



Data Monitoring Committee Manual

Version 3 Updated January 2012



Data Monitoring Committee: Mission and Principles

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- The following pages summarize the principles that govern the DMC in assuring that the rights and welfare of CICS students, staff, administration and data are protected. The subsequent documents have been considered:
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Data Monitoring Committee: Mission and Principles

Definition and Mission

Agency: Chicago International Charter School (CICS).

Definition: The Data Monitoring Committee (DMC) serves as the group formally designated by the institution to review, to approve the initiation of, and to conduct periodic review of, research involving human subjects affiliated with CICS.

Mission: The mission of Chicago International Charter School is: To provide, through innovation and choice, an attractive and rigorous college-preparatory education that meets the needs of today's students. In accordance with this mission, the DMC seeks to provide the support and security each student needs to achieve his or her best. As a result, the primary purpose of the DMC is to assure protection of the rights and welfare of human subjects in any research project using CICS affiliates.



Data Monitoring Committee: Mission and Principles

Quality of Research Statement

Agency: Chicago International Charter School (CICS).

- The DMC considers the quality of proposed research or the merit of a proposed study only in so far as it is related to ensuring the protection of the rights and well-being of human subjects. However, research design quality and merit are important in DMC members' analysis of a study's potential risks and benefits.

A poorly designed research project poses inherent risks to subjects. Studies that have little or no merit are unlikely to result in any benefit. An uninformed researcher may also pose a risk to subjects. During the evaluative review, DMC members consider evidence of the researcher's knowledge of research design, research methods, research ethics, and/or data analysis, and familiarity with the work of other researchers in the field or topic. Researchers should keep DMC criteria in mind throughout the development and implementation of their projects.

DMC members are members of the community, researchers and educators. The DMC may choose to make recommendations to improve a research project separate from its requirements for approval. Although researchers are not required to follow these additional recommendations, they should always be considered, as the DMC serves the interests of human welfare and quality research.



Data Monitoring Committee: Mission and Principles

Family Educational Rights and Privacy Act (FERPA)

Agency: Department of Education, 1974. The Buckley Amendment.

Mission: FERPA is a federal law that protects the privacy of student education records. Parents (and eligible students) have specific, protected rights regarding the release of such records and FERPA requires that institutions adhere strictly to these guidelines.

- Basic Overview:
 - Institutions must have written permission from the parent (or eligible student) in order to release any information from a student's educational record
 - Institutions may disclose directory information in the student's educational record without seeking the student's consent
 - It is good policy for the institution to notify the student about such disclosure and to seek the written permission of the student to allow disclosure of any educational records including directory information
 - Institutions should give the student ample opportunity to submit a written request that the school refrain from disclosing directory information about them
 - Institutions must not disclose non-directory information about students without their written consent except in very limited circumstances
 - Institutions should notify parents/students about their rights under FERPA through annual publications
 - When in doubt, it is always advisable to err on the side of caution and to not release student educational records without first fully notifying the parent/student about the disclosure
- Rights afforded under FERPA:
 - The right to access educational records kept by the school
 - The right to amend educational records
 - The right to file complaints against the school for disclosing educational records in violation of FERPA
 - The right to know about the purpose, content, and location of information kept as a part of their educational records
 - The right to expect that information in their educational records will be kept confidential unless they give permission to the school to disclose such information
- Definition of an Educational Record: 'Records that directly relate to a student and that are maintained by an educational agency or institution or by a party acting for the agency or institution.'
 - Such records are those related to the student either maintained by the school or by a party or organization acting on behalf of the school and may include:
 - Written documents
 - Computer media
 - Microfilm and microfiche



- Video or audio tapes or CDs
 - Film
 - Photographs
- Any record containing personally identifiable information that is directly related to the student is an educational record under FERPA. Therefore, this information can also include:
 - Student files
 - Student system databases kept in storage devices such as servers
 - Recordings or broadcasts which may include student projects
- Not Considered as Educational Records
 - Fall outside of FERPA guidelines
 - Private notes of individual staff or faculty NOT kept in the student advising folders
 - Campus police records
 - Medical records
 - Statistical data compilations that contain no mention of personally identifiable information about any specific student
 - These records may be protected under other state or federal laws (e.g. doctor/patient privilege)
- Disclosure Protections Regarding the Two Types of Defined Educational Records:
 - Directory Information
 - The school may disclose this type of information without the written consent of the student
 - The student can exercise the option to restrict the release of directory information by submitting a formal request to the school
 - This information can include:
 - Name
 - Address
 - Phone number and email address
 - Dates of attendance
 - Degree(s) awarded
 - Enrollment status
 - Major field of study
 - Non-Directory Information
 - Any information not considered directory information
 - This must not be released to anyone without prior written consent
 - Faculty and staff can access non-directory information only if they have a legitimate academic need to do so
 - This information can include:
 - Social security numbers
 - Student identification numbers
 - Race, ethnicity, and/or nationality
 - Gender
 - Transcripts; grade reports



- Written Consent:
 - Must include the following elements:
 - Specify the records to be disclosed
 - State the purpose of the disclosure
 - Identify the party or class of parties to whom the disclosure is to be made
 - The date
 - The signature of the student whose record is to be disclosed
 - The signature of the custodian of the educational record
 - Prior written consent is not required when disclosure is made directly to the parent (or eligible student) or to other school officials within the same institutions where there is a legitimate educational interest
 - A legitimate educational interest may include enrollment or transfer matters
 - Financial aid issues
 - Information requested by regional accrediting organizations
 - Prior written consent to disclose non-directory information is not required where the health and safety of the student is at issue, when complying with a judicial order or subpoena, or where, as a result of a crime of violence, a disciplinary hearing was conducted by the school and the alleged victim seeks disclosure
 - In order for institutions to be able to disseminate non-directory information in these instances FERPA requires that institutions annually publish the policies and procedures that the institutions will follow in order to meet FERPA guidelines.
- Additional Information:
 - Rights to Review and Seek Amendment:
 - Schools must give parents (and eligible students) the opportunity to inspect and review education records within 45 days of a written request
 - If, upon review, it is found that the record is inaccurate or misleading, they may request changes or corrections (preferably in writing)
 - Rights to Restrict Disclosure:
 - FERPA doesn't give students a veto over any of the permitted disclosures except the one for "directory information"
 - Influence of No Child Left Behind
- January, 2009 Amendments:
 - Definition of "in attendance" expanded to include distance education modalities.
 - Now includes when a student is not physically present in class on campus by virtue of the modality (i.e., internet courses).
 - Changes in definition of educational record
 - Alumni giving is not covered by FERPA, but a grade change and biometric data (fingerprints) is
 - The guidelines for meeting the health and safety provision were expanded, and only require an "articulable and significant threat" before information can be released



- How to be FERPA compliant:
 - 1. Notify current students annually in writing of their rights under FERPA
 - To seek amendments
 - To have some control over disclosure
 - To file complaints with the Family Policy Compliance Office, United States Department of Education, within 180 days of alleged violation of the policy of disclosing personally identifiable information
 - Criteria for determining school officials
 - Description of what constitutes legitimate educational interest
 - 2. Grant access by parents (eligible students) to education records
 - Within 45 days of written request
 - The institution is not required to provide a copy of the record unless failure to do so would deny access
 - A right to review records of requests for disclosure of their personally identifiable information



Data Monitoring Committee: Mission and Principles

The Belmont Report

Agency: Department of Health, Education, and Welfare, 1979. Instituted the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Mission: To identify the ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects, and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles.

- Directed to consider the following:
 - (i) the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine,
 - (ii) the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects,
 - (iii) appropriate guidelines for the selection of human subjects for participation in such research and
 - (iv) the nature and definition of informed consent in various research settings.
- Boundaries between practice and research
 - the term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success
 - the term "research" designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships)
 - When an investigator departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research
 - Research and practice may be carried on together; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.
- 3 Basic Ethical Principles
 - Respect for Persons
 - First, individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection
 - The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy
 - In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information (e.g. exception: prisoners)



- Beneficence
 - understood to cover acts of kindness or charity that go beyond strict obligation; maximize possible benefits and minimize possible harms
 - to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks
 - The obligations of beneficence affect both individual investigators and society at large
 - In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation
 - In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures
- Justice
 - equals ought to be treated equally
 - formulations for distributing burdens and benefits
 - (1) to each person an equal share,
 - (2) to each person according to individual need,
 - (3) to each person according to individual effort,
 - (4) to each person according to societal contribution, and
 - (5) to each person according to merit
 - The selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied.
 - Whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.
- Applications
 - Applications of the general principles to the conduct of research leads to consideration of the following requirements
 - (1) Informed consent
 - Information, comprehension, voluntariness
 - (2) Risk/benefit assessment
 - The nature and scope of risk/benefits (probability and magnitude)
 - Federal regulations often insist sum of benefits to individual and benefits to society outweigh risk
 - (3) The selection of subjects of research



Data Monitoring Committee: Mission and Principles

Code of Federal Regulations (CFR) – Title 45

Agency: Code of Federal Regulations. Department of Health and Human Services, 2005. Title 45.

- Part 46. 109. IRB Review of Research.
 - An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy
 - Info given to subjects is part of informed consent in accordance with 46.116. The IRB may require additional information be given to subjects
 - An IRB may require documentation of informed consent or waive documentation
 - An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity. Disapproval shall include a statement of reasons and an opportunity for the investigator to respond in person or in writing
 - IRB shall continue review of research at intervals appropriate to the degree of risk, but not less than once per year
- Part 46. 110. Expedited Review Procedures
 - An IRB may use expedited review to review either or both of the following:
 - Some or all of the research appearing on the list and found to involve no more than minimal risk
 - Minor changes in previously approved research during the period
 - May be carried out solely by the IRB chair
- Part 46. 111. Criteria for IRB Approval of Research.
 - In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:
 - **(1)** Risks to subjects are minimized by: a) using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes
 - **(2)** Risks to subjects are reasonable in relation to anticipated benefits
 - **(3)** Selection of subjects is equitable—and be particularly cognizant of the special problems of research involving vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons
 - **(4)** Informed consent will be sought from each prospective subjects or the subject's legally authorized representative (in accordance



- with 46.116)
 - (5) Informed consent will be appropriately documented
 - (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects
 - (7) Adequate provisions are made to protect the privacy of subjects and confidentiality of data
- When some or all of the subjects are likely to be vulnerable, additional safeguards should be included in the study to protect their rights and welfare
- 46. 112. Review by Institution.
 - Research covered by this policy that has been approved by an IRB may be subject to further review or approval of the institution. However, those officials may not approve the research if it has not been approved by an IRB.
- 46. 113. Suspension or Termination of IRB Approval of Research
 - An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements (decision should be immediately reported to investigator and institution)
- 46. 114. Cooperative Research.
 - If more than one institution is collaborating on a research project, each institution is responsible for safeguarding the rights and welfare of human subjects and complying with the IRB policy.
 - An institution entering into a joint project may enter into joint review or default to the other IRB, but avoid duplication of efforts
- 46. 115. IRB Records.
 - An IRB shall maintain adequate documentation of IRB activities including:
 - (1) Copies of all research proposals, sample consent forms, progress reports and injury reports
 - (2) Minutes of IRB meetings (actions, votes, basis for requiring changes or disapproval)
 - (3) Records of continuing review activities
 - (4) Copies of all correspondence between the IRB and investigators
 - (5) A list of IRB members
 - (6) Written procedures for the IRB
 - (7) Statements of significant new findings provided to subjects
 - Records shall be retained for at least 3 years after completion of the research
- 46. 116. General Requirements for Informed Consent.
 - See Informed Consent Outline
- 46. 401. Additional Protections for Children Involved as Subjects in Research
 - Exemptions at 410.101 (b)(1) and (b)(3) through (b)(6)
 - For research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving the observation of public behavior when the



- investigator(s) do not participate in the activities being observed
- 46. 402. Definitions.
 - *Children*: persons who have not attained the legal age for consent to treatments or procedures involved in the research
 - *Assent*: a child's affirmative agreement to participate in research
 - *Permission*: the agreement of parent(s) or guardian to the participation of their child in research
 - *Parent*: a child's biological or adoptive parent
 - *Guardian*: an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care



Data Monitoring Committee: Authority and Management

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Data Monitoring Committee: Authority and Management

The Institutional Authority under Which the DMC is Established & Empowered

- Establishment:

Chicago International Charter School has empowered the Data Monitoring Committee (DMC) as the institution's decision-making body with regard to research with human subjects. DMC determinations regarding proposed research are final—they may not be overridden or reversed by any individual or group. Researchers are obligated to abide by the DMC's decisions about their proposed studies or projects. Researchers may appeal and DMC decision to the DMC.

The DMC is administered through Chicago International Charter School. The DMC is comprised primarily of staff members from disciplines that conduct research involving human subjects (i.e., psychology, education, etc.). The data monitoring committee functions independently of, but in coordination with the administration of Chicago International Charter School.

The Chicago International Charter School (CICS) data monitoring committee (DMC) has been established in accordance with federal regulations. This DMC reviews all proposed research involving human subjects in order to ensure that subjects' rights and welfare are adequately protected. The DMC will not condone, support, or accept any research involving human subjects that:

- Does not have the prior authorization of the DMC, unless the requirement for such authorization has been waived by the DMC chairperson (see exempt review)
- Has been approved by another institution's DMC or IRB but has not been approved by the CICS DMC
- Has been denied approval by any constituted IRB or DMC (whether CICS or another IRB)



- Empowerment:2012

Whenever the Data Monitoring Committee reviews a protocol, an initial question to address is whether the DMC has jurisdiction over approval of the research. That is, the DMC must ask, "Is the research subject to DMC review?" The federal regulations that govern the DMC apply "to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency" that has adopted the human subject regulations.

Therefore, the DMC must determine whether the activity involves *research*, and whether it involves *human subjects*. **Research** is defined by the regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" [Federal Policy 102(d)]. **Human subjects** are defined by the regulations as "living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information" [Federal Policy 102(f)]. (Section 102(f) goes on to define the meaning of such terms as "intervention" and "private information.")

In addition, some research that involves human subjects may be exempt from the regulations requiring DMC review [Federal Policy 101(b)]. Examples include educational testing and survey procedures where no identifying information will be recorded that can link subjects to the data, and disclosure of the data could not reasonably place the subjects at risk of civil or criminal liability or be damaging to the subjects' financial standing, employability, or reputation; and research that involves the use of existing data, documents, or specimens, where no identifying information will be recorded that can link subjects to the data.

Jurisdictional questions arise, however, in that the regulations also require that, as part of their assurances, institutions agree to protect the welfare of all human subjects involved in research, whether or not the research is conducted or supported by a federal department or agency [Federal Policy 103(b)(1)]. While the regulations further specify that this requirement "need not be applicable to any research exempted...under §101(b)," many institutions' human subjects policies provide that all research, even research that is exempt from review under the federal regulations, is to be reviewed by the DMC. In such cases, the DMC has jurisdiction over all human subjects' research, thereby providing broader protection for subjects than that required by the regulations. It is crucial that the Data Monitoring Committee keep in mind that their authority to approve, require modifications in, or disapprove research derives from both federal law and institutional policy.



Data Monitoring Committee: Authority and Management

Authority of the Data Monitoring Committee (DMC)

Authority:

- The DMC may consider recommendations from other institutional or extramural review committees, but the DMC has the responsibility and sole authority to carry out its review responsibilities in accordance with these policies and procedures.
- The DMC shall define whether proposed research is acceptable based on regulations and policies, applicable law, validity of study design as it relates to risks and benefits, sensitivity to community standards and attitudes, as well as standards of professional conduct and practice. No one at the institution may approve a study that the DMC has disapproved; and administrators of the institution may not approve a study if it has not been approved by the DMC [45 CFR 46.112; 21 CFR 56.112]. In order to approve research studies, the DMC shall review the full proposal, the consent form and all supplemental information.
- If applicable, each DMC may require studies to be reviewed and approved by ancillary committees.
- The DMC has additional authorities which include:
 - (a) Authority to Require Progress Reports and to Oversee the Study: The DMC has the responsibility and the authority to review the progress of human subject research studies, to monitor the activities in approved studies including regularly scheduled continuing review at least annually, and to require verification of compliance with approved research protocols and informed consent procedures through means such as audit, observation or third party review. The authority to review the progress of studies includes the authority to require prompt reporting to the DMC of any planned changes in approved projects prior to the implementation of those changes and the authority to require prompt reporting to the DMC of any unanticipated problems (including adverse events) occurring in, or related to, approved protocols.



(b) Authority to Suspend or Terminate Approval of Research: The DMC has the authority to suspend or revoke approval of any study that was originally reviewed and approved for reasons such as unanticipated problems involving risks to human subjects, serious or continuing non-compliance with any federal regulation or serious or continuing non-compliance with the requirements or determinations of the DMC [45 CFR 46.113; 21 CFR 56.113]. Such actions by the DMC shall be determined at a convened meeting of the DMC with a quorum present and shall be incorporated into the minutes of the meeting. The DMC shall consider the rights and welfare of current research subjects when suspending or terminating approval of active studies.

(c) Authority to Restrict Research: The DMC has the responsibility and the authority to restrict any study that it has originally reviewed and approved if it determines that such action is warranted. Under this policy, 'restrict' is defined as suspending or terminating a portion of a study found in non-compliance either permanently or until it is brought into compliance. One example of this may be if an aspect of a study fails to comply with federal regulations or DMC requirements or determinations. The DMC may also request that a study audit be conducted.

(d) Authority to observe, or have a third party observe, the consent process: [45 CFR 46.109(e); 21 CFR 56.109(e)]. If the DMC approves a study, it has sole authority for oversight of the consent process. To carry out this responsibility, the DMC may observe (or have a third party observe the consent process and/or it may seek information on this process from the principal investigator or others.

(e) Authority to observe, or have a third party observe, the conduct of the research: [45 CFR 46.109(e); 21 CFR 56.109(e)]. If the DMC panel approves a study, it has sole authority for oversight of the study including the conduct of the research under the approved protocol.



Data Monitoring Committee: Authority and Management

Membership

Membership:

- The Data Monitoring Committee shall have at least two members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted through the institution. The DMC shall be sufficiently qualified through the experience and expertise of its members to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review the specific research activities, the DMC shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.
- No member may participate in the DMC's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the DMC.
- The DMC may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available of the DMC. Those individuals may not vote with the DMC.



Data Monitoring Committee: Authority and Management

Management

Management:

- Confidentiality:
 - DMC members may not discuss a proposed research study outside of the DMC review process. The DMC review process may, however, extend to consultation with individuals external to the DMC, such as a primary investigator's faculty advisor, or an employee's supervisor.
 - The DMC may also, if necessary, engage a consultant to provide additional expertise needed to make a decision on a proposed study.
 - When DMC approval is requested for externally funded research or for research to be conducted in collaboration with another institution, the DMC may also communicate with those parties about the study. Such communication will typically be limited to sending copies of official DMC correspondence (e.g., approval letters), and records of said correspondence will be maintained.

- Conflict of Interest:
 - To avoid conflict of interest, a DMC member may not review studies in which he or she has an actual or apparent conflict of interest, or is a primary or supporting investigator.
 - The member may answer questions or supply requested supplemental materials for the DMC's review only, and will not vote on approval of the research proposal.



- Advice versus Assessment
 - Each DMC member is available to provide general advice and information on DMC policies and criteria for research involving human subjects.
 - A DMC member may not assess a New Project application prior to submission for consideration. Doing so would create a prior relationship or affiliation to the project that would require the individual to excuse him or herself from consideration of the project.

- Record Maintenance
 - Each DMC member is available to provide general advice and information on DMC policies and criteria for research involving human subjects.
 - The DMC shall maintain documentation of DMC activities and copies of all research proposal reviewed, reviews that accompany the proposals, approved consent documents, and subsequent amendment reports submitted by researchers, and reports of any procedural deviations, if any.
 - Minutes of DMC meetings include attendance, actions taken, the vote on these actions; the basis for requiring changes in or disapproving research; and a written summary of the discussion of issues and their resolution.
 - Records of continuing review activities, modifications of research studies, official DMC approvals, copies of all correspondence between the DMC and the investigators, and statements of significant new findings provided to CICS and any third parties are also maintained.
 - All DMC records, including records relating to research conducted, are retained for at least three years after completion of the research. DMC application and research proposal records are destroyed by shredding three years after the research has been completed, withdrawn, or are no longer applying for continual review.

[Note: DMC records are maintained in accordance with 45 CFR 46. 115.]



Data Monitoring Committee: Required Information and Review Procedures

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Data Monitoring Committee: Required Information and Review Procedures

Required Information

- Overview
 - At minimum, all studies submitted for DMC review must contain a completed *New Project Application*. Additional items which may need to be included are:
 - Data request Review Form
 - Expedited Review Supplement
 - Exempt from Review Supplement
 - Co-PI Supplement
 - Data Security Supplement
 - Change or Renewal Form
 - Once a submission is determined complete, it is reviewed by the DMC chairperson.
 - The principal component of the *New Project Application* is the description of the research that the principle investigator plans to conduct. The focus of the write-up should include specific information describing:
 - 1) the goals of their research;
 - 2) the source of subjects and the selection criteria;
 - 3) the procedure;
 - 4) the potential risks and benefits for subjects;
 - 5) the methods by which confidentiality and anonymity will be protected,
 - 6) the consent form and debriefing processes, and the actions that will be taken in adverse situations;
 - 7) data protection, storage, management and destruction; and
 - 8) any other information that might be relevant to the approval decision.
 - Although the current application form only requires that the investigator answer these requests for information when the submission is for expedited or full review, **it is highly recommended that all submissions, including those requesting exempt review, answer these 8 requests**. It can't be guaranteed that the DMC will agree with you that your research is indeed exempt, and, in any case, this format is a simple, clear, concise way to describe your research to the DMC members.



- What follows is a brief discussion of each of the aforementioned requests for information delineated on the application form. Common mistakes, misconceptions, and omissions are described for each one.
 - 1) The goals of your research.
 - State the purpose of the research. Include major hypotheses and research design. If the study is part of a larger study, briefly describe that larger study and if applicable, indicate whether it has received DMC approval from another institution. Please keep in mind that the DMC is comprised of individuals from many disciplines and thus, the description of your research should be written in terms readily comprehensible by all potential readers.
 - Answers to the following questions should be considered in the PI write-up.
 - What are the major research questions that you are trying to answer?
 - Are you trying to assess the effectiveness of a particular program, device, method, etc. on student performance?
 - Are you trying to collect opinions about an existing program or method?
 - Are you using collected data (or data to be collected) to illustrate a particular strength or weakness of some program or method?
 - Whatever the goals of the research, they should be stated as clearly and precisely as possible.
 - When describing the hypothesis, the principal investigator should try not to describe it in a biased manner (e.g., “I intend to show that this new method is clearly more effective than the old method.”).
 - 2) The source of subjects and selection criteria
 - Selection of subjects must be equitable and, in the case of protected populations such as children, pregnant women, persons with disabilities, etc., should address their specific needs. The text of any advertisement, letter, flier, oral script or post-hoc report should be attached to the *New Project Application*.
 - A PI's subjects, target population, or the population that existing data represents must be described in detail to the DMC.
 - Include not only a description of the subjects, but also a separate description of the selection criteria if applicable.
 - The PI should keep in mind that the goal of the DMC is to ensure that subjects are treated fairly and adequately protected from research risks. This indicates that the selection process must not be biased in any way. Unless gender or ethnicity is a focus of the research, the method of selection should be nonbiased. Random selection of subjects from a larger available sample, for example, is a good nonbiased selection method.



- 3) The procedure.
 - If available, a PI should include copies of questionnaires and/or interview protocol, or a sufficiently detailed description of the intended measures to allow the DMC to understand the nature of the subjects' involvement.
 - The goal here is to make the procedure that the PI intends to follow clear to the members of the DMC. The following questions should be considered when answering related questions on the *New Project Application*.
 - When a participant begins this study, exactly what is he or she being asked to do?
 - Will participants be performing required tasks individually or in groups?
 - If existing data is being used, will participant information be evaluated individually?
 - Where will the study take place and how long will it take?
 - Also, a PI should keep in mind that the primary job of the DMC is to weigh the risks and benefits of your research for participants, and this means that in some cases, the validity of your design can become an issue for the DMC to address. If a study is determined to have no validity, then even minimal risks are not justified.
 - A PI should try not to design a study in which he or she is virtually guaranteed to get whatever results he or she is looking for.

- 4) The potential risks and benefits for subjects.
 - Describe any potential harms or benefits to be derived by subjects, with a discussion of the risk/benefit ratio. For approval of any study with more than minimal risk, the benefits must clearly be shown to outweigh the risk.
 - Describe how the study or research may expose participants to stress, physical, psychological or interpersonal hazard, including the possibility of pain, injury, discomfort, embarrassment, worry, or even violation of anonymity, and other legal rights.
 - The PI should be honest about any risks the research poses, and avoid misleading the DMC. Studies with limited risks are frequently approved, so long as adequate precautions are taken to ensure the benefits outweigh the risks.

- 5) The methods by which anonymity and confidentiality will be ensured
 - A difference between the two terms should be understood by the PI
 - Confidentiality and anonymity are two different things. Confidentiality refers to the fact that personal information will never be revealed by the researchers. Anonymity refers to the fact that even the researchers themselves will have no way of identifying any of the participants in the study from their data. The PI should make it clear whether his or her study provides confidentiality or anonymity and describe the procedure by which these are achieved.



- Also, as indicated in the question itself, provide a clear detailed description of how the data will be stored and who will have access to it.
- 6) The consent form and debriefing processes, and the actions that will be taken in adverse situations
 - Consent Form Process
 - Describe the oral and written consent processes and attach all consent documents to the *New Project Application*, including scripts for oral consent and assent form for research involving minors under the age of 12.
 - When the consent form used will be in a language other than English, an English translation must be provided.
 - Unless one or more of the required elements described below is explicitly waived by the DMC, informed consent documents should contain:
 - A fair explanation of the procedures to be followed and their purposes, including any procedures that are experimental
 - A description of any possible discomforts and risks reasonably expected
 - A description of any benefits reasonably expected
 - A disclosure of any appropriate alternative procedures
 - An offer to answer any inquiries concerning the goals of the research or the research procedures and to provide a summary of results upon request
 - A contact person and phone number should be provided
 - An instruction that the subject is free to withdraw or discontinue participation at any time without prejudice or penalty
 - A statement that the data are confidential or anonymous, and that the subject will not be identified by name in writing or orally
 - Provisions for parent or guardian approval for participation of minors, or for subjects from vulnerable populations when appropriate
 - Debriefing Process
 - In cases in which a debriefing seems warranted, a PI should indicate what it is that the subjects will be told and whether the debriefing will be verbal or written



- 7) Data Storage and Management
 - Data and record security is critical. It should be insured that all hard copy and electronic data is securely stored to prevent unauthorized access, disclosure or loss.
 - Hard copy data and records should be stored in a manner that limits access to only authorized individuals. Filing cabinets or storage areas should be locked.
 - Electronic data and records should be saved on a device that has the appropriate security safeguards. This should include such precautions as unique identification of authorized users, password protection, anti-virus controls, firewall configurations, and schedule and automatic backups to protect against data loss or theft.
 - The subject's privacy has to be protected
 - Types of confidential information include:
 - Personal information (SSN, birthdates, etc.)
 - Academic records (grades, evaluations, etc.)
 - Identifiable human subject research
 - Financial information
 - Medical information
 - Patentable research
 - Methods for maintaining privacy include:
 - Using encryption to protect confidential files
 - Storing all critical information on removable media with encryption
 - Keeping confidential files off of network drives
 - Removing identifiers and dummy coding variables
 - There are several questions to be asked before releasing any collected data outside of the institution to a third party:
 - Is there consent? Of the subject? Of CICS?
 - Is the data unequivocally anonymous, or is it possible to trace the data back to the subject?
 - If 'no' is the answer to any of the aforementioned questions, then release of the data to any other group or institution is not permissible, and a violation of CICS and federal regulations
 - Data Retention
 - In accordance with the Code of Federal Regulations, all research data, files, paperwork and related materials must be retained for 3 years after completion of the study
 - At this point, data sets (particularly those with identifiable information) must be destroyed.
 - Please note that data are not completely deleted off of the hard drive with the simple click of the 'delete' button



Data Monitoring Committee: Required Information and Review Procedures

Review of Protocol

- Overview
 - At minimum, all studies submitted for DMC review must contain a completed Data Request Form with \$50 non-refundable data processing fee and/or a New Project Application. Additional items which may need to be included are:
 - Any of the supplemental forms
 - Informed Consent
 - Evidence of approval by cooperative IRBs at other sites
 - Data collection instruments
 - Certification of translation for consents or instruments to be used
 - Brochure/recruitment materials
 - If relevant forms or materials are absent, the DMC chairperson may determine the submission is incomplete, and request the supplemental materials be provided before review may take place.
 - Once a submission is determined complete, it is reviewed by the DMC chairperson.

- New Project
 - For all research involving human subjects (including human data already collected), the primary investigator is responsible for completing all protocol forms required by the DMC. Common attachments include a copy of all proposed consent forms, any advertising material, copies of all data collection, survey and test forms, and authorization from appropriate personnel at cooperative research sites.
 - Even if certain questions are not applicable, The New Project Application must contain contact information, basic information about the proposed subjects/data in the study, certain procedural elements, answers to questions about risk and benefit information, and whether translation is required of any forms.
 - Certain key issues should be remembered:
 - Starting date indicated must allow time for the DMC to review the proposal and respond and thus, cannot be the day the application is submitted or shortly thereafter. It cannot be the date of the DMC meeting, as this does not allow for response. Unless otherwise indicated, the assumed start time of the project is “Upon DMC Approval.”
 - Any research in which the principal investigator is a student must have a co-investigator who is a faculty or professional staff member.



- If a section is not applicable to the study, “NA” should be written.
 - The principal investigator is also responsible for submitting a DMC Change or Renewal Form if he/she is seeking an extension of the DMC approval of the study or needs to make revisions to an already approved study.
- Submission of data requests and application to conduct research
 - The DMC meets on a quarterly basis to review all data requests and application for research. The DMC will review each application at the quarterly meeting and will respond to the applicant within 10 business days of the meeting.
 - *The submission deadlines and meeting dates for data requests are as follows:*

Submission Deadline	Meeting Date
February 15, 2012	March 1, 2012
May 15, 2012	June 1, 2012
August 15, 2012	September 5, 2012
December 15, 2012	January 2, 2013

- General Review
 - Researchers should be reminded that DMC approval is granted for no more than one (1) year (or less, if the board determines that a study must be seen before the 12-month deadline) and that the DMC must receive a completed Change/Renewal form no later than one month prior to the date of expiration of DMC approval.
 - No research activities may continue past the date of expiration of the DMC approval until the DMC has reviewed and approved the continuation
 - No revised protocol procedures may occur unless the DMC has approved the proposed changes. Investigators should also be made aware that a change in procedure may alter the type of review needed for approval by the DMC. A Change/Renewal form should always be submitted each time a change in procedure is desired.



Data Monitoring Committee: Required Information and Review Procedures

Types of Review and DMC Action

- Types of Review
 - Exempt Review
 - This level of review is reserved for research that represents no more than minimal risks to participants and does not involve subjects who are vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
 - This level of review is conducted by the DMC chairperson alone, at which time he/she determines that the protocol does not warrant an expedited or full review (it is exempt from further review).
 - Protocols must fall into at least one of the following categories to be determined as exempt from further review:
 - (1) Research involving the collection or study of existing data, documents, or records 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 through identifiers linked to the subjects.
 - (2) 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
 - Expedited Review
 - This level of research is reserved for studies that exceed what is permissible as exempted research, but also do not represent more than a minimal risk to the subjects involved or any violation of adherence to federal guidelines.
 - The DMC chairperson reviews the study and recommends this level of review.
 - A protocol may be elevated from expedited to full review at the discretion of the chairperson.



- Investigator requests for approval of minor changes to a protocol that initially received DMC approval may be approved via expedited review.
 - Minor changes are limited to changes to the protocol to add research sites, increase subjects, changes to informed consent documents that do not changed the informed consent procedures, and/or changes to instruments that do not increase the potential risk to human subjects or those subjects represented by existing data.
- In order for a protocol (either initially or via continuing review) to qualify for expedited review, it must meet one of the following categories:
 - **(1)** Research involving materials (data, documents, records) that have been collected, or will be collected solely for non-research purposes
 - **(2)** Collection of data from voice, video, digital, or image recordings made for research purposes.
 - **(3)** 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.
 - **(4)** Continuing review of research previously approved by the DMC as follows:
 - (i) the research is permanently closed to the enrollment of new subjects or additional data;
 - (ii) no additional risks have been identified;
 - (iii) the research remains active only for long-term follow-up of subjects; or
 - (iv) where the remaining research activities are limited to data analysis



- Full Review
 - Full review by the entire DMC is intended for research that does not meet the exempt or expedited levels of review
 - These studies have more than minimal potential risk to human subjects (including preservation of anonymity in existing data), and/or involve vulnerable populations.
 - It should be noted that the DMC chairperson may always recommend, at his/her discretion, to advance a study for full review even though it may qualify for expedited review.
 - Additionally, if the primary investigator is not satisfied with requested revisions, she/he may request a full review of his/her protocol.
- DMC Action
 - Types of Decisions
 - Approved
 - The protocol is approved as submitted, in keeping with OHRP, CFR and FDA criteria for DMC approval. Approval is reserved for studies reviewed at the expedited or full review level. Approval is valid for the time period specified in the correspondence to the primary investigator, but is not to exceed one year.
 - The date of continuing review (expiration of approval) for full reviewed studies is determined by the DMC, even if the approval is contingent upon revisions or corrections, and may not exceed 364 days from the convened meeting date of the DMC where the protocol was approved. The date of continuing review for expedited studies is determined based on the date of approval and the nature of the study and may not exceed one year (364 days), but may be for a lesser time.
 - The period of approval duration is based on a number of items and may be significantly less than the maximum period allowed by regulation (364 days).
 - Pending (Revisions or Further Information Requested)
 - A protocol is considered pending when the problems identified in the protocol are not serious and generally fall into two categories:
 - (1) the investigator needs to clarify an aspect of the study or provide additional information, or
 - (2) minor changes are required.



- In these cases, approval may be given after the investigator revises the protocol and/or informed consent and submits to the DMC chairperson, a written response to the questions, concerns, or revision items. For proposals requiring Full Review, the Chair can then poll DMC members to receive final approval, as appropriate, or can approve the changes as submitted, if that option had been the vote of the convened DMC during initial review.

- Disapproved
 - The DMC will disapprove the proposed research if it does not have a reasonable relationship between risks and anticipated benefits, has inequitable subject selection, does not appropriately provide for informed consent/assent, does not safeguard existing or collected data and have adequate provisions to protect subject confidentiality, or if it raises such ethical questions as to be unacceptable.
 - The DMC will provide thorough reasoning to the principal investigator if disapproval is the decision of the DMC.



Data Monitoring Committee: Required Information and Review Procedures

Monitoring of Approved Research, Approval Duration, and Continuing Review

- The DMC conducts continuing review of all research, funded or unfunded, in accordance with the policies and procedures outlined in this manual at intervals appropriate to the degree of risk, but not less than once per year for the life of the project. CICS and federal regulations require that DMC approved research be reviewed by the DMC by no later than one year from the date of approval—or sooner if the DMC determines that the nature of the research warrants shorter review intervals. No study may continue beyond the one-year approval until the DMC has reviewed the change or renewal request.
 - **Monitoring and Approval Duration**
 - It is the responsibility of the DMC to govern research that has been approved so as to ensure that research is conducted in accordance with governmental guidelines and regulations and with CICS DMC requirements.
 - In order to effectively do this, the DMC must conduct—as prescribed by federal regulation—continuing review of approved research not less than once a year.
 - When approving the study, the DMC will determine if the risks are of a sufficient magnitude that continuing review is required more often than annually.
 - Continuing review is required for any active protocol including those where the only activity that remains is data analysis.
 - The factors that shall be considered to determine whether a study requires continuing review more frequently than annually include, but are not limited to;
 - (1) studies that involve procedures in which a clear potential for significant adverse experiences has been identified at the time of review,
 - (2) the nature, probability and magnitude of anticipated risks to subjects is high,
 - (3) the qualifications of the primary investigator and other members of the research team are being questioned,
 - (4) the vulnerability of the population being studied including familiarity with the language on consent forms and other documents, and
 - (5) other factors that the DMC deem relevant.



- Continuing Review
 - Primary investigators who require continuation of study approval must request continuation at least one month before the end of study's approval. Federal regulations and CICS policy do not allow for any form of grace period. As a result, research with human subjects and/or their data must end should approval of continuing review not be obtained before the end of the approval period and may not begin again until the study has been approved for another continuing review period.
 - The protocol submitted for continuing review will be reviewed at the appropriate level (expedited or full review). Typically, studies are reviewed at the same level for continuing review as for initial review.
 - In some instances, continuing review of full reviewed protocols may be conducted at the expedited level; however, this will be determined by the DMC chairperson in keeping with the expedited categories enumerated by the DMC policy.
 - Once a decision has been made the primary investigator is notified in writing.
 - The DMC maintains all records of continuing review within the respective protocol's file. For continuing review conducted at convened meetings, the minutes also reflect any discussions related to the continuing review process.
 - Studies that have been concluded may also be reviewed by the DMC or CICS. As a result, the investigator should retain research-related documents for a minimum of three years from the date the study was concluded.
 - In the case of funded research, research-related documents shall be maintained until the time specified in the award document if longer than three years.



Data Monitoring Committee: Required Information and Review Procedures

Amendments to Research

- Changes to research may include, but are not limited to:
 - Changes to research staff, including principal investigator or co-investigators, or changes to the contact information of research staff
 - Changes to the types of or number of subjects to be recruited or enrolled in the study
 - Changes to the study procedures
 - Changes in instruments or data collection procedures
 - Changes in methods of recruitment, advertisement of the study, or to the wording of the informed consent(s).

- Policy:
 - Irrespective of the original level of review, the primary investigator must submit amendments for review via the DMC Change/Renewal form. Any revised documents must also be included with this submission.
 - The primary investigator should describe all proposed changes to the protocol and include the rationale for these changes.
 - Amendments to studies approved via the expedited procedure are typically reviewed via an expedited procedure. Amendments to studies approved via full review may only be reviewed expedited procedure if the amendments are minor and do not affect the risk/benefit ratio. All other amendments to full reviewed studies must be reviewed by the full board.
 - Amendments to protocols deemed exempt still require submission of all revisions or amendments to the DMC chairperson. If the amendment alters the risk/benefit ratio or adds procedures whereby exempt status is no longer applicable, then the amendment will be advanced to expedited or full review status by the DMC chairperson.
 - Once the amendment(s) to a study reviewed has/have been reviewed, the DMC notifies the primary investigator in writing.
 - A primary investigator may implement proposed changes before approval only when necessary, to eliminate immediate apparent hazards to the subject(s). If this occurs, the DMC should be immediately notified, and a change/renewal form must be completed before the study or project may continue beyond that point.
 - At this point, automatic full board review is required.
 - Cost to benefit ratios of continuing the project are to be assessed, and termination or cancellation of the project is a viable outcome of the review



- If it is decided that the project may resume its operations, hazards must be identified, risks must be minimal, and corrective action taken to prevent future occurrences by the principal investigator.
- Continuation of the project operates similar to probation, in that the principal investigator must report to the DMC on a quarterly basis that is not to exceed three months between communications.



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