The quarterly newsletter from Human Research Protections Program | **Fall 2014**

HRPP Outlook

Corporate IRB ▪ Office of Research Education, Training and Resources ▪ Office of Research Compliance and Quality Improvement

McLaren HEALTH CARE

Full Accreditation

Why Do IRBs Do What They Do?

How the IRB operates is often confusing to investigators. This article attempts to open the door a bit by showing you why IRBs were created and why it is important to follow regulations and guidelines.

To better understand the IRB, it may be helpful to understand the background regarding why federal regulations require the establishment of the IRB. Throughout history there have been instances in which unethical research has been conducted on human subjects without any regard to their rights. The most widely-known are the atrocities that took place in Nazi Germany which prompted the creation of the Nuremberg Code; the first legal attempt to deal with ethical issues regarding modern research. It may come as a surprise to some to know that unethical research has taken place right here in the United States. The Tuskegee Syphilis Study (formally entitled "Tuskegee Study of Untreated Syphilis in the Negro Male") which took place from 1932-1972 is a prime example. During this study research subjects, most of which were poor and illiterate sharecroppers, were left without effective treatment for syphilis which is a potentially fatal disease that was prevalent in their community. Subjects were told by the researchers that they were being treated for "bad blood", a catch-all term used locally to describe any number of ailments. Men were enticed to participate by the promise of receiving medical care, something that was not largely available to them. Despite penicillin being determined as a cure for syphilis in 1947, treatment was still withheld from subjects. Researchers never informed the men of the actual name of the study, its purpose, or the potential consequences of the treatment or non-treatment that they would receive during the study. At the end of the day, although

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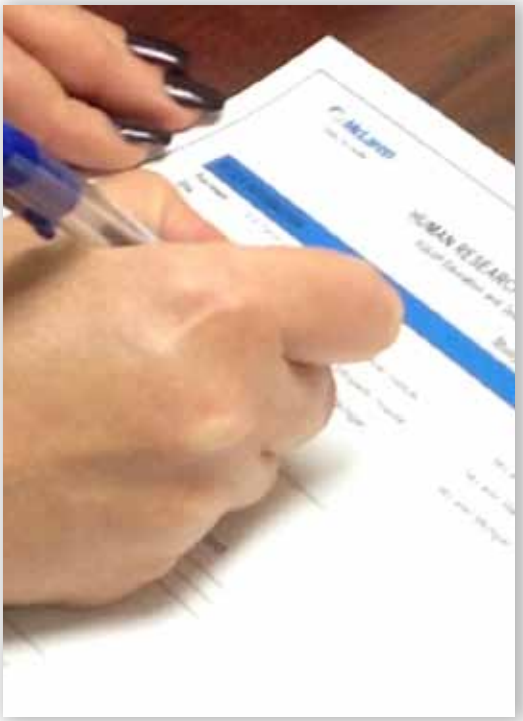


12 Tips To Ensure Study Compliance

1. **Do not commence any research project without approval from the IRB.** Even if you think your research project is exempt from some of the federal regulations or is not considered research involving human subjects you must obtain IRB approval. Only the IRB, not the investigator, student, resident nor academic advisor can make the determination of non-research or exempt status. IRB approval is required for study personnel participation, study protocol, consent forms, investigator brochures, recruiting material and any other supporting documents.
2. **Complete human subject protection training.** Any investigator, student, resident or study coordinator participating in research involving human subjects must complete the McLaren-required human subject assurance modules via the CITI program. This training must be completed prior to initiating any study activities.
3. **Consent subject properly**. Consenting is a process, not an event; it is more than the subject simply signing their name to a consent form. It starts the moment you interact with the subject and continues until the completion of the study. Investigators must educate potential subjects to ensure that they can reach a truly informed decision about whether or not to participate in the research. To properly obtain consent, a current version of the informed consent form is required. The subject must sign and date in their own handwriting. Some questions to ask yourself are:
   - Did you ensure the subject understood and was under no undue influence?
   - Were all the subject's questions answered?
   - Did the subject sign the documents before any study procedures?
   - Did the subject receive a copy of the consent form?

Do not forget to document the consenting process.
If it is not documented, it was not done!

4. **Submit reportable events to the IRB.** When do I report an event? This is a question often asked in reference to Unanticipated Problem Involving Risks to Subjects or Others (UPIRSO) reporting. HRPP policy MHC_RP0121 outlines how unanticipated problems involving risk to subjects or others are to be handled in research at McLaren. This policy provides information on the type of events that should be reported to the IRB and the time frame(s) in which they should be reported.

5. **Maintain organized, complete documents.** Disorganized records make it quite difficult for an auditor or a newly assigned research team member to know what did or did not take place. It is important to ensure you have all correspondence from the IRB, Sponsor, FDA, etc. regarding the research study. It is advisable to keep records in chronological order with the most current paperwork on top. Organizing all study files in the same manner allows transparency and eliminates many hassles and headaches at the time of an audit or site visit.
6. **Follow good documentation practices.** What you say and how you document is critical in ensuring the study data is complete and valid. Do not leave any data points missing without a thorough explanation. Explain any discrepancies with a note-to-file or annotation note dated in real-time. Follow ALCOA principles for documenting data: Date must be attributable, legible, contemporaneous, original and accurate.
7. **Do not allow a research protocol continuing review to lapse.** Pay close attention to the 30, 60 and 90-day reminders from the IRB reminding you that your study is up for continuing review. If continuing IRB approval is not obtained by the expiration date, all study activities must stop immediately! Otherwise, this will be considered a violation. The sponsor and IRB may disqualify any data obtained during a lapse in approval.
8. **Submit amendments and obtain prospective approval.** The IRB must be notified and approval obtained if there are any changes, deletions or additions to the protocol and corresponding consent. This refers to simple administration changes as well as changes to the study design. In addition, any changes in supporting study documents must undergo IRB review and approval before they are utilized.
9. **Follow all protocol procedures.** All protocol procedures must be followed and not be changed without prior IRB and sponsor approval.
10. **Make sure your research participant meets inclusion and exclusion criteria.** Check the protocol subject eligibility requirements throughout the screening period. The checklist must be completed, signed and dated by the person performing the assessment at the time of the assessment. Make sure the primary investigator reviews and signs off on the inclusion/exclusion criteria checklist before enrolling the subject into the trial. If the sponsor did not supply a checklist, create one of your own.
11. **Know the applicable laws and regulations that govern your research project.** State and local laws and regulations supersede federal regulations as long as they are more restrictive and do not put the subject at increased risk. An investigator must be familiar with state and local regulations that may directly affect research, such as legal age of consent, legal guardianship requirements and informed consent requirements. If you are conducting a study with an FDA-regulated product, you must follow FDA regulations 21 CFR 50 and all other applicable regulations. If you are conducting a federally funded study, you must follow 45 CFR 46. If you are conducting a federally funded study with an FDA regulated product...you must follow both sets of regulations.
12. **Know what you are responsible for.** The principal investigator (PI) is ultimately responsible and accountable to all study oversight, operations, and outcomes. However, the PI can delegate duties to other study team members with commensurate educational experience and scope of practice. All participating study team members should be listed on the delegation log. The log should indicate their start date, end date, and delegated duties. The study coordinator, under the direction of the PI, is responsible for coordinating / facilitating the daily activities of the study from start-up to closeout. The PI, study coordinator, and other assigned study personnel are all responsible ethically and legally to follow laws, regulations, and institutional policies.

If you have any questions regarding whether or not your study is in compliance, do not hesitate to contact the EQuIP office at 810- 342-1028. You can also choose to conduct a "Self QA Review". A self QA review form can be obtained by calling the EQuIP office.

Resident's Corner

Mobile Devices and Electronic Protected Health Information (ePHI)

Below are a few tips to ensuring data security on mobile devices:

- **Always ensure that mobile devices are kept in your possession**
- **If you are traveling or working at a remote location, devices should never be left unattended in an uncontrolled environment (i.e. the airport, hotel, etc.)**
- **When possible, your device should be locked with a password**
- **Remember to log out of a device when you are done using it**
- **Do not share your password(s)**

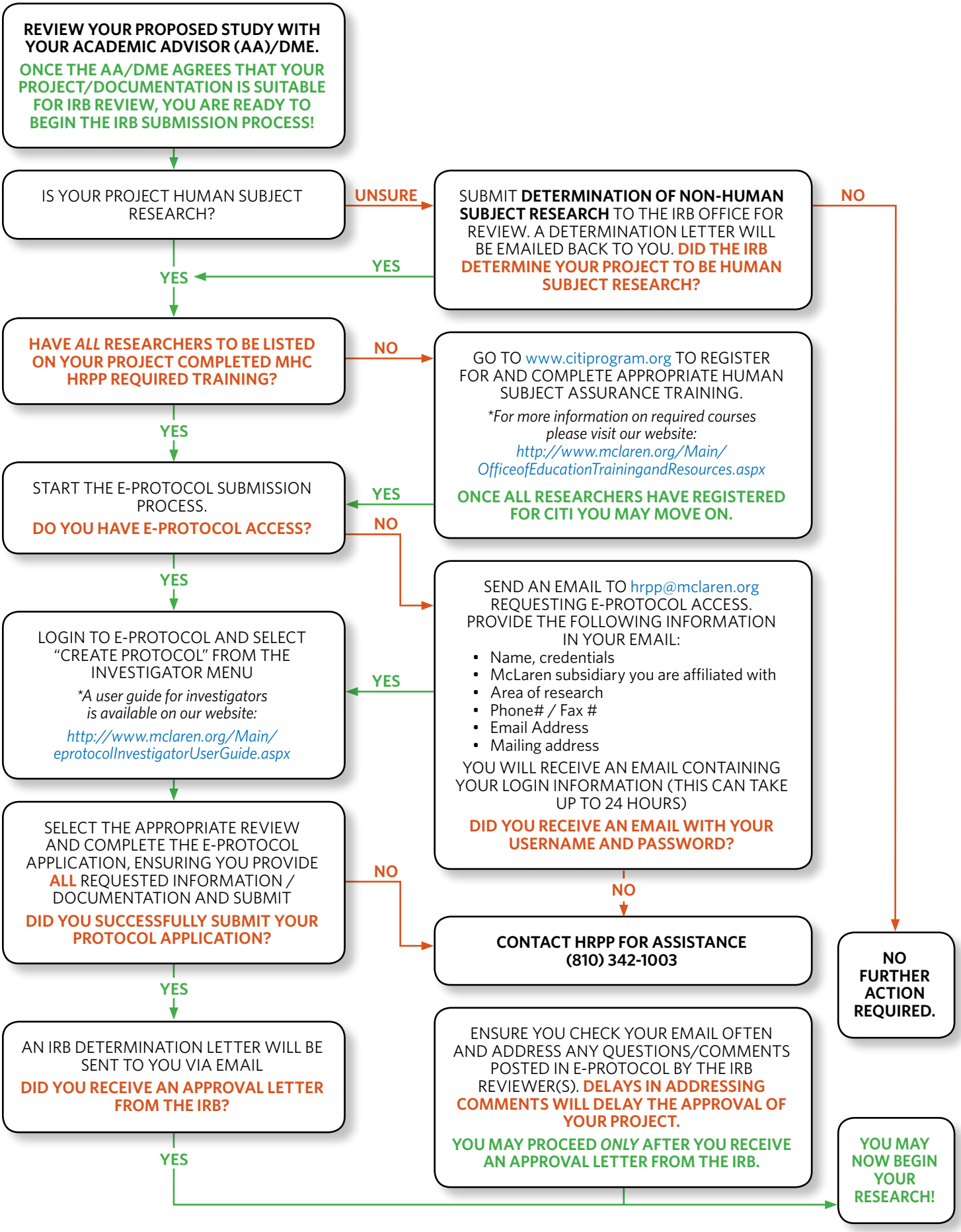
Section 4.11 of McLaren Health Care policy MHC_CC0106 Acceptable Use of Technology Resources covers, in detail, requirements for the security of technology resources/ePHI.

What is the IRB reviewer looking for?

Federal regulations outline 8 specific requirements that need to be satisfied in order for the IRB to approve research involving human subjects. The IRB reviewer is looking for the following basic elements:

1. Risks to subjects are minimized by using sound research design and do not expose subjects to unnecessary risks
2. Risks are reasonable in relation to anticipated benefit (include a list of risks and benefits)
3. Selection of subjects is equitable. In order for the IRB to make such a determination, the IRB needs to know:
   - Method of subject identification and recruitment
   - Number of subjects
   - Gender of subjects
   - Age of subjects
   - Racial and ethnic origin of subjects
   - Inclusion / exclusion criteria
   - Vulnerable subjects population, if any
4. Informed consent will be appropriately sought from each participant. The IRB reviewer needs to know:
   - Process of consent
   - Costs to the subject, if any
   - Compensation. Will subjects receive payment for participation?
5. Appropriate documentation of consent
6. Adequate monitoring of data collected to ensure safety of subjects
7. Adequate provisions to protect privacy of subjects and confidentiality of data
8. If any subjects will be vulnerable to coercion, (i.e. children, prisoners, pregnant women, economically or educationally disadvantaged persons) additional safeguards to protect the rights and welfare of these subjects

NOTE: A vital aspect of a residents research project is proposing the right type of project and making sure the protocol describes all of the steps that will be taken to answer the research question. A clear and concise protocol is crucial to the success of any research project. All projects should be thoroughly reviewed with your Academic Advisor prior to submitting to the IRB. ***The flowchart on Page 5 was designed to guide you through the remainder of the IRB submission process.***


REVIEW YOUR PROPOSED STUDY WITH YOUR ACADEMIC ADVISOR (AA)/DME.
ONCE THE AA/DME AGREES THAT YOUR PROJECT/DOCUMENTATION IS SUITABLE FOR IRB REVIEW, YOU ARE READY TO BEGIN THE IRB SUBMISSION PROCESS!
IS YOUR PROJECT HUMAN SUBJECT RESEARCH?
UNSURE
SUBMIT DETERMINATION OF NON-HUMAN SUBJECT RESEARCH TO THE IRB OFFICE FOR REVIEW. A DETERMINATION LETTER WILL BE EMAILED BACK TO YOU. DID THE IRB DETERMINE YOUR PROJECT TO BE HUMAN SUBJECT RESEARCH?
NO
YES
YES
HAVE ALL RESEARCHERS TO BE LISTED ON YOUR PROJECT COMPLETED MHC HRPP REQUIRED TRAINING?
NO
GO TO www.citiprogram.org TO REGISTER FOR AND COMPLETE APPROPRIATE HUMAN SUBJECT ASSURANCE TRAINING.
*For more information on required courses please visit our website:
http://www.mclaren.org/Main/OfficeofEducationTrainingandResources.aspx
ONCE ALL RESEARCHERS HAVE REGISTERED FOR CITI YOU MAY MOVE ON.
YES
START THE E-PROTOCOL SUBMISSION PROCESS.
DO YOU HAVE E-PROTOCOL ACCESS?
YES
NO
SEND AN EMAIL TO hrpp@mclaren.org REQUESTING E-PROTOCOL ACCESS. PROVIDE THE FOLLOWING INFORMATION IN YOUR EMAIL:
Name, credentials
McLaren subsidiary you are affiliated with
Area of research
Phone# / Fax #
Email Address
Mailing address
YOU WILL RECEIVE AN EMAIL CONTAINING YOUR LOGIN INFORMATION (THIS CAN TAKE UP TO 24 HOURS)
DID YOU RECEIVE AN EMAIL WITH YOUR USERNAME AND PASSWORD?
YES
LOGIN TO E-PROTOCOL AND SELECT "CREATE PROTOCOL" FROM THE INVESTIGATOR MENU
*A user guide for investigators is available on our website:
http://www.mclaren.org/Main/eprotocolInvestigatorUserGuide.aspx
YES
NO
CONTACT HRPP FOR ASSISTANCE (810) 342-1003
SELECT THE APPROPRIATE REVIEW AND COMPLETE THE E-PROTOCOL APPLICATION, ENSURING YOU PROVIDE ALL REQUESTED INFORMATION / DOCUMENTATION AND SUBMIT
DID YOU SUCCESSFULLY SUBMIT YOUR PROTOCOL APPLICATION?
NO
YES
AN IRB DETERMINATION LETTER WILL BE SENT TO YOU VIA EMAIL
DID YOU RECEIVE AN APPROVAL LETTER FROM THE IRB?
ENSURE YOU CHECK YOUR EMAIL OFTEN AND ADDRESS ANY QUESTIONS/COMMENTS POSTED IN E-PROTOCOL BY THE IRB REVIEWER(S). DELAYS IN ADDRESSING COMMENTS WILL DELAY THE APPROVAL OF YOUR PROJECT.
YOU MAY PROCEED ONLY AFTER YOU RECEIVE AN APPROVAL LETTER FROM THE IRB.
YES
NO FURTHER ACTION REQUIRED.
YOU MAY NOW BEGIN YOUR RESEARCH!

IRB Members are Invaluable

Getting to know the MHC IRB

In this edition we would like to introduce you to two of our non-scientific affiliated members. Non-scientific McLaren-affiliated members play a key role on the IRB, as they often have expertise in areas such as privacy and security.

Meet Ms. Nancy Smith

Ms. Smith's involvement with IRB activities began in 1999 when she started working at McLaren Regional Medical Center (now McLaren Flint) in the Medical Staff Office, where she also provided support to the IRB. Ms. Smith currently serves as the Privacy & Security Officer at McLaren – Flint and has served as a non-scientific member of the MHC IRB since 2012.

Meet Mr. Mike Jamrog

Mr. Jamrog serves as Director of Financial Assurance at McLaren Bay Region where he is also the Compliance, Privacy, and Security Officer. Mr. Jamrog has served as a non-scientific member of the MHC IRB since 2012.

Both HHS regulations (45 CFR 46.107(c)) and FDA regulations (21 CFR 56.107(c)) state:

"Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas." OHRP specifically describes non-scientist members as "members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline." In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews."

http://www.hhs.gov/ohrp/sachrp/20110124attchmentblettertosec.html

Active Research Projects

New studies open to enrollment at McLaren since June 2014 are listed below. ***For a complete list of studies please visit our website at: http://www.mclaren.org/Main/ClinicalTrialsHRPP.aspx***

Lipid-Rich Plaque (LRP) Study

McLaren Bay Region, McLaren Macomb

ST Monitoring to Detect ACS Events in ICD Patients Study (Analyze ST)

McLaren Bay Region

WEBSITE *– Over the next several weeks you may notice some changes to our website. This project was initiated in an effort to provide you with the most up-to-date information and resources, in the most efficient manner possible. We will be adding some resources to our site and rearranging some of the existing information. As always, contact the HRPP office at 810-342-1003 or hrpp@mclaren.org if you find yourself having difficulty navigating the site or if you have suggestions that will make our website more useful for you.*

IRB TIP

When submitting an amendment to a study, keep in mind that the IRB needs a clear understanding of what it is you are modifying / changing. The clearer you are when submitting the amendment – the less time needed to address questions / provide clarifications. Here are a few tips to follow when submitting an amendment:

- **Clearly summarize the change(s) being proposed**
- **Provide a clear / concise explanation of the reason for the change(s)**
- **Ensure all documents related to the modification / change are attached to the submission**

Why Do IRBs Do What They Do?

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the men agreed to be examined and treated, the study was conducted without their informed consent.

The shocking revelation of the human subjects' abuse in the Tuskegee study prompted the formation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and, ultimately, the establishment of institutional review boards (IRBs). The Commission was charged with identifying the basic ethical principles that should underlie the conduct of research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In response, the Committee created the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; more commonly known simply as "The Belmont Report". It identifies three core ethical principles: respect for persons, beneficence, and justice.

In response to the Commission's report, both the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) significantly revised their regulations regarding human subjects research. The three principles described in the Belmont Report and the Code of Federal Regulations (specifically 45 CFR 46) now serve as the measures by which the IRB reviews research studies.

The importance of adhering to regulations and ensuring compliance when conducting human subject research cannot be stressed enough. Detailed information regarding the Code of Federal Regulations can be found on the HRPP website under the Office of Education, Training, and Resources (http://www.mclaren.org/Main/EducationalResourcesirb.aspx).

DON'T FORGET

Research CANNOT begin until the proposed study has been approved by the IRB. If you are conducting human subject research without IRB approval, you are in violation of Federal Regulations and subject to non-compliance.

Assistance for Researchers:

Do you have questions related to eProtocol, IRB forms, policies, or review procedures?

Our Office of Research Education, Training and Resources holds office hours to help Researchers, including graduate students and residents, who are preparing Institutional Review Board (IRB) submissions and exemption requests. Sessions are intended to help researchers, students and their advisors navigate eProtocol (electronic IRB submission system) and learn about policies and review procedures.

No appointment is necessary. Please contact Jodi Reetz at (810) 342-1003 or (810) 342-1024 or via e-mail at Jodi.Reetz@mclaren.org for questions or more information.

Assistance for IRB Members:

Do you have questions related to eProtocol, IRB member checklists, policies, IRB review process or IRB criteria for approval?

Our Office of Research Education, Training and Resources holds office hours to help IRB Members to navigate eProtocol (electronic IRB submission system) and learn about policies and review procedures, including newly developed checklists. Sessions could be done either in person or via telephone.

No appointment is necessary. Please contact Jodi Reetz at (810) 342-1003 or (810) 342-1024 or via e-mail at Jodi.Reetz@mclaren.org for questions or more information.

Upcoming Education

COMING SOON - BROWN BAG SESSIONS!

The HRPP Office of Education is going to begin Brown Bag education sessions. These sessions will be in a webinar format and will take place around the noon lunch hour. Sessions are open to all research professionals, coordinators, residents, students, staff or faculty.

Topics will vary based on feedback / suggestions from the McLaren research community. If you have suggestions for a topic, please contact Patricia Ivery, Education & QI Specialist at patricia.ivery@mclaren.org.

Watch your email for further details and registration information.

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