Recombinant DNA Permit Application

Presentation to the Cambridge Biosafety Committee

MM/DD/YY

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Cambridge, MA 00000

[Sample Presentation Packet: rDNA Permit, Cambridge Public Health Department]

About This Sample Presentation

In Cambridge, conducting rDNA research requires a permit. A meeting with the Cambridge Biosafety Committee (CBC) is part of the application process. Many applicants have used a PowerPoint type presentation like this sample, paper or projected, to portray the scope of the proposed research and facilities to the CBC. The CBC has found these types of presentations to be effective, and encourages them to be used.

The Cambridge rDNA Ordinance bases its requirements on the widely employed National Institute of Health (NIH) Guidelines for Research Involving DNA Molecules.

[NOTE: The firm featured in the sample packet, New Pharm and its staff and vendors, are fictitious]

New Pharm Inc.

Founded 1999, currently ~42 employees

- **Scientific management**
  - Primo Centuri, Ph.D., Executive Director
  - Tracy Brilliant, M.D., Director of Research
  - Martin Redd, M.D., Ph.D., V.P. Clinical
- **Mission**
  - Develop new molecules for therapy of human viral diseases
    - Hepatitis B and Hepatitis C viruses; HIV
- **On-site rDNA research is necessary to support these efforts**
  - Research lab to be operational by end of 4Q 2002

[Sample Presentation Packet: rDNA Permit, Cambridge Public Health Department]

[-Slide 3- www.cambridgepublichealth.org/perm_license/rdna/rdna_index.html]

Proposed Research Facility

- **Existing Lab space at 123 Science Ave., Cambridge, 02138**
  - ~5,400 sq. ft. facililty
  - Previous occupants: Pharm Go Inc.
  - Prior permit for BSL-1 and BSL-2 used by Pharm Go (permit #xyz-99)
  - New Pharm will use existing space with minimal modification
- **Access Control**
  - I. Locked building entrance; II. Locked lab entrance
    - Lab space and office space are segregated
  - Alarm system
- **Location**
  - BSL-1 throughout main lab, authorized access only
  - BSL-2 work restricted to a single room (BSL-2 lab)
    - Located in low traffic area; authorized access only
    - Autoclave in room adjacent to BSL-2

[-Slide 4- www.cambridgepublichealth.org/perm_license/rdna/rdna_index.html]

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Infectious Agents

- **Hepatitis B virus (HBV)**
  - Enveloped DNV virus. Causes both acute and chronic infection
  - Some 350 million HBV carriers worldwide at risk for cirrhosis, liver cancer (HBV vaccine will not help carriers)
  - Currently approved therapies (interferon alpha, lamivudine) still limited - need for better therapy remains
  - Classified Risk Group 2. BSL-2 containment
- **Hepatitis C virus (HCV)**
  - Enveloped positive-strand RNA virus
  - Carriers worldwide: ~170 million, almost 4 million in US
  - Increased risk for cirrhosis, liver cancer
  - Current therapy (interferon + ribavirin) still not adequate
  - Classified Risk Group 2. BSL-2 containment

(Infectious Agents continued on next slide)

Infectious Agents (continued)

- **Human immunodeficiency virus (HIV)**
  - Enveloped retrovirus
  - Worldwide chronic infections ~34 million
  - FDA approved drugs ~15
  - Need for improved therapies remains
  - Classified Risk Group 3
  - Low levels of HIV require modified BSL-2 (i.e. incorporating some BSL-3 practices)
    - e.g. venting of exhaust air to outside, directional airflow into room, restricted access

[Sample Presentation Packet: rDNA Permit, Cambridge Public Health Department]

[-Slide 6- www.cambridgepublichealth.org/perm_license/rdna/rdna_index.html]

New Pharm Research Plans

- **Express individual viral proteins for mechanism of action** assays using recombinant DNA technology. Systems:
  - Plasmid pTRCHisB (In Vitrogen) / *Escheria. Coli* BL21
  - Plasmid pET21b / *E. coli* JM109 DE3
- **Employ cell lines expressing low levels of infectious virus to e.g. confirm antiviral activity or map resistance**
  - e.g. HepG 2.2.15 cells expressing HBV. MT2 cells for HIV
  - Cell lines may be created from infectious recombinant clones or replicons (e.g. HCV)
- **Analysis of human samples for clinical support**
- **ALL WORK TO BE DONE ON AN ANALYTICAL SCALE (LOW LEVEL)**

Permits and Timeline

Permit	Agency	Status
rDNA	Cambridge Public Health Department	In Progress
Wastewater	MWRA, and Cambridge Water Department	In Progress
Water supply	Cambridge Water Department	Upgrading system
Fire Safety	Cambridge Fire Department	TDB
Needle/Syringe	Mass. Dept. Public Health	MM/DD/YY
Haz. Waste	Mass Dept. Reg. Comp.	Form submitted MM/DD/YY

•In progress: application form for biosafety permit, health and safety manual, biosafety training program, detailed biosafety protocols
•Two Biosafety Cabinets ordered (class II)
•IBC members: Tracy Brilliant, Alice Justice, Doug Strong, and a Community Rep.

[Sample Presentation Packet: rDNA Permit, Cambridge Public Health Department]

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Contract In Place or In Progress

Sharps Disposal	Bio Sharps Co.
Pest Control	X-term inc.
Plumbing/Backflow Prevention	Purple Pluming
Lab Coat Laundry Service	White Service
Medical Surveillance	Med-watch
Water Testing for MWRA permit	Hydra-flow
Sprinkler System Testing	Fountain Inc.
Hazardous Waste	Disposal Group
Chip Tank Maintenance	Disposal Group
Bio Safety Cabinet Certification (Yearly)	ABC Testing
Air Balancing/Negative Pressure in BSL-2	Fresh Air Services
Timeline for completing process/walkthrough date	*MM/DD/YY*

[Sample Presentation Packet: rDNA Permit, Cambridge Public Health Department]

Notes Slide

Information about the Cambridge rDNA Ordinance, including a copy of the Ordinance, Permit Application, and Cambridge Biosafety Committee Procedures:
www.cambridgepublichealth.org/perm_license/rdna/rdna_index.html

For further information please contact:
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[-Slide 10- www.cambridgepublichealth.org/perm_license/rdna/rdna_index.html]

Helpful links slide

•Cambridge rDNA Ordinance, including a copy of the Ordinance, Permit Application, and Cambridge Biosafety Committee Procedures
www.cambridgepublichealth.org/perm_license/rdna/rdna_index.html

•NIH Guidelines for Research Involving rDNA Molecules (April 2002)
www4.od.nih.gov/oba/rac/guidelines/guidelines.html

•NIH Office of Biotechnology Activities: rDNA and Gene Transfer
www4.od.nih.gov/oba/Rdna.htm

•Guidelines on Primary Containment for Biohazards
www.niehs.nih.gov/odhsb/biosafe/bsc/bsc.htm

•Biosafety in Microbiological and Biomedical Laboratories, 4th Edition
http://bmbl.od.nih.gov/