## Appendices

## Appendix 1. Minimal Clinical Data Set

The Minimal Clinical Data Set in this appendix is the minimal clinical data that are recommended for annotation of disease state or risk of cancer in biospecimen resources. The items in this recommended data set are not meant to be inclusive and are only suggested examples. Different biospecimen resources may require more or less detailed annotations that focus on the primary use of the clinical biospecimens. Good practice suggests that the data set for clinical annotation be tailored to the needs of the users of the biospecimen resource. Also this Minimal Clinical Data Set is not to be confused with other data sets such as that used by CMS to evaluate nursing home patients (http://www.cms.hhs.gov/MDSPubQIandResRep/).

| Item                             |   | Notes  |
|----------------------------------|---|--|
| Age                              |   | or $\ge$ 90, at collection                               |
| Exposures (where<br>age > 18)    | Smoking   |  |
|                                  | Drinking  |  |
|                                  | Occupation                                      |  |
| Gender                           |   |  |
| Race                             |   |  |
| Ethnicity                        |   |  |
| Disease diagnosis/Normal         |   |  |
| Source/Method of diagnosis       |   |  |
| Treatment type/None              |   |  |
| Height                           |   |  |
| Weight                           |   |  |
| Family history of cancer         |   |  |
| For tissue<br>biospecimens only, | Histologic type                                 | Also record for blood biospecimens in bloodborne cancers |
|                                  | Grade   |  |
|                                  | Size  |  |
|                                  | Nodal status (pos/neg, # pos/total nodes, etc.) |  |
|                                  | Pathologic TNM status                           |  |
|                                  | Pathologic TNM stage                            |  |
|                                  | Procedure                                       | Procedure by which biospecimen was obtained              |

| Biomarkers  |                                      | Biomarkers used in routine care; e.g.<br>Estrogen and Progesterone receptor<br>sensitivity |
|---|--------------------------------------|--|
| Outcome—or will it<br>be possible to get<br>these data when<br>outcome is known | Death                                | Year only  |
|   | Date of last cancer follow-up        | Year only  |
|   | Recurrence (local, distant, unknown) |  |
| Collection method   |                                      |  |
| Comorbidity   |                                      |  |