# *Appendix 1B: Summary of Key Protocols and Policies in Birth Defects Surveillance Program Development*

This appendix provides examples of the documentation a birth defects surveillance program should discuss, develop, and maintain.

- **Birth defects surveillance program policies** may relate to confidentiality, security, privacy, and disclosure that add program-specific situational details to the agency's general policies.
- **Birth defects surveillance program procedures** may include a process for distinguishing addresses within their catchment area, in addition to the other procedures detailed below.
- **Training** for new staff or for program affiliates who may provide support (in-kind, or other). Each functional area should have separate training modules that are updated as procedures and information change over time. An onboarding and offboarding procedural checklist is also of use.
- **Data management procedures** detailing how information from data sources is received, managed, and stored.
- **Abstracting guidelines** that provide the procedures for recording information obtained from health records. See **Appendix 2A** for birth defects descriptions, which serves as abstraction guidance.
- **Data quality procedures**, including methods to verify accuracy, completeness, and timeliness of case information.
- **Program management** documentation, such as location within the agency's organizational structure, chain of authority, budget, memoranda of understanding, funding entities (grant management information), etc.
- **Database standards and infrastructure** include proper system documentation, which often occurs on the back end away from the user interface. The birth defects surveillance program's non-IT users may find it beneficial to develop documentation that describes upgrades or changes that affect the user interface (e.g., drop down windows, applications added to the case record abstract) or that have an impact on surveillance functions (e.g., new data elements, new surveillance system project database).
- **Health information classification system updates** can occur over time. Although many such updates do not pertain to birth defects surveillance, it is beneficial to have a working knowledge of updates to the program's classification system(s) of choice as a barometer for important national topics that were given more detailed diagnosis codes, added, or deactivated. Birth defects surveillance programs should monitor the classification system(s) relevant to their ascertainment methods to document any birth defects-related coding changes. See **Chapter 4** for discussion of classification system changes over time.

- **Data release policy** should be included in programmatic documentation. Although the agency often mandates these policies, birth defects surveillance program staff should be familiar with the policies and procedures, such as:
    - Proper mechanisms for release of information, which must detail the process for obtaining approval for access to the data and authorization for release of the information.
    - Appropriate preparation of tabular statistical data (including de-identifying micro-data files) prior to release. Micro-data files must be designed to guard against inadvertent disclosure of confidential information.
    - Clear approval process governing the release of identifiable (or potentially identifiable) data. Issues related to sending identifiable information about birth defects cases must be covered. Providing access to confidential information for research purposes must be discussed, describing the types of research projects that may gain access to these data, and the system's process for reviewing and approving such projects.
- **Data Use Policy** defines the conditions under which information can be used for administrative purposes, including using the data to ensure that children and families are referred appropriately for needed services if that is among the birth defects surveillance program's objectives. Once the data release policies have been developed, birth defects surveillance programs should develop specific forms that provide explicit detail regarding the request for data. At a minimum, such a form should include fields to:
    - Identify the **requestor**
    - Describe the **reason** for the data request
    - Detail the planned **uses** of the requested data
    - Enter a precise descriptive **list of the data requested**
    - Ensure the requestor is aware of explicitly detailed **provisions on data use**.