Audit Department

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Angela M. Darragh, CPA, CFE, CISA, Director

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Mr. Don Burnette
Clark County Manager
500 South Grand Central Parkway, 6th Floor
Las Vegas, Nevada 89106

Dear Mr. Burnette:

We recently completed an audit of the University Medical Center Institutional Review Board (IRB). The IRB was selected as an audit area based on the risk to the hospital if the IRB is not functioning properly. Audits of hospital IRBs were recommended as best practice at the recent Health Care Compliance Institute. The audit covered the period from July 1, 2011 through June 30, 2012. The last day of fieldwork was August 30, 2012.

The objectives of the audit were to determine whether:

- UMC's IRB effectively protects the rights and welfare of human research subjects.
- UMC's IRB complies with the Federal Regulations pertaining to Institutional Review Boards.

In order to achieve our objectives, we examined IRB minutes of meetings, documentation of the various reviews performed, member qualifications, policies and procedures, informed consents for patients of clinical trials and the IRB's restricted fund. We also interviewed management and staff as well as observed the monthly meetings.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

According to the Association of Healthcare Internal Auditors, "Institutional Review Boards are independent bodies constituted of medical, scientific, and non-scientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in clinical trials."

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They further define the role of IRBs as, "to review clinical research plans to ensure" the following:

- Research study subjects are provided adequate opportunity to give informed consent.
- Study subjects are not exposed to unreasonable risks.
- Human subjects' protections remain in force.

The mission of the UMC IRB is to protect the rights and welfare of human subjects in research. The IRB examines the plans set forth by the investigator by considering five generally accepted ethical norms:

- Good Research Design
- Competent Investigators
- Favorable Balance of Risk and Benefit
- Informed Consent of the Subject
- Suitable Selection of Subjects

All studies conducted at UMC are required to be approved by the IRB, and studies performed in physician offices that need to be performed under the supervision of an IRB may also go through the UMC IRB. The 10 members of the IRB meet monthly to discuss proposed research projects.

Conclusion

The IRB Coordinator and the Assistant Coordinator have done a very good job in assuring the hospital stays compliant with Federal Regulations. We found no exceptions in the testing of the different reviews. The minutes of the monthly meetings were well documented and the review of the Informed Consents contained the required elements for patients' welfare.

Based on our testing, we believe the UMC IRB effectively protects the rights and welfare of human research subjects. We also believe the UMC IRB complies with the Federal Regulations pertaining to Institutional Review Boards.

However, we did note two areas we feel may warrant additional attention. The current IRB Coordinator position is only part time. Following is a table comparing the UMC IRB staffing to staffing at other local IRBs (unaudited):

IRB	**# Active Protocols**	**# Actions Annually**	**# of FTE**
UNR	428	No response	6 FTE
UNLV	800	4800 (include telephone, letters)	3 FTE; 2 Students
Sunrise	160	1500	1.5 FTE
UMC	**400**	**3500**	**.5 FTE**

As UMC continues to pursue stronger alliances with the University of Nevada School of Medicine, the amount of research conducted will likely increase, and the current staffing may not be sufficient. This could affect the ability of the IRB to continue to meet federal requirements and protect the rights and welfare of human subjects.

Additionally, although we believe the current balance of the IRB's restricted fund is adequate, there has been a recent trend of diminishing revenues while expenses have increased. Consequently, there may be problems meeting future expenses if those trends continue. The IRB may need to consider alternate sources of revenue to continue operations at the current level.

We appreciate the cooperation and assistance provided by the UMC staff during our review.

Sincerely,

/s/ Angela M. Darragh

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Audit Director