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INSTITUTIONAL REVIEW BOARD

PROCEDURES

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Cape Cod Community College (CCCC) would like to thank Middlesex Community College, MA, (MCC) for permission to use the MCC IRB Policies and Procedures as a template for our document.

INTRODUCTION

The purpose of this document is to outline the responsibilities of the Cape Cod Community College (CCCC) Institutional Review Board (IRB) and provide a written description of the policies and procedures for the faculty, staff and students conducting human subject research. The mission of the IRB is to protect the rights and welfare of human research subjects. The policies outlined herein are in accordance with the Federal Policy on the Protection of Human Subjects (DHHS Policy 45 CFR Part 46 and FDA Policy 21 CFR Parts 50 and 56).

CCCC is responsible for the protection of human subjects for any research activities conducted by, or under the supervision of, its faculty, staff or students regardless of funding source and the location of the project. The IRB reviews research protocols involving human subjects and evaluates and protects against risk for those subjects. CCCC and the Principal Investigators (PI) are responsible for ensuring that high ethical standards are maintained for all research involving human subjects. The CCCC IRB reviews human subjects research proposals to ensure that the rights and welfare of human subjects used in research studies by CCCC personnel are protected; that risks have been considered and minimized; that the potential for benefit has been identified and maximized; that all human subjects only volunteer to participate in research after being provided with legally effective informed consent; that any research is conducted in an ethical manner and in compliance with established standards. Those individuals seeking to conduct such research may not solicit subject participation or begin data collection until they have obtained clearance by the Cape Cod Community College Institutional Review Board.

The IRB does not assume the role of evaluating the soundness of the proposed research study, the merits of the research design, nor the potential contribution of the research to the scholarly literature. Rather, the IRB is charged with evaluating each project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, and any risk to the participants.

Only human subject research [defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR part 46 s. 102d)] is subject to IRB review. Normal educational practices such as educational tests when the subjects are not identified and classroom activities that are solely for instructional purposes do not require review by the IRB. If the instructor of a class or a student wishes to present or publish information gathered from human subjects in a context beyond the class for which it was gathered, the activity is considered to be research and must be reviewed by the Institutional Review Board. Any researcher who is in doubt about the above policy is encouraged to contact the IRB Chair with questions or submit their proposal to the IRB.

These policies and procedures will be reviewed and updated as necessary. Any changes to applicable federal regulations will be implemented immediately, announced, and will supersede these procedures. PI's are responsible for following the latest version of this document and using the most recent forms that accompany it. Go to www.capecod.edu/web/irb for the most up to date information.

PURPOSE

The primary purpose of the IRB is to protect the welfare of human subjects used in research.

INSTITUTIONAL AUTHORITY

Research at CCCC is conducted in accordance with the approved Federal wide Assurance (FWA No._____) on file with the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) in which the CCCC IRB #1 is designated as the IRB of record. The FWA is an assurance that CCCC will comply with the federal regulations for the protection of human subjects in research. It is a commitment from the CCCC President that the institution will have written IRB procedures, provide review of nonexempt research covered by the FWA, obtain and document informed consent unless otherwise waived in accordance with the regulations, ensure that all collaborating institutions operate under an approved FWA, have formal written agreements of compliance from all nonaffiliated investigators, and the IRB will be provided with sufficient resources to fulfill these responsibilities. All sponsored human subject research must be reviewed by the IRB.

This Procedures document establishes and empowers the Cape Cod Community College (CCCC) human subject's protection committee. The IRB reviews all projects and programs involving human subjects in accordance with these Policies and Procedures, applicable federal regulations, laws of the Commonwealth of Massachusetts, and sponsor policies and guidelines. Individuals seeking to conduct research may not solicit subject participation or begin data collection until they have obtained clearance by the CCCC IRB. The IRB meets regularly to review research protocols. The IRB is authorized to review, approve, require modifications in, or disapprove research activities using human subjects conducted by or through the College. It is important to the institution that the CCCC IRB has a high level of respect from the research community in order to better fulfill its charge and develop trust between all parties concerned.

The IRB Senior Officer is appointed by the President to have responsibility for oversight of human subject research. Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by the President, designee or IRB Senior Officer. However, the President, designee, or IRB Senior Officer may not approve the non-exempt research if it has not been approved by the IRB.

CCCC's institutional policy conveys the authority to the IRB to:

- Provide advice and counsel to personnel engaged in activities involving human subjects
- Review all research studies involving human participants before their involvement may begin

- Require revisions in research studies and consent documents as a condition of approval
- Approve new research studies and the continuation of previously approved studies
- Disapprove the initiation of new research studies, if necessary
- Monitor the activities of approved studies. This includes a continuing review at least once per year. Monitoring may also involve, if necessary, verifying compliance with approved studies and informed consent procedures. Verification may include observing the informed consent process as practiced by any investigator or authorized person in any approved protocol especially in cases where the consentee is from a vulnerable population.
- Develop mechanisms for prompt reporting to the IRB of unanticipated problems occurring in approved studies, or in other studies related in context to the approved studies
- Suspend or terminate a previously approved study, if necessary
- Restrict aspects of a research study for the purpose of participant protections, if necessary.
- Access, and to make copies of, records related to any research approved by the IRB (or another body under an IRB Authorization Agreement), regardless of the location of those records, for any reason. Where feasible, appropriate notice will be given of the need to review, copy or duplicate records while being sensitive to causing the least inconvenience or disruption of on-going research.

GUIDING PRINCIPLES

The basic principles that govern the CCCC IRB are contained in *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* ("The Belmont Report"), and *The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*, April 18, 1979, (see http://www.hhs.gov/ohrp/humansubjects/index.html).

The following principles apply to all research, regardless of funding, that involves human subjects at Cape Cod Community College to ensure that adequate safeguards are provided:

1. Subjects' legal rights will be respected; their rights to privacy, dignity, and comfort will also be considered in approving proposed research.

2. Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

3. Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject. Faculty are responsible for all undergraduate student research from application to completion.

4. Adequate provisions should be made for recruiting a subject population that is representative of the population base in terms of gender and minority representation unless otherwise justified scientifically.

5. Research involving human subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions.

6. Participation of a human subject in research must be voluntary with the right of the subject to withdraw at any time. Information provided to gain subject consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.

7. All research programs involving human subjects must be reviewed by and must receive approval of a formally constituted review ***prior*** to their initiation or ***prior*** to initiating any changes to the protocol. Continuing research programs are subject to periodic review to be carried out no less often than once a year.

ENGAGEMENT IN RESEARCH

CCCC will be considered to be engaged in human subject research when research is conducted by or under the direction of any employee or agent of this institution using any property or facility of the College or the research involves the use of the College's non-public information to identify or contact human research subjects or prospective subjects. OHRP considers institutions to be engaged in human subjects research when employees or agents intervene for research purposes with any human subjects of the research by:

- manipulating the environment
- interacting with human subjects for research purposes
- performing invasive or noninvasive procedures
- obtaining the informed consent of human subjects.

OHRP does **not** consider institutions to be engaged in human subject research when employees or agents:

- Inform prospective subjects about availability of the research
- Provide prospective subjects with information about the research but do not obtain subjects' consent for the research or act as representatives of the investigators
- Provide prospective subjects with information about contacting investigators for information or enrollment and/or
- Seek or obtain the prospective subjects' permission for investigators to contact them.

OHRP's Guidance on Engagement of Institutions in Human Subjects Research provides additional information on this topic http://www.hhs.gov/ohrp/policy/engage08.html

Employees and students are responsible for insuring their research is guided by the ethical principles in the Belmont Report and thus determining whether their research activities require Institutional Review Board (IRB) approval; and if so, seeking such approval. If the employee or student has any doubt concerning the classification of the research activities s/he is encouraged to contact the IRB Chair at irb@capecod.edu.

Definition and Types of Research

Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (usually intended for publication or public dissemination). Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective. Program evaluations, assessments, institutional effectiveness and student learning that are used for internal purposes only are not considered to be research. Classroom research projects conducted for the primary purpose of a learning experience in the methods and procedures of research usually do not meet the federal definition of research. Consult the IRB Chair for more information.

A research protocol is a written description and scientific rationale for a proposed research activity. The protocol is submitted to the IRB and includes a discussion of the human subject protection issues that are relevant to the study. At a minimum, the protocol should address:

- the methods
- benefits and risks to subjects
- experimental procedures
- anticipated number of subjects
- proposed consent document and consent process to be used
- recruitment plan
- appropriate additional safeguards if potentially vulnerable subjects are to be enrolled.

The most common type of research conducted at Cape Cod Community College is socio-behavioral research, which may include survey, ethnographic, or experimental research where risks to the subjects are usually minimal and generally related to the release of information gathered, rather than direct interaction with the physical body. While all researchers must complete the training requirements for human research subjects, socio-behavioral research that involves surveys are usually considered low risk, non-invasive, and are usually designated as expedited or exempt status by the IRB. When reviewing behavioral and social sciences research, the IRB ensures that investigators have made every attempt to minimize risk and possible harm to participants, whether social, psychological or physical. Potential risks to participating in behavioral and social science research could be, but are not limited to, breach of confidentiality, invasion of privacy, embarrassment, and risk to reputation, employability, and insurability.

For faculty engaged in the scholarship of teaching and learning where classroom research is conducted with the consent of students, faculty must consider faculty-student dynamics when designing a research protocol. For instance, in order to avoid coercion, a faculty member engaged in classroom research is encouraged to announce research opportunities to the entire class rather than approach individual students. Professors also need to ensure that participation of students is not connected to grades. Employing the help of another person to collect and hold data until after grades are submitted is one approach that decreases ambiguity and minimizes concerns of students. Whereas classroom research is designed to focus on systematic investigations that lead to improved learning for all students, keeping a balance between systematic investigation and the needs of students in a particular classroom can present unique problems for a professor who is serving simultaneously as teacher and researcher. Consult the IRB Chair for navigating potential areas of conflict.

ORGANIZATIONAL STRUCTURE

The IRB functions administratively through the CCCC President's Office. This structure provides for administrative coordination for the IRB with the various academic and administrative units at CCCC.

The IRB advises and makes recommendations to the Signatory Official and President, to policy and administrative bodies, and to any member of the CCCC community on all matters related to the use of human subjects in research.

IRB MEMBERSHIP AND RESEARCH ROLES AND RESPONSIBILITIES

IRB members are appointed for a three-year renewable term on a rotating basis. The IRB is composed of at least five voting members. All appointments are made by the President and reported to OHRP. A quorum is needed to record all official actions. A quorum is one more member than half the membership and a nonscientist must be present to meet the quorum requirement. Alternates and non-voting members may also be appointed, with alternates authorized to vote at convened meetings only in the absence of the member for whom they are the designated alternate. Although an alternate may be designated for more than one IRB member, each alternate may represent only one regular member at a convened meeting.

The IRB is composed of members with varying backgrounds and expertise in special areas to provide complete and adequate review of the research. Committee members are required to complete training and should possess not only broad specific competence sufficient to comprehend the nature of the research, but also other competencies necessary for judgments as to acceptability of the research in terms of CCCC regulations, relevant law, ethical standards, and standards of professional practice. Consultants may be used to review proposals for which additional expertise is needed at the researcher's expense.

Federal regulations require that an IRB includes both men and women, at least one member whose primary concerns are in science areas, one whose primary concerns are nonscientific areas, and at least one community member who is not otherwise affiliated (either directly or through immediate family) with Cape Cod Community College. Members with a

behavioral/social science or biomedical research discipline should be considered a scientist, while members whose expertise would incline them to view research activities from a standpoint outside of a biomedical or behavioral scientific discipline should be considered a nonscientist. Degrees in education are considered nonscientific. No person shall be excluded from serving on the IRB based on sex, race, color or national origin.

Research roles and responsibilities include the following:

IRB Signatory Official

The Signatory Official is an individual who has the authority to make a commitment on behalf of the institution that the appropriate regulatory requirements will be met. This individual is responsible for preparing regulatory documents for review and has the authority to sign the Federal wide Assurance submitted to OHRP. The IRB Signatory Official is the Vice President of Academic and Student Affairs and reports to the President.

IRB Chair

The IRB Chair is the individual assigned with the administrative responsibility for oversight of the human protection programs. On the FWA this role is referred to as the Human Protections Administrator. He/she must maintain knowledge to serve as a regulatory resource on human subjects protection and to ensure that proposals are in compliance with federal regulations and guidelines. The IRB Chair shall have an understanding of ethical issues, state law, institutional policies, and federal human subject research protection issues and regulations. The Chair must be willing to commit the time required and possess administrative and organizational skills involved in conducting committee meetings. The Chair is responsible for assuring the protection of human subject research participants and serving in a leadership role to encourage respect and compliance for the IRB process.

The duties of the Chair may include:

- Reviewing protocols submitted for exempt or expedited review
- Assigning studies to IRB reviewers
- Soliciting feedback from at least two reviewers for research receiving expedited review
- Scheduling IRB meetings, arranging meeting location(s), creating agendas, distributing materials for review, taking meeting minutes, documenting meeting actions, communicating actions to PI's in a timely manner, and entering and tracking all related documentation in a database
- Summarizing IRB review recommendations for dissemination to PI's
- Reviewing and signing letters generated from board actions
- Approving minor amendments and determining which amendments go to the convened IRB
- Responding to concerns or complaints from research participants, research staff, or investigators and determining when they should be referred to the convened IRB
- Assisting with ongoing development of IRB Policies and Procedures
- Reviewing and approving protocol exemption requests or appointing a designee to do so
- Suspending or terminating research protocols if necessary
- Coordinating, reviewing, and managing all documents for the IRB to ensure that a) research protocols are reviewed appropriately and in a timely manner, b) records and files are maintained, c) information is communicated to the appropriate parties, and d) CCCC is in compliance with federal human research regulations and other applicable federal guidelines.

IRB Vice Chair

The IRB Vice Chair is a voting member of the IRB and presides over all convened IRB meetings in the absence of the Chair. The Vice Chair is appointed by the Chair and has authority to sign all IRB action items in the absence of the Chair. The above duties may be assigned to the Vice Chair in the Chair's absence or if a conflict of interest arises. The Vice Chair is an active, respected member of the IRB who is well informed of the regulations relevant to the use of human participants in research.

Board Members

Members are appointed for a period of three years and may be re-appointed. The term of appointment may be terminated by notice of the Committee member to the Chair or by notice from the Chair. Members are not compensated for their service. If a member finds that s/he is unable to attend meetings for an extended period, as a consequence of unavoidable conflicting activities, the IRB Chair must be informed so that a replacement may be appointed. Additionally, members may be removed from the IRB before their term is completed for reasons of poor attendance for which there is not reasonable justification, or for other manifestations of unwillingness or incapability to serve the committee adequately. In either event, the Chair will appoint a replacement. Tenure on the IRB may be extended by mutual agreement between the member and the Chair.

Members are required to meet training requirements, perform the assigned duties for the board or notify the Chair of their inability to do so, be available to attend regularly scheduled meetings, acquire and maintain a working knowledge of federal human subject protection through the education and training requirements, and review protocols and come to meetings prepared to discuss them. Board members also review and recommend approval of IRB Policies and Procedures.

Alternate members may be appointed to serve at-large or to take the place of a regular appointed member. If both the alternate and the regular member(s) attend the same meeting, only one may vote and the minutes must reflect who is in attendance as a voting member.

Liability coverage for IRB members is provided through the Cape Cod Community College liability insurance, whether or not the IRB member is an employee of Cape Cod Community College.

Principal Investigators

Principal investigators (PI's) are responsible for consulting with appropriate IRB staff to determine whether research requires IRB review and approval, regardless of whether it is funded research or not. PI's who intend to gather data as part of evaluations, assessments, service, reporting, classroom assignments, educational inquiry, or practice **AND** intend to use the data as research data for the purpose of publishing or sharing with a research community or the public at large, must obtain IRB approval from the CCCC IRB **PRIOR** to conducting the activity.

If review is required, PI's must ensure that an application and protocol are submitted to the IRB. PI's must comply with IRB decisions, conditions, and requirements and obtain informed consent to ensure that no human subject will be involved in the research without consent. PI's are responsible for retaining consent documents, providing progress reports on the research, submitting annual review reports on IRB forms and adverse event reports, reporting any

amendments for changes in research, and submitting a final report at the conclusion of each project.

PI's are also responsible for being aware of any new research publications in the peer-reviewed scientific literature that may impact their ongoing human subject research.

PI's and their personnel involved in conducting human subject research must agree to maintain in strict confidence the names, characteristics, data gathered from research instruments, incidental comments, and other information on all subjects and subjects' data they encounter so as not to conflict with state and federal laws and regulations. PI's and their personnel must understand that "confidentiality" means they may not discuss nor divulge in any manner a subject's name or any identifying information or characteristics, scores, ratings, comments, or information about a subject with anyone who is not an authorized member of the research team.

Student Researchers

Student researchers who are conducting human subject research as part of their degree work must be knowledgeable of human subject research, including ethics, and must meet the mandatory training requirement. Classroom or course projects that are developed for the sole purpose of education for individual students and involves data gathering from human subjects as part of evaluations, assessments, service, reporting, classroom assignments, educational inquiry, or practice must either seek IRB approval for their project or abrogate their rights to publish or present data as research. If students choose to share these observations with others in ways that do not fit the definition of research (contributing to generalizable knowledge), their actions should be governed by the ethical standards of their discipline. Data gathered may only be shared with the course instructor or faculty advisor, or in the case of an internship/practicum, the collaborating party.

Student investigators, who intend to gather data as part of evaluations, assessments, service, reporting, classroom assignments, educational inquiry, or practice **AND** intend to use the data as research data for the purpose of publishing or sharing with a research community or the public at large, must obtain IRB approval **PRIOR** to conducting the activity from the CCCC IRB.

TRAINING REQUIREMENTS

Institutional policy requires that all of the following individuals must complete the minimum institutional requirement for training to demonstrate knowledge of human subject research, including ethics:

- IRB members
- Principal investigators
- Members of the research team
- Student researchers

In order to demonstrate the guidelines and ethical principles for human subject research are understood, research projects may not begin until the training for all members of the research team is complete. A certificate of completion from the appropriate online training is required before any appointment to the board or application is approved. After completing the final lesson of the training you will need to print a certificate of completion. The IRB Chair will maintain a log of training completion dates. Certification must be renewed every three years.

To complete this requirement, CCCC offers the National Institutes of Health (NIH) training at http://phrp.nihtraining.com/users/login.php. This is a free web-based training program. Other training programs may be reviewed and approved by the IRB Chair.

CONFLICT OF INTEREST GUIDELINES

Conflict of interest, defined as a set of conditions in which judgment concerning a primary interest may be biased by a secondary interest, is inherent to the conduct of research. In any given situation, conflict of interest must be managed through a system of identification, disclosure, containment, reduction, and elimination.

A conflict of interest may include an affiliation with an organization, company, venture or other body with whom the person has a direct financial interest; this includes any financial benefit, directly or through relatives by blood or marriage, in the subject matter or materials of a research proposal. While the focus is often on financial conflicts, which are quantifiable, non-financial interests exist as well. Non-financial interests may clash with the protection of research participants and should also be disclosed and managed when present.

Management of IRB conflicts of interest will include (1) no IRB members will participate in the review of or vote on any research study in which the member has a conflict of interest, except to provide information requested by the IRB; (2) excusing members from the final deliberation to prevent them from voting on studies in which they have declared a potential conflict of interest; and (3) proactive education to increase awareness of existing policies and the potential for conflicts of interest.

Research Personnel

The IRB requires that PI's provide written information regarding any potential conflict of interest relevant to research studies submitted for IRB review. Investigators will disclose whether they have a vested interest in any commercial enterprise associated with any aspect of the protocol, and, if yes, to fully explain and identify the safeguards taken to prevent investigator bias in subject recruitment and/or the consent process.

To ensure that conflict of interest does not compromise the rights and welfare of human participants of research, the IRB will determine: (1) if methods used for management of financial interests of parties involved in the research adequately protect the rights and welfare of human participants; (2) whether other actions are necessary to minimize risks to participants; and (3) the kind, amount, and level of detailed information to be provided to research participants regarding a conflict of interest.

IRB Members

It is the responsibility of each IRB member to identify and avoid any situations in which he or she, either personally or by virtue of their position, might have a conflict of interest, or may be perceived by others as having a conflict of interest. If assigned as a reviewer for a matter with

which the IRB member feels that he or she may have a conflict of interest, the IRB member must notify the IRB Chair so the matter may be reassigned to another reviewer. In order not to delay the review process, it is essential that potential reviewers peruse the matters for which they are assigned upon receipt to determine whether they may have a conflict.

A member with a conflict of interest will be required to recuse him/herself and leave the room during final deliberation and voting for any research in which the member has a potential conflict of interest. Such members are excluded from the quorum count for the study being considered. The minutes will reflect by name all individuals not participating due to a conflict of interest and their absence from the room and re-entry.

IRB members are permitted to vote on studies submitted by members of their own department or division, because often they are the most knowledgeable about the topic being investigated, but only if the IRB member has no other potential conflicting interest, such as responsibility for the design, oversight or supervision of the study. Members who believe they have been involved in attempts by investigators or others to influence the review of a particular study will bring the matter to the attention of the IRB Chair. The member may be advised to recuse him/herself or abstain from the final deliberation and vote if a perceived conflict of interest exists.

Possible conflicts of interest for IRBs may originate at two levels and may include:

Individual Level

- Member is PI or researcher on a study under review
- Member or staff holds significant financial interest in research sponsor
- Loyalty to colleagues submitting for review
- Member is too closely tied to area of research under review
- Possible impact of decisions on member's own work (e.g. policy changes)
- Personal agenda
- Non-IRB role

Institutional Level

- Pressure or desire to protect the institution
- Concern for institution's reputation or prestige
- Promotion of research vs. protection of human participants
- Potential liability
- Institutional or community values
- Pressure for rapid reviews
- Institutional equity or ownership

Institutional Officials

As academic institutions have increasingly entered into financial and collaborative research arrangements with private industry, institutional conflicts of interest have become a topic of growing concern and increasing public scrutiny. To avoid potential conflicts of interest, executive leaders such as the president, executive vice president and vice presidents shall not serve as an IRB board member unless a compelling situation exists.

RECORD KEEPING

The IRB Chair prepares and maintains adequate documentation of IRB activities, including the following:

- All records for protocol reviews, including research applications, approved informed consent documents, annual/continuing review reports, modifications, statements of significant new findings provided to subjects, general project information provided to subjects (e.g., fact sheets, brochures) and final reports submitted by investigators.
- Detailed minutes of IRB meetings, showing all information required by HHS regulations in 45 CFR 46.115(a)(2).
    - Members present (any consultants/ guests/others shown separately).
    - Results of discussions on debated issues and record of IRB decisions.
    - Record of voting (showing votes for, against and abstentions).
- Copies of all correspondence between IRB and the investigators related to research applications. Significant emails or other electronic communication should be printed and kept on file at the Chair's discretion.
- Adverse reactions or incident reports and documentation that the IRB has reviewed such reports.
- List of IRB members that includes all of the information required by HHS regulations in 46.103(b)(3), including: name, earned degrees, representative capacity, indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board.
- Federal wide assurance documents.
- Written procedures of the IRB, including an assurance that the institution complies with the federal policy for the protection of human subjects as described in 45 CFR 46.103(b)(4) and 46.103(b)(5).
- Training certifications

The above documents should be kept on file for at least three (3) years in the Office of Institutional Research.

Records related to research shall be retained for at least three (3) years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services, and other federal regulatory agencies, at reasonable times and in a reasonable manner.

Principal investigators must keep all records, including evidence of informed consent, for at least three years after completion of the research. Informed consent forms must be accessible for inspection and copying by the CCCC IRB and authorized representatives of OHRP upon request.

The IRB Chair assigns a protocol number to incoming applications, records the number, and includes the number in all official documentation.

BOARD PROCEDURES

The primary concern of the IRB is the protection of the rights and welfare of human subjects in research. The efforts of the IRB are directed at (1) identification of the risk, (2) evaluation of the risk, (3) evaluation of procedures to minimize risk, and (4) evaluation of the informed consent document which explains the risks to the subjects. Only the IRB has the authority to approve research that involves human subjects.

MEETINGS

Meeting schedules are set to accommodate, as best as possible, the availability of all the members. Schedules are set by semester to accommodate faculty and to allow for the maximum number of board members to be available and present. The frequency of meetings is typically monthly during the semester and the duration is approximately two hours. The place and time of meeting, agenda, and study material to be reviewed are distributed to IRB members at least seven (7) days prior to the meeting.

Members may participate in meetings via phone and are included in the quorum. Meetings requiring a vote of the full board may not be held via email; discussion and deliberation must occur in real time.

Meetings during the summer months are scheduled based on need. Meetings by telephone or electronic communication are authorized if a meeting, but not a vote, is necessary and an in-person meeting cannot be scheduled.

Principal Investigators, including those who are also IRB members, may offer information and answer questions about their protocols at a convened meeting, but may not participate in the review or voting (even if this means being unable to continue the meeting because of quorum requirements). IRB is not scheduled during the summer months.

Although convened meetings of the IRB are open to the public, materials submitted for review, discussions of protocols, and individual votes are considered confidential and should not be discussed outside of the meeting context. If during an IRB meeting the Chair moves the meeting to executive session then any visitors will be asked to leave the room until the executive session has ended.

PROCEDURES FOR TYPES OF REVIEW

There are three types of IRB review: Exempt, Expedited, and Full Review.

Exempt and expedited applications are reviewed upon submission to the IRB Chair throughout the year. Every effort is made to complete exempt and expedited reviews in a timely fashion but the amount of time may vary depending on the clarity and completeness of the application, reviewers' schedules and whether there are concerns that will need to be addressed by the IRB. The IRB Chair may return applications that are incomplete or require clarification.

The IRB Chair is responsible for exempt status determinations and may consult with others as appropriate. The IRB Chair or designee, not the investigator, shall make the determination as to whether a project is or is not exempt. For research to qualify for exempt status determination, it must meet federal criteria for this category. The IRB Chair will notify the IRB of all decisions.

Expedited reviews will be assigned by the IRB Chair to two designated IRB members. The two designated IRB members will review the Expedited application and provide written feedback using the IRB Reviewer Approval form.

For full review applications, a primary and secondary reviewer will be assigned to lead the discussion of that protocol at the full board meeting. The full IRB will review application information and have access to additional study documentation upon request. If external reviewers are necessary, they must be subject to the same conflict of interest policies as IRB members. Every attempt will be made to complete the review process in a timely manner. Applications for full review that are submitted at least two weeks in advance of a scheduled IRB meeting should be able to be addressed at that meeting. Any necessary revisions to the application or the Informed Consent document will be addressed after the meeting. Incomplete applications or full review proposals requiring revisions may take longer for final approval, especially if the submission date is on or close to a scheduled IRB meeting.

The IRB Chair will notify the PI of all IRB decisions in writing.

Protocol changes or amendments must be submitted to the IRB for expedited review and approval. See below for full descriptions of the categories that qualify for exempt and expedited review and a sample timeline for project submission, review, and approval.

All grant-funded projects coming to Institutional Review Board must have their original grant proposal reviewed by the IRB chair in addition to the IRB application.

CONFLICT OF INTEREST

No member with a conflict of interest may participate in the IRB review or vote on an IRB action for any such project. This conflict of interest policy will be stated at the beginning of each meeting and members that do have a conflict of interest must identify and recuse themselves from voting on that application.

CONFIDENTIALITY STATEMENT

IRB members are required to keep all information related to research applications confidential.

This means that information reviewed by the members, which may be sensitive in nature, should not be discussed outside of the review process or discussed in a place where the discussion might be overheard.

BOARD ACTIONS

The IRB may vote to approve, approve with modifications, defer, or disapprove a research protocol. For applications requiring full board review, these actions require a vote of the majority

of the members present at a meeting with a quorum present. If the vote is not unanimous, the minority opinion(s) must be recorded in or attached to the minutes.

An IRB member may abstain from voting for any reason, without explanation. PI's are informed in writing of all IRB decisions. Decisions may include:

Approved

Approval of the application will be based on a majority vote and the following:

- Completeness of the application packet and supporting documents.
- The extent to which the human subject rights are protected.
- Justification that the potential benefits to the subject or the importance of the knowledge to be gained outweighs any potential risks that may be present.
- The adequacy of institutional facilities and other resources necessary for completion of the study and protection of subjects' rights.
- The adequacy of procedures for securing informed consent from the subject.
- The adequacy of measures for minimizing of risk and the protection of the health, safety, comfort, and legal rights of the subject.
- The adequacy of measures for protecting the privacy of subjects and maintaining confidentiality of data.

When a protocol has been approved, the Chair will issue a letter that indicates the IRB's action, signs and dates it, and distributes one copy of the form to the principal investigator and one to the IRB files.

Along with the notification of approval, PI's are informed that any subsequent changes in projects must be reviewed and approved by the IRB before they are initiated and that unanticipated problems must be reported.

Dissenting votes must be recorded with reason(s) noted.

Approval with modifications

Action taken if the IRB requires minor additional information and/or modifications. Necessary revisions are agreed upon and communicated to the PI. When the revisions are made by the PI, either the IRB Chair or the designated representative is authorized to provide approval for the study to begin. This action will be documented in the IRB records.

Defer

Action taken if substantial modification is required or if insufficient information is provided to evaluate the application adequately. To receive approval for a deferred protocol, it must again be submitted for an IRB review. The PI is notified by the Chair of the IRB and the additional information necessary for completion of the review is requested. In the case of a deferred protocol, the PI may be invited to attend an IRB meeting to present/clarify the protocol for the Board.

Disapprove

Action taken if a majority considers that the decision would not be changed by modifications to the protocol. If the protocol is disapproved, the PI will be informed in writing of the reasons for disapproval. The PI may revise and resubmit his/her protocol for another review.

Non-binding recommendations

The IRB may also offer non-binding recommendations with its action to approve or defer a protocol.

Dismissed/Withdrawn

Applications that are dismissed or withdrawn will be discarded and noted accordingly.

The IRB is authorized to modify, suspend, or terminate approval of research that has been associated with unexpected serious harm to subjects, or is not being conducted in accordance with 45 CFR 46 or the decisions, conditions, and requirements set forth by the IRB. PI's must respond in writing to IRB stipulations and recommendations on new protocols and continuing reviews within 90 days or the application will be terminated. Notification will be sent one month in advance of termination.

APPEAL OF AN IRB ACTION

The PI may appeal the decision of the IRB when a protocol has been disapproved or approved subject to restrictions and mutual agreement cannot be reached as to an acceptable alternative. By Federal regulations, institutional officials may not approve research that has not been approved by the IRB. A PI may approach the IRB to appeal or reconsider a decision regarding a human subject research activity. A final decision regarding the appeal will be made by a vote of the IRB. PI's do not, however, have the option to seek the reversal of an IRB decision by submitting the same protocol to another NIH IRB or the Signatory Official.

PERIODIC REVIEW AND UPDATE OF POLICIES AND PROCEDURES

IRB policies and procedures will be reviewed as necessary to assure compliance with changes in regulatory requirements, to provide additional information or improve clarification of information already contained within the document.

COOPERATIVE ACTIVITIES

Cooperative activities relating to human subjects are those which involve Cape Cod Community College and another institution. Normally, the research must be reviewed and approved by the IRBs at both institutions before it can be initiated. However, the IRB of one institution may rely on the IRB of the other institution under the following conditions:

- Both institutions have Federal wide Assurances (FWAs) approved by OHRP;
- Both institutions have entered into an Authorization Agreement (or equivalent document) that stipulates the responsibilities of both parties; and

- The appropriate section of the FWA of the deferring institution designates the IRB of the approving institution.

In the absence of these conditions, the PI must secure the approval of the IRB at each institution engaged in the research and submit documentation of such approvals to the other IRBs. The IRB Chair will verify (via the OHRP website) that the other institutions have approved FWAs.

TYPES OF IRB REVIEW

There are three types of IRB review: Exempt Status Determination, Expedited Review or Full Board Review. Depending on the level of risk of the research protocol and the participant population, IRBs may conduct either full board review or expedited review.

EXEMPT STATUS DETERMINATION

Only the IRB has the authority to make the Exempt Status Determination. Certain low-risk research in which no personal identifiers are collected is exempt from the requirements in the Federal regulations concerning IRB review and approval. Under Federal regulations [45 CFR 46.101 (b)], certain categories of activity are considered research but may be declared exempt from review by the IRB. This determination must be made by the IRB prior to the research being conducted. If a study falls into one of the exempt categories, researchers still have ethical responsibilities to protect participants' rights.

The six federally-approved categories of exemption under 45 CFR 46.101(b) are:

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, except under separate memorandum of understanding and advice of G. Council; 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 (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.

EXPEDITED REVIEW

Under federal regulations certain types of research may qualify for an expedited review [under 45 CFR 46.110]. For certain kinds of research involving no more than minimal risk, and for minor changes in approved research, the IRB Chair or a designated voting member or group of voting members review the proposed research rather than the entire IRB.

While personal identifiers may be collected, the type of data collection does not assume the level of risk. For example, it cannot be assumed that research poses minimal risk because it involves only interview or survey data collection. Sensitive questions may lead to distress that exposes participants to greater than minimal risk. Loss of confidentiality can cause harm to participants, their relatives, and others.

Research conducted under the expedited category should present no more than minimal risk to human subjects. It could also involve minor changes in previously approved research. The PI should designate on the application form which of the following categories that best applies to qualify the research for expedited review.

The list of categories of research that may be reviewed by the IRB through an expedited review process includes but is not limited to the following:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

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

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

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound,

diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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

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

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

8. Continuing review of research previously approved by the convened IRB as follows:
   a. where (1) the research is permanently closed to the enrollment of new subjects; (2) all subjects have completed all research-related interventions; and (3) the research remains active only for long-term follow-up of subjects; or
   b. where the remaining research activities are limited to data analysis; or
   c. where no subjects have been enrolled and no additional risks have been identified.

FULL BOARD REVIEW

For any research that does not meet either the criteria for Exempt Status Determination or Expedited Review, the PI must complete an application for Full Board Review. When full board review is necessary, the IRB application is presented and discussed at a meeting at which a quorum of IRB members is present. For the research to be approved, it must receive the approval of a majority of those voting members present. (Note that, in effect, an abstention counts as a negative vote.) Any IRB members with a conflict of interest should recuse themselves before voting. The PI may be invited to the IRB meeting to discuss the research application. The PI may not be present for the vote.

Adapted from The College of New Jersey and UML http://www.tcnj.edu/~irb/review.html

RECRUITMENT OF PARTICIPANTS, INFORMED CONSENT AND DOCUMENTATION

The regulations require that investigators obtain legally effective informed consent of the subject or the subject's legally authorized representative. The informed consent process is intended to educate potential subjects about the research project, outline their involvement and request their voluntary participation. It is intended to be an active process of sharing information and providing critical communication about the research study between the PI and the prospective subject. A verbal explanation of the project, with discussion and questions, is important in augmenting the written consent form. The informed consent document is a guide to this process and is the written record that the subject entered the study voluntarily and with full understanding of the research project. The informed consent document serves as a reminder to the participant of what they have agreed to do or are considering.

RECRUITMENT OF PARTICIPANTS

Advertising to recruit study participants should be conducted to ensure that participation is voluntary. The IRB reviews all recruitment documents and the methods and materials that PI's propose to use to recruit subjects. The recruitment information is submitted with the application to the IRB for review, regardless of the type of review. Direct advertising includes methods such as newspaper, radio, television, bulletin boards, posters and flyers intended for prospective subjects. The materials are reviewed by the IRB to assure that the recruitment method is not unduly coercive. This is especially important for studies that may include subjects who are likely to be vulnerable to undue influence. Procedures should be clearly outlined so that the IRB is assured that the information collected is handled appropriately and if sensitive information is gathered, the PI should outline the steps that will be taken to protect the subjects' confidentiality. PI's must recruit college students by public announcement and not by personal solicitation. If a PI intends to recruit participants in any other way, justification must be presented to the IRB and approval must be granted.

It is not uncommon for incentives to be offered to subjects for participation in research (e.g., payment, gift cards, extra credit, etc.). This is not considered a benefit but a recruitment incentive. Incentives, if used, must be clearly explained in the informed consent document. An explanation of procedures for early withdrawal must be included. Incentives should be set to encourage participation in the research but not an amount that could be considered coercive. The amount and schedule of all incentives should be presented in the informed consent document.

Steps of the informed consent process

1. Inform the prospective subject that there is a study in which s/he might wish to participate
2. Provide the prospective subject a consent form to review
3. Explain the potential risks and/or benefits of participating in the research study
4. Ask the prospective subject whether s/he has any questions
5. Collect a signed informed consent document, if required, and retain original for a minimum of three years after the close of the study.
6. Provide a duplicate copy of the informed consent document for the participant to keep.
7. Forms must be available for the IRB to review upon request.

INFORMED CONSENT FORM PROCESS

When an individual participates in a research project, the individual is entitled to certain information. This information includes a full and frank disclosure of all the facts, probabilities, options, and opinions which a reasonable person might be expected to consider before giving his/her consent.

Since each research project is different, there is no generic informed consent form. However, the following provides a description of required sections and the specific information that is required in each section. In developing a consent form for a specific research project, please note the following points:

1. The informed consent document must provide full and complete information about the project and be organized carefully so that the specific elements of informed consent, described below, are covered thoroughly.
    a) Study purpose and statement that the study involves research
    b) Description of procedures, including duration and types of activities
    c) Statement of any risks and benefits
    d) Statement of data confidentiality
    e) Statement that participation is voluntary and a person may withdraw from the study at any time without penalty or consequences
    f) Description of incentives, if any
    g) Contact information of the researcher, faculty advisor (if appropriate) and the CCCC IRB
    h) Verification that participant is 18 years of age or older
    i) Date and signature lines for the participant or legally authorized representative
2. The informed consent document must be written in language that is understandable without using jargon or technical language. Writing it at a sixth- to eighth-grade reading level is suggested.
3. The language should be written in the second person. The final Statement(s) of Consent, however, should be written in the first person.
4. The degree of detail, and the length of the consent form, should reflect the level of risk that the project entails for the subject.

5. If a study involves minors or participants with impaired decision-making ability, consent must be provided by the legally authorized representative and assent of the participants in addition to informed consent.
6. Separate forms may be required for different subject groups (e.g., parents, minors, non-English speakers), different types of activities and different kinds of information (photographs, audiotapes, videotapes).

CONFIDENTIALITY/ANONYMITY

Every effort must be made to ensure confidentiality of data. Security of storage, limitation of access, and coding constitute the best measure to minimize risk of inadvertent disclosure to unauthorized parties. Measures to prevent this problem should be described in applications for studies in which the data collected are sensitive. The IRB recommends the following language be included in the informed consent form related to privacy and confidentiality: “Every effort will be made to protect your privacy and confidentiality, but there may be a slight risk of disclosure from participating in any research study.”

RETENTION OF SIGNED FORMS

Signed consent forms must be stored so as to be available upon IRB request. Consent forms must be stored securely in locked files or a locked office by the PI, but procedures must be developed to ensure that the consent forms are kept in a secure location and can be retrieved expeditiously when necessary upon request by regulatory authorities or CCCC IRB administrative personnel.

DECEPTION STUDIES

In studies that propose to mislead or deceive the subjects during data collection, the IRB has even more responsibility to protect the rights of the subjects. The IRB may set limits for such procedures and recommend alternate procedures to achieve research objectives that involve deception.

Special considerations and consent documents are required when disclosure of the purpose and/or methodology could bias the outcome of the study. In situations where participants will be deceived, some information may be omitted and participants are told (on the signed form) that disclosure of the purpose and/or methodology could bias the outcome of the study and that they will be debriefed at the conclusion of the activity.

WAIVERS OF INFORMED CONSENT

Waiving the consent procedure may be used if the research is considered minimal risk or justification is provided to document the request for the waiver.

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent as stated, or waives the requirement to obtain informed consent as outlined in 45CFR 46.116 (d) provided the IRB finds and documents the

- Research involves no more than minimal risk to the participants;
- Waiver or alteration will not adversely affect the rights and welfare of the participant;
- Research could not reasonably be carried out without the waiver or alteration; and
- Participants will be provided with additional pertinent information after participation, when appropriate.

Requests for any type of waiver for informed consent must be specifically approved and documented by the IRB member(s) reviewing the application.

WAIVERS OF DOCUMENTATION OF INFORMED CONSENT

The IRB may choose to waive the requirement to obtain a signed consent form for some or all subjects in some cases when it finds either:

- That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.
- That 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. Collecting data by survey or interview are examples of research where use of a cover letter is generally appropriate.
- A request for waiver of documentation by the PI must include justifiable reasons in the IRB application.

APPLICATION PROCESS

BEFORE YOU APPLY

As soon as you decide to pursue a research project, contact the IRB Chair or a member of the IRB to discuss your project. Gathering information about human subjects protections and the IRB process will allow you to better prepare your project timeline. Your aim should be to understand the level of risk your project entails and the steps involved in submitting an IRB application. The IRB website provides information on the application process, forms and frequently asked questions. The IRB Chair and members of the IRB are available to review draft applications and answer questions along every step of the process. All training must be completed before submitting an IRB application.

APPLICATION SUBMISSION PROCESS

Applications and all supporting documentation should be submitted to the IRB Chair electronically as MS Word documents. Original signatures must be included on the PI Signature and Assurance page and may be scanned and sent electronically, faxed or mailed to the IRB Chair. Applications will be checked for completeness and assigned a protocol number. The IRB Chair verifies the appropriate level of review (full, expedited or exempt from further IRB oversight). All research involving human subjects that is conducted by those acting as an agent

of Cape Cod Community College, regardless of where the research is to be conducted or the designated review category must be submitted to the IRB for review regardless of funding, if any.

REVIEW PROCESS

IRB members are assigned responsibility for expedited reviews on a rotating basis. Complex research applications may require certain types of expertise for adequate review. In these situations, applications will be assigned specifically to those IRB members with the appropriate expertise needed. Assignment of a review allows for IRB members to anticipate when they need to make themselves available to review applications and ensure proper turn-around time.

The IRB Chair is authorized to determine research that meets exempt status requirements. Projects reviewed and approved under exempt status do not require submission of any other forms for IRB review unless a change to the research results in a change of the exempt status determination. If a research protocol changes, it is the responsibility of the PI to consult with the IRB Chair.

Once an application has been reviewed, the IRB Chair will notify the PI in writing of the IRB's decision. For approved protocols, the written notification should include the date of the approval, the date (anniversary of the approval date) of continuing review or a final report.

CONTINUING REVIEW, FINAL REPORTS AND STUDY CLOSURE

Continuing review

Projects that extend greater than one year are required to be reviewed at least annually. PI's must file a continuing review form with the IRB. The purpose of the continued review is to meet regulatory requirements, update the informed consent form and provide a summary to the IRB of the research activities that have occurred over the past year. Minor changes to the research protocol may be submitted under the continuing review process. Major changes must be submitted through the amendment process.

PI's wishing to retain identifiable information must file for continuing review before the anniversary date of their initial approval. The IRB recommends that the PI include a plan for the use of data so identifiable information is kept for only a limited time. Data that has identifiers removed may be maintained indefinitely in this manner as there is no risk to linking the data to the subjects who originally participated in the research.

Continuing review information should summarize:

- Number of subjects that participated in the study
- Unanticipated problems
- Withdrawal of subjects
- Complaints about the research
- Recent literature that may be relevant to the research
- Copy of current informed consent form
- New proposed consent documents

If the research is no more than minimal risk, the expedited review process may be used for continuing review.

PI's are sent a notice from the IRB approximately 30 days before the anniversary date of their approval. If a PI fails to provide continuing review information to the IRB, the research must stop, unless the IRB determines that it is in the best interest of the individual subjects to continue participating in the research. Enrollments of new subjects cannot occur after the expiration of IRB approval. If continuing review of a research protocol does not occur prior to the end of the approval period, approval automatically expires.

Final reports

A final report is required to close out a project upon completion or by the expiration date of the IRB approval. The IRB Chair will notify PI's approximately 30 days in advance of the expiration date, requesting that either the PI close out the project by submitting a final report or a continuing review form. It is the PI's responsibility to complete continuing review and final reports in a timely manner. If no continuing review or final report is received within 30 calendar days following the expiration date, the IRB Chair will mark the file "expired" and close the project. No research involving human subjects or their identifiable data will be allowed to continue.

COMPLIANCE AND INCIDENT REPORTING

Research conducted at Cape Cod Community College is expected to follow Cape Cod Community College Policies and Procedures and adhere to federal regulations regarding the protection of human subjects, regardless of who is conducting the research. Failure to do so may result in noncompliance, which may result in disciplinary actions or sanctions such as suspension or termination of IRB approval of specific or all research protocols, institutional or individual action by the federal Office of Human Research Protections (OHRP), recommendations for individual disciplinary action for failing to secure IRB approval before commencing human subject research will be reported to the Signatory Official, suspension or termination of project support, loss of indemnification from liability by the institution for adverse events if a PI fails to follow approved procedures.

Noncompliance is defined as research that is not conducted in accordance with institutional policy or federal regulatory requirements for human subject protection. Protocol deviations and variances from the protocol do not fall within these definitions until they are considered serious or continuous. Serious or continuing practices are those that appear to cause injury (physical, psychological, emotional, etc.) or any other unanticipated problems involving risks to participants and/or others or constitute serious/continuous noncompliance with IRB determinations or federal regulations.

IRB actions on a noncompliance event are final and not subject to appeal. Copies of all letters of warning from the IRB Chair to PI's must be sent to the Signatory Official. Copies of all

responses to program audits related to IRB compliance submitted to outside agencies must be reviewed by the Signatory Official prior to submission.

Adverse events and unanticipated incidents that occur during the research should be reported immediately to the IRB Chair. The report should provide the IRB Chair with a reasonably detailed analysis of the incident and allow the PI to assess the situation and determine whether the protocol requires modification to minimize risk, whether the informed consent should be revised, or if subjects should be contacted to re-consent to participate in the research study. Incident reports should include:

- Description of the event in sufficient detail as to allow an informed review of the occurrence
- Explanation as to why the event is unexpected and related to the research study
- Description of changes to the protocol to minimize further risk or a rationale if no changes are required
- Description of changes to the informed consent or a rationale if no changes are required
- Description of the plan to re-consent current participants or a rationale if no re-consent is required
- Risk/benefit analysis update – explain why the overall risk/benefit relationship of the research is still acceptable in light of the information of the incident.

APPENDIX

OHRP DECISION CHARTS

Chart #1: Is an activity research involving human subjects?

Chart #2: Is the research involving human subjects eligible for exemption?

Chart #3: Does exemption for educational settings apply?

For more information on OHRP Decision Charts, visit
http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c1

Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

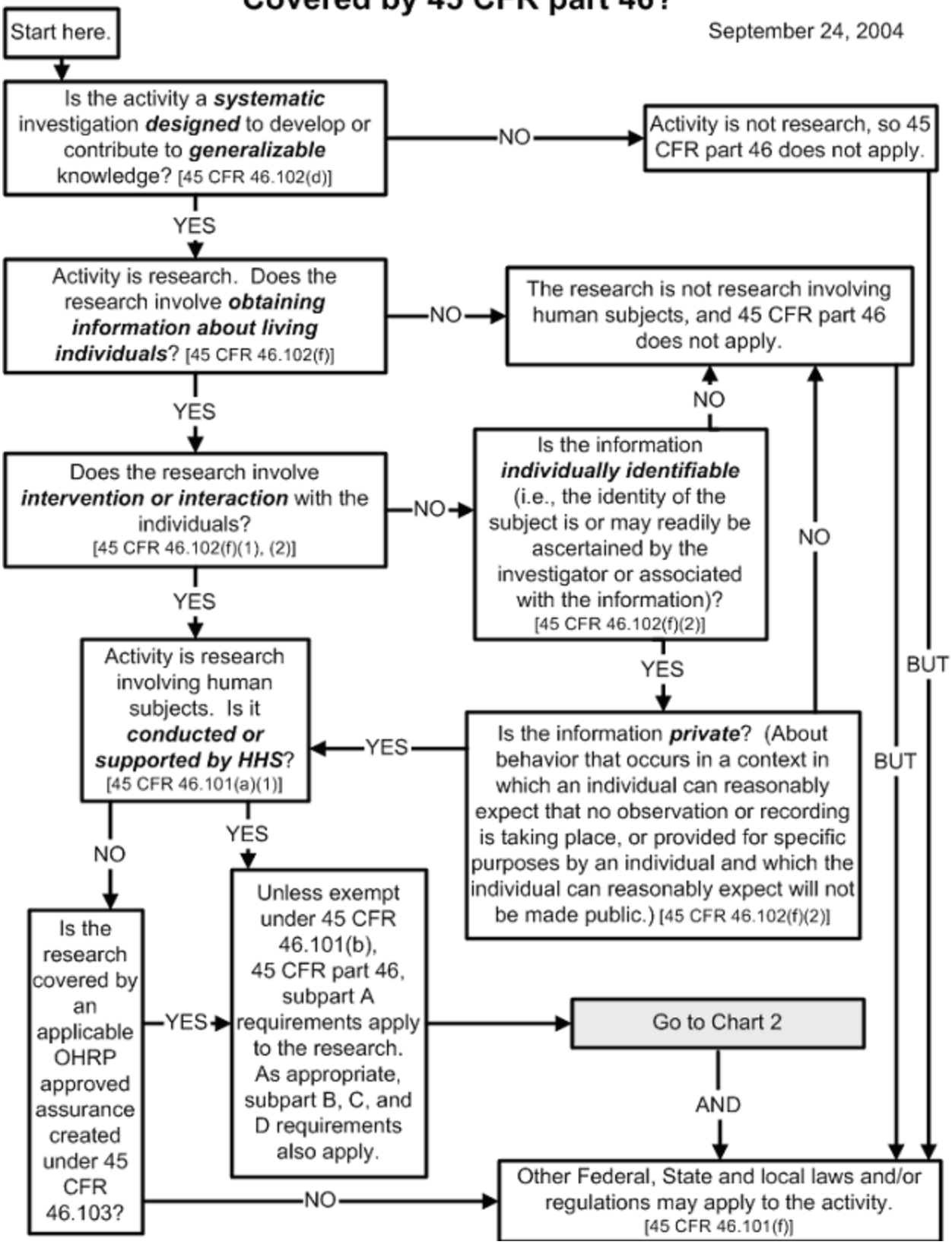


Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

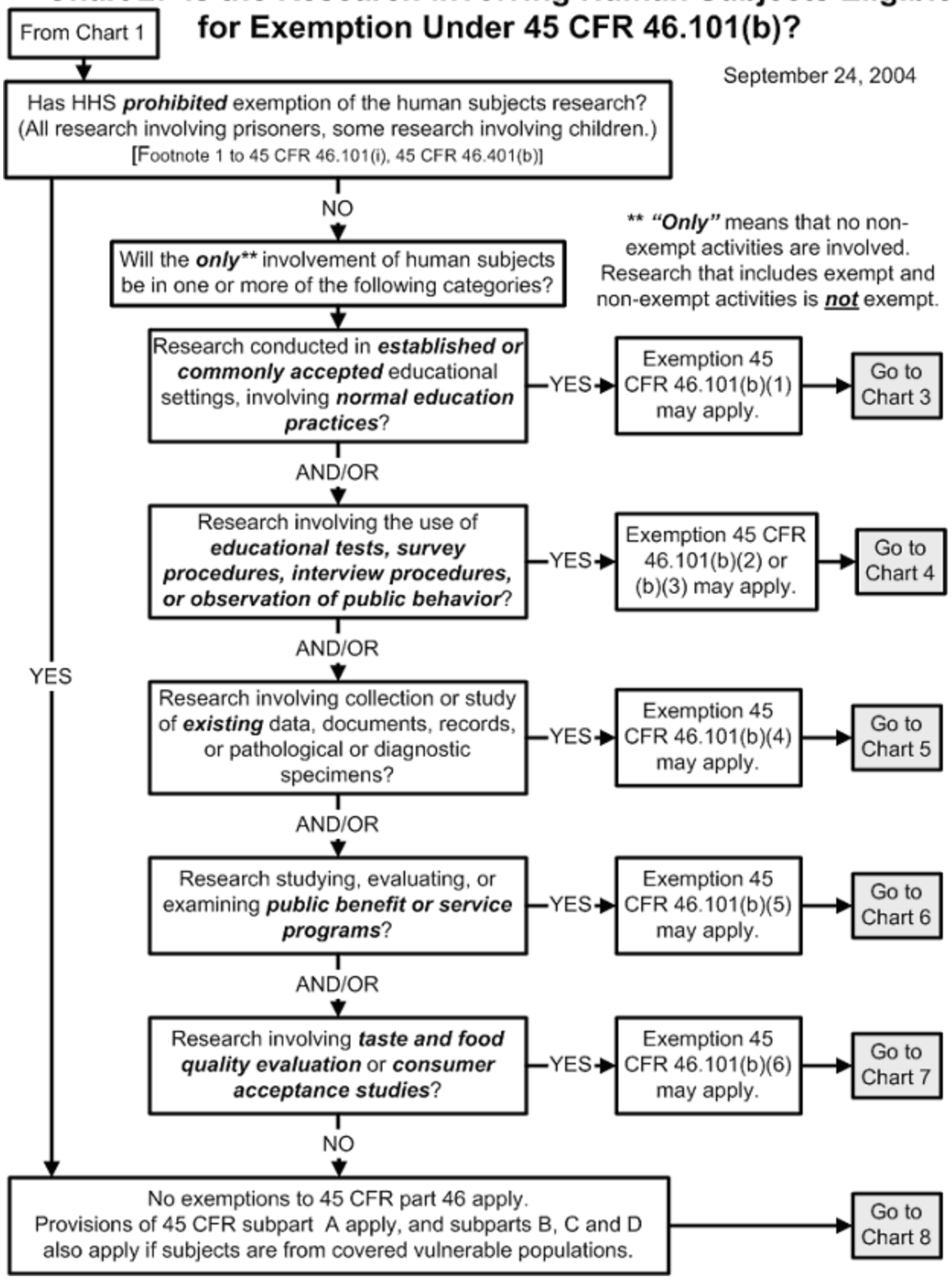
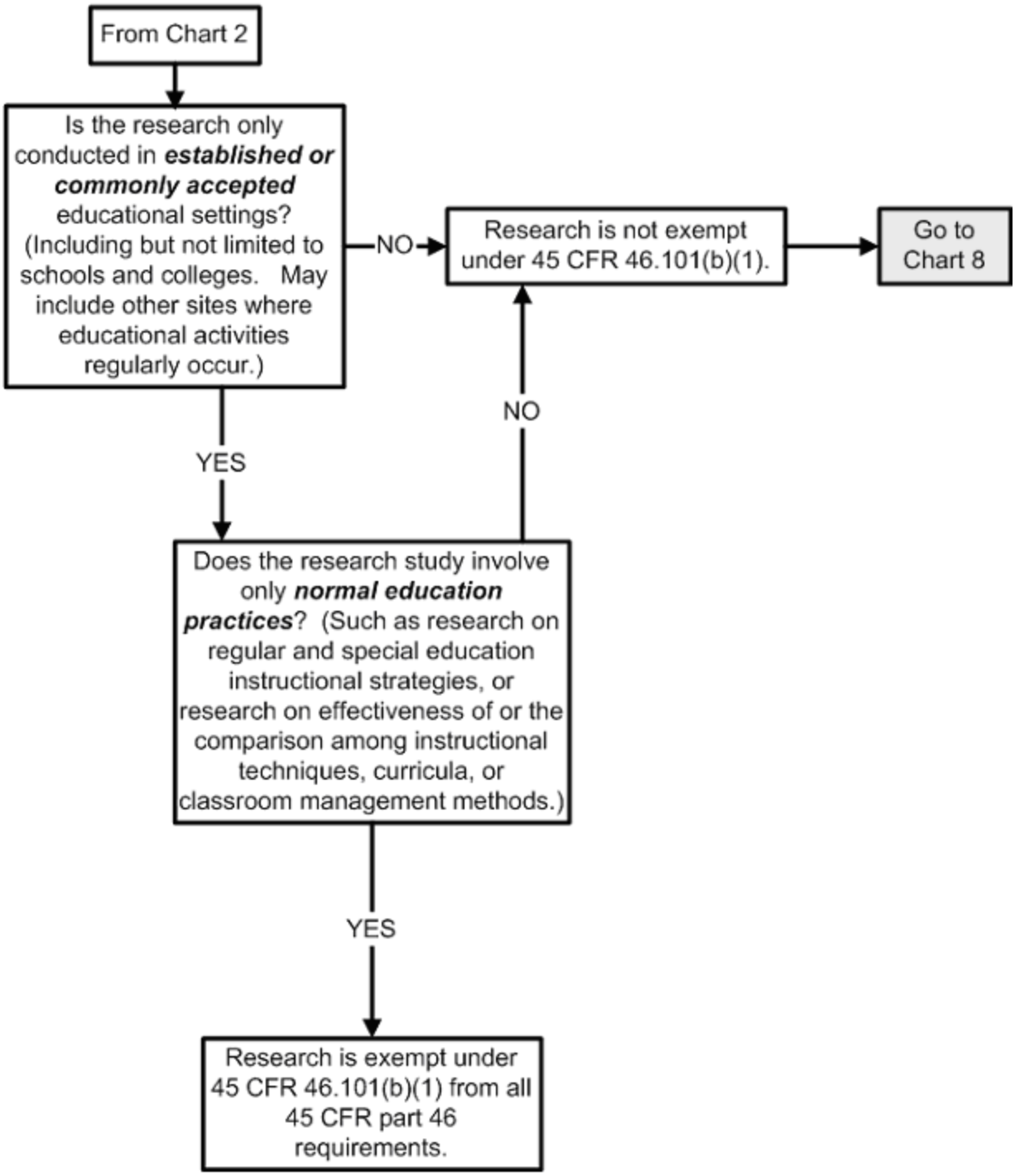


Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?



September 24, 2004

IRB QUICK START GUIDE FOR PRINCIPAL INVESTIGATORS

CAPE COD COMMUNITY COLLEGE IRB

QUICK START GUIDE FOR PRINCIPAL INVESTIGATORS

The Cape Cod Community College (CCCC) Institutional Review Board (IRB) reviews research protocols involving human subjects and evaluates and protects against risk for those subjects. CCCC and the Principal Investigators (PI) are responsible for ensuring that high ethical standards are maintained for all research involving human subjects. Individuals seeking to conduct human subjects research may not solicit subject participation or begin data collection until they have obtained clearance by the Cape Cod Community College Institutional Review Board.

Principal Investigators should review the CCCC IRB Policies and Procedures before submitting an application. This Quick Start Guide is intended as a reference for PI's and does not substitute the requirements outlined in the CCCC IRB Policies and Procedures.

- Determine if your project is considered human subjects research. Consult the OHRP Decision Charts in the CCCC IRB Policies and Procedures and/or consult with the IRB Chair or a member of the IRB to determine if your project is considered research under the federal guidelines.
- If your project is considered human subjects research, consult with the IRB Chair to determine the level of review needed.
- Visit the IRB website for forms, CCCC IRB Policies and Procedures, and meeting dates.
- Complete the online human subjects protections training. The link to the training can be found on the IRB website. Include a copy of the training certificate with your IRB application.
- Review the sample informed consent forms and the Elements of Informed Consent in the CCCC IRB Policies and Procedures. The IRB Chair and members of the IRB are available to assist you in the development of informed consent documents.
- If you have questions, share a draft of your application with the IRB Chair prior to submission.
- Submit your application electronically to the IRB Chair at IRB@capecod.edu.

ELEMENTS OF INFORMED CONSENT

Unless otherwise authorized by the IRB, researchers are responsible to obtain informed consent of participants. This is to ensure that only those human subjects who have consented to participate are involved in the research. It is recommended that research be limited to individuals who are 18 years or older.

The informed consent must include the following (sequential order recommended) and in language that the participants can understand:

a) Study purpose and statement that the study involves research

b) Description of procedures, including duration and types of activities

c) Statement of any risks and benefits

d) Statement of data confidentiality

e) Statement that participation is voluntary and a person may withdraw from the study at any time without penalty or consequences

f) Description of incentives, if any

g) Contact information of the researcher, faculty advisor (if appropriate) & CCCC IRB

h) Verification that participant is 18 years of age or older

i) Date and signature line for the participant or legally authorized representative

The informed consent document must be written in language that is understandable without using jargon or technical language. Writing it at a sixth- to eighth-grade reading level is suggested.

The language should be written in the *second* person. The final Statement(s) of Consent, however, should be written in the *first* person. The degree of detail, and the length of the consent form, should reflect the level of risk that the project entails for the subject. If a study involves minors or participants with impaired decision-making ability, consent must be provided by the legally authorized representative and assent of the participants in addition to informed consent.

Separate forms may be required for different subject groups (e.g., parents, minors, non-English speakers), different types of activities and different kinds of information (photographs, audiotapes, videotapes).

The signature of a participant or the participant's representative who may provide legally effective informed consent is required for signed informed consent.

SAMPLE INFORMED CONSENT FORMS

Sample statement for exempt survey research conducted online, without identifiers, and not requiring documentation of informed consent

This online survey is part of a research study being conducted at Cape Cod Community College in the xxxx area. The survey in its entirety should take less than 15 minutes to complete.

The purpose of this study is threefold: 1) to investigate xxx; 2) to develop an understanding of xxx and 3) to identify which services may contribute to xxx.

While it is generally agreed that xx services result in xx, the current economic climate, coupled with increasing mandates for student success, requires community colleges to make deliberate and considered choices about what resources can be directed toward student services. The results of this survey will provide important information about xxx.

Participation in this survey is anonymous. Your answers will go to a secure location without your name or any identifying information about you. Your responses cannot be linked to you, your specific school and results will only be reported in aggregate.

Completing the online survey will indicate that you've consented to participate. If you choose not to participate in this study simply close the survey browser window. You are free to exit out of the survey at any time you choose, and you should feel free not to respond to any questions with which you are uncomfortable.

Thank you very much for your consideration. If you have any questions you may contact the researcher at xxx or the Cape Cod Community College IRB at IRB@capecod.edu.

Sample informed consent form for face-to-face interviews

Consent form for: *Integrating Faculty to Enhance Student Success*

Introduction and Contact Information:

You are being asked to participate in a research project that is exploring strategies for integrating faculty who teach developmental level courses. The researcher is xxx, currently a fellow in the Community College Leadership Academy. Please read this form and feel free to ask questions. If you have further questions later, xx will discuss them with you. You can reach xx at 508-xxx-xxxx or xx@capecod.edu.

Description of the Project:

The purpose of the study is to ascertain current level of integration and support of faculty teaching developmental courses. A literature review of best practices will be completed, along with a survey of adjuncts currently teaching developmental courses at Cape Cod Community College as well as evaluation of data related to faculty and interviews with eight CCCC staff who work directly with adjunct faculty teaching these courses.

The one-on-one interviews will be conducted by xxx, and will take approximately 30 minutes to complete. During the interview, you will be asked:

- what are the current practices for providing information, support and supervision for adjunct faculty with whom you work
- how satisfied you are with these current practices and why
- what you feel might further support adjunct faculty

The interviews will not be recorded. xx will take notes; you may ask to review xx notes and interpretations of your interview for accuracy.

Risks and Discomforts:

This research is of minimal risk. You may discuss any distress or other issues related to your participation with the researcher. Your name will not be used in any written reports of this study. While this study does not directly benefit participants, your participation may help other community college faculty in the future.

Confidentiality:

Xx will not ask you for any personal information that is not directly associated with the purpose of this study. The information gathered for this project will not be published or presented in a way that would lead to your identity. Only xx xx will have access to the notes taken during the interview, and these notes will be destroyed by July x, xxxx.

Voluntary Participation:

Your participation in this study is entirely voluntary. If you decide to take part in this study, you may terminate participation at any time without consequence. You may decline to answer any of the interview questions without consequence. If you wish to terminate participation, please contact xxx.

Rights:
You have the right to ask questions about this research before you sign this form and at any time during the study. If you have any questions or concerns about your rights as a research participant, please contact the Cape Cod Community College Institutional Review Board (IRB) which oversees research involving human subjects. The IRB may be contacted through the following email at IRB@capecod.edu.

Signatures:
I HAVE READ THE CONSENT FORM. MY QUESTIONS HAVE BEEN ANSWERED. MY SIGNATURE ON THIS FORM MEANS THAT I CONSENT TO PARTICIPATE IN THIS STUDY. I ALSO CERTIFY THAT I AM 18 YEARS OF AGE OR OLDER.

_____ _____
Signature of participant Date

_____
Printed name of participant

_____ _____
Signature of researcher Date

_____
Printed name of researcher