

Office of Research Integrity Small Organization Statement for Handling Allegations of Research Misconduct Involving Public Health Services Research and Related Activities

Berkshire Biomedical Corporation has incorporated into its policies and procedures the following approach for handling and reporting possible research misconduct and agrees to comply with other provisions of 42 C.F.R. Part 93:

- 1. Upon becoming aware of an allegation or other evidence of possible research misconduct, the designated misconduct policy and procedures official of Berkshire Biomedical Corporation will immediately contact the Office of Research Integrity (ORI) at (240) 453-8400, and Berkshire Biomedical Corporation will submit an annual report to ORI.
- 2. Berkshire Biomedical Corporation will work with ORI or other appropriate offices of the Department of Health and Human Services (HHS) to develop and implement a process consistent with the regulation at 42 C.F.R. Part 93 to fully explore the allegation or evidence of misconduct involving PHS support research or research activities. This may entail ORI/HHS taking primary responsibility for conducting the inquiry and/or investigation.
- 3. Berkshire Biomedical Corporation will cooperate fully with the ORI/HHS in conducting its oversight and review of possible research misconduct involving PHS supported research or research activities.
- 4. Berkshire Biomedical Corporation will inform its employees of their option to report any allegation or evidence of research misconduct directly to ORI rather than to Berkshire Biomedical Corporation's designated misconduct policies and procedures official.
- 5. Berkshire Biomedical Corporation has one employee and three appointed officers of whom are involved in PHS research or research activities as defined in 42 C.F.R. Part 93.

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Institutional Official's Name: John Timberlake

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Institutional Official's Title: President & Chief Executive Officer

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