MEDICAL COLLEGE OF OHIO

Subject: PROTECTION OF HUMAN SUBJECTS IN RESEARCH

Policy No.: 02-001

[NOTE: World Wide Web URLs for many of the regulations and documents (including MCO IRB application forms) mentioned in this policy are identified at the end of this policy]

The Medical College of Ohio assumes responsibility for safeguarding the rights and welfare of human subjects at risk in all research activities conducted under the auspices of this institution. The Medical College of Ohio is guided in that respect by the statement of principles in the Declaration of Helsinki (1964, as revised in 1989), the Ethical Guidelines for Clinical Investigation adopted by the American Medical Association in 1966, the Belmont Report of 1979, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Guidance, the 1993 Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects, the 1998 Medical Research Council of Canada Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans**,** and applicable laws, regulations and standards of local, state, and Federal (including the Common Rule, 45 CFR 46 (including all subparts), 45 CFR Parts 160 and 164), and 21 CFR 50) government agencies concerning the protection of human subjects.

1. The Medical College of Ohio has established an Institutional Review Board (IRB), appointed by the Executive Vice President and Provost, to recommend and implement policies and regulations for protection of human subjects in research.

2. The Medical College of Ohio has an Assurance on file with the Public Health Service (PHS) Office for Human Research Protection (OHRP). This Assurance sets forth the policies for the protection of human subjects and includes the duties and procedures of the IRB.

3. ALL MCO-related research which involves human subjects directly or through the use of records, tissues, or other indirect means must receive prior MCO IRB review and approval before any project can begin (MCO OHRP Assurance and MCO Medical Staff Bylaws, Rules and Regulations). **"MCO-related research"** means research carried out on- or off-campus (including other states or countries) by MCO faculty, students, or other employees, and any studies conducted by any investigator using MCO facilities and/or MCO patients as subjects, including patient records or surveys. This requirement will, at times, entail review of projects by the IRB of two or more institutions, for example, when an MCO faculty member is involved, as a co-investigator, in studies involving human subjects at another institution or wishes to access records at or obtain materials from another institution. The MCO IRB only can approve clinical research performed at MCO-Affiliated practice sites. A list of these sites, provided by APMCO, is available in RGA.

4. All MCO-related research involving human subjects must be reviewed by the MCO IRB.

5. Approval from any non-MCO IRB (including "central" and "national" IRBs) does not replace approval from the MCO IRB.

6. Although approval for research use of autopsy/cadaveric material is not required by Federal Regulations, it is MCO policy that such research must be reviewed by the IRB prior to initiation of a project.

7. The assurance between the government and MCO only covers MCO faculty, volunteer faculty, staff, registered students, and registered volunteers who are engaged in human subject research. Only MCO faculty, volunteer faculty, staff, registered students, and registered volunteers must be listed as study personnel on a MCO IRB application. If other individuals are included on the MCO IRB application it must be documented that these individuals are either not engaged in research (their role must be defined) or, if they are engaged in research, what IRB's review and approval covers each individual's research conduct. Moreover, only MCO salaried faculty or appropriately qualified salaried/contract MCO personnel can be Principal Investigator on a MCO IRB application.

The PI/PD must be in a position to provide direct, personal, day-to-day oversight of activities and personnel associated with the IRB protocol. Any exceptions to the above criteria regarding the eligibility of an individual to serve as the PI/PD of an IRB protocol must be approved by the Associate Vice President for Research.

8. All study personnel must submit their qualifications to participate in research to the MCO IRB. The MCO IRB must review and approve all study personnel prior to their participation in any research activity. For non-MCO personnel included on an MCO IRB application, the Principal Investigator is responsible for providing to the MCO IRB written proof (current IRB approval letter signed and dated by the appropriate IRB designee) of current IRB approval (throughout the duration of the research) from the IRB that covers that individual's required human subject research training and conduct.

9. Definition Of Research Involving Human Subjects:

   A. **RESEARCH** is defined by Federal Regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46.102[d]). [NOTE: In a recent document entitled "NIH Primer: Research and Privacy," (Jan. 4, 2000) NIH has clarified the meaning of the term "Generalizable Knowledge". In this publication NIH defines the term as follows: "Generalizable Knowledge is knowledge related to health that can be applied to populations outside the population served by the covered entity."]

   B. A **HUMAN SUBJECT** is defined as "a living individual about whom an investigator (whether professional or student) conducting research obtains: 1) data through interventions or interactions with the individual or 2) identifiable private information. Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Distinction must be made between interventions/procedures being done as part of the individual's clinical care and those that are "protocol -induced". **Protocol-induced interventions/procedures (including lab tests, drugs, radiation exposure, or devices) means interventions/procedures that the study subject would not have been exposed to had he/she not volunteered to participate in the research protocol.** Interaction includes communication or interpersonal contact between investigator and subject. Private Information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place; and information which has been provided for specific purposes by an individual which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects" (45 CFR 46.102[f]). For research involving human subjects, IRB approval is required not only during the period when patients are being entered into the study, but for the entire time that PRIVATE INFORMATION about study subjects is being collected/analyzed/stored for research purposes.

10. Types of IRB Review

There are three types of IRB review/approval for research involving human subjects: CONVENED BOARD, EXPEDITED, AND EXEMPT. Each type of review/approval is specifically defined in the Federal Regulations. The MCO IRB must follow these specifications for designating the review type to remain in compliance with our Assurance. All reviews involve a determination by the MCO IRB as to compliance with 45 CFR Parts 160 and 164 (Health Information Portability and Accountability Act (HIPAA Privacy Rule).[NOTE: Each review type requires a special type of protocol form for submission to the MCO IRB. These forms may be obtained from the MCO Research Office website <http://www.mco.edu/research>. Look for Forms / MCO in the Site Guide.]

Convened Board Review

All Projects involving human subjects exposed to more than minimal risks (including all research that exposes the subject to x-rays and/or microwaves) must be submitted for review by the convened IRB. Such projects require submission of the standard application form, informed consent/assent form(s), and supporting documents (e.g. protocol documents, advertising material, questionnaires/surveys, Investigator Brochures (for sponsored pharmaceutical research) and grant/contract proposals (if applicable) by 5:00 PM on the last Monday of each month for review at the next month's meeting. MINIMAL RISK means that the probability and magnitude of the harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life [of the population or class of research subjects involved] or during the performance of routine physical or psychological examinations or tests.

Review by the Convened Board also is required for studies that could (or may appear to) potentially expose a participant to additional risk because of a physician's dual role as physician and researcher. An example would be when a physician removing tissues for non-research (medical treatment or diagnosis) purposes as part of his/her clinical duties is also a researcher who might use some of the excess material left over after pathological evaluation for his/her own research.

Following initial review and approval by the MCO IRB, investigators conducting research designated by the IRB as Convened Review are required to have all modifications to the research protocol reviewed and approved by the MCO IRB prior to instituting them; in addition to reporting adverse events to the sponsor, required regulatory agencies and MCO IRB in a timely manner; maintaining IRB approval until data collection and analysis is complete and all research activity has ceased; and submitting reports/information to the MCO IRB as requested (including a final report to the IRB upon completion of the data collection and analysis).

Expedited Review

Those studies which involve no more than minimal risk, as defined above, or no risk to living subjects (e.g., existing record review, use of existing pathology, autopsy, or cadaveric material) AND which are included on the list of types of research designated by Federal Regulations as qualifying for expedited review may be approved through the expedited review process (45 CFR 46.110, as revised 11/98). See World Wide Web URL at the end of this policy for the list of types of research which might receive expedited review. Such protocols do NOT have to wait for a convened meeting of the IRB, but may be reviewed and approved by the IRB chair or his/her designee and reported to the convened IRB. Every effort will be made to obtain approval within 5 business days, but approval time in that period of time is dependent upon IRB receipt of a completed application form (including all required (original) signatures) a well written protocol and informed consent document (if required), and receipt of all required supporting documents to be used in the research (including questionnaires/surveys and an Investigator Brochure (for pharmaceutical sponsored research) which can be approved "as is". Approval time also is dependent upon the IRB receiving responses from the Principal Investigator to any questions that they may have.

Following initial review and approval by the MCO IRB, investigators conducting research designated by the IRB as qualified for expedited review are required to have all modifications to the research protocol reviewed and approved by the MCO IRB prior to instituting them; in addition to reporting adverse events to the sponsor, required regulatory agencies and MCO IRB in a timely manner; maintaining IRB approval until data collection and analysis is complete and all research activity has ceased; and submitting reports/information to the MCO IRB as requested (including a final report to the IRB upon completion of the data collection and analysis).

Exempt Research

Certain types of research may be designated as exempt (45 CFR 46.101[b]). Investigators do not have the authority to make an independent determination that research involving human subjects is exempt from the review process. Only the IRB chairperson, or the MCO IRB office staff, has the authority to designate a research protocol as "exempt," and this can be done only after review of the research protocol and/or procedures.

Investigators conducting research designated by the IRB as exempt are required to have all modifications to the exempt research protocols reviewed and approved by the MCO IRB prior to instituting them, in addition to submitting status updates to the MCO IRB every 2 years, and a final report to the IRB upon completion of the data collection and analysis.

Short-form applications for expedited or exempted designation review are possible for projects involving minimal or no risk to subjects (for example, study of existing diagnostic or pathologic specimens, review of existing medical records, collection of small amounts of blood from healthy persons, educational or behavioral testing and surveys) and can be submitted at any time.

NOTE: For the purposes of exempt status, the OHRP defines “existing material” to mean that ALL material to be used in the study MUST be in existence, i.e., "on the shelf" at the time of IRB review of the protocol. If any study material is to be obtained prospectively, the study is NOT eligible for exempt status under the “existing data” criterion.

IRB applications

The most current versions of the three types of application forms (exempt, expedited, and convened review) are available through Research and Grants Administration, Room 148, Health Science Building (extension 4252) or via the MCO Research Office Web page <http://www.mco.edu/research> (look in the Site Guide under Forms / MCO) and should be returned to the same office for MCO IRB review. The most current version of the applications must be used for all submissions

11. An Ohio Statute (section 2919.14) forbids experimental use or sale of products of human conception which is aborted. Legal opinions obtained by MCO indicate that this statute extends to the use of cell lines originally derived from aborted fetal tissue, even if an Ohio investigator brought them from another state or received them from a colleague at an out-of-state institution.

12. MCO IRB approval is required for any research involving fresh samples of umbilical cord blood for research prior to the start of such projects. If samples are to be obtained from other hospitals, a copy of that institution’s IRB approval must be submitted to the MCO IRB before MCO IRB approval can be granted.

13. Financial information, such as study budget, schedule of payments to investigators and enrollees, and monetary or other enrollment incentive/bonus payments, if offered, must be submitted with the application for IRB review. If, as the study progresses, there are changes in financial arrangements or a sponsor decides to institute incentive/bonus offers, these new arrangements must be submitted for the IRB and Research & Grants Administration review and approval prior to instituting these changes. It is the policy of MCO that neither it, nor its investigators, subunits or other study personnel, will accept incentives or bonuses tied to the rate of recruitment of study subjects or to early enrollment of subjects in clinical trials, whether such incentives or bonuses are offered as a part of a research agreement or at any other time. For the purposes of this policy, the terms incentives and bonuses include anything of value.

14. In compliance with MCO Policy # 03-005 (Conflict-of-Interest), all study personnel must apprise the IRB of any financial or other interest (including, but not limited to, consulting agreements) that they, or any member of their family, have in a sponsoring company or any interest in the technology being studied. For this reason, all study personnel must complete a Disclosure of Potential Conflict-of-Interest Form to provide the IRB information necessary to assess the potential for conflict-of-interest. When human subjects research is associated with a grant or research agreement, the IRB will receive a copy of the Disclosure form submitted to RGA with the grant proposal or research agreement, but for unsponsored research an IRB-specific Disclosure form is required. The IRB may request that the Provost refer to the MCO Conflict-of-Interest Review Committee any issues that it considers to have a potential for representing a conflict-of-interest, or the appearance thereof. Final IRB approval for any study will be withheld pending resolution of any conflict-of-interest issues to the satisfaction of the IRB.

[NOTE: For the purposes of this item, "study personnel" includes, but is not limited to, the principal investigator, co-investigators, study coordinators, research collaborators, or any other provider of direct services or patient care. The term is not intended to apply to individuals who provide primarily technical support or who are purely advisory, with no direct access to the data (e.g., control over its collection or analysis) or, in the case of research with human subjects, to the study participants or their private information, unless they are in a position to influence the study's results or have privileged information as to the outcome]

15. Patient-physician confidentiality, patient-employee/volunteer confidentiality and the absolutely voluntary nature of participation in research protocols must be considered and maintained when recruiting potential subjects.

    A. Publicly placed flyers, posters, brochures, and advertisements in newspapers and other such publications are good means for recruitment that avoid any possibility of coercion and promote voluntary participation. See below for further details on such instruments.

    B. Review of departmental log books, medical charts, and databases for potential subjects is not an acceptable practice prior to IRB review and approval. It is acceptable to request information on the number of cases that might fit the criteria an investigator wants to study in order to determine whether there is an adequate population size to support a research study. Such a request must not include patient identifiers. Persons with access to patient names and diagnoses should not, nor should they be asked to, provide such lists for an investigator to use to contact potential participants, who could view such an unexpected communication to be an invasion of privacy and a breach of doctor-patient confidentiality.

    C. If an investigator plans to recruit subjects that are not his/her own patients, he or she should enlist the assistance of the potential participants' own physicians to introduce the study. An invitational, informational letter from the personal physician or clinic doctor to the potential participants should be used to explain that there is a research study being conducted and state by whom, what the study is designed to investigate, why they are being asked to participate (medical diagnosis, age/sex criteria, caregiver to someone with a specific condition, and such), and whom to contact if interested in learning more details. In the letter, the potential participants may also be asked to give permission for the investigator(s) to make direct contact. The personal physician would then relay the names of the "positive" responders to the investigator. A draft of this letter must be submitted to the IRB with the remainder of the application materials.

16. ALL forms of advertisement to recruit human subjects for research studies (including, but not limited to, newspaper ads, flyers, posters, announcements disseminated by e-mail, webpages, phone scripts announcements) must be submitted to the MCO IRB for review and approval <u>prior</u> to use or publication. They should be part of the original protocol application whenever possible

17. All deviations from the MCO IRB approved protocol including, but not limited to over-enrollment, violation of inclusion/exclusion criteria, use of non-IRB approved personnel or facilities engaged in research, must be reported to the MCO IRB by the Principal Investigator as soon as he/she becomes aware of it.

18. It is MCO policy not to allow any compensation to professionals who refer subjects for research studies (i.e., "Finder's Fees), except in rare circumstances. The principal investigator must justify to the IRB his/her reason(s) for offering such remuneration by including a separate statement with the protocol application. If compensation is approved by the IRB, it must not be contingent upon the subject's acceptance into the protocol, agreement to participate, or completion of the protocol, and the subject must be informed in the consent form that the referring professional received compensation for his/her time and effort

19. Investigators are required to submit Final Reports within thirty days following the expiration date of MCO IRB approval or within 30 days of the completion of data collection, analysis and cessation of all study activity (whichever date occurs first).

20. MCO Procedures For Specific Types Of Research

Procedures for the Use of Medical Records

Any review or use, for the purpose of research, of medical records information at Medical College Hospitals and clinics must receive prior approval of the MCO IRB and authorization by the Medical Record Department and be reviewed for compliance with the HIPAA Privacy Rule. The statement of IRB approval will be communicated to the Principal Investigator, who should take a copy of the IRB approval document to the Medical Records Department, which can then release the requested materials.

Procedures for Genetic Testing and Other Markers

A. Any request for genetic testing or testing of other markers at any time during, or at the conclusion of a clinical trial or other research project must be specifically submitted to the MCO IRB for review and approval and determination of compliance with the HIPAA Privacy Rule. Approval for "routine blood tests" should not be construed to include genotyping or any other type(s) of genetic study.
B. Protocols seeking approval for "hypothesis-driven" research involving genetic testing or testing for other markers must have a demonstrated specific goal. The MCO IRB will determine whether a study meets the standards of "hypothesis-driven" research.
C. The disposition of samples at the completion a study involving genetic testing must be determined. Where possible, provisions in the Study Agreement should provide for proper disposition of the samples once the study is complete.
   1. For company sponsored studies, samples should be returned to MCO to be destroyed, destroyed by the sponsor, or maintained without identifiers with prior IRB approval and the informed consent of the subject
   2. For MCO Investigators, the samples should be destroyed or maintained with prior IRB approval and the informed consent of the subject.
   3. The length of time that a specimen is maintained must be the minimal determined necessary to maintain the integrity of the research.
D. Regarding protocols that contain requests for samples for future, unspecified "non-hypothesis-driven" research
   1. For company sponsored studies involving genetic testing or testing for other markers, the samples collected must be used only for the research proposed in the IRB-approved protocol, unless additional collection and use is specified in the company protocol and reviewed and approved by the IRB. If the Sponsor requests collection of additional sample for future, unspecified "non-hypothesis-driven"

research, those samples must be stripped of identifiers. The subject must be given the option whether or not to participate in the additional collection of samples. An explanation of intended use and potential risks of genetic testing should be clearly explained in the consent form and a separate statement of consent, specific to the genetic testing, must be signed or initialed by the subject (this may be contained within the study consent form).

2. For MCO Investigators, identified and/or unidentified samples may be maintained with prior IRB approval and the consent of the subject. Through the informed consent process, the subject must be given option whether or not to participate and as much information as possible about the future use of the samples. Additional research projects with the stored samples must be approved by the IRB. Samples sent outside the institution must be stripped of identifiers

E. Research protocols that involve genetic testing or testing for other markers should not include minors or those who are mentally incapacitated unless there is specific scientific justification for including that particular vulnerable population.

1. The IRB feels that the risks of genetic testing or testing for other markers in children are potentially greater than the risks for adults. The IRB determined that the long term risks may be greater since the consequences of future discoveries are not known.

2. A minor cannot give his/her own consent. Information gained from genetic testing or testing for other markers of disease susceptibility could potentially follow the individual throughout his/her life.

F. In studies where the outcome of genetic testing or testing for other markers is not related to therapy, the risks outweigh benefit to the minor.

Procedures for the Use of Tissues and/or Hardware Removed during Surgery:

The Medical College of Ohio Medical Staff Bylaws, Rules and Regulations require that all tissues and hardware removed during surgery be submitted to the Department of Pathology. Investigators requiring the use of human tissues from MCO Hospital's surgical procedures should contact the Director of Clinical Laboratories or the Chairman of Pathology prior to submission of a protocol to the IRB in order to ensure availability of required material. Research which requires ONLY existing specimens (i.e., archived “on-the-shelf” specimens), all of which are in existence at the time of IRB review and none of which have patient identifiers associated with the specimen, can normally be designated by the IRB Chair as exempt research. Research which requires existing specimens, as described above, but which have patient identifiers associated, can normally be reviewed by the IRB Chair via the expedited review mechanism. The determination of “exempt” designation or “expedited” review can only be made by the IRB chairperson or his/her designee. After proposed procedures are reviewed and approved by the IRB, a statement of approval or determination of exempt status will be forwarded to the principal investigator, who should take a copy of the IRB approval document to the Department of Pathology, which can then release the requested material(s). All such research must be reviewed for compliance with the HIPAA Privacy Rule.

Procedures for the Use of Autopsy Material:

It is MCO policy that research involving autopsy material must be reviewed by the IRB prior to initiation of a project. Investigators requesting the use of this material should contact the Chairman of Pathology, prior to submission of a protocol to the IRB in order to ensure availability of required material. After proposed procedures are reviewed by the IRB, a statement of review and designation as exempted research will be forwarded to the principal investigator, who should take a copy of the IRB approval document to the Department of Pathology, which can then release the requested material(s). All use of autopsy material must be reviewed for compliance with the HIPAA Privacy Rule.

Procedures for the Use of Cadavers and Cadaveric Material:

It is MCO policy that research involving cadavers and cadaveric material must be reviewed by the IRB prior to initiation of a project. Investigators requesting the use of cadavers should contact the Chairman of Anatomy and Neurobiology, or his/her designee, prior to submission of a protocol to the IRB in order to ensure availability of required material. After proposed procedures are reviewed by the IRB, a statement of review and designation as exempted research will be forwarded to the principal investigator, who should take a copy of the IRB approval document to the Department of Anatomy and Neurobiology, which can then release the requested material(s). All use of autopsy material must be reviewed for compliance with the HIPAA Privacy Rule.

21. Principal Investigator Responsibilities In Research Involving Human Subjects

A. Principal Investigators must acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable Federal Regulations, as well as MCO policies regarding research with human subjects. It is the responsibility of each investigator to know and understand those regulations and policies prior to initiating any such research.

B. Principal Investigators will not make the final determination of the category of IRB review (i.e. exempt, expedited or convened board) for research involving human subjects. Federal Regulations apply to all MCO-related research unless reviewed by the MCO IRB and determined (stated in writing) to be exempt. The MCO IRB makes that determination after review of the proposed research protocol.

C. Principal Investigators are responsible for providing a copy of the MCO IRB-approved informed consent document (signed by the individual explaining the protocol and obtaining consent from the subject) to each subject at the time of consent, unless the IRB has specifically waived this requirement. All signed consent documents must remain confidential and must be retained in a manner approved by the MCO IRB and the Office of Research & Grants Administration.

D. Principal Investigators will promptly report all proposed changes in previously approved human subject research activities to the MCO IRB. The proposed changes will not be initiated without MCO IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.

E. Principal Investigators are responsible for reporting progress of approved research to the MCO IRB for review, as often as and in the manner prescribed by the IRB on the basis of risks to subjects and in accordance with Federal Regulations. For protocols requiring convened board and expedited review this must occur at least once per year and for protocols determined by the MCO IRB to be exempt this must occur at least every 2 years.

F. Principal Investigators will promptly report to the MCO IRB (and any other agency required by regulation or contract) any injuries or other unanticipated problems involving risks to subjects or others. This includes instances when the subject outcome is death, life-threatening, disability, congenital anomaly and/or requires or prolongs hospitalization and/or requires intervention to prevent permanent impairment or damage.

G. Principal Investigators will promptly report to the MCO IRB (and any other agency required by regulation or contract) any deviations, violations or participant non-

compliance from the MCO IRB approved protocol in compliance with the guidance stated in RGA Form 309 (Deviation/Violation/Participant Non-Compliance Reporting Form for MCO IRB Approved Protocols).

H. No Principal Investigator or any member of his/her research team will seek to obtain research credit for, or use data from, patient interventions that constitute the provision of emergency medical care without prior MCO IRB approval. A physician may provide emergency medical care to a patient without prior IRB review and approval, to the extent permitted by law (see Section 116[f]). However, such activities will not be counted as research nor the data used in support of research.

I. Principal Investigators will advise the MCO IRB, Office of Research & Grants Administration and the appropriate officials of other institutions of the intent to admit human subjects into another institution (e.g., into another hospital) who are involved in research protocols. When such admissions are a planned part of DHHS-supported research, those institutions must possess an applicable Human Research Assurance prior to involvement of such persons as human subjects in those research protocols at those institutions.

J. Principal Investigators are responsible for providing accurate information to the IRB for determination of compliance with the HIPAA Privacy Rule and for adhering to the Rule at all times.

Further information regarding approval of research protocols, application requirements, and submission deadlines may be obtained from Research and Grants Administration.

WORLD WIDE WEB URLS FOR REGULATIONS AND DOCUMENTS:

Declaration of Helsinki (1964, as revised in 1989) <http://www.fda.gov/oc/health/helsinki89.html >

Belmont Report of 1979 <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm>

CIOMS International Ethical Guidelines <http://www.cioms.ch/>

PHS/OHRP Regulations (45 CFR 46) <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>

FDA Regulations (21 CFR 50) <http://www.fda.gov/oc/ohrt/irbs/appendixb.html >
(21 CFR 56) <http://www.fda.gov/oc/ohrt/irbs/appendixc.html >

Health Insurance Portability and Accountability Act (45 CFR Parts 160 and 164)
<http://www.hhs.gov/ocr/hipaa/finalreg.html >

MCO Human Research Assurance <http://www.mco.edu/research/human_assurance/human_assurance.pdf >

MCO IRB Forms and Guidance <http://www.mco.edu/research/rga300s.html >

Medical Research Council of Canada Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans <http://www.sshrc.ca/english/programinfo/policies/ethics.htm>

NIH Primer: Research and Privacy, <http://www.mco.edu/research/nih_privacy_primer.pdf>

Research which may be eligible for EXPEDITED REVIEW
<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm>

Research that may EXEMPT from the requirement for IRB approval:
<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/basics.htm#Exempt >
<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/hsdc95-02.htm >

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