

DREXEL UNIVERSITY AND DREXEL UNIVERSITY COLLEGE OF MEDICINE

Exhibit V-a

Classification of Human Etiologic Agents on the Basis of Hazard

This section includes those biological agents known to infect humans as well as selected animal agents that may pose theoretical risks if inoculated into humans. Included are lists of representative genera and species known to be pathogenic; mutated, Recombined, and non-pathogenic species and strains are not considered. Non-infectious life cycle stages of parasites are excluded. This section reflects the current state of knowledge and should be considered a resource document. Included are the more commonly encountered agents and is not meant to be all inclusive. Information on agent risk assessment may be found in the Agent Summary Statements of the CDC/NIH publication, Biosafety in Microbiological and Biomedical Laboratories. Further guidance on agents not here may be obtained through: Centers for Disease Control and Prevention, Biosafety Branch, Atlanta, Georgia 30333, Phone:(404) 639-3883, Fax: (4tz4) 639-2294; National institutes of Health, Division of Safety, Bethesda, Maryland 20892, Phone: (301) 496-1357; National Animal Disease Center, U.S. Department of Agriculture, Ames, Iowa 50010, Phone: (515) 862-8258.

Classification of Biohazardous Agents by Risk Group (RG)

Risk Group 1 (RG1)

Agents that are not associated with disease in healthy adult humans

Risk Group 2 (RG2)

Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available

Risk Group 3 (RG3)

Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk)

Risk Group 4 (RG4)

Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk)

Risk Group 1 (RG1) Agents

RG1 agents are not associated with disease in healthy adult humans. Examples of RG1 agents include asporogenic *Bacillus subtilis* or *Bacillus lichenifomlis*, *Escherichia coli*-K12 and adeno-associated virus types I through 4.

Those agents not listed in Risk Groups (rgs) 2, 3 and 4 are not automatically or implicitly classified in RG I; a risk assessment must be conducted based on the known and potential properties of the agents and their relationship to agents that are listed.

Risk Group 2 (RG2) Agents

RG2 agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

Risk Group 2 (RG2) - Bacterial Agents including Chlamydia

- Acinetobacter baumannii (formerly Acinetobacter calcoaceticus)
- Actinobacillus
- Actinomyces pyogenes (formerly Corynebacterium pyogenes)
- Aeromonas hydrophila
- Amycolata autotrophica
- Archanobacterium haemolyticum (formerly Corynebacterium haemolyticum)
- Arizona hinshawii - all serotypes
- Bacillus anthracis
- Bartonella henselae, B. Quintana, B. Vinsomi
- Bordetella including B. Pertussis
- Borrelia recurrentis, B. Burgdorferi
- Burkholderia (formerly Pseudomonas species)
- Campylobacter coli, C. Fetus, C. Jejuni
- Chlamydia psittaci, C. Trachomatis, C. Pneumoniae
- Clostridium botulinum, Cl. Chauvoei, Cl. Haemolyticum, Cl. Histolyticum, Cl. Novyi, Cl. Septicum, Cl. Tetani
- Corynebacterium diphtheriae, C. Pseudotuberculosis, C. Renale
- Dermatophilus congolensis
- Edwardsiella tarda
- Erysipelothrix rhusiopathiae
- Escherichia coli - all enteropathogenic, enterotoxigenic, enteroinvasive and strains bearing K1 antigen, including E coli 0157:H7
- Haemophilus ducreyi, H. Influenzae
- Helicobacter pylori
- Klebsiella- all species except K. Oxytoca (RGI)
- Legionella including L. Pneumophila
- Leptospira interrogans - all serotypes
- Listeria --Moraxella
- Mycobacterium including M. Avium complex, M. Asiaticum, M. Bovis BCG vaccine strain, M. Chelonei, M. Fortuitum, M. Kansasii, M. Iepae, M. Malmoense, M. Marinum, M. Paratuberculosis, M. Scrofulaceum, M. Simiae, M. Szulgai, M. Ulcerans, M. Xenopi
- Mycoplasma, except M. Mycoides and M. Agalactiae which are restricted animal pathogens
- Neisseria gonorrhoeae, N. Meningitidis
- Nocardia asteroides, N. Brasiliensis, N. Otitidiscaviarum, N. Transvalensis
- Rhodococcus equi

- Salmonella including S. Arizonae, S. Cholerasuis, S. Ententidis, S. Gallinarum-pullorum, S. Meleagridis, S. Paratyphi, A, B. C, S. Typhi, S. Typhimurium
- Shigella including S. Boydii, S. Dysenteriae, type 1, S. Flexneri, S. Sonnei
- Sphaerophorus necrophorus
- Staphylococcus aureus
- Streptobacillus moniliformis - Streptococcus including S. Pneumoniae, S. Pyogenes
- Treponema pallidum, T. Carateum
- Vibrio cholerae, V. Parahemolyticus, V. Vulnificus
- Yersinia enterocolitica

Risk Group 2 (RG2) - Fungal Agents

- Blastomyces dermatitidis
- Cladosponum bautianum, C. (Xylohypha) trichoides
- Cryptococcus neoformans
- Dactylaria galopava (Ochroconis gallopavum)
- Epidermophyton
- Exophiala (Wangiella) dermatitidis
- Fonsecaea pedrosoi
- Microsporum
- Paracoccidioides brazi liensis
- Penicillium mameeffei
- Sporothrix schenckii
- Tnchophyton

Risk Group 2 (RG2) - Parasitic Agents

- Ancylostoma human hookworms including A duodenale, A. Ceylanicum
- Ascaris including Ascaris lumbricoides suum
- Babesia including B. Divergens, B. Microti
- Brugia filaria worms including B. Malayi, B. Timori
- Coccidia
- Cryptosporidium including C. Parvum
- Cysticercus cellulosae (hydatid cyst, larva of T. Solium)
- Echinococcus including E. Granulosis, E. Multiloculans, E. Vogeli
- Entamoeba histolytica
- Enterobius
- Fasciola including F. Gigantica, F. Hepatica
- Giardia including G. Lamblia
- Heterophyes
- Hymenolepis including H. Diminuta, H. Nana
- Isospora
- Leishmania including L braziliensis, L. Donovanii, L. Ethiopia, L. Major, L. Mexicana, L. Peruvania, L. Tropica --Loa loa filaria worms
- Microspodium
- Naeglina fowlen
- Necator human hookworms including N. Amencanus
- Onchoerca filaria worms including, O. Volvulus

- Plasmodium including simian species, P. Cynomologi, P. Falciparum, P. Malariae, P. Ovale, P. Vivax
- Sarcocystis including S. Sui hominis
- Schistosoma including S. Haematobium, S. Intercalatum, S. Japonicum.S. Mansoni, S. Mekongi
- Strongyloides including S. Stercoralis
- Taenia solium
- Toxocara including T. Canis
- Toxoplasma including T. Gondii
- Trichinella spiralis
- Trypanosoma including T. Brucei brucei, T. Brucei gambiense, T. Brucei rhodesiense, T. Cruzi
- Wuchereria bancrofti filaria worms

Risk Group 2 (RG2) - Viruses

Adenoviruses, human - all types

Alphaviruses (Togaviruses) - Group A Arboviruses

- Eastern equine encephalomyelitis virus
- Venezuelan equine encephalomyelitis vaccine strain TC-83
- Western equine encephalomyelitis virus

Arenaviruses

- Lymphocytic chomeningitis virus (non-neurotropic strains)
- Tacaribe virus complex
- Other viruses as listed in the reference source

Bunyaviruses

- Bunyamwera virus
- Rib Valley fever virus vaccine strain MP-12
- Other viruses as listed in the reference source

Cal civiruses

Coronaviruses

Flaviviruses (Togaviruses) - Group B Arboviruses

- Dengue virus serotypes 1, 2, 3, and 4
- Yellow fever virus vaccine strain 17D
- Other viruses as listed in the reference source

Hepatitis A, B, C, D, and E viruses

Herpesviruses - except Herpesvirus simiae (Monkey B virus)

- Cytomegalovirus
- Epstein Banr virus

- Herpes simplex types I and 2
- Herpes zoster
- Human herpesvirus types 6 and 7

Orthomyxoviruses

- Influenza viruses types A, B, and C
- Other tick-borne orthomyxoviruses as listed in the reference source

Papovaviruses

- All human papilloma viruses

Paramyxoviruses

- Newcastle disease virus
- Measles virus
- Mumps virus
- Parainfluenza viruses types 1, 2, 3, and 4
- Respiratory syncytial virus

Parvoviruses

- Human parvovirus (B19)

Picornaviruses

- Coxsackie viruses types A and B
- Echoviruses - all types
- Polioviruses - all types, wild and attenuated
- Rhinoviruses - all types

Poxviruses - all types except Monkeypox virus and restricted poxviruses including Alastrim, Smallpox, and Whitepox

Reoviruses - all types including Coltivirus, human Rotavirus, and Orbivirus (Colorado tick fever virus)

Rhabdoviruses

- Rabies virus - all strains
- Vesicular stomatitis virus - laboratory adapted strains including VSV-Indiana, San Juan, and Glasgow

Togaviruses (see Alphaviruses and Flaviviruses)

- Rubivirus (rubella)

Risk Group 3 (RG3) Agents

RG3 agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available.

Risk Group 3 (RG3) - Bacterial Agents Including Rickettsia

- Bartonella
- Brucella including B abortus, B. Canis, B. Suis
- Burkholderia (Pseudomonas) mallei, B. Pseudomallei
- Coxiella burnetii
- Francisella tularensis
- Mycobacterium bovis (except BCG strain, Risk Group 2 (RG2) - Bacterial Agents including Chlamydia),
M. Tuberculosis
- Pasteurella multocida type B -"buffalo" and other virulent strains
- Rickettsia akari, R. Australis, R. Canada, R. Conorii, R. Prowazekii, R. Nckettsii. R. Sibenca, R.
Tsutsugamushi, R. T phi (R. Moosen)
- Yersinia pestis

Risk Group 3 (RG3) - Fungal Agents

- Coccidioides immitis (sporulating cultures; contaminated soil)
- Histoplasma capsulatum, H. Capsulatum var.. Duboisii

Risk Group 3 (RG3) - Parasitic Agents

None

Risk Group 3 (RG3) - Viruses and Prions

Alphaviruses (Togaviruses) - Group A Arboviruses

- Semliki Forest virus
- St. Louis encephalitis virus
- Venezuelan equine encephalomyelitis virus (except the vaccine strain TC-83)

Arenaviruses

- Flexal
- Lymphocytic choriomeningitis virus (LCM) (neurotropic strains)

Bunyaviruses

- Hantaviruses including Hantaan virus
- Rift Valley fever virus

Flaviviruses (Togaviruses) - Group B Arboviruses

- Japanese encephalitis virus
- Yellow fever virus
- Other viruses as listed in the reference source

Poxviruses

- Monkeypox virus

Prions

--Transmissible spongiform encephalopathies (TME) agents (Creutzfeldt-Jacob disease and kuru agents)

Retroviruses

--Human Immunodeficiency virus (HIV) types 1 and 2
--Human T. Cell lymphotropic virus (HTLV) types 1 and 2
--Simian immunodeficiency virus (SIV)

Rhabdoviruses

--Vesicular stomatitis virus

Risk Group 4 (RG4) Agents

RG4 agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.

Risk Group 4 (RG4) - Bacterial Agents

None

Risk Group 4 (RG4) - Fungal Agents

None

Risk Group 4 (RG4) - Parasitic Agents

None

Risk Group 4 (RG4) - Viral Agents

Arenaviruses

--Guanarito virus
--Lassa virus
--Junin virus
--Machupo virus
--Sabia

Bunyaviruses (Nairovirus)

--Crimean-Congo hemorrhagic fever virus

Filoviruses

--Ebola virus

--Marburg virus

Flaviruses (Togaviruses) - Group B. Arboviruses

--Tick-borne encephalitis virus complex including Absetterov, Central European encephalitis, Hanzalova, Hypr, Kumlinge, Kyasanur Forest disease, Omsk hemorrhagic fever, and Russian spring-summer encephalitis viruses

Herpesviruses (alpha)

--Herpesvirus simiae (Herpes B or Monkey B virus)

Paramyxoviruses

--Equine morbillivirus

Hemorrhagic fever agents and viruses as yet undefined

Animal Viral Etiologic Agents in Common Use

The following list of animal etiologic agents is appended to the list of human etiologic agents. None of these agents is associated with disease in healthy adult humans; they are commonly used in laboratory experimental work. A containment level appropriate for RGI human agents is recommended for their use. For agents that are infectious to human cells, e.g., amphotropic and xenotropic strains of murine leukemia virus, a containment level appropriate for RG2 human agents is recommended.

Baculoviruses

Herpesviruses

--Herpesvirus ateles

--Herpesvirus saimiri

--Marek's disease virus

--Murine cytomegalovirus

Papovaviruses

--Bovine papilloma virus

--Polyoma virus

--Shope papilloma virus

--Simian virus 40 (SV40)

Retroviruses

--Avian leukosis virus

--Avian sarcoma virus

--Bovine leukemia virus

--Feline leukemia virus

--Feline sarcoma virus

--Gibbon leukemia virus

--Mason-Pfizer monkey virus

--Mouse mammary tumor virus

--Murine leukemia virus

--Murine sarcoma virus

--Rat leukemia virus

Murine Retroviral Vectors

Murine retroviral vectors to be used for human transfer experiments (less than 10 liters) that contain less than 50% of their respective parental viral genome and that have been demonstrated to be free of detectable replication competent retrovirus can be maintained, handled, and administered, under BLI containment.