

**Details of the Project sanctioned under the Human Resource Development scheme of  
Department of Health Research**

**1. Project Title:** Optimization & assessment of predictive utility of zebrafish embryo genotoxicity test – a promising alternative test

**2. Category of fellowship:** Start-up project Grant under HRD scheme of DHR

**3. PI (Name & Address):** Dr.Banappa S Unger  
Present Address: Dr.Banappa S Unger, Scientist 'D' Regional Medical Research Centre (ICMR), Belagavi-590010, Karnataka, India.

**4. Qualifications:** M.Pharm(Pharmacology), Ph.D (Pharmacology)

**5. Mentor or Co.PI (Name & Address):** Dr.Geeta R Vanage,  
Dr.Geeta R Vanage, Scientist F, National Center for Preclinical Reproductive and Genetic Toxicology, National Institute for Research in Reproductive Health (NIRRH), Jehangir Merwanji Street, Parel, Mumbai-400 012

**6. Duration of the project:** Two years

**7. Broad area of Research:** Toxicology

**7.1 Sub Area:** Genotoxicity

**8. Summary of the Project:**

Genotoxicity assessment of pharmaceuticals is mandatory element of preclinical safety testing & comprises of a battery of complementary tests. One of in-vitro test in test battery "Ames test", although efficiently detects genotoxic mutagens, owing to prokaryotic system may miss some genotoxins. Hence, to complement mammalian cell based assays are employed. However, most of these in-vitro mammalian cell based assays are found to generate exaggerated false positive results, necessitating testing in animals which is expensive, time-consuming and associated with serious ethical issues. In this context there is an urgent need for alternative sensitive method to detect potential genotoxins with a low false positive rate. The zebrafish embryo test is emerging as a promising whole organism, short term, simple and cost efficient alternative in-vitro test for toxicology. Hence, the present study is aimed to optimize zebrafish embryo genotoxicity test as an alternative to the mammalian cell based in vitro genotoxicity tests & evaluate its predictive potential.

**9. Objectives of the Proposal:**

1. To optimize the zebrafish embryo micronucleus test & comet assay
2. To evaluate the predictive potential of zebrafish embryo micronucleus test & comet assay as an alternative to the mammalian cell based in-vitro genotoxicity tests

**10. Innovations in the project :**

Development, optimization & investigation of the specificity & sensitivity of zebrafish embryo genotoxicity test for its predictive utility.

**11. Significance of the outcome of the project :**

Development of optimized, whole organism based, simple and cost efficient alternative predictive genotoxicity test will help to identify potential risk of chemical or drug candidate. It may also facilitate reduction of animal use & translation potential preclinical testing in drug discovery & development.

**12. Relevance in Public Health:**

The outcome of study may greatly enhance our ability to predict potential risk and improving the drug discovery & development which in turn will have an impact on the protection of human health

A handwritten signature in blue ink, appearing to read 'Banalla', is written over a faint, illegible stamp.

**Signature of the Fellow /Faculty**