BCoN Workshop
Addressing Legal Issues Involved in Digitized Collections:
The Nagoya Protocol as a Test Case

GGBN "Permits" (and other Legal Documentation) List

- Collecting Permit
- Contract
- Copyright
- Data use
- Exemption Permit
- Export Permit
- Import Permit
- Human Pathogens
- Genetically Modified Organisms
- Intellectual Property Rights
- Internationally Recognized Certificate of Compliance
- Material Transfer Agreement
- Memorandum of Understanding
- Memorandum of Cooperation
- Patent
- Phytosanitary
- Salvage
- Veterinary Certificate
- Other

Missing permits identified during working group discussions

- IACUC: part of approval process before collecting occurs
- IRB: Informed Consent (human) is completed by patient at the time the sample is collected
- Research Approval or Permission to Conduct Research
- Transport Permit, e.g., USDA
- USFWS authorization to possess, e.g., confiscated material
- Hunting, fishing license- create as "recreational permit" category?
- Post-entry quarantine agreements, similar to phytosanitary but for animal
- Infectious disease: human, zoonotic, agriculture, animal husbandry (Combine with other category, e.g., imports)
- Receiving permits: authorization to receive/hold/possess under certain conditions; sometimes used for soil samples, includes specifications on housing, and how to destroy
- Notification of release – USDA for genetically modified organisms, under GMO

Questions from working group discussions

- What is an exemption permit? In the US, document that states that a separate permit is not required.
- Is there a permit to certify that something is GMO or does it certify that something is not GMO?
- Similarly, does a permit certify that something has an infectious disease or pathogen or is there certification that materials are free from infectious diseases or pathogens?
- Can MoU and MoC be combined? Is there a real difference between the two?

Working Group 1 Suggested "Permit" Categories
Primary categories:

- "Specimen" = physical object, specimen or any part including a derived part, such as a DNA extract
- "Data" = derived use from the physical object, e.g., genetic sequence, isotopic data, CT scan, publication

Secondary categories (Specimens or Data can have multiple secondary document categories):

- Permit
- Agreement
- Certificate

Broad categories: Collecting, Transport, Possession of physical object
Separate permits for the specimen itself vs. specimen data usage; accession (physical object) =collecting permits, MOUs vs usage (loans, publication, hosting public data)

- Specimen permits (e.g., collecting, import, export) versus Data Use (e.g., patent, data use, copyright, contract, agreements, loan agreements)
- All agreements could be in both categories, MOUs, etc.
- Allow for multiple permit types for a single permit (e.g., "collect, salvage, import, export" all under one permit)
- Separately track regulations: CITES, ESA, USDA, CDC (e.g., CDC import permit versus USFWS import permit versus USDA transport permit)
- Add new permit every time permit is renewed, new dates, authorized individuals
- Need for standardized definitions across the entire community, nationally and internationally; this should go to Nagoya after we have community consensus
- Need to develop ontologies for terminology
- Discussion regarding data management consideration versus end users who may simply want access to genetic resources from the specimens.
    - Need to ensure that materials are developed to pay the repository/museum for the shipping and personnel time (including time to prepare legal docs), and materials that reflect ABS for country of origin of the material (e.g., so that profits are shared from products that may be developed by pharm company from the material)
    - Should consider adding MTA conditions to loans to document that the museum fulfilled its responsibility in disclosing the conditions under which these specimens are made available; also to specify the conditions under which future benefits from use, patent rights, etc., are distributed and returned
    - Doing this on a loan by loan basis will be difficult, needs to be institutional policy?
    - Problem with having multiple MTAs for single loan including specimens from multiple countries; library example, BCoN Kansas meeting

Working Group 2 Suggested "Permit" Categories

1. Specimen Intake/Accession
    a. Institutional Compliance (legal/ethical):
        i. IRB
        ii. IACUC
    b. Collecting
        i. Collecting Permit(s)
        ii. Export Permit
        iii. Import Permit
        iv. Exemption Permit
        v. Informed Consent
        vi. Salvage
    c. Access/Use Permits
        i. Genetically Modified Organisms,
        ii. Human Pathogens
        iii Intellectual Property Rights
        iv. MOU, MOC
2. Loans/Use of Specimens
    a. Shipping
        i. MTA
        ii. Internationally Recognized Certificate of Compliance
        iii. Phytosanitary
        iv. Human Pathogens
        v. Veterinary Certificate
    b. Allowing Use
        i. MOU
        ii. MOC
        iii. Contracts
        iv. Data use
    c. Benefit
        i. Patents
        ii. Copyright