**Unanticipated Problem in Data Integrity Report**

For Distribution to DSMB

To be completed by DCC or clinical team

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| When and how was the problem identified? |  |
| Description of Problem in non-technical terms |  |
| Proportion and count of participants affected |  |
| How could this impact participant safety? |  |
| How could this affect delivery of intervention? |  |
| How could this problem disproportionately affect a subgroup? |  |
| How could this be a threat to generalizability? |  |
| Is there a plan to solve problem? What does it entail? |  |
| Estimated timeline to remediate problem |  |
| Should this be considered a protocol deviation? |  |
| What other points are important for DSMB to consider not mentioned? |  |