Commercially/For-Profit Funded/Outside Entity Project Fee

Effective September 1, 2014:

The University of Maryland College Park Institutional Review Board (UMCP IRB) will assess a one-time initial review fee for commercially/for-profit funded projects involving human subjects. This also applies to outside entities utilizing the UMCP IRB to conduct human research review and approval. This is a one-time fee and covers all IRB transactions for a particular project. A project undergoing Full Board Review will be assessed a fee of $2000, while a project undergoing Expedited review will be assessed a fee of $1000. This practice is consistent with the policies and fees incurred at peer institutions, and will be used to support the administrative costs associated with reviewing human subject research projects.

The volume of commercially/for-profit funded research has grown at the University and while this increase is desired and a sign of the University’s growth as a premier research institution, the UMCP IRB has experienced a concurrent increase in applications requiring review. This increase has required the expansion of staffing in the UMCP IRB Office.

Commercially/for-profit funded applications represent some of the most complex and resource-demanding research reviewed by the UMCP IRB. The collected IRB Fees will be used to continue staffing improvements, quality assurance efforts, and continuing education for staff and IRB Members.

- IRB Applications for research studies that are funded by non-business/non-industry sponsors (e.g. Federal, State, non-profit foundations, or internal funds) are not subject to the IRB Fee.
- When an IRB Application is received and is not designated as commercially/for-profit funded, but is later determined by the IRB to be commercially/for-profit funded, appropriate IRB Fees will be assessed.
- It is expected that Investigators or their staff incorporate applicable IRB Fees into the research proposal.

Departments should incorporate the IRB Fee into the budget of all commercially/for-profit funded research projects. To make the new fee clear to research sponsors, departments should refrain from referring to any other review fees they charge to sponsor’s as “IRB Review Fees.”

Frequently Asked Questions

Q. Why are only commercially and for-profit funded projects being charged a fee?
A. The costs incurred for reviewing IRB applications for non-commercially supported studies are included in the Facilities and Administrative (F&A) rate, which is applied to those research projects. Commercial and for-profit funded projects reimburse the University for indirect costs at a rate that is lower than the Federally negotiated rate. These projects are some of the more complex applications received and tend to be very demanding of IRB resources. The goal is to enhance the recovery for work expended on these studies and maintain a level of service that is acceptable to the research community.

Q. How was the amount of the fee determined?
A. The fee was determined by assessing the administrative costs of managing study review processes in HRPP. The fee is consistent with the policies and fees at Big Ten and other peer research institutions.
Q. Are there other fees I should be aware of related to this change?
A. The initial review fee is a one-time fee. Changes in protocol, continuing review, and other submission reviews are encompassed by the initial review fee.

Q. Will potential contracts be affected by this new fee?
A. An IRB Review Fee is standard practice for the University of Maryland’s peer institutions and business and industry sponsors are accustomed to paying a fee for review services. Research areas affected by this change should not see a difference in the attractiveness of the University of Minnesota as a study site.

Q. Why do some schools have such a fee and not others?
A. Most of the University of Maryland’s peers have seen an increase in commercial and for-profit funded research, and have started assessing a similar fee to cover the increasing costs of providing this service. The new fee helps the institution bridge that gap in funding to keep pace with the studies received.

Q. What is to prevent the University from requiring researchers to pay this fee for reviewing IRB Applications for research that is supported by non-sponsored funding?
A. The review of these projects is already supported by institutional funds. This fee will not be assessed on research that is funded from non-sponsored sources.

Q. Is it ethical for an IRB to charge a potential sponsor a fee for the review of a proposal?
A. The fee covers the cost of providing a specific service to the sponsor. IRB members do not consider any potential financial benefit of the study to the University when reviewing the application. Payment of the fee does not guarantee approval of the study protocol. The fee covers the cost of the service – which is why the fee must be paid even if the industry funding does not ultimately materialize.

Q. For some commercially/for-profit funded projects the IRB Application is submitted before an agreement is reached on the final budget. Must the fee be paid at the time of IRB submission?
A. No, however, after the protocol is reviewed, the IRB will begin tracking the study to see when the industry-funded contract arrives. This is done by working closely with Office of Research Administration.

Q. Will the IRB Approval process be held up if the IRB Fee is not paid?
A. Yes, the review process will remain on hold until the IRB Fee is paid in full. Exceptions include the situation in the above Q & A.