#### CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY

DEPARTME	NT OF PUBLIC HEALTH	1					
STATEMENT OF S	F DEFICIENCIES CORRECTION	(X1) PROVIDER/SUPPI IDENTIFICATION I 050599		(X2) MULTIP  A. BUILDING  B. WING	PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
NAME OF BOOK	VIDER OR SUPPLIER		STREET ADDRESS, C	ITY STATE Z	IP CODE		
	Y OF CALIFORNIA DAV	IS MEDICAL	The second secon		ento, CA 95817-2201 SACRAME	NTO COUNTY	-
(X4) ID PREFIX ! TAG	(EACH DEFICIENC	TATEMENT-OF DEFICIENC Y MUST BE PRECEEDED I LSC IDENTIFYING INFORI	BY FULL	ID I PREFIX I TAG I	PROVIDER'S PLAN OF CO (EACH CORRECTIVE ACTION SH REFERENCED TO THE APPROPR	OULD BE CROSS-	(X5) COMPLETE DATE
	The following reflect of Public Health during Complaint Intake N CA00319646 - Subsequence of Public Health and Surveyor ID # 2796  The inspection was event investigated a findings of a full inspection was event investigated a findings of a full inspection was event investigated a findings of a full inspection with the surveyor ID # 2796  Health and Safet purposes of this means a situat noncompliance with licensure has cause injury or death to the surveyor ID # 279.1 Health and Safet (a), (b), or (f) adverse event to days after the adverse event to days after the adverse includes any of the (7) An adverse extending the surveyor ID # 279.1 Adverse Event (b) For purposes includes any of the (7) An adverse extending the surveyor ID # 279.1 Adverse Event (b) For purposes includes any of the (7) An adverse extending the surveyor ID # 279.1 Adverse Event (b) For purposes includes any of the (7) An adverse extending the surveyor ID # 279.1 Adverse Event (b) For purposes includes any of the (7) An adverse extending the surveyor ID # 279.1 Adverse Event (b) For purposes includes any of the (7) An adverse extending the surveyor ID # 279.1 Adverse Event (b) For purposes includes any of the (7) An adverse extending the surveyor ID # 279.1 Adverse Event (b) For purposes includes any of the (7) An adverse extending the surveyor ID # 279.1 Adverse Event (b) For purposes includes any of the (7) An adverse extending the surveyor ID # 279.1 Adverse Event (b) For purposes includes any of the (7) An adverse extending the surveyor ID # 279.1 Adverse Event (b) For purposes includes any of the (7) An adverse extending the ID # 279.1 Adverse Event (b) For purposes includes any of the (7) An adverse extending the ID # 279.1 Adverse Event (b) For purposes includes any of the (7) An adverse extending the ID # 279.1 Adverse Event (b) For purposes includes any of the (7) An adverse extending the ID # 279.1 Adverse Event (b) For purposes includes any of the (7) An adverse extending the ID # 279.1 Adverse Event (b) For purposes includes any o	umber: stantiated  epartment of Public 6, HFEN  limited to the speciand does not represent of the facility by Code Section "immersion in which one or more sed, or is likely to be patient.  Safety Code Section 1250 the department of Section 1250 the department of the section, following: went or series of Ado of this section, following: went or series of death or serious or visitor.	c Health:  c Health:  ific facility sent the ty.  1280.1(c): For ediate jeopardy the licensee's requirements of o cause, serious on ant to subdivision shall report an to later than five a detected.  verse Events "adverse events disability of a		UC Davis Medical Center (UC submits its Plan of Correction to the Statement of Deficient received on May 23, 2013. Tonstitutes a summary of UC with the cited regulations. this POC is not an admission, of any of the allegations or constitutes as understood forth in the 2567.  This plan of correction descriptates with regulations, standards, and accepted medicompliance with regulations of correction also descriptate to educate staff about procedures and monitor compliance with compliance with editional medicological procedures and monitor compliance with one or more requirement caused, or was likely to cause death to the patient. CDPH is policies were not followed, by violations did not cause, nor vicause, serious injury or death patients. Thus, a situation medical procedure in the following of the complexity of the complexity of the following policy violations did not rejeopardy" for UCDMC patient that were the focus of the CM August 2012 constituted the patients.	in (POC) in response cies (2567)  This POC  This POC  The submission of direct or implied, onclusions set  The submission of direct or imp	POC ACCEPTED RLOWNEY COURTIS

3:38:45PM

LABORATORY DIRECTOR OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

J. Douglas Kirls, M.D., Assoc Chief Medical Officer

By signing this accument, I am acknowledging receipt of the entire citation packet. Page(s), I thru 20

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined.

TITLE

(X6) DATE

(X6) DATE

(X6) DATE

(X7) DOUGLAS CHIEF MEDICAL OFFICER

(X8) DATE

(X9) DAT

Any deficiency statement ending with an asterisk ( ) deficiency while the institution may be excessed from concerning his determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these-documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program

participation.

	IT OF PEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPL IDENTIFICATION N 050599		A BUILD B. WING	ADMINI TO THE PARTY OF THE PART	DATE SUR COMPLETE	
NAME OF F	ROVIDER OR SUPPLIER		STREET ADDRESS	CITY, STATE	E ZIP CODE		
UNIVER:	SITY OF CALIFORNIA D	AVIS MEDICAL	2315 Stockton B	lvd, Sacra	mento, CA 95817-2201 SACRAI	MENTO COUNTY	
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	of written policies with other approach administration. Polygoverning body, the administration appropriate.  Based on observer eview, the hospit therefore process designed, implements the achievement standards of medical staff contract the performed on hospital policies, and 3. The failure to fully educated on scheduling, process), and 3. The failure to pand post-operative hospital policies practice, including administration of the policies practice, including administration of the process of the post-operative hospital policies practice, including administration of the process of the	maintenance and in a sand procedures in opinate health professibilities shall be approprieted and medical staff where the sand medical staff where the sand medical staff where the sand medical consumers and maintenance and maintenance that is a sevidenced by:  In implement a procedure of the sand medical practice and particles and particles and particles, including the sand innovative.	consultation ssionals and oved by the approved by here such is and record policies, and all care were do to ensure e of high ment care for experimental, treatments treatments a biological entra-operative cordance with standards of e nationally		innovative care to patient: following the diagnosis of multiforme, an aggressive The purpose of the care th these patients was to give that would trigger an immu Properly labeling syringes of staff about their roles in ha should have been done, bu things were not done is not patients developed infectio were the intended outcome care. Each of the glioblasto received the innovative care informed consent to have th patients as well as their fam that the circumstances were that this was not standard of had not been approved by the state or federal agency; that involved deliberately infective brain in order to trigger a loc potentially beneficial immun attack the deadly form of bra essentially untested; and tha outcomes were uncertain. The for each case was extensive a consent forms, which were si patient and at least one othe described the proposed treat live gram negative bacteria in and in the bone flap"), and st proof that the treatment migh and that the innovative treatm ineffective or even harmful.  2. Sixteen months before the CMS complaint validation survented.	glioblastoma form of brain cancer, at was provided to them an infection une response. or educating the OR inding the biologic to the fact that those is the reason that the ins. The infections is of the innovative mapatients who is gave their he procedures. The inflies understood is extremely dire; are; that the care he FDA or any other the procedure in the process to ain cancer and was to the potential he consent process and detailed. The igned by each in family member, ment ("implant to the tumor bed atted there was no in the beneficial, ment might be	

	TOF DEFICIENCIES OF COMMECTION	(X1) PROVIDER/SUI IDENTIFICATIO 050599		(X2) MUL A BUILD B WING		(X3) DATE SUR- COMPLETE	
	NOVIDER OR SUPPLIER BITY OF CALIFORNIA DA	VIS MEDICAL	STREET ADDRESS 2315 Stockton I		E ZIP CODE mento, CA 95817-2201 SACRA	AMENTO COUNTY	
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Event ID	cancerous brain tu or partial removal 3 underwent impli- aerogenes bacteria the gastrointestinal policies as a surrounding bone to wound infection the bacterial agent us humans and both (IRB-an internal u- the protection of and the Food a government consum	to conduct a ding a root causents within a six ents within a six ents witten crite is (untoward medior potential harm to ecognize violation really recognized sent 1, who suffered non-compliance harm to Patients 2:  If from 10 10 1, MD 2) performance in the patients 1, 2, 3) in the first tumor, In addition to the tumors, Patients 1, 2, 3) in the first tumor, In addition of the tumors, Patients and definition of the tumors, Patients and definition of the tumors, and tract and definition to the institutional inversity committee human participant and Drug Adminitration of Drug Adminitration of the Institutional participant and Drug Adminitration of Drug Ad	to 11, two med surgery on with end stage ickly growing to the complete tients 1, 2, and Enterobacter monly found in eed by hospital ne brain and ent to create a sumor cells The een tested on Review Board at that oversaw is in research) stration (FDA-a		investigation was conduct further cases from occurri jeopardy situation existed remedied long before the more than two years before was received in May 2013 who performed these three permission to perform the Chief Medical Officer. The among the involved partie permission was given to piccase, and agreement that sought from the Chief Medical Review Board 2011, when it was distinctional Review and third case occurred and not been secured, the UCDMC immediately issued a cease the physicians involved, corrective investigation, and to corrective action. No furth performed.  3. To protect patients who compassionate or innovation in "Innovative Care" policing May 2011 to provide a protect that is not standard care, bunder the purview of the lithese three cases occurred have a policy and procedur formalized the processes sperformance of innovative provided to these patients implantation of an infection (30:27PM).	ing. If an immediate at UCDMC, it was CMS survey and re the CDPH 2567. The neurosurgeons are cases were given a first case by the are is disagreement as whether erform the second permission was not dical Officer or a for the third case. In discovered that the at IRB approval had a Medical Staff and desist notice to anducted a peer took appropriate her cases were a part and a management of a was initiated in a management and the second permission was not dical Officer or and desist notice to anducted a peer took appropriate her cases were a part and a peer took appropriate her cases were a part and a peer took appropriate her cases were a permission of the care, creation of a peer took and a peer took appropriate her cases to address care and does not fall a peer took and a peer took and a peer took appropriate her care. The time that a peer took and a peer took and a peer took appropriate her care. The care involved the	

STATEMENT OF DEPICIENCIES AND PLAY OF CORRECTION	(X1) PROVIDERSUPPLIERCUA IDENTIFICATION NUMBER. 050599	A BULD B WNG	TIPLE CONSTRUCTION  NG	COMPLETE  08/30	
NAME OF PROVIDER OR SUPPLIER UNIVERSITY OF CALIFORNIA DAY CENTER	STREET ADDRESS IS MEDICAL 2315 Stockton E		ZP CODE nento, CA 95817-2201 SACRA	MENTO COUNTY	
PREFIX (EACH DEFICIENC	ATEMENT OF DEFIC ENGIES Y MUST BE PRECEEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF (EACH CORRECTIVE ACTION REFERENCED TO THE APPR	4 SHOULD BE CROSS-	(X5) COMPLETE DATE
MD 1 and MD 2 dia Pharmacy of their biologic and did not post-operative pharmacy of patients 1, 2, and 3.  MD 1 and MD 2 Director of Peri-ope Operating Room (Of the experimental bit was taken into the instructions for use, him MD 1 and MD 2 has plan for care, white expected post-operations disease in the intentionally or after the infections.  The Manager of M 1), in an Entrance a.m., stated the investigation of hot following the surgerial AM 1 stated mediaters and the involved addressed in Peer committee of physicians.	d not prepared a post-operative ch substantially deviated from ative standards, and did not and timely consults from specialists for the management induced infections either before developed.  Ledical Staff Administration (AM Conference on 8/27/12 at 8:45		surgical site intended to tri response that would effect cancer. The fact that the c was innovative but not par study set it apart from the clinical research cases that almost all surgical cases at deviations from practice th part of the innovative care, of bacteria to cause an infe withholding of antibiotics t to create an immune respon the scope of UCDMC's ther and procedures governing human subjects research.  Therefore, as a central part correction, first submitted CMS survey in August 2012 established new policies an revised existing policies, to unusual occurrences in the cornerstone of the plan of o policy 2516, Innovative Can innovative care, describes t getting approval for innova staff about the care, and re to assure compliance. The application and Frequently attached to the policy.	cively fight the care being provided to fan IRB approved standard care or are provided in UCDMC. The cat were an inherent e.g., implantation oction, as well as a callow the infection inse, was not within existing policies standard care and cof its plan of in response to the UCDMC diprocedures, and prevent similar future. The correction is UCDMC et that defines he process for tive care, educating viewing the process innovative care	

	OF CORRECT ON	(X1) PROVIDER/BUPFLIER/OLI IDENTIFICATION NUMBER 050599		LE CONSTRUCTION	(N3) DATE SU COMPLE 08/3	
	ROVIDER OR SUPPLIER SITY OF CALIFORNIA DA	MAN AND	EET ADDRESS, GITY, STATE, ZI Stockton Blvd, Sacrame	P CODE nto, CA 95817-2201 SACR	AMENTO COUNTY	
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	In an interview wi and Safety (AMC stated her first events was when 7/22/12. The AM incident report (a unusual occurrence 2, and 3. The hospital committee find any discussified and the revealed, "I will be in an attack at present 1, 2, or 3 other newspaper. The Call a quality of care is research, medical the events had be nursing action will repeated "we something is wrong Continuing on, si innovative issue to nurses are only patient has] an	th the Acting Manager for (2S) on 8/29/12 at 10 a.r. knowledge of the three she read it in the newsp QS stated there had be report by a staff member of the stated in the cases of Pa AMQS stated she review meeting minutes and on of the three surgical as made aware" Peer Revind was not asked to concorn as "nothing bubbine or safety."  Care Services Officer (Conursing services through interview on 8/30/12 at she had no knowledge of than what she had read CPCSO firmly stated, "The staff issue." The CPCSO seen reported to the FDA as required Again, the only conduct investigating and there was nothing the further stated. "This prought in by the physicial responsible for [ensurinformed consent. Only any." The CPCSO stated it were staff."	Quality m., she surgical aper on een no r of an atient 1, wed all did not cases, iew was fuct any led up  PCSO - out the 10 a.m., Patients in the s is not e it is a ) stated and no CCPSCO lons if wrong." was an ins and ing the y Peer vas	27PM		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER 050599	A BUILDING B WING	PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED 08/30/2012	
NAME OF PROVIDER OR SUPPLIER UNIVERSITY OF CALIFORNIA DA CENTER	HICCOMPANIES OF STREET	SS CITY STATE 2 Blvd, Sacramo	ento, CA 95817-2201 SACRA	AMENTO COUNTY	
PREFIX (EACH DEFICIEN	STATEMENT OF DEPICIENCIES ICY MUST BE PRECEEDED BY FULL OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF FACH CORRECTIVE ACTION REFERENCED TO THE APPR	N SHOULD BE CROSS-	(X5) COMPLETE DATE
procedures performance whistleblowers strongly these we events and incident. The CPCSO, ho events should he monthly meeting of the current Chieffinterview on 8/27 been no department surgical events. Meeting the mechanism to calcaddressed in resulting and staff must report the strong of the Scholar of the	The CPSCO stated she felt are not a sentinel or adverse the reports did not need to be filed, wever, did acknowledge these averbeen discussed with the the Quality Committee.  of Neurosurgery (MD 3), in an 1712 at 3 p.m. stated there had not at review of Patient 1, 2, or 3's D 3 acknowledged there was no puture activities which were not earch protocols unless reported at if they see something."  the the Governing Body (GB - the or Human Health Services) on the GB acknowledged there had of the systems that failed.				
Event ID 1K5X11	5/20/201	3 3:30	0:27PM		

	STATEMENT OF DEFICIENCIES (K1) PROVIDENT DENTIFICAT DENTIFICAT 050599					(X3) DATE SURVEY COMPLETED 08/30/2012		
	GOVIDER OR SUPPLIER ITY OF CALIFORNIA DA	VIS MEDICAL	100 m	ADDRESS, CITY, STATE, Z.P.CODE ockton Blvd, Sacramento, CA 95817-2201 SACRAMENTO COUNTY				
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	Patient 1 experience and multiple infect life functions consciousness, more managed in accorpractices.  Within five hours Patient 1 had seizoneeded to have a suspected bacteria administered from continued despite, function exhibited consciousness, b) that grew bacteria the presence of error longer long	of arrival to the ures, became un artificial airway in the blood.  a) a decline in by an alte a culture from t and c) an imaging the properties of different types on urine, lung se and his death regained independent as death regained independent as death regained as having re resulting from to, the physicians	recovery room, responsive and (intubation) for Antibiotics were 10 but not nervous system red level of he brain cavity a study showing or of the brain coretions and a con 10, dent breathing. On 10, a septic shock bacteria in the sconfirmed the					
	withdrew life supp expired  Patient 2 Date of su	<u></u> 0	after Patient 1					
	Review of the medic		Patient 2					

STATEMENT OF DEFICIENCIES. AND PLAN OF CURRECTION	(XI) PROVIDER/QUPPLIER/CLIA IDENTIFICATION NUMBER 050599	A BUILDING  B WING	PLE CONSTRUCTION	COMPLETED  08/30/2012	
NAME OF PROVIDER OR SUPPLIER UNIVERSITY OF CALIFORNIA DA CENTER	AND AND ADDRESS OF THE PARTY OF	ess, city, state z n Blvd, Sacramo	P CODE into, CA 95817-2201 SACRA	MENTO COUNTY	
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treated with convichemotherapy In developed left si imaging test show 10, MD 1 are the same processimplantation of the During Patient 2's 0, the left 0, an imaging swelling and press from the brain cavilimplanted bacter administered Patien Nursing Facility, month period post the brain and chro	ded body weakness. A brain and recurrence of the tumor. Or and MD 2 performed surgery and adure was followed for the live bowel bacteria into the brain hospitalization, from to sided weakness increased. Or and test showed increased brain ure. On 10, fluid was taken the live and showed the growth of the				
presented to the 11 with recent traveling down the causing falls. An integral terms of the consultation, offere trial options, as	edical record revealed Patient 3 hospital emergency room or t onset of stabbing neck pain right arm and right leg weakness maging test was suspicious for a or MD 1 provided treatmen d standard and clinical research well as the non-standard				
and 2. On	ment performed on Patients 1 1, MD 1 and MD 2 performed nor with implantation of the bowe on Patient 3 rapidly				

	TOF DEFICIENCIES OF CORRECTION	DENTIFICATION ( 050599		(X2) MULTI A BUILDIN B WING	PLE CONSTRUCTION	(X2) DATE SUI COMPLET	
	ROVIDER OR SUPPLIER SITY OF CALIFORNIA DA	VIS MEDICAL	STREET ADDRESS 2315 Stockton E		ZIP CODE ento, CA 95817-2201 SACRAN	MENTO COUNTY	
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Event III	Immediately follow seizures and sympinfection of the bit experienced breat intubation. On the 3 began to decommands. Pati (brain/spinal fluid, bacteria that had cavity Patient 3 at the mouth and a tract. Infectious I rationale for transibiotics and not placed in the brathe swelling could expired on 11.  1 Failure to verifice search activities. In an interview Associate Chief Many drugs related by the Investigat division of the protocol was beinnovative or non acknowledged the identify non-stand approval. The ACA currently had no plansible interview and plansible in the protocol was beinnovative or non acknowledged the identify non-stand approval. The ACA currently had no plansible interview.	ing surgery, Patient noms of sepsis (a li ood) After one wer thing difficulty wh 12th post operative line and no lon	t 3 developed of threatening ek, Patient 3 mich required e day, Patient ger followed ole cultures ositive for the to the brain al infection of of the urinary provided no ections with a drain was sed pressure and Patient 3 mpliance with the color of the train and Patient 3 mpliance with the color of the train was sed pressure and Patient 3 mpliance with the color stated that the dispensed acy (IDP), a the stated a all unusual, the ACMO of process to diverify IRB medical staff	i c c ii a p n	f1. Failure to verify medical with research activities.  How the correction was accounted a policare, in March 2012 to provide the provided and the provided actions in the treations. The guidelines are infinimize the potential risk to hysicians in the delivery of integration.	mplished: The licy, Innovative de guidance and mbers in the rapies, devices atment of intended to both patients and	

	FOR DEFICIENCES OF CORRECTION	(X1) PROVIDER/SUPPLER/CLI IDENTIFICATION NUMBER 050599		A COMM	CGMPLETE	
NAME OF P	ROVIDER OR SUPPLIER	STRE	ET ADDRESS, CITY, STAT	E ZP CODE		
UNIVERS	ITY OF CALIFORNIA DA			amento, CA 95817-2201 SACRA	MENTO COUNTY	
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	When asked he identified, the A sense, someone will MD 3, in an introduced and acknowledged the Patients 1, 2, and been scientifically proven to be unprecedented." Moreover the unprecedented of the moreover the infection in the of infections in other than the identification of the infections in other than the infection in the of infections in other than the infection in the of infections in other than the infection in the of infections in other than the infection in the of infections in other than the infection in the of infections in other than the infection in the of infections in other than the infection in the of infections in other than the infection in the of infections in other than the infection in the of infections in other than the infection in the of infections in other than the infection in the of infection in the of the infection in the of the infection in the of the infection in the infection in the of the infection in the infection in the infection in the of the infection in the infec	erview on 8/27/12 at 10: brain tumor treatments g if 3 were not standard, has studied in humans, had no effective and were D 3 revealed no clear ben Patients 1, 2, and 3 a very high risk for harm  hysician Director of Infection, was interview in MD 4 indicated the a that routinely inhabit the ful in other body location system, was not a s tumors MD 4 stated this ans would be investigation had approvals, protocols ince in animal testing t research in humans he determine whether the tre eteror determining how to brain to prevent the deve-	alld be common off."  30 a.m., given to do never on been "highly efit had and the Hospital wed on lat the bowel, as such standard type of hal and so and MD 4 lad not leatment were to was no isolate lopment.	compassionate care, as we UCDMC's academic mission includes an application that applicant to identify the mass used for innovative care, in drugs, devices and biologics. Care Review Committee with information during the appwill ensure that unapprover and biologics are used safel with UCDMC policies and stregulations. The innovative process includes the develor monitoring and evaluating of policy requires that the innovative care plan, minimic continued use of ineffective practices, and ensure that the UCDMC meet ethical and lepprocess for applying to provide details that are included and the oversight of the Mecorganization of the delivery that are required in the Innoprovide the necessary accounded. Staff to the Governion of care and compliance with and hospital policies.	n. The revised policy to requires the aterials that will be cluding unapproved in the Innovative and process and dod drugs, devices, and in compliance that and federal is care application appeared by the positive care will be dical Officer to approved itse or eliminate the for unsafe the physician and gal obligations. The ide innovative care, in the application, dical Staff of innovative care policy intability of the ing Body for quality	

	TO DEFICIENCIES OF CORRECTION	DENTIFICATIO		A BUILD B WING		(X3:DATE SURV COMPLETED 08/30/	7
	ROVIDER OR SUPPLIER SITY OF CALIFORNIA DA	VIS MEDICAL	STREET ADORESS 2315 Stockton E		. ZIP CODE mento, CA 95817-2201 SACRA	AMENTO COUNTY	
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	that all patients a quality care and that medical star document their ab treatment in according standards of caresponsibility of the establish an ongo patient care and practice within the Bylaws define Chief Medical Of authority to, a) precedence over a consultations whe require medical stand medical staff policies and procedu.  The CMO, in an acknowledged MD treat Patient 1 in one time compass biologic. The CM consultation from the treatment was CMO stipulated documentation in 1's conversations to plan with the complications in outreatment and end MD 1 did not complete the treatment and end MD 1 did not complete the treatment and end MD 1 did not complete the treatment and end MD 1 did not complete the treatment and end MD 1 did not complete the treatment and end MD 1 did not complete the treatment and end MD 1 did not complete the treatment and end MD 1 did not complete the treatment and end MD 1 did not complete the treatment and end MD 1 did not complete the treatment and end MD 1 did not complete the treatment and end MD 1 did not complete the treatment and the treatment	reatment." The by fif members were fility to provide payordance with genera. The Bylaws e Clinical Departing review proces ensure departre privileges (autoed the Chief of ficer's (CMO) dusensure patient all other concerns in deemed necestaff to comply with bylaws, rules a sures, or face disciplinaterview on 8/28/1 approached him early 20 sionate use of a O directed MD the "ethics expert in the patient's be that there he medical record with the IRB. MD patient and famirder to agree on point of care. The byly with these instituted in the patient's and he instructed in the patient and famirder to agree on point of care. The byly with these instituted in the patient and he instructed in the patient and famirder to agree on point of care. The byly with these instituted in the patient and he instructed in the patient and the patient an	ylaws stipulated by a stipulat		The Medical Staff will be elinnovative Care policy and process in at least two war an email that was sent out and Resident Medical Staff 2012, and at the Medical Staff 2012, and at the Medical Stocommittee, and clinical desafety meetings by the Quentite of the North Medical Staff 2012, and at the Medical Staff 2012, and at the Medical Staff 2012, and at the Medical Staff began 2012.  The revised policy, new apprequently asked questions attached to this plan of condition of the Medical Officer.  Description of monitoring of innovative care, all aspectate will be assessed during process by the Innovative Committee and will be monitored to a compliance with hospital pregulations will be monitored to the Medical Officer. This will connovative care, but may has innovative care, but may has innovative care cases of the Medical Staff began 2012.  Policy 2516: Innovative Care.	the application ys: electronically via to all Medical Staff f on November 29, itaff Executive ifety Operations epartment quality and ality and Safety  plication, and s document are rrection below.  : Chief Medical  process: In all cases cts of the innovative g the approval Care Review nitored when the l. The quality and patients and policies and federal red by the Chief occur for each case of appen infrequently, cur infrequently.  vised Innovative Care edical Staff Executive 19, 2012. Education on October 24,	

	TOF DEFICIENCIES OF CORRECTION			A BUILDING B. WING		COMPLETE  08/30	
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	ITY OF CALIFORNIA DA	AVIS MEDICAL	The State of the s		mento, CA 95817-2201 SACRA	MENTO COUNTY	
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	formal approvals regulatory agenci acknowledged MI treatment on without complying prior case. The Cl again repeated his treatments without was notified by following the thirr thereafter learned cases.  The CMO stated to MD 1 and MD 1 and MD 2 to activities. The (multi-disciplinary on 4/18/11 and the "issue" needed two neurosurgeons similar research maintained in a "s files of MD 1 and MI in an interview with a maintained in a "stated the Pocases was present Advisory Council acknowledged the without detail in second acknowledged	by the IRB ares was obtained to 1 arranged for 0 without his lead to with his instructions not to approvals. The Country of disurgery on MD 1 had planned to "cease and de CMO stated physician review) we determination with to go back to the swould be authorized to the chadow" file, not in	ad appropriate The CMO Patient 2's mowledge and ons from the with MD 1 and perform other MO stated he the Pharmacy 11 and shortly o do five more tion" was sent instructed MD sist" research Peer Review was conducted as made that IRB before the ted to perform letters were the credentials  Medical Staff at 12 45 p.m. three surgical the Governing 1. The AM 1 was presented the discussion		I. PURPOSE To provide guidance and or of the University of Californ Center (UCDMC) Medical Suse of medical therapies, demedications in the treatment guidelines are intended to potential risks to both patie in the delivery of innovative care, as well as to further Unission. These guidelines approved patients and to supply sicians in the consideral II. SETTING Medical Center  III. DEFINITIONS Innovative Care—is the apply device, or medication to a puthat departs in a significant or accepted medical practice enhance the well-being of a The sole purpose of innovative patient, not to collect dehypothesis or theory. Innovative that is subject to Food Administration (FDA) expandapproval. Innovative care and are synonymous. Innovative care and are synonymous. Innovative Care Review Continuous in the Care Review Continuous in the Care Review Continuous in the patient of the care Review Continuous in the Union of	versight to members hia, Davis Medical taff in the innovative evices and/or int of patients. These minimize the ents and physicians e and compassionate ICDMC's academic are designed to port, not impede, tion of care options.  Ilication of a therapy, patient in a manner e way from standard the in order to a specific patient. Five care is to benefit that to support a pative care includes frug, biologic or and Drug ded access liso includes unusual tess of FDA approved but does not include the purposes of this compassionate care	
	MD 1 was interview	ed on 8/30/12 at 11.4	10 a.m. MD		subcommittee of the UCDM Safety Operations Committe appointed by the Chief of St	ee. Members are	

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	interviewed stated "probiotic" (the ter two of the three however they never definition or the biologic. None of	ing, use, and discolored followed for Patient did not know how here were no promine this. MD 1 read been defined then to rescue earlierse effects of the "we told the nursing the OR" and "It use required approcessing, labeling, on-approved biologic did not inform the Oscheduling Patient he biologic agent animal research h Assistant (RA) cructions for han of the periop they were familiarm used by the neer questioned leader handling, use or the OR nurses in steed or scrubbed informing the M (MOR) of the owners and the owners and the owners are the owners and the owners are the OR nurses in steed or scrubbed informing the M (MOR) of the owners are the owners and the owners are	isposal of the its 1, 2, and 3, is much bacteria from studies to excelled no post to denote the chipatient from the treatment. MD is graff we were went against all eval, scheduling, storage, use a stransported laboratory by a single and an unlabeled in the term eurosurgeon on the disposal of the interviewed, who on the three danager of the courrence of a stransported laboratory by a single and the term eurosurgeon on the three danager of the courrence of a stransported laboratory by a single and the term eurosurgeon on the three danager of the courrence of a stransported laboratory by a single and the term eurosurgeon on the three danager of the courrence of a stransported laboratory by a single and the stransported		basis each time an applica care is received and may in Medical Officer (CMO), Ass representatives from Phani Engineering, Perioperative Care Services, Quality and Institutional Review Board will be sought, as needed, a depending on the subject in IV. POLICY  A. UCDMC recognizes that circumstances arise in which therapies for treatment or or devices may be warrant assist providers in appropri innovative care and resolving planned treatment.  The primary physician is residetermining that a planned to be considered innovative the approval process descripent. The Innovative Care Revimake the final recommenda innovative care, seeking conthicists and individuals expelinical care and research, as 2. Outcomes will be monito patient safety and appropri innovative care.  C. The patient will be flagge recipient of innovative care.  C. The patient will be flagge recipient of innovative care.  Care Application form (Attascanned into the EMR.  V. PROCEDURE/RESPONSIBILA. Physician Responsibility	aclude the Chief sociate CMO, and macy, Clinical Services, Patient Safety, and the (IRB). Consultations from content experts natter.  medical th non-standard novel uses for drugs ed. This policy will sately identifying ing issues involving  sponsible for I treatment is likely to care and to initiate bed in section V.A. ew Committee will ations regarding the insultation from perienced in both is needed. red to ensure that use of ed in the EMR as a and the Innovative chment A) will be	

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Event ID	biologic were not MD 1 revealed he to implant as the reference to determine the composition of the transfer operative plan has actions to be take life-threatening advisory of the composition of the compo	formal procedures for ing, use, and disposal of followed for Patients 1, 2, and did not know how much backers were no prior studies in the this. MD 1 revealed no deen defined to denote en to rescue each patient erse effects of the treatment, we told the nursing staff we to the OR!" and "It went against the OR!" and "It went against the OR!" and "It went against the original patient 1, 2, and the biologic agent was transposed by the perioperative nurse for the perioperative nurse for the perioperative nurse for the perioperative nurse patient Informed Consert questioned leadership about handling, use or disposal of the OR nurses interviewed. Ited or scrubbed on the transmitted of the occurrence of the sesses outside of established	ad 3. Atteria is to post the from MD were st all alling, use the se of 3's ported by a pole or arses term is on ints), the the who here the of a OR	1. Any physician who wished innovative care utilizing and biologic or device must first determination of whether is requires FDA expanded according to their regulatory approval.  2. To proceed with innovative care application A) to the CMO for consideration including a dinnovative care Review Consideration including a dinnovative care, specific convinque risks and benefits, a course of treatment including lan changes, and coordinal infection Prevention, Laborn Services, Tumor Board, Bios Committee, Risk Managem. The application will clearly issues, EMR documentation staff/team education to provide the provided innovative care application plan for monitoring, outcomplan for monitoring, outcompanting and reporting.  3. If the innovative care application plan for monitoring, outcomplan for monitoring, outcompanting and reporting.  3. If the innovative care application with the patient of the information of the info	t obtain an IRB the innovative use tess approval or live care approval, submit a complete form (Attachment ation by the mmittee, levant details for escription of the insent including a care plan and ing triggers for care ention with Pharmacy, atory, Perioperative ethics Consultation ent, if applicable, address billing a requirements and betect patient safety ency. The will also address the ine evaluation belication is a document in the document of the ative reflecting the per this/her erstanding that the el approach and has roved prior to using tive care. The afor assuring that	

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	1				Name of clinician or team		
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	biologic were not MD 1 revealed he to implant as t	did not know how	w much bacteria		Description of innovative us biologic, technique, etc.)	se (drug, device,	
	reference to deter- operative plan his actions to be tal-	mine this. MD 1 r ad been defined sen to rescue ea	evealed no post to denote the ch patient from		Attach sample consent form risks and benefits (must cor and ability to give consent)	nsider patient status	
	life-threatening add 1 further revealed going to do this [i OR rules."	"we told the nursing	ng staff we were		Care Plan mapping out cour triggers for changes in plan needed, intubation, code st	(e.g., rescue if	
	Failure to ensign procurement, pro and disposal of a new control of the cont	cessing, labeling,	storage, use		Does the proposed innovati use of an investigational dru therapy?		
	MD 1 and MD 2 d a biologic when brain surgeries T	scheduling Patient he biologic agent	1, 2, and 3's was transported		What is the plan for the acq and storage of the item(s) n innovative care?		
	from a university university Research	h Assistant (RA)	in an unlabeled		Is a contract or purchasing o		
	vial without ins disposal None	of the periop	perative nurses		Pharmacy issues/coordinati		
	interviewed stated "probiotic" (the te				Infection Prevention issues/	coordination	
		ee patient Inform			Laboratory issues/coordinat	ion	
		er questioned lead			Perioperative Services issues	/coordination	
		handling use or			Tumor Board communicatio		
		the OR nurses			Bioethics consultation		
	had either circul	ated or scrubbed	on the three		Risk Management issue		
		I informing the M			Billing issues		
		(MOR) of the o			EMR documentation require	ments (description	
	treatment and pro standards of care	cesses outside of	established OR		of device, biologic, technique Staff/team education regard	e, etc.)	

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	acquisition, handle biologic were not MD 1 revealed he to implant as it reference to deter operative plan had actions to be tall life-threatening and 1 further revealed going to do this [iii OR rules."  2. Failure to ensprocurement, programment, programment, programment and disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of a new MD 1 and MD 2 disposal of	formal procedures for the ing, use, and disposal of the followed for Patients 1, 2, and 3, did not know how much bacteria here were no prior studies to mine this. MD 1 revealed no post ad been defined to denote the item to rescue each patient from verse effects of the treatment. MD "we told the nursing staff we were in the OR]" and "It went against all ure required approval, scheduling, cessing, labeling, storage, use on-approved biologic agent was transported animal research laboratory by a think assistant (RA) in an unlabeled tructions for handling, use or of the perioperative nurses they were familiar with the term mused by the neurosurgeon on see patient Informed Consents), ar questioned leadership about the handling, use or disposal of the the OR nurses interviewed, who ated or scrubbed on the three I informing the Manager of the (MOR) of the occurrence of a cesses outside of established OR		plan/course of care Plan for monitoring, outcome tracking, reporting  Innovative Care Frequently (FAQs) Attachment B  Q. Is what I am doing researcare?  A. Federal regulations define systematic investigation, includevelopment, testing and evento develop or contribute to general to seek new knowledge, to recommend to seek new situation.  In contrast, the primary purpurare is to benefit a patient(s) data to support a hypothesis innovative care is a non-stantent that is solely attentive wellbeing of a patient. In sometimes called "nonvalida since it has not been formally safety or effectiveness.  Q. What kind of oversight is research?  A. Procedures and therapies to determined to be research recommend to be research recommend to provide innovative care utili unapproved drug, biologic or first obtain an IRB determination.	Asked Questions  Trch or innovative  Tresearch as a luding research aluation, designed eneralizable esearch is primarily corder existing ing knowledge to a lose of innovative, not to collect or theory, dard procedure or inpted to enhance inovative care is ted" treatment, evaluated for least or equire review by d (IRB). If you wish lizing an device, you must	

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acquisition, handlibiologic were not MD 1 revealed he to implant as the reference to detern operative plan has actions to be take life-threatening advice 1 further revealed going to do this [in OR rules."  2. Failure to ensure procurement, proportion of a not MD 1 and MD 2 did a biologic when brain surgeries. The from a university university research vial without instead disposal. None interviewed stated "probiotic" (the test two of the threshologic None of had either circult cases, considered Operating Room.	followed for Patient did not know how here were no purine this. MD 1 read been defined then to rescue earlierse effects of the "we told the nursing the DR]" and "It the DR]" and "It the DR]" and "It the DR]" and the DR] are the DR] and the DR] are the DR] and the DR] are the DR] ar	isposal of the its 1, 2, and 3, is much bacteria nor studies to evealed no post to denote the chipatient from a treatment. MD ig staff we were went against all eval, scheduling, storage, use 2.  OR of the use of 1, 2, and 3's was transported laboratory by a in an unlabeled indling, use or erative nurses in with the term eurosurgeon on ned. Consents), ership about the disposal of the interviewed, who on the three danager of the courrence of a		#2. Failure to ensure requischeduling, procurement, storage, use and disposal chiologic  How the correction was ac UCDMC policy 2517, Research and innovative undergoing surgery or anesprovides for communication Services staff regarding research and innovative undergoing surgery or anesprovides for communication Services staff regarding research acases, a review process regarding their roles in the communication to surgery other safeguards to ensure receive safe, approved care professional standards are rattached to this document to the communication of the communication	complished: rch and Innovative ew was developed ew appropriateness care in patients thesia. The policy n to Perioperative earch and innovative earch and innovative s, education of staff case, schedulers, and that patient's and the met. The policy is pelow.	

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	In an interview warm, she revealed produce and transitions hospital to be impatients 1, 2, and follow any formal package, label and In an interview will policy materials the FDA. The Eintended for pat investigational and to ensure the information and storage requirements for patients and storage requirements for pharmacy, transfer labeling requirement. Policy #1508, title an investigational regulated products use when there we approval before ren	d she was asker sport the biologic splanted during the 3. The RA indicate written protocols of transport the biologic shift the Director of 2 at 10 a.m., the stall policies required be approved for DOP stated that sent use would would require revitegrity, security, irrements in according to the storage and stall policies in place attents 1, 2, and gives noted:  The distribution of the storage and terms maintained and disposal of the storage and terms maintained and t	d by MD 2 to material to the e surgeries for ted she did not reprocedures to commaterial.  The Pharmacy DOP indicated did all drugs and human use by biologic agents be considered lew by the IDP labeling, safety dance with the east the time of 3, (10 to 10 to 11 to 12 to 15 to 16 to 17 to 17 to 18 to 18 to 19 to 18 to		Description of monitoring promanager of Perioperative Seresponsible for the re-educative Seresponsible for the re-educative Services staff of 2517, and is also responsible competency assessment of Perioperative Services nursing staff. Follow re-education of nursing staff of December 2012, the Nursimonitor each case of research care in the Perioperative Suit that staff members appropriately appractice standards.  Date of correction: December Policy 2517, Research and Image of December 2012, the Nursimonitor each case of research Policy 2517, Research and Image of Correction: December 2012, the Nursimonitor each case of research Policy 2517, Research and Image of Correction: December 2012, the Nursimonitor each care in the Policy 2517, Research and Image of Correction: December 2012, the Nursimonitor each innovative use in undergoing surgery or anestiful SETTING UC Davis Medical Center (UC) Room  POLICY The principal investigator (PI) research protocol or the prime submits the approved innovative application to the Operating in review. The review is conduct with the Medical Director and Director of Perioperative Serview Servie	ervices is tion of regarding policy of the annual Perioperative wing the during the month of the Manager will the or innovative tes and monitor arely advocated for professional of the movement of the moveme	

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to save a life. The dispensing through the or other oversight directed that investigated for the treatment of the United State document which list materials legally appropriated that applicate manner that departs standard or accept unapproved biologics addition, this policy assessment by an obtained.  The new hospital por Policy presented in by the hospital to provide direction for the Biologic or Devacknowledged this polyet by the governing to the old policy in physician to obtain biologic from the IRB FDA with notification however failed to require formally documented misinterpretation of evidence of approval addition, the policy dissues including how	same requirements applied e IDP and notifying the agency. The policy for gational drugs and biod ment of disease be recognised Pharmacopoeia (USP) the all drugs and biodoved for sale and use in colicy further defined innovation of a medication in a significant way ted practice and included practice and included practice and included practice and independent of the maximum of the maximum of the maximum of the maximum of the use of an Unapproved larger than the tagain directed approval of the use of (or, in an emergency, from to the IRB). The purire the approval process the control of the process to the policy of the process to the process to the interest of the process to the interest of the process to the interest of the policy of the process to the interest of the policy of the process to the interest of the process to the interest of the policy of the process to the interest of the policy of the process to the interest of the policy of the process to the interest of the policy of the policy of the process to the interest of the process to the interest of the policy of the policy of the policy of the policy of the process to the interest of the process to the interest of the process to the interest of the policy of the process to the interest of the process to the process to the interest of the process to the process to the interest of the process to the pr	If the research or innovative care for the OR setting and resources of addressed, the Assistant Director Operating Room Manager (backut letter of approval.  Item Interest of approval.  Item Interest of approval.  Item Interest of approval.  Item Interest of patients' rights related to the research/innovative care.  Item Interest of approval in submission packet to submission packet to submission packet to submission packet to submission process.  Interest of approval in submission packet to submission process.  Interest of approval in submission packet to submission process.  Interest of approval in submission packet to submission process.  Interest of approval in submission packet to submission process.  Interest of approval in submission packet to submission process.  Interest of approval in submission packet to submission process.  Interest of approval in submission packet to submission process.  Interest of approval in submission packet to submission process.  Interest of approval in submission packet to submission process.  Interest of approval in submission packet to submission process.  Interest of approval in submission packet to submission process.  Interest of approval in submission packet to submi	is appropriate pre adequately (principle) or p) issues a  safeguarding  letter of School of part of the tracts and  is list of e projects h/innovative dulers should on protocols is w process.  whysician ovative care ires. is not the iten, the iten), then the y the OR atient is, or innovative This must be identified.

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	am, he stated is regarding the use he was called by mid of 2 stated he talked "found nursing was anything about it's something was to knowledge, he investigation. The the nurses invo anything "changin neurosurgeons] of the nursing staff stated he didn't kithe nurses had in probiotic on the life Patient 1, 2, and	ne was not aware of an of the non-approved biology the Risk Management of the Risk Manageme	y issues ogic until office in itery. He ime and in't know ned that hout his internal erviewed emember hey [the field he MOR is or why he word R stated ussed at	necessary to accomplish the innovative care and informatives deviations.  Surgery Scheduling Appropriately identifies the research subjects/innovative information entered on the (see policy related to innovative scheduled for the operating approved protocol/innovative Notifies Operating Room M. Nurse of any non-approved patients.  Operating Room Clinical States	e research or staff of their roles in staff of their roles in ase patients who are recare patients by scheduling request ative care).  The care subjects aroom are on the role care list.  The care and Charge protocols or	
	MOR stated it necessity to do regarding the use MOR stated he das he was information by	evelop or revise any e of an unapproved biologic id not file an Incident Re	was no policies gic The port (IR) e being MOR	Review operating room of current, signed protocol information for those patients identified research/innovative care protocol of treatment or equipment.  Office of Research/School of	ormed consent form l as participants in a otocol. Documents is well as any	

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what processes environmental and place	were needed to patient safety mea			Check surgical study submi room approval letter.	ssion for operating	
3 Failure to pro and post-operative policies and accept In an interview we a.m., he stated	ovide pre-operative, care in accordance able standards of pra- ith the MOR on 8/ ne was not aware	e with hospital ctice 27/12 at 10:30 of any issues		If approval letter is absent investigators to the Operat Director or Manager. Maintain accessible electro research protocols	ing Room Assistant	
he was called be mid of 2 stated he talked "found nursing was anything about it." something was anything about it. something was to knowledge, he investigation. The the nurses invo anything "changir neurosurgeons" of the nursing staff stated he didn't ket the nurses had in probiotic on the lit Patient 1, 2, and any hospital com MOR stated it necessity to did regarding the use MOR stated he das he was info	of the non-approve the Risk Manage of the Risk Mana	ment office in disurgery. He that time and ey didn't know concerned that R without his an internal ad interviewed dn't remember ted "they [the ne sterile field ith." The MOR ic" was or why se of the word ne MOR stated or discussed at attended The here was no any policies biologic. The ent Report (IR)		How the correction was ac UCDMC policy 3091, Labeli the Perioperative and Processor followed. The policy was reclear that it applies to biolic has always been the intent previously elucidated. Periostaff were re-educated about the policy at staff meetings via an all-staff electronic "Perequired reading for all staff Room Documentation Audi designed and routed for rewith the audit of approprial labeling practices to begin i 2012. The policy is attache. Title of responsible person: Perioperative Services  Description of monitoring properating Room Document was designed by the Nurse Perioperative Services and responsible persons designed by the Nurse Perioperative Services and responsible persons designed by the Nurse Perioperative Services and responsible persons designed by the Nurse Perioperative Services and responsible persons designed by the Nurse Perioperative Services and responsible persons designed by the Nurse Perioperative Services and responsible persons designed by the Nurse Perioperative Services and responsible persons designed by the Nurse Perioperative Services and responsible persons designed by the Nurse Perioperative Services and responsible persons designed by the Nurse Perioperative Services and responsible persons designed	ing of Medications in edural Areas was not evised to make it origical products, as ion but was not operative Services out the content of and electronically dead Mail" file that is off. The "Operating to Tool" was view and approval the medication of early December displayed below.  Director of the original process: The estation Audit Tool" Manager of	

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place.  3 Fa and p policies. In an a.m., regard he was mid stated "found anythir someti knowle investigated the manythir neuros the nu stated the nu probio Patien any h MOR necess regard MOR as he handle	illure to provious ost-operative is and acceptable interview with the stated he ing the use of 201 he talked win nursing was and about it." And a stated he digation. The Murses involved in the didn't know t	were needed to patient safety medicate in accordance of standards of practice in accordance of the MOR on 80 was not aware of the non-approved the Risk Manage 1, after the third the nurses at not involved," "the Although he was bught into the Cold not conduct MOR stated he had and they did not involved we what a "probiotion of the state of an involved we what a "probiotion of the consent Tills cases were never the meetings he has his belief to the state of an unapproved not file an Incidental incidents incidents incidents incidents and accordance of the incidents and accordan	intra-operative with hospital ctice  27/12 at 10:30 of any issues did biologic until ement office in d surgery. He that time and vey didn't know concerned that is an internal had interviewed dn't remember ted "they [the ne sterile field with." The MOR ic" was or why se of the word he MOR stated er discussed at attended The here was no any policies di biologic The ent Report (IR) s "were being The MOR		expiration date/time unless in less than 24 hours.  D. All labels are verified bot visually by two qualified inaperson preparing the medic person administering the medical labeled at one time.  F. Any medications or soluti are immediately discarded.  G. All original containers from solutions remain available of perioperative/procedural are conclusion of the procedure.  H. All labeled containers on discarded at the conclusion of the procedure and solutions both on and of and their labels are reviewed exiting personnel.  J. The only exception to the requirement is if during the peri-procedural process, a symedication (either in the stee poured, drawn into a syring removed from its original commediately administered by individual. For example, the may draw up a medication of administer and/or dispose of contents of the syringe with or moving to another function administration or disposal.	th verbally and lividuals when the ation is not the edication.  Intion or solution is one found unlabeled on medications or or reference in the ea until the the sterile field are of the procedure.  It is, all medications of the sterile field do by entering and the sterile field are of the sterile field are out is a continuous or otherwise on the sterile field are of the entire of the entire out leaving the area	

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	environmental and place.  3. Failure to provand post-operative policies and acceptation in an interview with a.m., he stated the regarding the use he was called by mid of 20 stated he talked without nursing was anything about it something was be knowledge, he investigation. The the nurses involving "changing neurosurgeons" did the nursing staff with stated he didn't knowledge he investigation. The the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses had no probiotic on the Interview of the nurses ha	vide pre-operative, care in accordance in accordance in ble standards of practice in the MOR on 8 is a not aware of the non-approved the Risk Manage 11, after the thir with the nurses at a not involved," "the Although he was cought into the Codid not conduct MOR stated he had and they did hands." He start is something on the commend consent. The commend consent is cases were nevertited meetings he was his belief the velop or revise of an unapproved in not file an Incidented Innical Affairs."	intra-operative is with hospital actice (27/12 at 10:30 of any issues and biologic until ament office in disurgery. He that time and any didn't know concerned that IR without his an internal and interviewed don't remember ted "they [the the sterile field with." The MOR ic" was or why se of the word and MOR stated are discussed at attended. The here was no any policies I biologic. The ent Report (IR) is "were being The MOR		#3. Failure to provide pre-o- intra-operative, and post-op- accordance with hospital pol- acceptable standards of prace How the correction was accessional praceproviders to act as a patient as specialized dialogue appropria facilitate communication between professionals to enhance patient and consult with the appropria providers to determine a neet treatments. UCDMC Nursing Committee ensures that the sprofessional practice are outlineasured in the nursing compecting to each patient care is surveyors did not find deficient UCDMC's policies or compete correction for this deficiency is staff regarding the expectation Perioperative Services staff we patients who are receiving calinnovative or part of a research Policy 2517, Research and Innovative Operating Room Review, has a process to be followed to procommunication to Perioperatiregarding research and innovative were process, education of stheir roles in the case, communication to the case, communicatio	erative care in licies and citice.  Implished: The citice call for advocate, seek late to the patient, ween health care dent outcomes, late health care dent late and petencies that are letting. The late late late late late late late lat	

5/20/2013

3:30:27PM

Event ID:1K5X11

	EMENT OF DEFICIENCIES  PLAN OF CORRECTION  DENTIFICATION NUMBER  050599  STREET ADDRE		(X2) MULTIPLE CONSTRUCTION  A BUILDING  B WING		COMPLETE  08/30		
	ROVIDER OR SUPPLIER SITY OF CALIFORNIA DA	AVIS MEDICAL	STREET ADDRESS		ZP CODE mento, CA 95817-2201 SACRA	MENTO COUNTY	
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	for the nursing staff on standards of care, practice, safety or conduct in the OR following these events.  The Director of Peri-operative Services (DPS), in an interview on 8/29/12 at 11 a.m., stated he first learned about the surgeries after the third case. The DPS stated he made assumptions at the time that this would be handled in Peer Review. The DPS stated he never addressed these surgeries as being outside of expected OR standards of care.  In a subsequent interview conducted with the MOR on 8/30/12 at 8:50 a.m., he stated he did not recall a request from the Compliance Office to review OR policies and procedures. In review of the current OR policies and procedures, there was no reference to a) how staff would verify the approval of a non-standard, non-approved biologic, or b) what steps staff would take to ensure the safe scheduling, acquisition, packaging, use, handling and disposal of a biologic.			surgery schedulers, and ot ensure that patient's recei care and the professional strile of person responsible Perioperative Services  Description of monitoring Manager of Perioperative responsible for the re-educ Perioperative Services staf 2517, and is also responsible competency assessment of Services nursing staff. Follower re-education of nursing staff December 2012, the Nurmonitor each case of resear care in the Perioperative Strikat staff members appropriately and followed practice standards.  Date of correction: December 10 perioperative Strikat staff members appropriately standards.	ve safe, approved standards are met. : Director of  process: The Nurse Services is cation of fregarding policy pole for the annual freciperative powing the furing the month rise Manager will process and monitor risely advocated for I professional		
	That afternoon, af of several docume meeting held with on 9/27/11 wheret policy that would unapproved substa 7/13/12, ten mont and the Assistan "IRB policies cove created.  In an interview via me, she stated MI	ented e-mails, the n two Compliance by he was instru- prevent anyone ances to the OR, hs later the MOI at Manager had ared this" and no with the RA on 8	MOR recalled a staff members cted to draft a from bringing in In an e-mail on R responded he determined the new policy was		How the correction was ac Medical Staff developed a p Care, in March 2012 to pro- oversight to Medical Staff r innovative use of medical to and/or medications in the to patients. The guidelines are minimize the potential risk physicians in the delivery of compassionate care, as wel	policy, Innovative vide guidance and members in the herapies, devices creatment of e intended to to both patients and f innovative and	

	MID PLAN OF CORRECTION DENTIFICA 050599		IFPLIER/CLIA IN NUMBER	A BUILD B. WING	A13.2.2	(X3) DATE SURVEY COMPLETED  08/30/2012	
THE PROPERTY OF THE PARTY OF TH	ROVIDER OR SUPPLIER SITY OF CALIFORNIA DAY	/IS MEDICAL	STREET ADDRESS 2315 Stockton E		E, ZIP CODE mento, CA 95817-2201 SACRA	MENTO COUNTY	
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	agent had been ap and 3. The RA, who of Patients 1 and 2 the surgical team bacteria isolated for she observed the sand the solution be stated the surgical procedure if it was She replied, "yes, without a spill.  In an interview Manager (IPM) on 8/ stated she learner from the newspap as a bacteria "rarely stated no one has procedures or clarif was published. The [Infection Prevential approved the use knowledge of its procedured in the learner of the procedure	was in the OR stated both sur and told them om other "tools" crub nurse "clearing poured into a staff asked is safe to handle if it was had with the Infect 27/12 at 2:53 p.m. of the three er." She identified asked her for ication either before IPM stated in Leadership] of the biologic proposed use be opriate handling acteria had be andling as need the bacteria's the IPM indicatement would have call care of the icedures been received and 1/28/12 at ally approved res	for the surgeries regeons spoke to a to keep the The RA said of the bench" a bowl. The RA her during the e "the material." andled correctly tion Prevention, she neurosurgeries of the organism spital." The IPM or any policies, ore or after this t was "unlikely would have chad advance en known. The cleaning and the cleaning and the infection e followed the patients, had gived.  4 p.m., revealed search protocols		UCDMC's academic mission on Innovative Care was rev. 2012 to include an applicat about contracts, agreemer acquiring, handling, and stineeded for innovative care applying to provide innovat that are included in the appoversight of the Medical Stithe delivery of innovative trequired in the Innovative the necessary accountability Staff to the Governing Bod and compliance with feder hospital policies.  Title of person responsible Officer  Description of monitoring of innovative care, the use drugs, devices and biologic the innovative care will be Innovative Care Review Coapproval process. The acquiring and biologic materials will the next four months, all approval in the next four months, all approval cases will be reported to the Operations Committee, including and monitoring reports. The responsibility of the Chito ensure that outcomes are will occur for each case of in may not happen frequently.  Date of correction: The revenue.	rised in September tion with questions ats, and the plan for point the plan for pring the items. The process for tive care, the details plication, and the aff Organization of the transport of the Medical or quality of care all regulations and the transport of the Medical or quality of care all regulations and the transport of the Medical or quality of care all regulations and the transport of the Medical or assessed by the maittee during the distinction, storage, of drugs, devices, the addressed. For opproved innovative the Quality and Safety luding outcomes the reafter, it will be the Medical Officer the monitored. This innovative care, but the plansport of the transport of the transpor	

	STATEMENT OF DEFICIENCIES  AND PLAN DE CORRECTION  (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER  050599  NAME OF PROVIDER OR SUPPLIER  STREET ADDRESSES			(X3) MULTIPLE CONSTRUCTION (X3) DATE SUS GOMPLETS AL BUILDING B. WING 08/30			
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	in order to define and post-operative use of the biologic FDA approved, ch clear instructions fo of the product surgical cases, all had not been dis- Committee meeting.	plan of care incl He expected treanneled through the handling us MD 4 acknowledg which involved se	uding the safe eatments to be the IDP, with e and disposal sed the three prious infection.		policy was approved by the Executive Committee on No The education of the Medic October 24, 2012.	ovember 19, 2012.	
	In multiple interview leaders stated they bacterial agent net approved for use diseases, introduction with the adverse event.  In review of a Sentinel Events, of was defined as health care associor senous physical risk thereof." The occurrence be exitterial defined whimore than one even month period or Dipotentially underning the policy.	ritinel event  vs previously refer or did not believe ver tested on hu in the treatme led without OF cation, to intentic vith no post-oper e separate occas  hospital policy li lated 5/10/10, a "an unexpected ated infection resil or psychological e policy further valuated with the ch included: "C T nt of the same ty to the nature of ti line public confis	enced, hospital the use of a mans and not and not and of human to staff prior nally cause a ative plan for sions was an D #1440 titled sentinel event occurrence or ulting in death injury or the directed the ne established here has been pe within a six he event could dence in the		#4. Failure to conduct a co- investigation for an adverse CLARIFICATION: On page 20 reads "In review of a hospit titled Reporting Serious Adv was also definition of specif outcomes that would qualif an adverse event. This inclu- death or serious disability as use of a biologic provided A key element of the descrip policy #1513, the word "com- been omitted in the 2567.  UCDMC policy 1513, Report Events, requires reporting o in which the following occur or serious disability associate contaminated drug, device o by the hospital."  The California Health and Sa 1279.1(b)(2)(A) identifies th reportable adverse event as serious disability associated	e or sentinel event. D of the 2567, it al policy ID: #1513, erse Events, there ic adverse y to be reported as ided: 'B. Patient ssociated with the d by the hospital.'" Dotive language in intaminated," has ing Serious Adverse f an adverse event is: "Patient death ed with the use of a probiologic provided if the total probiologic provided if the total probiologic provided is type of a patient death or	

directly involved will be responsible for reporting submitting an incident report. The policy further directed "If the event is determined to be a sentinel event, a root-cause analysis will be conducted."  In review of a hospital policy ID: #1513 titled Reporting Serious Adverse Events, there was also definition of specific adverse outcomes that would qualify to be reported as an adverse event. This included: "B. Product or device events, including the following 1. Patient death or serious disability associated with the use of abiologic provided by the hospital."  A non-approved biologic was used on three patients without proper FDA and hospital approvals over a six month period. In accordance with statute and per hospital policy ID #1513, the facility failed to identify these surgeries as adverse events, and failed to report the events in a timely manner as required by statute. The cumulative effect of the failures identified in this document, caused, or was likely to cause, serious injury or death to the patients.  This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious privace of care and provided by the health facility when the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of the contamination or the product.  The materials used in these three cases were not contaminated and therefore do not meet the State or UCDMC adverse event reporting criteria.  How the correction was accomplished: All UCDMC patient care staff were re-educated about the content of policy 1440, Sentinel Events, and policy 1466, Confidential Incident Reports, reminding them to report any practices that they observe or learn about that they believe are acceptable standards of practice. Staff can report events by notifying their supervisors or filing an incident report.		T OF DEFICIENCIES OF CORRECTION	OS0599		(X2) MULTIPLE CONSTRUCTION (X A BUILDING B WING		(X3) DATE SLIPE COMPLETE	
UNIVERSITY OF CALIFORNIA DAVIS MEDICAL  (X4 10 SUMMARY STATEMENT OF DEFICENCES IDENTIFYING INFORMATION)  DIPORT REGULATORY OR ISC IDENTIFYING INFORMATION)  directly involved will be responsible for reporting submitting an incident report. The policy further directed "If the event is determined to be a sentinel event, a root-cause analysis will be conducted."  In review of a hospital policy ID. #1513 titled Reporting Serious Adverse Events, there was also definition of specific adverse outcomes that would qualify to be reported as an adverse event. This included. "B. Product or device events, including the following 1. Patient death or serious disability associated with the use of abiologic provided by the hospital."  A non-approved biologic was used on three patients without proper FDA and hospital approvals over a six month period. In accordance with statute and per hospital policy ID #1513, the facility failed to identify these surgeries as adverse events, and failed to report the events in a timely manner as required by statute. The cumulative effect of the failures identified in this document, caused, or was likely to cause, serious injury or death to the patients.  This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious linky to cause, serious linky to cause, serious plury or death to the patients.	NAME OF D	ROVIDER OR SUPPLIER	1	STREET ADDRESS	CITY STATE	E 2W CODE		
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constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.1(c).  Title of responsible person: Chief Medical Officer, Chief Patient Care Services Officer, Director of Pharmacy, Director of Perioperative Services  Event ID 1K5X11  5/20/2013  3:30:27PM		submitting an incidirected "If the event, a root-cause overt, and overt, a root-cause overt, and overt, an	hospital policy II Adverse Events, the control of t	policy further to be a sentine lucted."  D: #1513 titled here was also less that would see event. This rents, including erious disability it provided by three patients provals over a lith statute and acility failed to be events, and ely manner as the effect of the laused, or was death to the liciency (les) as kely to cause, and therefore within the Code Section		by the health facility when the the result of generally detecta in the drug, device, or biologic source of the contamination of the materials used in these the not contaminated and therefor the State or UCDMC adverse excriteria.  How the correction was accord UCDMC patient care staff were about the content of policy 14 Events, and policy 1466, Confiderents, reminding them to repractices that they observe on they believe are unsafe or depthey believe are acceptable stapractice. Staff can report eventheir supervisors or filing an infincident reporting system, or the will create a report on the incident reporting system. Incident reporting system. Incident reporting system. Incident reporting system. Incident reports, for review an assigned responsibility for that incident reports, for review an action.  Title of responsible person: Choofficer, Chief Patient Care Serv Director of Pharmacy, Director	contamination is ble contaminants ble contaminants regardless of the reference cases were been do not meet event reporting mplished: All ere-educated 40, Sentinel dential Incident report any learn about that port any learn about that part from what part from what part from what provides the electronic of a supervisor, electronic reports are langement, anager who is a category of dispropriate lief Medical vices Officer,	

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	directly involved submitting an incid directed "If the ever event, a root-cause and In review of a harmonic reporting to be reported to the following 1 Parassociated with the the hospital "  A non-approved biological without proper FDA six month period, per hospital policy identify these surgificated to report the required by statute, failures identified in likely to cause, so patients.  This facility failed to described above that serious injury or desconstitutes an immediating of Health 1280 1(c).	ent report. The int is determined to malysis will be conductored by the conductored by th	policy further be a sentinel acted."  It #1513 titled tere was also that would be event. This ents, including rious disability to provided by three patients provals over a thin statute and cility failed to events, and the refect of the aused, or was death to the ciency (ies) as ely to cause, and therefore within the		Description of monitoring pro Management oversees the into a daily basis. Monthly, the Pa Events Committee will review incident reports from the pre- breaks out the incident report and provides detail of all incident flagged as causing harm to a pathe potential to cause harm to activity will allow the Patient Committee to systematically reports that may identify practor departs from acceptable st practice and do further study unsafe practice is addressed at Date of correction: June 1, 20	cident reports on titient Safety of a report of the vious month that its into categories, dent reports patient or having of a patient. This Safety Events monitor incident citice that is unsafe andards of to ensure that and prevented.	
Event ID:1	K5X11		5/20/2013	3	30:27PM		