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Supplementary Materials for

From Free to Free Market: Cost Recovery in Federally Funded Clinical Research

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METHODS

The interview script in table S1 was used to lead the discussions on cost recovery with *n* = 19 CTSAs across the country. The initial interviews were largely unstructured, other than the Primary Questions shown in Table 1, to afford each interviewee the opportunity to identify and expand upon issues which were, in their experience, of the highest importance. This prevented any 'leading' by the interviewer and enabled the interview process to evolve as the CTSAs self-reported on the issues which were the highest priority for them. As the interviews progressed, we identified issues that were commonly self-reported across multiple institutions. The initial responses were then analyzed and used to develop more detailed questions in the relevant areas which were addressed in follow-up interviews.

From their responses, we identified trends in approaches to this new field with regards to policies, models and objectives of the program. This information refined our enquiries and ultimately enabled us to identify components common to those CRMs which were described by the institution as successful. We then went on to define initiatives that worked or which were tried and then either discarded or in the process of being significantly altered. As a result of this iterative process, we also shared experiences which were highlighted by the institutions as important with regards to CRM implementation.

SUPPLEMENTARY FIGURE

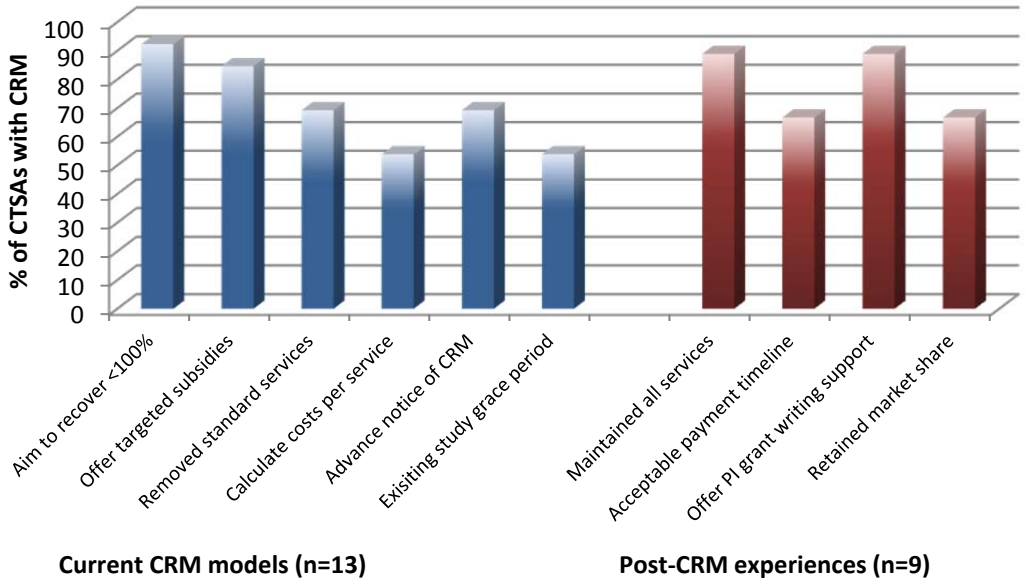

Figure S1. Overview of the current CTSA cost recovery landscape and the associated impact. Of the 19 organizations surveyed herein, 13 operate a CRM, 3 are in the early stages of developing a CRM, and the remaining 3 have no model in place with no plans to introduce one at this stage. The key features most frequently incorporated into individual CRMs are illustrated in blue and the most common impact areas following implementation are in red.

SUPPLEMENTARY TABLES

Table S1 shows the questions that were developed for the interview guidance notes during the course of this work.

Table S1. CTSA cost recovery interview guide.
The primary questions were used in the first round of interviews, during which trends were initially identified. These trends were then clarified and confirmed through iterative interviews using the follow-up questions.

Question number	Primary questions	Follow-up questions
1	**Do you have a cost recovery model for federally funded research?**	Are you considering a cost recovery model for the future?
2	**If you have a current cost recovery model, do you:** a) Offer a scale for charges b) Offer additional subsidies or exemptions. c) Aim for 100% recovery? • If you aim for <100% - by how much? d) Do you operate a bundled charging mechanism or individual charging?	b) If you offer additional subsidies or exemptions, are any of these specifically targeted to: • Young investigators? • Pilot studies? • Other PIs / research areas etc? c) On introduction of your cost recovery mechanism, did you maintain any free 'standard' services?
3	O**n introduction of your CRM did you grandfather existing studies:** a) Permanently? b) For a set grace period? (if so, for how long?) c) Did not Grandfather	
4	**Did you give notice that a CRM was being introduced?** a) To existing PIs? b) If so, of how many months?	a) To potential new PIs? b) If so, of how many months?
5	**Following the introduction of a CRM did you:** a) See a fall in your level of new studies? b) Cut some services? c) Experience a lag time on payments?	a) If so, was the fall evenly distributed e.g. between young vs. senior PIs? b) If so, which ones and what were your criteria? c) How long was the payment lag time? d) Did you introduce a service to help PIs write the new CSC costs in their grants?
6	**Are you 100% happy with your current model?**	Are there any features you looking to change?

Table S2. Current CTSA approaches to the main cost recovery focus areas.

Focus area	Current CTSA approaches	Example
Level of recovery	Charge a % recovery for all services offered.	Recover a % charge for every service carried out within the CRU
	Charge a variable % for different services.	Recover a % charge for nursing services, another % charge for labs etc.
	Charge for just a set class of services.	Recover up to 100%, just for services considered too expensive to offer for free.
	Charge only for Primary Outcome Variable.	Cost recover the most significant service for each study i.e. charged services vary by study.
	Costs reflect infrastructure differences.	Variables such as rent result in different costs for the same service at different sites.
	Target charges at high users / senior PIs.	Offer a set number of inpatient beds for free per year, anything more carries a charge.
	Significantly raise rates for services currently charged	Charge high rates for lab work to avoid introducing charges to new areas.
Cost recovery initiation	Determine date of cost recovery implementation.	Implement CRM immediately, offer grace period, or stage implementation.
Managing the CRM	Price all services individually.	Shopping cart style –one hourly rate for nursing, another hourly rate for rooms etc.
	Operate a mix of bundled and individual prices.	Bundle common combinations of service but maintain individual price options.
	Bundle services into an all-inclusive charging model.	By service, by time or a mix of each.

Table S3. Current CTSA policies for cost recovery subsidies.

Policy area	Current CTSA approaches	Example
Existing studies	Charge as for a new study.	Full study costs applied from the date of cost recovery implementation.
	Grandfather for a set time.	Offer a blanket grace period to all studies or initiate a 'Grandfather subsidy' by % or time limit.
	Variable Grandfathering subsidies.	Grandfathering policy is decided on a case-by-case basis by the Subsidies Committee.
	Grandfather indefinitely.	This can be defined as until the end of the funding period or the end of the study.
	Charge only for study changes.	Limit cost recovery to protocol changes which require additional CSC resources.
	Offer competitive subsidy funding.	For studies which demonstrably cannot re-budget and have tried to win external funding.
Subsidies by study features	Subsidize pilot studies.	CSC services free of cost for pilot funded studies and/ or for pilot ideas even without pilot funding.
	Subsidize specific types of study.	Such as very short, simple or inexpensive study types or those which utilize only limited services.
	Subsidize certain research fields.	Such as priority or emerging fields within the institution, internally funded research etc.
	Benchmark study costs/subsidies.	Subsidize studies based on an agreed proportion of industry/ Medicare rates,
	Variable subsidies	Subsidy award decided on a case-by-case basis by the Subsidies Committee.
	Offer no subsidies by study type.	All studies pay the same rates, regardless of structure or funding source.
	Match external PI funding.	With or without a cap at a $ or %.
Subsidies by PI type	Target subsidies to new PIs.	Assistant professor level or those PIs who are new to clinical research.
	Offer the same subsidy to all PIs.	Offer subsidized introductory work to PIs, who then 'graduate' to fee paying.
	Offer competitive subsidies.	Award subsidies as competitive 'grants' or by special application i.e. case-by-case basis.
	Offer no subsidies by PI group.	All PIs pay the same costs, regardless of status.