

## SUMMARY FOR INSPECTOR GENERAL

prepared by Jeffrey Fudin, R.Ph.

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The following is a summary of items that may be relevant for investigation by the Inspector General. Please see attachments for more detail related to the various items below. I will be happy to provide details beyond that which is provided in this packet and/or more examples upon your request, if required.

1. XXXXXXXXX has routinely entered patients onto investigational drug studies without informed consent. This has been confirmed at an Albany Medical Center investigation(s). In my opinion, investigations of XXXXXXXXX at the VAMC have either been "incomplete" or have failed to yield the proper punishments based on the findings.
2. XXXXXXXXX customarily treats patients according to a research protocol without entering the patient(s) onto the protocol officially. Sometimes he uses the general concepts of the study but changes the medication treatment schedule or dose or inclusion criteria. There may be a financial incentive, depending on the study. (see attachment 1,2,3)
3. In some cases, a patient clearly does not meet the specific criteria for entry onto a particular protocol. A possible incentive for entering these patients onto a study is the financial incentive offered by the sponsor of the study. In this example, I believe it to be \$2000.00 per patient. (see attachment 4)
4. XXXXXXXXX has treated patients with variations of research protocols which have been presented at international or national meetings, where a limited number of patients had been treated by a particular protocol. Please note that the investigators at these other institutions have proper institutional and/or FDA approval for that research at their institution. XXXXXXXXX has used this very preliminary data, and chose to treat his patient(s) with a similar regimen, often in a different tumor type, and often with a drug regimen that varies slightly from that which had or is being studied. He does not submit the proper paperwork to do this research, he has not obtained informed consent, and I suspect that first line therapy and/or no therapy is not offered as an option to these patients. In many cases he has coerced patients into believing that "this innovative therapy" is their only hope. This can be confirmed by the oncology nurses listed below. Attachment 5 is an example of three such patients. (see attachment 5)

5. XXXXXXXXX has been responsible in many cases for needless premature patient suffering and/or death. I provided an example of such a case to Dr. Rivera in writing on 2/6/96. (see attachment 6) This memorandum theoretically and according to station policy should have been reviewed by Larry Flesh, MD since it was part of a testimony that was given during an Administrative Investigation of me. To the best of my knowledge, although this case was submitted by me to the Peer Review Committee 2/95, nothing ever came of the results in way of reprimanding XXXXXXXXX.
6. I have suspected for some time that research money in this institution has been embezzled and/or misappropriated by several practitioners, and that administration is aware of this. On 7/30/96, I had a meeting that helped to substantiate my suspicions. (see attachment 7) XXXXXXXXX has an exorbitant amount of money in research funds at this institution. It just doesn't make sense to me that multiple investigations have proven XXXXXXXXX to be guilty of certain medical activities, yet he continues to practice medicine at this institution. In addition, this institution investigated me for patient abuse after I questioned XXXXXXXXX's clinical activities on multiple occasions.
7. Finally, the Inspector General may be interested to know that I have been requested only to answer certain questions to the Inspector General by administrative personnel at this hospital. (see attachment 8)

*Jeffrey Rivera*