

Internal Wear Study Protocol Checklist

Medical Wearable Adhesives



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Step 1: Define Wear Study Objectives

- ☐ Establish measurable goals for wear time, device functionality, and adhesion performance
- ☐ Identify key performance indicators aligned with product requirements and user needs
- ☐ Document target outcomes, success criteria, and acceptable performance ranges
- ☐ Define specific parameters to be measured throughout the study duration

Step 2: Design Wear Study Protocol

- ☐ Define participant demographics ensuring relevant representation across age, skin types, and activity levels
- ☐ Specify anatomical application areas, environmental conditions, and activity restrictions
- ☐ Establish detailed data collection methodology following ISO 16269-6 guidelines
- ☐ Design a statistical analysis framework for quantitative and qualitative data

Step 3: Develop Study Materials

- ☐ Generate identifiable test samples with comprehensive tracking system and batch documentation
- ☐ Create informed consent documentation explaining risks, benefits, and participant responsibilities
- ☐ Develop illustrated application and removal instructions with step-by-step guidance
- ☐ Design study diary including comfort assessment, adhesion tracking, and environmental exposure

Step 4: Train Internal Study Team

- ☐ Conduct protocol implementation training including theoretical and practical sessions
- ☐ Demonstrate and validate consistent application techniques across team members
- ☐ Train on data collection methods, measurement tools, and documentation standards
- ☐ Establish clear roles, responsibilities, and communication channels
- ☐ Review emergency procedures and adverse event reporting protocols

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Step 5: Participant Onboarding

- ☐ Conduct briefing sessions covering study objectives, timeline, and expectations
- ☐ Document baseline measurements including skin condition and relevant health factors
- ☐ Provide hands-on training for device application, removal, and maintenance
- ☐ Review diary completion requirements and demonstrate proper documentation techniques
- ☐ Obtain consent and provide emergency contact information

Step 6: Conduct Internal Wear Study

- ☐ Monitor participant compliance through regular check-ins and diary review
- ☐ Maintain consistent communication schedule for updates and support
- ☐ Document all adverse events, protocol deviations, and participant feedback
- ☐ Collect and verify wear study diary entries for completeness and accuracy
- ☐ Implement systematic remote data collection procedures

Step 7: Data Collection & Assessment

- ☐ Implement standardized assessment
- ☐ Document and categorize all participant feedback and observations
- ☐ Verify data completeness and initiate quality control checks

Step 8: Analysis & Reporting

- ☐ Perform statistical analysis of quantitative and qualitative data
- ☐ Evaluate results against predefined study objectives and success criteria
- ☐ Document detailed findings, trends, and unexpected observations
- ☐ Compile recommendations for product improvements and protocol refinements
- ☐ Prepare detailed final report with supporting evidence and statistical analysis

Note: This checklist should be used in conjunction with your organization's standard operating procedures and relevant regulatory requirements.

Document Version: 1.0

Last Updated: June 2025

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