Policy Feature	Current Policy	Summary of Comments Received	Recommendations/Questions
Full Data Package Retention Period	Maintenance of the Full Data Package for Data Sharing for a period of seven (7) years (Section IV.B.1.b)	• General consensus that 7 years is appropriate. Two respondents suggested that it be retained indefinitely, though they recognize resource constraints may limit ability to do so. • Some respondents noted a need to be specific about when the retention period begins, and to think through contingencies should PCORI cease to operate.	Retention period of 7 years, with more details to be specified, per the comments received.
Restrictions on Data Use in Data Use Agreement (DUA)	Not addressed	• Broad consensus on prohibition on re-identification of study participants, and that data will be used only for research and not commercial purposes. • Policy should articulate expectations for qualitative data (tapes, transcripts or other original material) that can be difficult to de-identify. • Policy should articulate the stipulations and requirements to be included in a DUA. • Policy should articulate governance structure to evaluate requests and monitor compliance with the terms. • Policy should distinguish between different types of data sets that might be created for research projects and that require different types of data agreements (e.g., limited datasets vs. de-identified datasets)	Policy should be revised to include prohibition on re-identification and stipulate that data will be used for research purposes only. Policy should be revised to explicitly address qualitative data. Many open questions about the level of specificity needed in the policy (elements of DUA, process for evaluating requests and monitoring compliance, among others). Will require input of RTC and expert group.
Qualifications of 3rd party requestors	Not addressed	• Majority of respondents endorse view that those requesting data should be required to identify their expertise and prior experience in utilizing and safeguarding research data. Many of these respondents believe that requestors must be working in	Inclined to revise policy in keeping with the view expressed by majority of respondents (requests restricted to those with demonstrated expertise and with affiliations to FWA/IRB), but we

		established research institutions with an FWA and an IRB in order to be eligible. • A number of respondents (5) believe that restrictions should not be placed on the education level or specific scientific expertise of the requestors, while recognizing the need that this may require additional safeguards.	think this is worthy of further discussion with RTC and expert group.
Documentation required of 3rd party requestors	Not addressed	• Broad consensus that all requests must include: (1) Scientific purpose that is clearly described, (2) Assurance that data requested will be used to create or materially enhance generalizable scientific knowledge, (3) Assurance that proposed research can be reasonably addressed using the requested data. • Most respondents believe that requests must include information comparable to that required of any research award application: explicit research questions, full protocol and statistical analysis plan, IRB approval, statement of intended uses, timeline, source of funding, COI declarations. • A small number (3) expressed the view that only information sufficient to allow the scientific merit of the proposed research to be judged and to assure protection of data should be required. They believe that a study protocol, statistical plan (among other things) should not be required.	Policy should be revised to include the more detailed list of required documentation. Further input from RTC and expert group will be needed to fine-tune this list.

Data repository standards	Brief mention that PCORI will provide a list of suggested repositories (Section IV.B.2.b)	• 4 respondents expressed the view that PCORI should use existing repositories that are HIPAA and FISMA compliant and that PCORI should develop standards that are consistent with other federal funders, including any models that might be supported or approved by the NIH, and with practices of existing data repositories (don't reinvent wheels). • 2 respondents recommended against using centralized repositories. Rather, they favor investigators maintaining data at their own institutions – they would provide PCORI with documentation of adequate security standards and qualifications necessary for safely maintaining and sharing study databases.	Policy language requiring deposit of data package in selected repositories should be preserved. Additional details about repository standards should be added following the data sharing pilot project.
Informed consent	Appropriate documentation of patient consent that permits data collected as part of the study to be de-identified, used for future research purposes and shared broadly with researchers not affiliated with the institution conducting the study. (Section IV.B.1.d)	• While some respondents endorsed the policy as presently written, others felt that it was under-specified and in need of more details. • Policy as written applies both retroactively and prospectively. For an already funded study, will need to see if the consent form used stipulated "future uses." Where no such stipulation exists, IRB will have to determine how to re-contact participants, and 3rd party researchers will not have access to info required to contact those participants. • Policy is silent on data requests from studies which used a waiver of consent for all or part of the data collection, which may restrict third party sharing.	Current policy language seems generally adequate for informed consent related to not-yet-funded clinical trials. More thought needs to be given to already-funded research, as well as all studies that include a waiver of consent.

		• If the newly issued amendments to the federal Common Rule are retained by the new administration, many IRBs will create consent templates that reflect a new requirement to disclose to prospective participants the possibility of data sharing. PCORI might profitably urge awardees to use that language, since their IRBs will (eventually) become familiar and comfortable with it.	
Other – Funding/Costs	PCORI will cover reasonable costs associated with maintaining and depositing the Full Data Package in a PCORI suggested repository for a period of seven (7) years following acceptance by PCORI of the final research report. (Section IV.D)	• General consensus that funding support will be instrumental to a successful policy. • Some respondents recommend earmarking specified amounts of funding for data preparation and curation, in addition to reasonable costs associated with maintaining and depositing the full data package. • For data packages that are not deposited into repositories, funds should be included within the original awards to cover the cost of study investigators to retain the data package for seven years. • Some respondents noted that "reasonable costs" language is vague, and that consideration to the fact that maintaining data in a repository involves ongoing IRB oversight, with tracking and reporting each time the dataset is accessed, as well as annual review. Funding this effort for the 7-year retention period will be necessary.	The "reasonable costs" language seems adequate at present. Additional details about costs could be added following the data sharing pilot project.
Other- Definitions	Section III	• A number of respondents proposed revisions/additions to the language contained in Section III. These include:	Revise language to address these concerns, with input from RTC and expert group.

		specific definition of metadata; inclusion and definition of collected datasets, not just the analyzable datasets; data dictionary.	
Other – Enforcement	Not addressed	• Policy lacks specification of penalty(ies) for investigators who do not prepare or follow through with data management and data sharing plans. Policy could be strengthened by explicitly defining penalty(ies), such as exclusion from consideration for PCORI-funded research for a 3-year period. PCORI will need to develop mechanisms for monitoring the data sharing activities of funded researchers.	Policy needs to be revised to include enforcement mechanisms, with input from General Counsel, RTC, and expert group.
Other – Data ownership	Not addressed	• Questions around data ownership and sharing when: (1) Ongoing grants are still using the data? (2) PCORI contracts curate data that are owned by others (e.g., health plan data from electronic health records, state or regional agency partners? (3) Data included in the contract incorporates data from prior study(ies). In some of these situations, data from another source/study (e.g., NIH funded) may have their own data sharing requirements?	Policy needs to be revised to include language on data ownership mechanisms, with input from General Counsel and RTC.
Other – Applicability to observational studies	Not addressed	• A number of respondents noted that the policy is silent on observational studies, namely one that use health system data, (EHR data, facilities and/or individual provider-level data) and administrative claims data. These respondents raised a number of concerns about contractual and legal obligations to these data sources. • One respondent proposed that for EHR and administrative claims research, researchers	This is a significant issue that the policy must address. Needs further input from General Counsel, RTC, and expert group.

		be required to make available their code for performing the study that would enable reproducibility by someone with access to the source data from the data provider, but that they not be required to deposit individual level data.	
Other – Incentives for data generators	Not addressed	• A number of respondents recommended that PCORI establish ways to ensure data originators receive credit for their work, including inviting the original investigators to participate as authors on subsequent scholarly works produced from the dataset.	PCORI should consider what, if any, incentives should be articulated in the policy.
Other – Lead time for original investigators to publish	Not addressed	• Respondent recommendations ranged from 12 months to 24 months.	Policy should be revised to include language about this issue. Needs further input from RTC.