CONSULTATION QUESTIONS

**Are you responding *primarily* as a data custodian, data user or data subject? *(We recognise all people are data subjects and many organisations act as data guardians and data users, but please tick only one box)***

Data Custodian ☐

Data User (e.g. researcher) ☒

Data Subject (e.g. member of the public or group representing citizens) ☐

**1. Are there any benefits of data linkage for statistical and research purposes that are not sufficiently described here?**

Yes, there are further benefits ☒ No, the benefits are described fully ☐

If you ticked 'yes', please describe the further benefits of data linkage for statistical and research purposes.

Benefit 5 discusses the role of record linkage in Randomised Controlled Trials. However, the emphasis here is very much on the extended follow-up of participants in trials. Our unit increasingly uses record linkage in RCTs to identify study endpoints. This "streamlined" approach to clinical studies facilitates the identification of endpoints, reduces the workload of study investigator (including GPs) and helps to reduce the costs of large scale drug safety studies. It will increasingly be a major benefit to the use of record linkage.

**2. Are there challenges or barriers preventing more effective and efficient data linkages for statistical and research purposes taking place that are not sufficiently described here?**

Yes, there are further challenges ☒ No, the challenges have been identified ☐

If you ticked 'yes', please describe the challenges or barriers.

Point 1 discusses uncertainty regarding to the legalities of record linkage. Related to this, our experience is that *bureaucratic hurdles* associated with obtaining patient level data can frequently be a time consuming and onerous burden. Our experience has been that such bureaucracy can be applied differently in different regions. This point relate not only to Data Custodians but also to those whose authority required to access data (e.g. Caldicott Guardians)

**3. Are the guiding principles sufficient and appropriate? Please explain your answer fully and make suggestions for improvement.**

Yes, they are sufficient and appropriate ☐ No, they are not ☒

Please explain your answer fully and make suggestions for improvement.

1. **Privacy**. Point 14 states: “Every effort should be made to consider and minimise risks of identification (or re-identification) to data subjects and their families arising from all aspects of data handling.” We would prefer this to say “Every ***reasonable*** effort…” The important point here is that there are a number of ways in which data privacy can be achieved; however, to apply all such measures (as is suggested by the current wording) could be an overreaction which would make the data harder to use. For example, with anonymised data where privacy is inherently protected, further potentially restrictive privacy measures should not be required. This is the model that has long been used by the Clinical Practice Research Datalink (CPRD formerly GPRD).
2. **Consent**. A distinction should be drawn between consented and unconsented data. Most administrative data are not consented at the time of collection; however, such data are a valuable resource which has been widely used for many years. Point 21 (regarding trying to obtain consent from all subjects prior to linkage) seems to imply that using data without consent is not the desired ideal. However, it would be a more honest approach to state that unconsented data are a valuable resource that have been (and will continue to be) used to good effect. The important point is that such data should only be used when subject to the constraints outlined in point 25.

**4a. Are the objectives set out for a Privacy Advisory Service in Section 3c the right ones?**

Yes, the objectives are right ☐ No, they are not ☒

Please explain your answer fully and make suggestions for improvement.

It is not clear how this body would fit in with existing organisations that offer such facilities. If “technical suggestions” (point 5) were to be made by this body, what authority would there be to enforce them. If this body simply introduces an additional layer of bureaucracy to that which already exists, it would not be welcomed by us.

**4b. Do you wish to be consulted on firmer proposals for a Privacy Advisory service as and when they are developed?**

Yes ☒ No ☐

**5a. Are the functions that will be led by the National Data Linkage Centre set out in section 3d the right ones?**

Yes, they are the right functions ☐ No, they are not ☒

Please explain your answer fully and make suggestions for improvement.

It is not clear how this Centre would interact with existing bodies that currently deal with such data. Point 6 states it will have as its function: “co-ordination and support for any ‘satellite’ data linkage units/safe havens that continued to function in other bodies”. What does this mean? As with the *Privacy Advisory Service* mentioned above, we would be very concerned if this Centre were to introduce addition hurdles to research that could impede current established mechanisms for using such data. However, any actions that will genuinely facilitate research would be welcomed.
Further information is needed about how this Centre would operate. We would be keen for alternatives models to be considered, for example that used by CPRD (formally GPRD) were data are linked and then anonymised at once.

**5b. Do you wish to be consulted on firmer proposals for a National Data Linkage Centre as and when they are developed?**

Yes ☒ No ☐