Member	Member of an Institutional Review Board who has no ties to the parent institution, its staff, or faculty. This individual is usually from the local community
Not Human Subjects Research	An activity that does not meet the definitions of "research" and "human subject" under either FDA or DHHS regulations. If an investigator is unsure whether the proposed activity is human subjects research, the IRB recommends that the investigator e-mail a synopsis of the proposed activity (2-3 paragraphs) to the IRB.
Nuremberg Code	A code of research ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human subjects.
Obligations	The obligations that a principal investigator must meet while conducting a study. The obligations can be found in SOP 207 listed HERE.
Permission	The "agreement of parent(s) or guardian to the participation of their child or ward in research." The term "parent" means a "child's biological or adoptive parent."

Post-approval monitoring (PAM)	The program to ensure that ethical and regulatory requirements are followed by investigators. This program is also designed to improve the quality of research by ensuring congruence between what is described in the research protocol and what is occurring during the actual performance of research activities. PAM methods include: protocol review; laboratory visits; observation of selected procedures; and follow-ups to concerns. All studies, even those determined to qualify for exempt status, are subject to PAM.
Primary or Secondary Schools	Schools before college. Note that if the investigator is in the Psychology Department and the research will take place in primary or secondary schools, Rosemarie Stevenson will act as your liaison in contacting those schools. RoseMarie Stevenson can be reached at: rosemari@Princeton.EDU
Principal Investigator (PI)	The PI is the person who is ultimately responsible for the conduct of the study. For student-initiated research, the student's faculty advisor serves as the PI and is ultimately responsible for the conduct of the study. For the eligibility criteria to serve as a PI at Princeton University, please see this document.
Prisoner	"Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Common examples of the application of the regulatory definition of "prisoner" are as follows: Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners; however, individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners. Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration are prisoners; however, individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness, or who have been civilly committed to non-penal institutions for treatment because their illness makes them a danger to themselves or others, are not prisoners. Parolees who are detained in a treatment center as a condition of parole are prisoners; however, persons living in the community and sentenced to community-supervised monitoring, including parolees, are not prisoners. Probationers and individuals wearing monitoring devices are generally not considered to be prisoners; however, situations of this kind frequently require an analysis of the particular circumstances of the planned subject population. Institutions may consult with OHRP when questions arise about research involving these populations.
Privacy	Privacy is about people and means respecting an individual's right to be free from unauthorized or unreasonable intrusion, including control over the extent, timing and circumstances of obtaining personal information from or about them. For example, individuals may not want to conduct the consent process in an open area or may not want to be seen entering a study site that might stigmatize them.
Private Information	Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a tax record, educational record, or medical record).

Procedures	The activities that subjects will undergo as part of their participation or investigators will follow to conduct the study. For example, in a data analysis study, the procedures would include an investigator reviewing subjects' records. In a study involving interaction or intervention with subjects, procedures would describe the nature of the intervention or interaction, such as administering surveys or questionnaires. Study procedures need to be described in detail.
Protocol	The formal design or plan of an experiment or research activity that is described in the IRB initial review application The protocol describes how the investigator will carry out the research. Note that if the protocol requires a procedure or mandates how a procedure is performed, then the procedures are considered by the IRB to be research procedures, including disclosing to the subject that if they take part in the research, they will undergo that procedure. The procedure may not be an experimental procedure, but it is a procedure involved in the research. For example, if the protocol requires minors to take cognitive tests, the cognitive test is a research procedure, though the students would have to take the tests anyway as part of classroom instruction. Similarly, if the protocol requires subjects to undergo physical training, the physical training is a research procedure, though the individuals would undergo them anyway as part of their athletic program.
Quorum	Quorum means that greater than half of the IRB members are present at an IRB meeting and the following criteria are met: at least one member whose primary concerns are in scientific areas is present at the meeting; at least one member whose primary concerns are in non-scientific areas is present at the meeting; and at least one unaffiliated member is present at the meeting. A Board member may fulfill more than one criterion.
Reportable New Information	The information that investigators must report to the IRB. This information is listed in SOP 206.
Research	A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Note that if the research activity involves a drug, device, or biologic, other regulations and definitions may apply. Please contact the IRB for further clarification.
Research Personnel	Those involved in the design, conduct, or reporting of the research. Research personnel can include students.
Respect for Persons	An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.
Risk	The discomforts, hazards, or inconveniences to the subjects related to the subjects' participation in the research. The probability, magnitude, duration, and reversibility of the risks should be described in the application. Consider physical, psychological, social, legal, and economic risks.
Site Visit	A visit by agency officials, representatives, or consultants to the location of a research activity to assess the adequacy of IRB protection of human subjects or the capability of personnel to conduct the research.
Study measurements	The measurements used to obtain information from subjects, such as surveys, questionnaires, interview guides, and psychological tests.
Surveys	Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.
Systematic	Having or involving a system, method, or plan.
Vaccine	A biologic product generally made from an infectious agent or its components — a virus, bacterium, or other microorganism — that is killed (inactive) or live-attenuated (active, although weakened). Vaccines may also be biochemically synthesized or made through recombinant DNA techniques.

Voluntary	Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.