INFECTIOUS DISEASES AND MICROBIOLOGY (IDM) Integrated Review Group (IRG) Proposed Guidelines and Shared Interests for New Study Sections

The Infectious Diseases and Microbiology Integrated Review Group (IDM IRG) will consider applications involving the basic biology of microbes (excluding HIV), multicellular parasites, their vectors, and the infections and diseases caused by many of these agents. Principally the IDM IRG reviews research grant applications concerning virology and viral pathogenesis, bacteriology and bacterial pathogenesis, mycology and fungal pathogenesis, parasitology and parasitic diseases, the innate and adaptive host responses to these microbes, and the development of anti-infective agents and vaccines to treat and prevent infectious disease.

The following study sections are included within the IDM IRG:

- Microbial Cell and Molecular Biology (MCMB)
- Bacterial Pathogenesis (BP)
- Pathogenic Eukaryotes (PE)
- Basic Virology (BV)
- Viral Pathogenesis (VP)
- Clinical Research and Epidemiology of Infectious Diseases (CRE)
- Drug Discovery and Mechanisms of Antimicrobial Resistance (DDR)
- Vaccine Development and Immunology of Infectious Diseases (VDI)
- Vector Biology (VB) Special Emphasis Panel (SEP)

Special Remarks

The IDM Study Section Boundaries Team discussed and developed positions on a number of crosscutting issues.

The biochemistry and molecular biology of bacterial cells. The review of research on basic bacterial gene function, metabolism, and cell processes should be retained within the IDM IRG. Improved understanding of these basic life processes in diverse bacteria, which are logical targets for antimicrobials, are best evaluated by considering pathogenic and model systems side-by-side. Further, our understanding of mechanisms of bacterial pathogenesis is increasingly derived from analyses of orthologous systems in model prokaryotes. Finally, bacterial applications are seriously disadvantaged when evaluated as a minority component in review groups dealing mostly with eukaryotic applications.

<u>Host-pathogen relationships</u>. The primary function of the immune system is to defend the host against infection. The evaluation of the immune response to infectious disease and the development of safe and effective vaccines require the integration of contemporary immunological science with a detailed knowledge of the complexity and diversity of pathogenic and infectious disease processes. As such, applications that deal with the immune response to infectious agents should be assigned for review to IDM study sections.

<u>Carcinogenesis</u> and infectious causes of disease. Because of the complex relationships between the virus life cycle and viral oncogenesis, applications dealing with viral carcinogenesis should be reviewed within the IDM IRG. In contrast, applications dealing with cellular factors and mechanisms in transformation, including oncogenes, should be reviewed within the ONC IRG. This principle should also apply to other infectious causes of malignancy and chronic disease.

Review home for applications on pathogens and pathogenic mechanisms. If the focus of a grant application is a pathogen or a pathogenic mechanism, assignment for review should be to an IDM study section.

1. MICROBIAL CELL AND MOLECULAR BIOLOGY (MCMB) STUDY SECTION

The Microbial Cell and Molecular Biology study section reviews applications addressing the genetics, structure, physiology and behavior of microbes, primarily of bacteria, archaea and their phages. Proposals can include studies of model organisms and pathogens at the genetic, molecular, biochemical, cellular, and community levels.

Subject areas of MCMB include:

- Genome organization and dynamics
- Mobile genetic elements and gene transfer
- Replication, recombination, mutation, and repair
- Transcription and RNA processing
- Gene expression and regulation
- · Protein synthesis and processing
- Export, secretion, trafficking, and localization
- Supramolecular structures and their function and assembly
- Morphogenesis and cell division
- Regulatory networks and dynamics
- Computational modeling of cell processes
- Intercellular signaling and other cell-cell interactions
- Environmental interactions and symbiosis
- Intermediary metabolism and energetics
- Development and differentiation
- Stress responses, survival, and death
- Chemotaxis and motility
- Functional genomics and proteomics

Shared interests within IDM:

- Bacterial Pathogenesis (BP): If the studies are directed principally at understanding the biology of pathogenicity, the assignment should be to BP. If studies are directed principally at basic mechanisms in the bacteria themselves, including pathogenic bacteria, they should be assigned to MCMB.
- Drug Discovery and Mechanisms of Antimicrobial Resistance (DDR): If applications are focused on
 particular microbial molecular targets for the purpose of discovering new antibiotics or microbicides,
 or to understand resistance mechanisms, review should be by DDR. If applications involve potential
 antimicrobial targets, but do not focus on identification of novel compounds, they should be
 assigned to MCMB.
- Vaccine Development and Immunology of Infectious Diseases (VDI): If focus of an application is on immune responses to pathogens and the development of vaccines, then review should be by VDI. Applications limited to definition of protein sequence and structure should be assigned to MCMB, BV, or other IDM study sections.
- Vector Biology (VB) SEP: If the emphasis is on the vector, the proposal should be assigned to VB.
 If the emphasis is on the microbe, the proposal should be assign to MCMB or another appropriate IDM study section.

Shared Interests outside IDM:

- IRG 1 (Biological Chemistry & Macromolecular Biophysics): If the emphasis is on understanding a
 general mode of action (an enzyme molecule, for example), assignment should be assigned to IRG
 If the emphasis is on understanding the molecule in the context of the microbial cell, assignment
 should be to MCMB.
- IRG 2 (Molecular Approaches to Gene Function) and 3 (Molecular Approaches to Cell Function and Interactions): Fundamental genetic studies of prokaryotes (bacteria, archaea, or their phages) should be assigned to MCMB.

- IRG 4 (Fundamental Genetics & Population Biology): Studies on the fundamental genetics and
 population biology of host cells without reference to permissiveness or resistance to infection or the
 pathology of infection should be assigned to IRG 4. Studies using evolutionary relationships for
 gene discovery or to understand microbial function should be assigned to MCMB. Studies dealing
 with functional genomics should go to MCMB, whereas those focused on sequencing and sequence
 data collection should go to IRG 4.
- IRG 6 (Bioengineering Sciences & Technologies): Studies that employ computational modeling and simulation to understand complex processes such as metabolism and gene circuitry in bacteria and archaea should be assigned to MCMB. Studies targeted at the development of models and simulations for process design should be assigned to IRG 6.

2. BACTERIAL PATHOGENESIS (BP) STUDY SECTION

The bacterial pathogenesis study section reviews proposals focused on mechanisms of bacterial commensalism, infection, and disease.

Subject areas of BP include:

- Genetic and biochemical characterization of determinants of pathogenicity, including capsules, toxins, bacterial immunomodulators and other effector molecules, and supramolecular structures
- Genetic and biochemical mechanisms of virulence regulation
- Molecular basis for bacteria-host interactions (including adherence to and invasion of host cells, intracellular replication, and intercellular spread)
- Interplay between bacteria and host cell components and processes
- Subversion and manipulation of normal host cell processes
- Genetics and physiology of in vivo survival and growth
- Multiplication and dissemination in host tissues
- Manipulation and evasion of innate and adaptive immune responses
- Mechanisms of asymptomatic colonization (including the balance between infection and disease, also commensalism and pathogenicity)
- The composition of the indigenous microbiota and its role in health and disease
- The role of bacterial behavior and developmental processes in the host pathogen interaction, including biofilms, chemotaxis, sporulation, and stress responses
- The role of infectious agents in noninfectious diseases
- Mechanisms of persistence and transmission
- Ecology of bacterial pathogens
- Animal models of infection and disease (including host genetic determinants of susceptibility and resistance and surrogate hosts)
- Exploration of small molecules and drugs as modulators of virulence regulators and determinants
- Genetic and phylogenetic analyses of pathogen evolution (including horizontal gene transfer, genomic plasticity and comparative genomics)
- Functional genomic and proteomic approaches to understanding pathogenesis

Shared interests within IDM:

- Microbial Cell and Molecular Biology (MCMB): If studies are directed principally at basic
 mechanisms in the bacteria themselves, including in pathogenic bacteria, they should be assigned
 to MCMB. If the studies are directed principally at understanding the biology of pathogenicity, the
 assignment should be to BP.
- Drug Discovery and Mechanisms of Antimicrobial Resistance (DDR): Applications on target identification, characterization, and validation would be considered in the DDR study section if the primary focus is the antimicrobial agent rather than the target. Studies that include antimicrobial target identification and validation as a specific aim would be more properly reviewed in BP.

- Vaccine Development and Immunology of Infectious Diseases (VDI): Applications that focus on mechanisms of innate or adaptive immunity against microbes should be reviewed by VDI. BP will review applications that include immune responses to pathogens when the emphasis is on virulence determinants that manipulate host responses or the evasion of host immunity.
- Clinical Research and Epidemiology of Infectious Diseases (CRE): Applications on bacterial diseases in human populations or on field-based settings will be reviewed by CRE. Laboratory and model-based studies would be assigned to BP.

Shared interests outside of the IDM IRG:

- IRG 4 (Fundamental Genetics & Population Biology): Studies on the fundamental genetics and population biology of host cells without reference to permissiveness or resistance to infection or the pathology of infection should be assigned to IRG 4. Studies using evolutionary genetic relationships to understand bacterial pathogenesis should be assigned to BP.
- IRGs 15, 16, 17, 18, 19, 20, 24 (Cardiovascular Sciences, Endocrinology, Metabolism, Nutrition, & Reproductive Sciences, Musculoskeletal, Oral, & Skin Sciences, Digestive Sciences, Pulmonary Sciences, Renal & Urological Sciences, and Brain Disorders & Clinical Neuroscience): Although some applications involving bacterial infectious diseases may be appropriately reviewed by study sections focused on specific organ systems, applications focusing on the pathogen should be reviewed by BP.
- IRG 10 (Immunology): Applications that focus on basic immunological processes should be assigned to IRG 10. If the focus is host-bacterial interactions, assignment to BP would be appropriate.
- IRG 12 (AIDS & Related Research): Fundamental studies of the molecular and cellular biology and biochemistry of bacterial pathogens should be reviewed in BP unless conducted in the context of HIV infection.
- IRG 17 (Musculoskeletal, Oral, & Skin Sciences): Oral microbiology applications may be reviewed in IRG 17; however, BP should review applications involving bacteria that colonize the oral cavity when the emphasis is on mechanisms of pathogenesis and/or colonization.
- IRG 21 (Surgical Sciences, Biomedical Imaging, & Bioengineering): While surgery applications should be reviewed by IRG 21, applications on bacterial pathogens causing disease in surgical patients should be reviewed by BP when the focus is the pathogen.

3. PATHOGENIC EUKARYOTES (PE) STUDY SECTION

The Pathogenic Eukaryotes study section reviews applications involving protozoal, helminthic, and fungal pathogens of humans, and relevant animal models.

Subject areas of PE include:

- Basic mechanisms of pathogenesis, including pathogen-host cell receptor interactions, signaling
 pathways in both host cell and pathogen, molecular mechanisms of virulence, manipulation of host
 cell biological pathways, and factors associated with asymptomatic infection and/or commensalisms
- Primary host defenses, including genetic basis of host resistance and susceptibility to infection and disease, induction and regulation of innate and acquired immunity, evasion of host immune response
- Biochemical processes of the pathogen, including metabolism, enzymology, physiology, and replication
- Identification and preclinical validation of potential chemotherapeutic targets and diagnostic strategies
- Pathogen cell biology, including novel organelles, secretory processes, and mechanisms of motility
- Pathogen differentiation, morphogenesis, and developmental processes required for the infectious cycle, including transmission and persistence

- Genetic processes, including gene structure, regulation of gene expression, molecular evolution, genetic diversity, and improved genetic methodology
- Functional genomics, comparative genomics, proteomics, and other broad-based technologies for studying genomes
- Improved models of infectious cycles and diseases

Shared interests within IDM:

- Clinical Research and Epidemiology of Infectious Diseases (CRE): Applications on protozoal, helminthic and fungal diseases in human populations or in field-based settings should be reviewed by CRE. Laboratory and model-based studies would be assigned to PE.
- Drug Discovery and Mechanisms of Antimicrobial Resistance (DDR): Applications on design and validation of potential chemotherapeutic agents for protozoal, helminthic, and fungal infections should be reviewed in DDR. Studies where the primary focus is on identification and validation of processes and pathways that may serve as chemotherapeutic targets should be reviewed by PE.
- Vaccine Development and Immunology of Infectious Diseases (VDI): Applications on mechanisms
 of innate or adaptive immunity as they relate to vaccine design for protozoal, helminthic and fungal
 infections should be reviewed by VDI. PE will review proposals that focus on mechanisms whereby
 pathogens manipulate or modulate host immune responses when emphasis is on the pathogen.
- Vector Biology (VB) SEP: If the focus of an application is a relevant pathogen, assignment should be to PE. If the focus is the host vector, then review should be by VB.

Shared interests outside IDM:

- IRG 1, IRG 2, IRG 3, IRG 4 (Biological Chemistry & Macromolecular Biophysics, Molecular Approaches to Gene Function, Molecular Approaches to Cell Function and Interactions, and Fundamental Genetics & Population Biology): Fundamental studies of model organisms, such as Saccharomyces cerevisae, Schizosaccharomyces pombe, Neurospora, Tetrahymena, and Chlamydomonas, in nonpathogenic settings, should typically be reviewed by the appropriate basic science study sections.
- IRG 10 (Immunology): Basic studies on immunologic processes should be reviewed in IRG 10.
 Applications involving research on parasitic or fungal pathogens that manipulate or modulate immune responses, with emphasis on the pathogen, should be reviewed by PE.
- IRG 12 (AIDS & Related Research): Fundamental studies of the molecular and cellular biology and biochemistry of parasitic and fungal pathogens should be reviewed in PE unless conducted in the context of HIV infection.

4. BASIC VIROLOGY (BV) STUDY SECTION

The Basic Virology study section addresses fundamental aspects of viral structure, genetics, infection and replication.

Subject areas of BV include:

- Viruses, subviral agents, prions, and their infections in humans, animals, simple eukaryotes, and plants (with the exception of HIV and bacteriophages)
- Cellular and molecular biology of viral replication, including the roles and interactions of viral and host cell components, in areas such as:
 - Virus attachment to cells, entry, trafficking and uncoating
 - Gene expression and regulation (including structure, synthesis, processing and modification of RNA transcripts, proteins, and other viral macromolecules)
 - Viral genome replication (including nucleic acid synthesis, transport, and integration)
 - Virion and subviral particle assembly, trafficking, maturation, and egress

- Virus effects on host signal transduction, host gene expression, and cellular physiology
- Reconstitution and study of virus infection processes in cell-free systems
- Biochemical and biophysical properties of virions, sub-viral particles and other viral assemblies such as intracellular replication factories, integration complexes, etc
- Viral variation, evolution and their mechanisms, including mutation and recombination (intra-virus, inter-virus and virus-host)
- Virus co-infection effects (including cooperative, dependent, competitive and interfering interactions)
- Factors influencing host cell permissivity or resistance, including host genetics, cell differentiation state, and cell culture conditions
- Viral gene delivery and expression vectors

Shared interests within IDM:

- Viral Pathogenesis: Assignment should be to VP if the primary focus is on interactions of a virus with
 the host at the organismal, tissue or multi-cellular level. Assignment should also be to VP if the
 focus is on cell transformation. If the primary focus of an application is on interactions of a virus with
 the host cell at the single cell or subcellular level, assignment should be to BV, unless such
 interactions lead to alteration of host cells relevant to disease, whereupon assignment should be to
 VP. If the application deals with viral gene(s) implicated in oncogenesis with a primary focus on the
 role of the gene(s) in basic virus replication, the assignment should be to BV.
- Drug Discovery and Mechanisms of Antimicrobial Resistance (DDR): If the primary focus of an
 application is drug development or resistance, assignment should be to DDR. If the primary focus is
 the identification of an antiviral drug target or use of a drug to study basic mechanisms of virus
 infection, assignment should be to BV.

Shared interests outside IDM:

- IRG 1 (Biological Chemistry and Macromolecular Biophysics): If the emphasis of an application is on studying a macromolecule solely for the sake of its basic chemistry or physics with no consideration of relevance to infection, assignment typically should be to IRG1. If the emphasis is on studying the structure, chemistry, or physics of a molecule to better understand its relation to viral infection, it should be assigned to BV.
- IRG 2 and IRG 3 (Molecular Approaches to Gene Function and Molecular Approaches to Cell Function and Interactions): Where a virus, viral gene or virus component is used as a tool or a general example to study a cell process, with no consideration of relevance to infection, assignment typically should be to IRG 2 or IRG 3. Where viral genetics or cell biology is studied in relation to virus infection, assignment should be to BV.
- IRG 4 (Fundamental Genetics & Population Biology): Applications dealing with the genomics, genetics and population dynamics of viruses, or similar studies of host cells in relation to permissivity for or resistance to virus infection should be assigned to BV. Studies on the fundamental genetics and population biology of host cells without reference to permissiveness or resistance to infection or the pathology of infection should be assigned to IRG 4.
- IRG 6 (Bioengineering Sciences & Technologies): Applications using existing viral gene delivery and expression vectors for other applied purposes should be assigned to IRG 6 or, as appropriate according to the emphasis of the application, to another relevant disease- or organ-specific IRG. Applications to design, construct and test new virus gene delivery and expression vectors for the purpose of advancing understanding of infection processes typically should be assigned to BV. Also, applications that apply quantitative modeling and simulation to understand virus infection processes should be assigned to BV.
- IRG 12 (AIDS and Related Research): Applications dealing with the replication of viruses that are
 involved in AIDS-related opportunistic infections should be assigned to IRG 12 if they are dealing
 with an AIDS-related infection, but to BV if the infection is not being studied in the context of AIDS
 and HIV.

• IRG 13 (Oncological Sciences): Applications on cellular oncogenes (e.g., cSrc, cAbl, cJun) and translocations involving cellular oncogenes should be reviewed by IRG 13. Applications involving the roles of viral oncogenes in basic virus replication should be assigned to BV. Studies involving oncogenesis as a consequence of viral infection should be reviewed by VP.

5. VIRAL PATHOGENESIS (VP) STUDY SECTION

The Viral Pathogenesis study section reviews applications involving cellular and host responses to viral and prion infections and mechanisms of disease pathogenesis in plants, animals and humans.

Subject areas of VP include:

- Viral-host cell interactions:
 - -Cellular responses to viral infection (including interferon induction, apoptosis and cytopathology)
 - -Virus effects on cellular production of cytokines and chemokines
 - -Effects on cell growth and division
 - -Effects on DNA synthesis and repair
 - -Effects on RNA synthesis, stability, processing and transport
 - -Effects on protein synthesis, modification and stability
- Interference and enhancement of virus infection and cellular control of virus replication (including the effects of interferon and other cellular inhibitory responses such as RNAi)
- Transformation and oncogenesis:
 - -Detection of tumor viruses
 - -Viral interactions with oncogenes and tumor suppressors
 - -Dysregulation of cell growth and cell death by viral products
 - -Animal models of viral carcinogenesis
- Identification of new molecular targets relevant to viral pathogenesis:
 - -Genomics, proteomics
 - -Development of new approaches for identifying cellular changes relevant to pathogenic mechanisms
- Viral determinants of disease:
 - -Virus diversity within a host
 - -Virulence and attenuation
 - -Transmission
 - -Teratogenicity
 - -Spread within the host
 - -Tissue and cell tropism
 - -Mechanisms of tissue injury
 - -Viral mechanisms of immune evasion, including viral proteins that modify host responses
 - -Animal models of disease pathogenesis
- Host response to virus infection:
 - -Genetic and acquired determinants of host susceptibility
 - -Hormonal effects
 - -Mechanisms of viral clearance
 - -Establishment of latency and persistence
 - -Inflammation
 - -Animal models of host responses.
- Viral etiology of chronic disease:

- -Identification and detection of viruses associated with chronic disease
- -Validation of etiologic relationships
- -Animal models of virus-induced chronic disease

Shared interests within IDM:

- Basic Virology (BV): If the focus of the application is on the structure or assembly of the virus or on
 the processes of virus infection, replication, expression and maturation, or on host factors and
 responses related to these processes, review should be by BV. If the primary focus is on
 interactions that lead to alterations of host cells relevant to disease or interactions at the organismal
 or tissue level assignment should be to VP. If the primary focus of the application is on the role of
 an oncogene in basic viral replication then assignment should be to BV and if the emphasis is on
 cellular transformation the assignment should be to VP.
- Clinical Research and Epidemiology of Infectious Diseases (CRE): Laboratory and model-based viral studies should be assigned to VP. Applications on viral diseases in human populations or fieldbased settings should be reviewed by CRE.
- Drug Discovery and Mechanisms of Antimicrobial Resistance (DDR): If the primary focus of an
 application is the development of an antiviral drug or preclinical testing of an antiviral drug review
 should be by DDR. If the primary focus is target identification, review should be by VP.
- Vaccine Development and Immunology of Infectious Diseases (VDI): If the focus of the application is
 on the host immune response to infection or on the development of a vaccine to prevent infection,
 the application should be assigned to VDI. Applications focusing on viral induction of interferon,
 chemokines, and cytokines or viral proteins that modulate host immune responses should be
 assigned to VP.
- Vector Biology (VB) SEP: If the focus of an application is the pathogen, assignment should be to VP. If the focus is the host vector, then review should be by VB.

Shared interests outside IDM:

- IRG 4 (Fundamental Genetics and Population Biology): Applications focusing on genetic
 determinants of susceptibility and resistance of cells or hosts to viral infection should be reviewed by
 VP. Studies on the fundamental genetics and population biology of host cells without reference to
 permissiveness or resistance to infection or the pathology of infection should be assigned to IRG 4.
- IRG 10 (Immunology): Applications focusing on viral induction of interferon, chemokines, and cytokines or viral proteins that modulate host immune responses should be assigned to VP.
- IRG 12 (AIDS and Related Research): Applications dealing with the pathogenesis of viruses that are
 involved in AIDS-related opportunistic infections should be assigned to VP if studied in the absence
 of HIV, or to AARR if dealing with AIDS-related infection.
- IRGs 13 and 14 (Oncological Sciences and Hematology): Applications on cellular oncogenes (e.g., cSrc, cAbl, cJun) and translocations involving cellular oncogenes should be reviewed by IRGs 13 and 14. Studies involving oncogenesis as a consequence of viral infection should be reviewed by VP.
- IRGs 14, 15, 16, 17, 18, 19, 20, 24 (Hematology, Cardiovascular Sciences, Endocrinology, Metabolism, Nutrition, & Reproductive Sciences, Musculoskeletal, Oral, & Skin Sciences, Digestive Sciences, Pulmonary Sciences, and Renal & Urological Sciences): Viral infections of specific organs or tissues should be reviewed by VP when the focus of the application is on the pathogen or pathogenic mechanisms.

6. CLINICAL RESEARCH AND EPIDEMIOLOGY OF INFECTIOUS DISEASES (CRE) STUDY SECTION

The Clinical Research and Epidemiology of Infectious Diseases study section reviews applications that address population based studies on the emergence, spread, control, and prevention of the infectious diseases of humans.

Subject areas of CRE include:

- Design and execution of investigator-initiated clinical trials for testing agents or strategies for preventing and treating infectious diseases
- Identification of factors involved in the pathogenesis, emergence and spread of infectious diseases, including studies of vectors and the contribution of environmental and societal influences.
- Field studies of strategies to control the transmission of infectious diseases by invertebrate vectors or reservoir hosts
- Diagnostic studies for the detection, identification, and surveillance of infectious diseases
- Molecular epidemiology of infectious diseases, including genetic characterization of both the pathogen and the host
- Studies that address the potential infectious etiology of human disease (e.g., Helicobacter pylori as the etiology of gastric carcinoma)

Shared interests within IDM:

- Bacterial Pathogenesis (BP): Laboratory and model-based studies should be assigned to BP.
 Applications on bacterial diseases in human populations or on field-based settings should be reviewed by CRE.
- Pathogenic Eukaryotes (PE): Applications focused on laboratory and model-based studies should be assigned to PE. Applications on protozoal, helminthic and fungal diseases in human populations or field-based settings should be reviewed by CRE.
- Viral Pathogenesis (VP): Laboratory and model-based viral studies should be assigned to VP.
 Applications on viral diseases in human populations or field-based settings should be reviewed by CRE.
- Drug Discovery and Mechanisms of Antimicrobial Resistance (DDR): Applications that focus on the
 preclinical aspects of drug discovery and development only should be reviewed by DDR. CRE may
 consider proposals that devise clinical trials to test the efficacy of antimicrobial agents.
- Vaccine Development and Immunology of Infectious Diseases (VDI): Applications that focus on
 preclinical studies to develop and test the efficacy of vaccines should be reviewed by VDI. CRE may
 consider applications that devise clinical trials to test the efficacy of vaccines, assess populationbased studies of immune responses, and investigate the pathogenesis of infectious diseases in
 human populations.
- Vector Biology (VB) Special Emphasis Panel: If the study involves laboratory-based research, then
 the application should be assigned to VB. If the application concerns research on invertebrate
 vectors conducted in a field-based setting, such as ecology or pathogen transmission studies, then
 review should be by CRE.

Shared interests outside IDM:

- IRG 7 (Health of the Population): CRE should consider epidemiology applications if the principal focus is a microbe. Epidemiological studies with other foci should be assigned to IRG 7.
- IRG 10 (Immunology): CRE should consider immunology applications if the principal focus is a microbe.
- IRGs 15, 16, 17, 18, 19, 20, 24 (Cardiovascular Sciences, Endocrinology, Metabolism, Nutrition, & Reproductive Sciences, Musculoskeletal, Oral, & Skin Sciences, Digestive Sciences, Pulmonary Sciences, Renal & Urological Sciences, and Brain Disorders & Clinical Neuroscience): Although some applications involving infectious diseases may be appropriately reviewed by study sections focused on specific organ systems, clinical applications focusing on the pathogen should be reviewed by CRE. Examples may include studies of such heart diseases as endocarditis and of Helicobacter pylori-caused ulcers if the principal focus is the microbe.

7. DRUG DISCOVERY AND MECHANISMS OF ANTIMICROBIAL RESISTANCE (DDR) STUDY SECTION

The Drug Discovery and Mechanisms of Antimicrobial Resistance study section reviews applications that are concerned with the identification of novel antimicrobial agents for the prevention or treatment of infectious diseases and with the evolution, mechanisms, and transmission of resistance.

Subject areas of DDR include:

- Target identification, characterization and validation
- Assay development
- Development of novel screening methods
- Molecular characterization of inhibitors
- Studies of the mechanisms and regulation of antimicrobial resistance
- Epidemiology of the emergence, dissemination, and maintenance of resistance, including the identification of environmental reservoirs in the hospital and the community and molecular characterization of resistant pathogens
- Strategies for the prevention of antimicrobial resistance
- Structure-guided drug design
- Preclinical studies that involve animal models

Shared interests within IDM:

- Microbial Cell and Molecular Biology (MCMB): The biology of mobile genetic elements should be considered in MCMB or BP. Applications on mobile genetic elements would be considered in DDR if they specifically address antimicrobial resistance.
- Bacterial Pathogenesis (BP): Studies that include antimicrobial target identification and validation as
 a specific aim would be more properly reviewed in BP. Applications on target identification,
 characterization, and validation should be considered in the DDR study section if the primary focus
 is the antimicrobial agent rather than the target.
- Pathogenic Eukaryotes (PE): Studies that include antimicrobial target identification and validation as
 a specific aim should be reviewed in PE. Studies of target identification, characterization, and
 validation should be considered in the DDR Study Section if the primary focus of the proposal is on
 the antimicrobial agent, rather than the target.
- Basic Virology (BV): If the primary focus of an application is identification of an antiviral drug target
 or use of a drug to study basic mechanisms of virus infection, assignment should be to BV. If the
 primary focus is drug development or resistance, assignment should be to DDR.
- Viral Pathogenesis (VP): Studies that include antimicrobial target identification and validation as a specific aim should be reviewed in VP. Applications on target identification, characterization, and validation should be considered in the DDR Study Section if the primary focus of the proposal is on the antimicrobial agent rather than the target.
- Clinical Research and Epidemiology of Infectious Diseases (CRE): Applications that devise clinical
 trials to test the efficacy of antimicrobial agents should be assigned to CRE. Applications that focus
 on the preclinical aspects of drug discovery and development should be reviewed by DDR.

Shared interests outside IDM:

- IRG 1 (Biological Chemistry & Macromolecular Biophysics): Applications that are primarily concerned with chemical syntheses should be reviewed by IRG 1, while those determining structure-activity relationships could be reviewed by either DDR or IRG 1.
- IRGs 3 and 18 (Molecular Approaches to Cell Function & Interactions and Digestive Sciences):
 Applications concerned with the formulation and delivery of antiinfective agents would best be considered in IRGs handling pharmacology, while studies that involve pharmacokinetics and pharmacodynamics could also be reviewed by DDR.
- IRG 6 (Bioengineering Sciences and Technologies): Applications concerned with drug development or delivery in general should be assigned to IRG 6. Applications concerned with antimicrobial drug development and delivery could also be reviewed by DDR.

8. VACCINE DEVELOPMENT AND IMMUNOLOGY OF INFECTIOUS DISEASES (VDI) STUDY SECTION

The focus of this study section is on immune responses to pathogens and the development of safe and effective vaccines for pathogens other than HIV. An understanding of the complex biology of the pathogens as well as the interactions between pathogen and the host is critical to maximize the development of innovative strategies for preventing and treating infectious diseases.

Subject areas of VDI include:

- Characterization of the innate and acquired immune responses that mediate recovery from infectious diseases or induce immunopathology
- Identification of pathogen components responsible for eliciting protective or pathogenic immune responses
- Determination of T and B cell epitopes and the roles of T and B cells in protective immunity or pathogenic response to microbes
- Analysis of immune responses of mucosal and epithelial surfaces to commensal and pathogenic microbes
- Development of suitable in silico, in vitro, and in vivo methods to define the local and systemic responses to commensal and pathogenic microbes
- Development of suitable animal models for assessing vaccine-induced protection and other immunoprophylatic or immunotherapeutic approaches to prevent or treat infectious diseases
- Development of vaccines or other immunomodulators to prevent or treat chronic diseases due to or exacerbated by infectious agents
- Examination of immune responses to infectious diseases capable of inducing autoimmunity
- Modulation of immune responses to improve the safety and efficacy of vaccines
- Development of vaccine strategies to address antigenic changes in the infectious agent
- Identification of pathogen strategies for subversion and/or evasion of host immune mechanisms as they relate to persistent carriage and vaccine development
- · Design of surrogate biomarkers for protective immunity for use in clinical trials of vaccines
- Examination and development of genetically engineered microbes for optimizing the delivery of vaccines or immunomodulators
- Development of new and improved adjuvants and vaccines for key "at risk" populations (e.g., children, the elderly, and immunocompromised people)

Shared interests within IDM:

- Microbial Cell and Molecular Biology (MCMB) and Basic Virology (BV): Applications limited to
 definition of protein sequence and structure should be assigned to MCMB, BV, or other IDM study
 sections. If focus is on immune responses to pathogens and the development of vaccines, review
 should be by VDI.
- Bacterial Pathogenesis (BP), Pathogenic Eukaryotes (PE), and Viral Pathogenesis (VP):
 Applications dealing with interactions of the organism with host cell components or in which the
 emphasis is on virulence determinants of the organism but not to cells in the immunological system
 should be assigned to BP, PE, or VP. If the emphasis is on host defenses, immune responses, or
 immune evasion, assignment should be to VDI.
- Clinical Research and Epidemiology of Infectious Diseases (CRE): Applications that deal with clinical evaluation of vaccines should be assigned to CRE. Translational research focusing on human responses to organisms or their components and to vaccines should be assigned to the VDI.

Shared interests outside IDM:

 IRG 10 (Immunology): Applications that focus on basic immunological processes should be assigned to IMM. If the focus is on host defense and immune responses to infectious organisms, assignment should be to VDI.

- IRG 12 (AIDS & Related Research): Vaccine applications for diseases other than HIV should be assigned to VDI.
- IRGs 15, 16, 17, 18, 19, 20, 24 (Cardiovascular Sciences, Endocrinology, Metabolism, Nutrition, & Reproductive Sciences, Musculoskeletal, Oral, & Skin Sciences, Digestive Sciences, Pulmonary Sciences, Renal & Urological Sciences, and Brain Disorders & Clinical Neuroscience): Although some vaccine applications involving organs/diseases may be appropriately reviewed by study sections focused on specific organ systems, vaccine applications focusing on the pathogen should be reviewed by VDI.

VECTOR BIOLOGY (VB) SEP

<u>Philosophical statement</u>. The review of vector biology applications poses special challenges. Vector biology spans multiple pathogens and host systems, making its dispersal across multiple study sections an impossible task for achieving consistent, high quality reviews. A variety of alternatives for addressing the VB challenge were considered, and all were deemed to have serious flaws. A similar analysis led to the creation of the VB SEP. Thus, at the present time, the recommendation is to continue Vector Biology as a SEP. This status should be monitored periodically, and when warranted by growth, it should be converted to a chartered study section. Alternatively, should applications decrease or the field evolve in other ways, the SEP could be dissolved, and the applications reassigned.

The Vector Biology Special Emphasis Panel reviews applications on all aspects of arthropod and molluscan intermediate hosts of parasitic (e.g., nematode/helminth), viral, or bacterial pathogens and arthropod ectoparasites, including model systems where the intent is to yield information relevant to human diseases.

Subject areas of VB include:

- Basic biology, ecology and molecular biology of vectors of human pathogens
- Metabolism and physiology
- Development of novel laboratory approaches for arthropod maintenance
- Genetics, including population genetics
- Genomics, including comparative and functional genomics, and proteomics
- Improvements of genetic technology and its application in areas such as reducing vector capacity, including transgenic, selected gene silencing and knockout, and parasite transmission-blocking
- Host immune responses to arthropods
- Pharmacological aspects of arthropod salivary and other secretory products
- Development and laboratory-based testing of novel approaches to control vector and disease transmission
- Arthropod symbionts and introduction of genes encoding anti-microbial products
- Vector/host interactions
 - -Vector competence
 - -Pathogen impact on host fitness
 - -Laboratory-based studies of pathogen development and transmission
 - -Pathogen/vector interactions, including biochemical and genetic processes
 - -Vector immune responses to pathogen and surrogate vector systems
 - -Molecular basis of transmission interference (including identification of molecular and cellular targets)

Shared interest within IDM:

- Microbial Cell and Molecular Biology (MCMB): If the emphasis of an application is on the microbe, it should be assign to MCMB or another appropriate IDM study section. If the emphasis is on the vector, the proposal should be assigned to VB.
- Pathogenic Eukaryotes (PE): If the focus of an application is the pathogen, assignment should be to PE. If the focus is the host vector, then review should be by VB.

- Viral Pathogenesis (VP): If the focus of an application is the pathogen, assignment should be to VP. If the focus is the host vector, then review should be by VB.
- Clinical Research and Epidemiology of Infectious Diseases (CRE): If the application concerns
 research on invertebrate vectors conducted in a field-based setting, such as ecology or pathogen
 transmission studies, then review should be by CRE. If the study involves laboratory-based
 research, then the application should be assigned to VB.

Shared interests outside IDM:

- IRGs 2, 4, and 6 (Molecular Approaches to Gene Function, Fundamental Genetics & Population Biology, and Bioengineering Sciences & Technologies): Projects to sequence vector and vector-borne pathogen genomes should be reviewed outside IDM.
- IRGs 16 and 22 (Endocrinology, Metabolism, Nutrition, and Reproductive Sciences and Molecular, Cellular, and Developmental Neurosciences): Fundamental studies of arthropod or molluscan organisms that do not serve as vectors/intermediate hosts for parasites, where no attempt is made to translate findings to relevant vector system should be reviewed outside IDM, e.g., metabolism/endocrinology to IRG 16 and neurosciences to IRG 22.