

**UMASS Memorial Health Care
Investigational Drug Service Study Charges**

Date: _____ **Principal Investigator:** _____

Protocol Title: _____

Investigational Drug Service (IDS) charges are based on accumulation of categorical points dependent upon the characteristics of the individual studies. The total number of points is a function of the complexity and involvement required for the management of the study by the IDS. For each category, choose the selection that best describes that component of the study, then circle the corresponding point amount to the right of the question.

<i>Category</i>	<i>Points</i>			
1. Number of study patients anticipated:	0	1	2	3
a. small <16 (1 point)				
b. medium 16-30 (2 points)				
c. large >30 (3 points)				
2. Patient entry is:	0	1	2	3
a. scheduled (24 hours advance notice) (1 point)				
b. unscheduled (<24 hours advance notice) (2 points)				
3. Study location:	0	1	2	3
a. in-patient (1 point)				
b. out-patient (1 point)				
c. in and out patient (2 points)				
d. multi-institutional (2 points)				
4. Storage requirements:	0	1	2	3
a. room temperature (59-86 degrees F) (1 point)				
b. standard refrigerator (36-46 degrees F) (2 points)				
c. subzero freezer (-10 or -70 degrees C) (3points)				
5. Randomization:	0	1	2	3
a. none (0 points)				
b. performed by the manufacturer (1 point)				
c. performed by IDS (2 points)				
6. Double-blinding:	0	1	2	3
a. none (0 points)				
b. by the manufacturer (1 point)				
c. by IDS (2 points)				
7. Crossover:	0	1	2	3
a. none (0 points)				
b. single (1 point)				
c. double (2 points)				
8. Inventory located in:	0	1	2	3
a. outpatient pharmacy (1 point)				
b. outpatient pharmacy vault (2 points)				
c. central pharmacy vault (3 points)				

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|---|---|---|---|---|
| 9. Total number of drugs and dose forms, including placebo: | 0 | 1 | 2 | 3 |
| a. one (1 point) | | | | |
| b. two (2 points) | | | | |
| c. ≥ three (3 points) | | | | |
| 10. Preparation of drug before dispensing: | 0 | 1 | 2 | 3 |
| a. none (0 points) | | | | |
| b. from stock supply (1 point) | | | | |
| c. sterile intravenous technique (2 points) | | | | |
| d. special manufacturing (3 points) | | | | |
| 11. Packaging for dispensing: | 0 | 1 | 2 | 3 |
| a. one-time dose (0 points) | | | | |
| b. daily dispensing (1 point) | | | | |
| c. sequential dosing (2 points) | | | | |
| 12. Label printing: | 0 | 1 | 2 | 3 |
| a. pre-printed labels (0 points) | | | | |
| b. IDS prepared label (1 point) | | | | |

VARIABLE CHARGES

- | | | | | |
|---|---|---|---|---|
| 13. Time of patient randomization/start-up: | 0 | 1 | 2 | 3 |
| a. Monday-Friday 9am-5pm (0 points) | | | | |
| b. Monday-Thursday 5pm-9am (1 point) | | | | |
| c. Friday 5pm-9am (2 points) | | | | |
| d. Major Holidays (3 points) | | | | |

TOTAL POINTS = _____

\$500.00 (Start Up Fee) - payable at time of Study Initiation Visit or prior to enrolling first patient

Total estimated cost = (# patients) x (total points) x (\$20.00) = _____

Per patient cost = $\frac{\text{_____}}{\text{(POINTS)}} \times \$20.00 = \frac{\text{_____}}{\text{(COST PER PATIENT)}}$

Approved by:

Investigational Drug Pharmacist: _____
(Sign) (Date)

Principal Investigator: _____
(Sign) (Date)

Research Coordinator: _____
(Sign) (Date)