<u>Details of the Project sanctioned under the Human Resource Development scheme of</u> <u>Department of Health Research</u>

1. Project Title: Development of an aptamer based detection system for *Neisseria* gonorrhoeae

2. Category of fellowship: Women Scientist

3. PI (Name & Address): Dr. Shilpi Malhotra, 1361, Laxmi Bai Nagar, New Delhi-110023

4. Qualifications: Ph.D (Biochemistry)

5. Mentor or Co.PI (Name & Address): Dr Seema Sood, Professor, Department of Microbiology, AIIMS, New Delhi-110023

6. Duration of the project: 3 years

7. Broad area of Research: Biotechnology

7.1 Sub Area: Biosensors

8. Summary of the Project: (Give in about 300 words)

Gonorrhoea is one of the oldest known bacterial sexually transmitted infections (STIs) that continue to cause a significant morbidity among the sexually active individuals. A total of 106 million infections are estimated to occur each year globally attesting to its public health importance. A number of techniques have been developed for detection of urogenital infections caused by N. gonorrhoeae. Because of the fastidious nature of the causative pathogen and the difficulties associated with its cultivation, it has been proposed that nucleic acid based assays hold greater promise for diagnostic purposes. Various techniques have been evaluated for detection of N. gonorrhoeae. These include the conventional PCR, more rapid and sensitive real-time PCR, strand displacement assay and the transcription mediated amplification. However, all these methods have an intrinsic disadvantage of requiring highprecision instrumentation and no possibility of miniaturization. Aptamers are the new molecular recognition elements that hold great potential in development of detection systems. Aptamers are ssDNA or RNA molecules (40-80 nucleotides) selected from large combinatorial nucleic acid libraries with high affinity to their target. Like antibodies, aptamers have high affinity and specificity to target molecules. Aptamers provide additional benefit, like easy storage at ambient temperature, increased robustness against reducing

conditions and easy synthesis by chemical methods. Aptamers are generated through an iterative cycles of selection-amplification and the process is known as systematic evolution of

ligands by exponential enrichment (SELEX). Keeping the above in mind, the present proposal is aimed to select, characterize and evaluate the aptamers for rapid, sensitive and accurate detection of *N. gonorrhoeae*.

Firstly, aptamers specific to *N. gonorrhoeae* will be selected by the process of cell-SELEX. Then, the aptamers so selected will be characterized to determine their binding affinity and specificity. The aptamers found to possess high affinity would be put to use in development of a point of care test for *N. gonorrhoeae* using lateral flow method or electrochemical sensor.

9. Objectives of the Proposal:

- i) Selection of aptamer(s) specific for *Neisseria gonorrhoeae* by Cell-SELEX
- ii) Characterization of the selected aptamer(s)
- iii) Determination of specificity and sensitivity of selected aptamer(s)
- iv) Application of lateral flow/biosensor platform for detection of *Neisseria gonorrhoeae* using selected aptamer(s)

10. Innovations in the project: (Give in about 100 words)

Quick tests with high sensitivity for diagnosis of *Neisseria gonorrhoeae* are not available. This project aims to develop the same for the detection of *Neisseria gonorrhoeae* utilising aptamers selected for the purpose by process of cell-SELEX.

11. Significance of the outcome of the project: (Give in about 150 words)

There are no quick and reliable tests available for diagnosis of *Neisseria gonorrhoeae* infections. The test existing so far are either time consuming or require extensive laboratory set up. So, World Health Organization (WHO) recommends the use of syndromic approach for the management of STIs. This approach is based on prescribing therapies based on the symptoms of the patients. This leads to excessive use of antibiotics for the treatment of such infections. Further, the stigma, privacy, and confidentiality issues associated with STIs emphasize the need for development of an affordable point-of-care (POC) or near POC diagnostics for these infections. So, in this study we aim to develop a quick test for the detection of *Neisseria gonorrhoeae* employing aptamers which may help in accurate diagnosis of *Neisseria gonorrhoeae* infections and thus combat excessive use of antibiotics and prevent the sequelae associated with this infection.

12. Relevance in Public Health:

As per WHO estimates, 106 million gonococcal infections occur each year globally, attesting to its public health importance. Approximately 50-80% of infections in women and 10% in men are asymptomatic thereby leading to significant ramifications to reproductive, maternal and newborn health including increase in transmission of HIV, infertility, ectopic pregnancies, abortions, neonatal eye infections. It is pertinent to

mention that the vaccine development for gonorrhea is a distant goal and control relies largely on timely and accurate diagnosis and appropriate treatment.

The resource-rich settings are relying on nucleic acid amplification tests (NAATs) for diagnosis while resource limited setting like ours on syndromic approach. In view of the limitations of each, there is very urgent need for the development of a point of care test to provide guidance as to presence or absence of infection at initial presentation. This in turn will reduce widespread and empirical administration of broad spectrum antibiotics. We propose to use aptamers to develop a point of care test for detection of *N. gonorrhoeae*.

Signature of the Fellow /Faculty