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Northwest Community EMS System

**Research & Development Committee**

**New Product Request and**

**FIELD TRIAL PROPOSAL**

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| **Device to be trialed:** |
| **Objective: What is the purpose of the field trial?**  To evaluate the feasibility, effectiveness, benefits, risks, and outcomes of the use of the in the pre-hospital setting. |
| **Justification for necessity of trial. What new knowledge, not already known/published in literature, will the trial provide? What problem will this equipment/device solve? How will this equipment/device improve quality of patient care?** |
| **Commitment: If the field trial is successful, will the item be purchased?** |
| **Literature to support safety and efficacy** |
| **Protocol and procedure for use** |
| **Responsible party:** |
| **Personnel involved: how selected to participate**  . |
| **Equipment/devices involved: numbers and location** |
| **Duration of field trial (# patient uses to be enrolled)** |
| **Education: plan – initial and continuing, objectives, methods, materials, instructors, evaluation** |
| **Evaluation: methodology, including forms, procedure for completion, and submission for review**  **Data to be collected. How will the results be reported? Who is responsible for compiling the data results?**  **Data collection method**: |
| **Device function during transport:** |
| **Clinical outcomes of the patients:** |
| **Crew feedback:** |
| **Hospital feedback:** |
| **Actions in the event of any adverse effects or equipment malfunction:** |
| **Patient safety data monitoring: procedure & methods**  . |
| **Does anyone involved in the trial have a conflict of interest (business/financial/relationship) regarding the product?**  . |
| **Is evaluation site receiving anything, from the manufacturer/vendor, in return for the field trial?** |
| **Signatures:**    Primary investigator for the EMS Agency (author of proposal) Date    Chief, EMS Agency conducting the trial Date    Chair, NWC EMSS R&D Committee Date    NWC EMSS Liaison to R&D Committee Date   |  |  |  | | --- | --- | --- | | * Approve | * Approve Field Trial | * Reject (rationale) |   If approved: Go-live date:  Comments:    NWC EMSS EMS Medical Director Date |

CJM 11/16