

Sample Email – Modifications Required by Researcher

Researcher Name: Ronald McDonald

The Marian University Institutional Review Board for the Protection of Human Subjects (IRB) has reviewed your project titled *"The Effect of Cheeseburgers on Health"*. Prior to completing their review, the IRB requires additional information related to your project.

- Within an email reply, address the following:
 - Marian University policy states that you are responsible for maintaining all records related to this project for at least three years after completion of the research project. Please revise the date that your data will be destroyed and provide the date to the IRB.
- Please revise the Parent Consent Form to include the following:
 1. Date for Parent Signature
 2. Faculty Research Advisor name & contact information
 3. Your contact information (telephone and e-mail)
 4. A statement that the child may choose not to participate in the study even if the parent gives permission. (If so, the child will still take part in the classroom activities, but the child's information will not be used for the study.)
 5. A description of the procedures explained in simple terms of what the child will be asked to do.
 6. Expected duration of the child's participation (time required/involved).
 7. Use either plain paper or Marian University letterhead only; do not use the letterhead from your respective school.
 8. State the potential risks to the child from taking part in the study. (psychological, social, loss of confidentiality, etc.) Describe the precautions that are being taken to minimize risks and steps that will be taken if risks occur. Do not state that there are no risks.

*Emphasize **possible risk** and describe any foreseeable risk or discomfort the child will bear (inconvenience, bodily pain, confidentiality, embarrassment; risks associated with sensitive questions, such as distress, discomfort, etc.) Describe the probability of each risk in terms of "likely," "possible," or "unlikely."*

For example, "the potential risk to the child from taking part in this study is loss of confidentiality although the probability of this is unlikely. Describe the precautions that are being taken to minimize risks and steps that will be taken if risks occur. For example, The surveys will be immediately collected and placed in a secure"

You may submit the required modifications to the Office of Research and Sponsored Programs electronically by "replying" to this message and attaching the revised document. **DO NOT** resubmit the IRB Protocol; any revisions to a portion of the original protocol should be sent within an email.

No research may begin until the IRB has received and approved the required modifications. Please do not hesitate to contact ORSP if you have questions or require additional information.

Sample Email – Approval

Researcher Name: Ronald McDonald

Your project titled "*The Effect of Cheeseburgers on Health*" has been reviewed by the Marian University Institutional Review Board for the Protection of Human Subjects (IRB). It has been determined that under rules governing protocol review, the project qualifies for expedited review and is approved for one year without modification.

1. If you should make any future changes in the protocol involving 1) method, 2) subjects, 3) informed consent, and/or 4) subject identification, you must submit a protocol modification. Contact the Office of Research and Sponsored Programs for instructions regarding protocol modification.
2. The case number assigned to this protocol is **Z091006329Q**; please reference this number in all future correspondence. You are responsible for maintaining all records related to this project for at least three years after completion of the research project.
3. Your protocol approval is valid from 7/09/2009 to 7/08/2010. You will be required to submit an Annual Progress Report (APR) to the IRB. Before your protocol approval period ends, you will be sent an APR form, which must be completed and returned to the Office of Research and Sponsored Programs to disclose the status of the research. You are required to complete this form even if you have completed your research. You may also use this form to request extension of IRB approval for another year.

Please do not hesitate to contact the ORSP (orsp@marianuniversity.edu or 920-923-8976) if you have questions or require additional information.