Harms Risk of Bias Assessment Form

| Reviewer: Re | f ID: |
|--------------|-------|
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| Question | Yes | No | Comments |
|---|-----|----|----------|
| Were the harms predefined using standardized or precise definitions? (mcharms) | | | |
| Are all pre-specified harms reported? (RTI case series) | | | |
| Did the author(s) use STANDARD scale(s) or checklist(s) for harms collection? (mcharms) | | | |
| Are the statistical methods used to assess the main harm or adverse event outcomes adequate? (RTI cohort) | | | |