

## WORKSHEET: Closure Criteria

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This worksheet is used by staff to determine whether a study or site can be closed.

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All criteria in 1 must be met. The criterion in 2 must also be met for studies subject to federal oversight other than FDA.

### 1. For all studies (see Footnote 1)

- |     |                          |   |
|-----|--------------------------|---|
| 1.1 | <input type="checkbox"/> | The protocol is permanently closed to enrollment  |
| 1.2 | <input type="checkbox"/> | All subjects have completed all protocol mandated interventions and interactions (see Footnote 2)   |
| 1.3 | <input type="checkbox"/> | All protocol mandated collection of identifiable private information about the subjects is complete |

### 2. For studies subject to federal oversight other than FDA

- |     |                          |  |
|-----|--------------------------|--|
| 2.1 | <input type="checkbox"/> | Analysis of private identifiable information is completed (see Footnote 3) |
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### 3. Notes

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### 4. Footnotes

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| 4.1 | For closure of a site, the questions refer to the site. For closure of a study, the questions refer to all sites   |
| 4.2 | This includes interventions and interactions related to collection of long-term follow-up data, including final visits and any follow-up activities (such as phone calls, post-card contacts, or long-term follow up required by the protocol) |
| 4.3 | This can be checked even if another organization (e.g., statistical center, sponsor, or CRO) will analyze private identifiable information from subjects   |