

Welcome

This tutorial will help you and your research team to learn more about the development of codes and principles of research ethics, the informed consent process, selection and recruitment of research participants, protection of confidentiality of subjects, and regulation of research. You will also learn the basics of submitting VT IRB protocols and what will be expected of you, as a researcher, after you have obtained initial VT IRB approval.

This tutorial is certainly not exhaustive, and the VT IRB promotes further education of researchers regarding the principles of research ethics.

Reason for Training

In October 2000, the National Institute of Health (NIH) established a policy requiring education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects.

To further demonstrate Virginia Tech's commitment to the protection of human subjects, the VT IRB's policies state that it will hold all research conducted at the institution to the same standards as federally funded research.

In conclusion, the VT IRB requires completion of human subjects protections training for all investigators (internal or external) of a project. This tutorial is only one of several options available that are accepted by the VT IRB. Visit our website at <http://www.irb.vt.edu/pages/training.htm> for additional training options.

The Importance of Research Ethics & Compliance

Societies and cultures around the world establish for themselves moral standards or rules (personal ethics) which define right or wrong conduct by members within the societies, and which establish punishments for those who violate those standards/rules. Those moral standards seek to ensure that people act in ethical ways in their interactions with others in society. Professional groups and organizations within a society also establish ethical principles which mandate practices and behavior of professionals when they act in an official capacity (e.g., business, legal, medical, and scientific research ethical practices). In contrast to personal ethics, which are generally written into legal codes, adherence to professional ethics is typically self-regulated within the professional organization.

As noted in the "History" section below, some individual researchers have valued the acquisition of scientific knowledge more highly than the protection of human subjects' rights and well-being. Significant harm to and death of subjects has occurred when scientists failed to adhere to basic moral standards/rules such as:

- Concern for the well-being of others
- Respect for the autonomy of others
- Trustworthiness & honesty
- Willing compliance with the law (with the exception of civil disobedience)
- Basic justice; being fair
- Refusing to take unfair advantage
- Benevolence: doing good
- Preventing harm

When professional organizations fail to adequately regulate the conduct of their members (through voluntary regulation), the Government generally steps in to enact involuntary (mandatory) regulations which must be followed, and if violated, the perpetrator risks legal action and criminal punishment or financial sanctions. Because of problems with research conducted in the past in the U.S., Congress has passed a variety of legislation intended to force professionals to adhere to personal and professional ethical principles which they should innately follow.

Virginia Tech expects its faculty and student researchers who use human subjects in research to: (1) adhere to established personal (societal) ethical practices; (2) follow professional ethical principles established by their respective disciplines; (3) ensure full compliance with federal regulations governing protection of human subjects; and, (4) ensure full compliance with Virginia Tech policies and procedures which address protection of human subjects. Failure to comply with those four points may result in loss of privileges to conduct research at the University, and could result in loss of federal funding, or withdrawal of federal permission to conduct research affecting all researchers at the institution.

History

Beginning of the Tuskegee Syphilis Study

The Tuskegee study of untreated syphilis in the Negro male began in Macon County, Georgia in 1932 and was conducted by the United States Public Health Service. The purpose of the study was to follow the progression of the disease untreated in hopes to demonstrate the need for establishing syphilis treatment programs.

This study consisted of more than 400 black men with syphilis as study participants. To begin with, the subjects were recruited into the study without informed consent. They were not informed of their disease nor were they informed that this research would not benefit them personally. These men were misled to believe that the spinal taps involved as a study procedure were “special free treatments.”

Although at the beginning of the study there was no intent to deny anyone treatment for a long period of time, when Penicillin, known as an effective treatment, became available after 1943, it was purposefully withheld from subjects. Findings of the study, including high death rates and occurrences of complications, even as early on as 1936, clearly indicated the severe progression of the disease.

Even so, researchers continued to keep the subjects enrolled in the study and uninformed of their diseases. In their defense, researchers claimed that, with the development of Penicillin, this research was “the last opportunity to study the progression of the untreated disease”, even though from 1891-1910, long-term studies of syphilis in 2000 untreated patients in Oslo, Norway were completed.

The announcement of the Nuremberg Code (discussed below) had no effect on the study. The study was exposed to the public through an article published in the New York Times and Washington Star in 1972. Although the study was never hidden and was previously discussed openly by the Centers for Disease Control and Prevention officials, the public reacted strongly to this exposure.

Nazi Experiments

During World War II, medical experiments were performed on thousands of unwilling concentration camp prisoners. These experiments were torturous and most often led to the death of these subjects. Examples of these studies include forcing concentration camp prisoners to endure high altitude decompression in order to determine the maximum safe altitude for German Air Force pilots, hypothermia research to determine survival time for soldiers parachuting into the cold water of the North Atlantic, and inflictions of gunshot and stabbing wounds or traumatic amputations to study different treatment affects.

Nuremberg Code

In 1946, 23 leading members of the German medical hierarchy involved with the Nazi experiments were indicted for their participation. In August 1947, all were found guilty. Sixteen were imprisoned and seven were sentenced to death for conducting “crimes against humanity.” During this verdict, the judges included a section called “Permissible Medical Experiments”, which became known as the Nuremberg Code.

The Nuremberg Code mandated protections for human subjects in medical and non-clinical experiments. The code established basic principles that must be observed in order to satisfy moral, ethical and legal concepts. The following list is an outline of these basic principles:

- Voluntary (informed) consent is essential
- Experiment to yield fruitful results for society, and not random or unnecessary
- Research to be based upon animal experimentation or knowledge of the disease or problem to ensure that the results justify the undertaking of the experiment
- Experiment conducted so as to avoid unnecessary physical and mental suffering and injury
- Experiment not conducted if possibility that death or disabling injury will occur
- Degree of risk not to exceed the humanitarian importance of the problem to be solved
- Proper preparations and facilities to protect the subject from remote possibility of injury, disability, or death
- Conducted only by scientifically qualified persons using highest degree of skill and care
- Subject at liberty to withdraw from the experiment at any time
- Scientist in charge must be prepared to terminate the experiment at any stage if continuation likely to result in injury, disability, or death to the subject

Radiation Experiments

From 1944 to 1974, the government sponsored thousands of radiation experiments. These studies were conducted to advance biomedical, national defense, or space exploration science. Some of these experiments involved prisoners and military personnel, at times unknowingly. If consent was obtained, it was found that the documents were difficult to comprehend and sometimes misleading. At times, consent documents overemphasized the benefits of the research and overstated the therapeutic potential. These consent documents often did not properly discuss the potential risks involved with participation, in particular psycho-social risks and financial costs that could be incurred.

Belmont Report

Due to the public's expression of concern resulting from public exposure of research abuses, such as the experiments previously discussed within this tutorial, Congress passed the National Research Act in 1974. The Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which subsequently released the Ethical Principles and Guidelines for the Protection of Human Subjects of Research, also known as the Belmont Report, in 1979.

The Belmont Report is the basis for all current laws, regulations, and policies governing the use of human subjects. The three fundamental ethical principles of this report are respect for persons, beneficence and justice.

Respect for Persons

There are two basic moral requirements underlining this principle:

- To acknowledge autonomy (i.e., freedom to deliberate and make considered choices) of research participants
- To protect those with diminished autonomy. For example, immature children, geriatric/senile individuals, persons with diminished capacity from illness or mental disability, and persons with conditions that severely affect individual liberty (e.g., prisoners)

The extent of protection afforded to those with diminished autonomy depends on the risk of harm and likelihood of benefit of being involved with the research. In certain circumstances, extensive protection or exclusion is required. While other circumstances warrant only the assurance that involvement with the research is undertaken willingly, and that they are aware of possible adverse consequences.

One application of this principle is the consent process. Subjects must be given ample time to consider all of the information of a study they need before consenting to participate without pressure. Participants are free to withdraw participation at any time without penalty.

Beneficence

Beneficence is acts of kindness or charity that go beyond strict obligation. In the research context, those actions now become obligatory. There are two basic rules underlining this principle:

- Do no harm
- Maximize possible benefits and minimize possible harms

Thorough forethought in planning/designing the study is required to maximize benefits and reduce risks. The research must be designed to reduce risks to those necessary to achieve research objectives. When risks are significant, the researcher must adequately justify the risk to the IRB. Researchers must supply potential subjects with an adequate description of the risks and benefits within the consent process and consent document. It is essential that subjects are made fully aware of all potential risks and benefits. Being fully informed will allow subjects to choose whether participation is right for them (i.e., autonomy).

Researchers and the IRB are charged with analyzing the delicate balance of risk versus harm of a particular research study. When discussing beneficence, one must examine the risks and benefits potential to both the individual and society. Many times it is the individuals participating in the research who are exposed to the risks of the research; however, those individuals are rarely directly exposed to the benefits of the project. The researchers and IRB must assess whether the risks that will be presented to the subjects are justified. It may be determined that the benefits to society at large outweigh the potential risks to individual participants. Anyway

one looks at it, the benefits must outweigh the risks.

Risk: A combination of the probability of experiencing a harm and the severity of the envisioned harm

Benefit: Something of positive value related to health or welfare of the subject

The nature and scope of risks and benefits:

- Psychological
- Physical
- Legal
- Social
- Economic
- Dignity

Justice

Researchers and IRBs must ensure that the risks and benefits of research are distributed fairly. They must determine whether certain social classes or groups of people are not unjustly targeted for research, for example, because of ease of recruitment. The Belmont Report states that, “An injustice occurs when some benefits to which a person is entitled is denied without good reason or when some burden is imposed unduly.”

Selection of Research Subjects

The principle of justice is applied during the selection of subjects. There lies a moral requirement for fair procedures and outcomes in the selection of research subjects.

There are two levels of justice in selection of subjects:

- **Individual:** don't offer potentially beneficial research to some individuals who are held in favor, and select only “undesirable” individuals for risky research.
- **Social:** draw a distinction between classes of subjects who ought and ought not to participate, based upon the ability of members of that class to bear burdens, and on the appropriateness of placing further burdens on already burdened persons.

There should be an order of selection of classes of subjects (e.g., adults before children).

Incarcerated or institutionalized subjects should be involved only when appropriate safeguards are met.

Injustice arises from social, racial, sexual, and cultural biases institutionalized in society. It is also injustice when vulnerable subjects (e.g., racial minorities, the economically disadvantaged, the very sick, and the institutionalized) are used because of their vulnerability and manipulability or for sake of convenience.

When determining the population of research, researchers must not target a specific gender or ethnicity unless it is appropriately justified.

Vulnerable Populations

Researchers must also provide compelling justification for the use of vulnerable populations within research. Individuals within vulnerable populations may have limited autonomy. In other words, they may not be able to

provide sufficient informed consent. This may be because they cannot fully understand the research or are within a coercive environment.

Examples of vulnerable populations:

- Children
- Cognitively impaired
- Comatose patients
- Prisoners
- Pregnant women & fetuses (clinical studies)
- Students
- Employees
- Terminally ill

Children

"Children" are persons who have not attained the legal age for consent (18 years of age in most states), and thus cannot legally provide "consent" to treatments or procedures involved in research. In some instances, the child may be considered an "emancipated minor" as defined by applicable law in the jurisdiction where the research will be conducted, and may in that case provide legal consent.

"Assent" means a child's affirmative agreement to participate in research. It is an act signifying understanding (recognizing that the minor has not reached full legal age). Mere failure to object by the child should not, absent affirmative agreement, be construed as assent.

The assent process, while not legally binding, should involve taking the time to explain to a child, at whatever age they can begin to understand, what is going on in the proposed study, why the study is being done, what will be done to them, and that if they object, the research will be terminated, and they will not be punished or scolded. As children develop, they should gradually become the primary guardians of personal health and the primary partners in medical decision-making, assuming responsibility from their parents. Just as is the case with informed consent, the emphasis on obtaining assent should be on the interactive process in which information and values are shared and joint decisions are made.

"Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research. For most research studies, parents must provide their permission (parental consent) to allow their child to participate in the research study. [NOTE: Unless waived, it is required that a signed Parental Permission (Consent) form be on file for each participating minor. "Passive" consent, i.e., sending the child home with a form which states "please let us know if you don't want your child to participate", and then in the absence of a response (failure to object) from the parent, construing this to mean agreement that the child can participate, is not allowable.]

Cognitively Impaired

The predominant ethical concern in research involving individuals with psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders), an organic impairment (e.g., dementia), cognitive disorder, or developmental disorders (e.g., mental retardation), or who are substance abusers is that their disorders (affecting cognitive or emotional functions) may compromise/diminish their capacity for judgment and understanding of the information presented and their ability to make a reasoned decision about participation. Others, including 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.

Many individuals with disabilities affecting their reasoning powers may be residents of institutions responsible for their total care and treatment. The impact of institutionalization may further compromise their ability to exercise free choice (voluntariness). (These concerns apply both to voluntary patients and those committed involuntarily.) The eagerness for release may induce an institutionalized person, especially one who is involuntarily confined, to participate in research out of a desire to appear "rational" and "cooperative" to those who will make decisions about his or her release. Persons who are institutionalized, particularly if disabled, should not be chosen for studies that bear no relation to their situation just because it would be convenient for the researcher.

As a general rule, all adults, regardless of their diagnosis or condition, should be presumed competent to consent unless there is evidence of serious mental disability that would impair reasoning or judgment. Even those who do have a diagnosed mental disorder may be perfectly able to understand the matter of being a research volunteer, and quite capable of consenting to or refusing participation. Mental disability alone should not disqualify a person from consenting to participate in research; rather, there should be specific evidence of individuals' incapacity to understand and to make a choice before they are deemed unable to consent.

Persons formally adjudged incompetent have a court-appointed guardian who must be consulted and consent on their behalf. Officials of the institution in which incompetent patients reside (even if they are the patient's legal guardians) are not generally considered appropriate, since their supervisory duties may give rise to conflicting interests and loyalties. Family members or others financially responsible for the patient may also be subject to conflicting interests because of financial pressures, emotional distancing, or other ambivalent feelings common in such circumstances.

Students

The problem with student participation in research conducted at the university is the possibility that their agreement to participate will not be freely given. Students may volunteer to participate out of a belief that doing so will place them in good favor with faculty (e.g., that participating will result in receiving better grades, recommendations, employment, or the like), or that failure to participate will negatively affect their relationship with the investigator or faculty generally (i.e., by seeming "uncooperative," not part of the scientific community). A way to protect against coercion is to require that faculty-investigators advertise for subjects generally (e.g., through notices posted in the school or department) rather than recruit individual students directly. Requiring participation in research for course credit (or extra credit) is also controversial, though common in the social and behavioral sciences. As with any research involving a potentially vulnerable subject population, IRBs must pay special attention to the potential for coercion or undue influence and consider ways in which the possibility of exploitation can be reduced or eliminated.

Another concern raised by the involvement of students as subjects is confidentiality. As with research involving human subjects generally, the Virginia Tech IRB is aware that research involving the collection of data on sensitive subjects such as mental health, sexual activity, or the use of illicit drugs or alcohol presents risks to subjects of which they should be made aware and from which they should be protected, to the greatest extent possible. The close environment of the university amplifies this problem.

If a research project includes the need to access student records (i.e., SAT or GRE scores, or student GPA), a separate signed consent/permission form must be obtained from the student subject and submitted to the Registrar's office.

Employees

The issues with respect to employees as research subjects are essentially identical to those involving students as research subjects: coercion or undue influence, and confidentiality. Employee research programs raise the possibility that the decision will affect performance evaluations or job advancement.

Recruitment of Research Subjects

Recruitment begins with the advertisement of the study and/or the invitation into the study. The IRB must review and approve all forms of advertising and recruitment, including invitation letters/e-mails, telephone or in-class recruitment scripts, flyers, and radio/television/internet advertisements.

Advertising Dos . . .

- Supply adequate information about the study
- Use simple language
- Provide contact information
- Obtain approval to post ads, if necessary
- Be careful of subtle coercion
- State the inclusion/exclusion criteria
- Briefly describe the study procedures & location
- State that it is research

Advertising Don'ts . . .

- DO NOT overemphasize compensation
- DO NOT offer “free care”
- DO NOT claim that the study is superior to alternatives
- DO NOT use coercive language

Consent Process & Document

Under the principle of respect for persons, subjects, to the degree that they are capable, must be given the opportunity to choose what shall or shall not happen to them.

There are three elements to the informed consent process:

1. Information
2. Comprehension
3. Voluntariness

Information

Subjects must be given adequate information to properly make an informed decision regarding participation. At a minimum, federal regulations require the following information to be included in the consent process and consent document:

- Brief description of the research procedures, including length of procedures
- Statement that the study involves research
- Purpose of the research
- Risks and anticipated benefits
- Alternative procedures (if therapy – clinical/surgical treatment involved)
- Description of confidentiality/anonymity provided
- Explanation of compensation provided, if any
- Statement indicating that subject is free to withdraw at any time from the research project without penalty
- Statement that questions can be asked, and names and addresses/telephone numbers of PI and IRB Chair provided

The VT IRB has additional requirements that must be contained within a consent form. Visit our website at <http://www.irb.vt.edu/pages/consent.htm> for a checklist that will help you ensure that all required elements are included.

Comprehension

Subjects must be able to adequately understand the project, his/her role, and the risks involved. As the risks become more serious, the obligation to ensure subject comprehension greatly increases.

Timing

To achieve understanding, potential subjects should not be presented information all at once or only at the last minute. People need time to think about whether or not they want to participate. They may wish to discuss the decision with family, close friends, or religious advisors. They should not feel rushed or coerced. They need time, especially if the information is disturbing or particularly complex, to digest the information and come to terms with it. Researchers should be prepared to give adequate time to the subjects for review – one day, a week, or more, depending upon the level of risk and complexity of the subject's involvement in the research.

During lengthy studies, the researcher must also “maintain” consent. This may be accomplished by checking with the subject throughout the study to accomplish the following:

- To ensure that the subject still has a full understanding of the study
- To answer any questions that may have developed after the initial consent process
- To address issues of discomfort, confusion, or to have the subject decline continued participation
- To gather the opinion of the subject as of how the study is going or if he/she has any recommendations for the improvement of the study
- To discuss the remainder of the study procedures to remind the subject where he/she is at in the study process

Consent Process: Ensuring Comprehension

The informed consent process is different from the consent form. It involves meeting with a potential subject, finding out whether he or she is capable of giving consent, and discussing the purpose, risks, and benefits of participation. The consent form formalizes the agreement to participate and should be designed to document the process. Obtaining informed consent is not just giving a prospective subject a consent form and getting it signed. If consent by the subject involves their being truly informed, the subjects must genuinely understand the study; hence, researchers should strive to convey information to subjects, not merely disclose it to them. Subjects should be able to say what they are consenting to (i.e., be able to describe the project and their

involvement in their own terminology).

Barriers to Comprehension

- Disorganized descriptive materials
- Rapid presentation with too little time for questions
- Subject's intelligence, rationality, maturity, culture, and language
- Illiteracy
- "Incompetency" – infants, young children, mentally disabled or comatose patients

Voluntariness

Voluntary recruitment involves the free-will choice of individuals in conditions free of extreme urgency, with little time to ponder choices and undue influence / coercion. Recruitment not free of these conditions invalidates any consent that may be given.

Undue influence / coercion =

- To offer excessive, unwarranted, inappropriate, or improper rewards or overtures to obtain consent
- To manipulate a person's choice through the controlling influence of a close relative or friend
- To threaten withdrawal of a service to which the person is otherwise entitled

Obtaining a Waiver of Informed Consent from the IRB

If necessary and adequately justified, researchers may request a waiver for the requirement to obtain informed consent from subjects. In other words, subjects are unaware that they are participating in the research. Obtaining this waiver is sometimes necessary in order to conduct research.

Obtaining a Waiver of Signed Consent from the IRB

Many socio-behavioral research projects qualify for a waiver of the requirement for the researcher to obtain signed consent documents from subjects. If this waiver is approved, researchers must ensure that subjects are fully consented to participate in the study. In other words, the research project and all of its elements are fully disclosed to subjects in order for subjects to make an informed decision about participating; however, the researchers do not need to obtain each subject's signature on the consent form. If seeking a waiver of signed consent, the IRB highly recommends and may require that the investigator provide subjects with a written statement regarding the research. This is typically called an information sheet. The information sheet provides subjects with much of the same information required in a consent document; however, signatures are not obtained from subjects.

Both of the waivers discussed above may be requested for either some or all of the study's procedures involving human subjects. If the waiver does not cover all study procedures involving human subjects, a consent form or the informed consent (depending on the type of waiver sought) may be required to cover the additional study procedures.

Paying Research Subjects

Paying individuals to participate in research has been a controversial issue within the IRB community for many

years; however, there are few regulatory guidelines to address this issue.

Compensation must not be large enough to be considered coercive. Researchers and the IRB must consider the subject pool's socioeconomics while reviewing protocols involving payment for research participation. Unfortunately, there are no set standards for what amount is considered coercive. Considerations for compensation will be made on an individual (per study) basis by the IRB.

Institutional Review Board's are charged with the responsibility to review both the amount and method of payment to ensure that neither are coercive or present undue influence to participate or to continue participation.

If a study includes a large amount of compensation, depending upon the socioeconomics and study procedures expected from participants, the IRB may require that the researchers delay informing participants of the compensation until after the subject completes study procedures. This will help to ensure that subjects are participating because of voluntariness instead of compensation (i.e., undue influence).

Compensation should be prorated based on duration of study participation. Payment must not be contingent on the participant completing the study procedures. In other words, even if the subject decides to withdraw from the study, he/she must be compensated, at least partially, based on what study procedures he/she has completed.

Protecting Confidentiality & Anonymity

Researchers need to be creative to ensure that the utmost confidentiality or anonymity is provided to their research participants.

Do not collect identifying information from participants unless it is absolutely necessary to the research. If identifying information is collected, keep this information separate from subjects' responses (e.g., responses to questionnaires/interviews, biological specimens, lab information, etc.). To do so, use a study code/ID to link identifying information to study responses. Keep the document linking study ID with identifying information in a separate locked area and limit access to head researchers.

Identifying information:

- Names
- Addresses
- Employers' names or addresses
- Relatives' names or addresses
- Dates (e.g., birthdate, date of death)
- Phone/fax numbers
- Email addresses
- Social Security Number
- Member account numbers
- Voiceprints
- Fingerprints
- Full face photos & comparable images

Who Regulates Your Research?

The Department of Health and Human Service's (DHHS) Office for Human Research Protections (OHRP) is responsible for the implementation of the US Code of Federal Regulations and the requirement of the establishment or use of an IRB for projects receiving federal funds.

Per Virginia Tech's policies all research at Virginia Tech that includes the use of human subjects and/or private information about humans must comply with all of the regulations in the Code of Federal Regulations (CFR) at 45 CFR 46.

OHRP ensures regulatory compliance in the protection of human subjects and requires that Virginia Tech, an institution receiving federal funding for research, provide written assurance documenting how it will comply with requirements for the protection of human subjects.

Virginia Tech Institutional Review Board (IRB) for the Protection of Human Subjects

Responsibilities:

- Provides local assurance of compliance
- Reviews and approves, disapproves or requires modifications of protocols
- Conducts annual re-evaluation of ongoing protocols
- Ensures that Principal Investigators and staff are appropriately trained
- Reports noncompliance to Institutional Official and OHRP

Virginia Tech IRB Submissions, What You Need to Know

Please visit the Virginia Tech IRB website at <http://www.irb.vt.edu> for information regarding:

- How to complete an application
- To find IRB application forms
- To learn more about the Virginia Tech IRB
- For help developing your study procedures and forms, for example, your consent form
- Overview of & links to federal regulations
- And more

VT IRB Approval, When is it Required?

The flow chart on the following page is an aid for researchers to determine when VT IRB approval is required.

Researchers must seek and obtain IRB approval BEFORE conducting any research type activities involving human subjects, including informal recruitment.

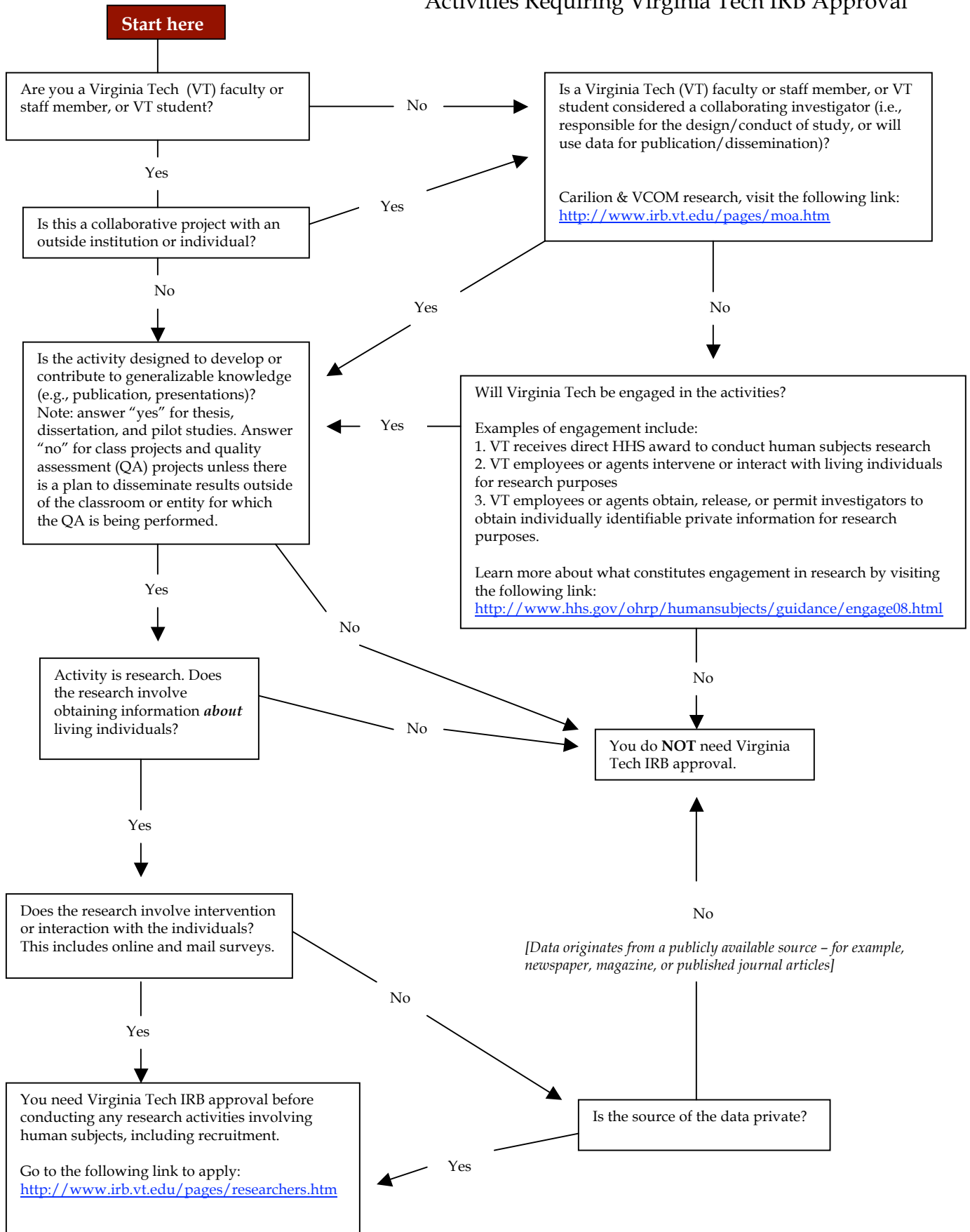
There is occasional confusion about research that is "exempt." Some individuals have mistakenly assumed that "exempt research" does not need IRB review. However, "exempt" means that it falls within a narrowly defined category of research needing administrative review rather than full board review. For further information about different review types (e.g., Exempt, Full Board Review), visit our website at <http://www.irb.vt.edu/pages/categories.htm>.

A **human subject** is a living individual about whom a researcher obtains either: 1) data through intervention with the individual; or (2) identifiable private information.

Research is defined as a systematic investigation, including research and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102d). This is generally interpreted to mean that if the results of the work are meant to be published or disseminated to an unrestricted audience, it is considered as regulated human subjects research. However, the benchmark/goal of 'publishing' is not a part of the federal code. If an activity follows a deliberate plan whose purpose is to develop or contribute to generalizable knowledge, such as an exploratory study or the collection of data to test a hypothesis, it is research.

In addition, VT IRB approval must be obtained for all senior theses and dissertation research even if there is no intention to publish or disseminate the results. IRB approval is no longer required for class projects.

Activities Requiring Virginia Tech IRB Approval



Note: This decision chart was constructed with the help of the Office of Human Research Protections' "Human Subject Decision Chart, September 24." <http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c1>.

Types of Submissions

All application forms are located on our website for downloading at:
<http://www.irb.vt.edu/pages/researchers.htm>.

New Study

Before beginning your research involving human subjects, you need to obtain IRB approval. The IRB must review and approve all study documents pertaining to human subjects, including but not limited to: 1) advertisements & invitation letters, 2) survey instruments, including questionnaires & interview scripts, 3) consent document(s), and 4) the Research Protocol (which is an application form found on our website at the above link).

Amendment Request

Researchers must report all changes of study procedures, study personnel, or changes to study forms (e.g., questionnaires, interview questions, invitation letters, etc.) to the IRB BEFORE implementing the change. Basically, if there is a change to any of the documents originally submitted to the IRB, or if there is an addition of a study document, the IRB needs to be informed. To report changes, researchers must complete an Amendment Request form (found on our website at the above link).

Continuing Review Request

(Also called re-approval)

Studies are approved for a specified period of time, no longer than 12 months. Your IRB approval letter will contain your study's expiration date (Exempt approvals do not expire). It is essential that you request and obtain IRB re-approval to your study before it expires if you plan to continue the study past the 12-month approval period. If you close your study (i.e., data analysis is complete at Virginia Tech and all activities involving human subjects are complete), report this to the IRB via e-mail at irb@vt.edu.

The IRB office will prompt you to re-approve your study or report it as closed within two months of your study's expiration date; however, it is ultimately the responsibility of the Principal Investigator to re-approve the study or report the study as closed in a timely fashion.

Failure to report your study as closed, or to request and receive IRB re-approval before the study's expiration date will result in the following:

- Letter to department head and all researchers reporting that the study has expired
- All study procedures involving human subjects and data analysis must halt immediately
- Any data collection occurring during the period of expiration must be destroyed
- The expiration will be recorded by the IRB office as an incident of noncompliance
- Additional consequences may occur

Adverse Event Reports

Adverse Events are new findings or unexpected problems whose nature, severity, and frequency are not described in the information provided to the IRB or to study participants. Examples include unexpected complications experienced by a subject, missteps in the documentation of consent, or breaches of confidentiality. It can represent a new symptom experienced by a study subject or an exacerbation or worsening

of an existing condition.

Any problems involving the conduct of the study or subject participation (including recruitment, consent, screening and termination) should be reported immediately. For example, if a subject complains about any aspect of his or her treatment as a study subject, this should be reported and the subject should be referred to the IRB Chair for assistance. An Adverse Event Report form can be found on our website at the above link.

Approved Applications

All correspondence from the IRB office is through email. Once an application is approved by the IRB, all investigators listed on the application will receive an official approval letter via email. Retain this official approval letter. The Graduate Department will request a copy of this letter prior to graduation.

Continued Compliance

Compliance does not end with initial IRB approval. To continue compliance, researchers have the following responsibilities:

- To conduct the study according to the protocol / IRB application
- Report to the IRB any deviations from the protocol / IRB application
- Report to the IRB any proposed changes to the originally approved IRB submission
- Report to the IRB any adverse events
- Unless waived by the IRB, obtain informed consent from each individual participant before conducting any study procedures with that particular participant
- Unless waived by the IRB, document consent by obtaining signatures of involved participants on the consent form
- Maintain signed consent documents for three years
- Report progress of approved research to the IRB in the manner prescribed by the IRB at the time of approval
- Monitor the rights and welfare of participants throughout the study