

Biobank Certification: Development of a Program By the Canadian Tumour Repository Network (CTRNet)

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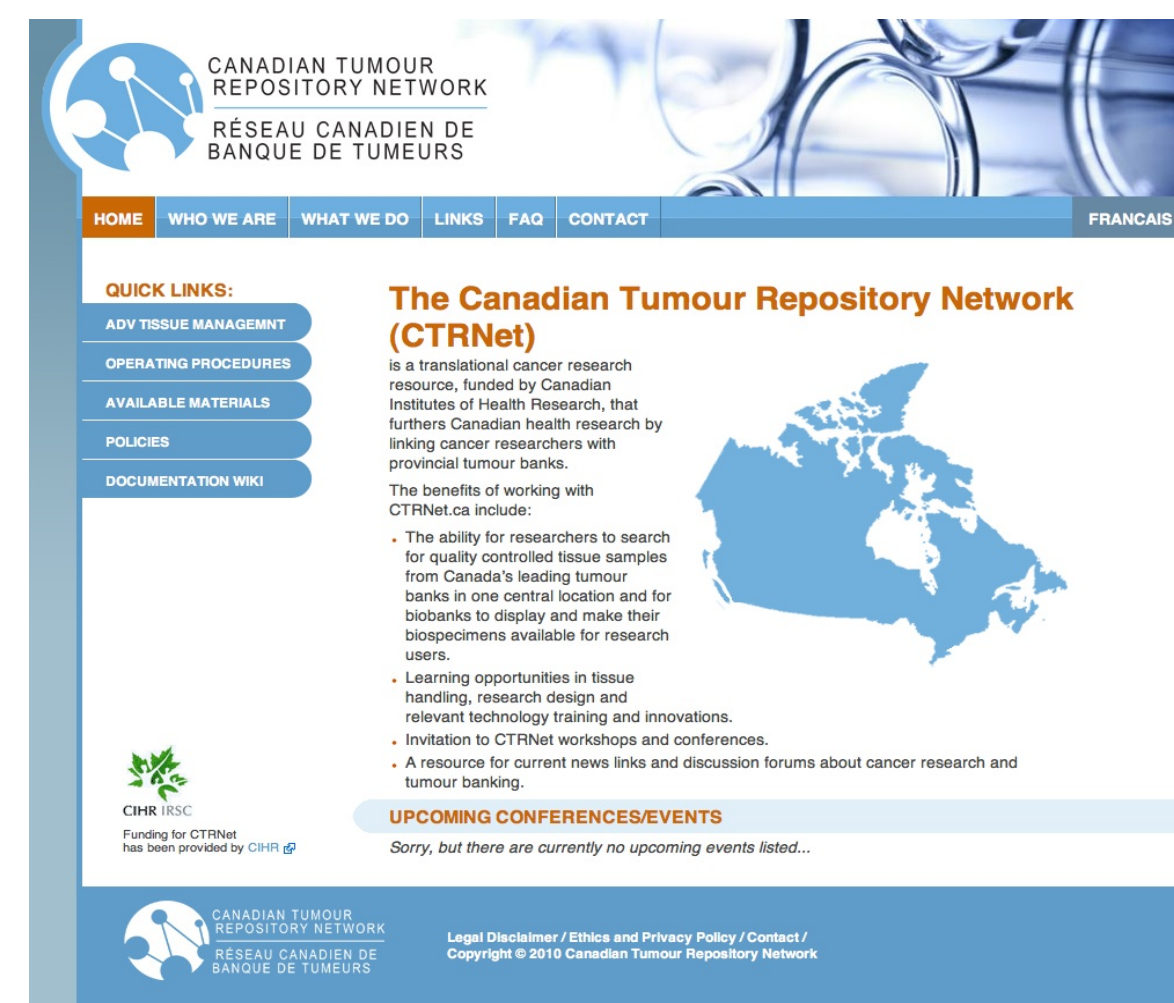
CTRNet Background

Origin of CTRNet

- CTRNet was founded in 2003 through an initiative led by the Canadian Association of Provincial Cancer Agencies (CAPCA) and funding from the Canadian Institutes for Health Research, Institute for Cancer Research (CIHR-ICR) to harmonize tumour biobanks.
- Initiated as a network of leading Canadian tumor banks across five provinces:
 - 1) Alberta Research Tumour Bank
 - 2) BC Cancer Agency's Tumour Tissue Repository (BCCA-TTR)
 - 3) Centre hospitalier de l'Université de Montréal-Fonds de la Recherche en santé Québec (CHUM-FRSQ) Tumour bank
 - 4) Manitoba Breast Tumour Bank (MBTB)
 - 5) National Cancer Institute of Canada-Clinical Trials Group (NCIC-CTG)
 - 6) Ontario Tumour bank
- Mission: To improve capacity/quality of cancer biospecimens and data through standardization and improvement of biobanking processes and frameworks.
- Model: To create a network with functions that link, harmonize and improve access to provincial biobanks through national research funding (CIHR-ICR). The network builds on independently funded and governed provincial biobanks.

Achievements to Date

- Generation and publication of a set of 54 publicly available policies and SOPs for tumour biobanking (available through CTRNet web portal; (www.ctrnet.ca))
 - ~ 3000 average yearly downloads
- Advanced Tissue Management (ATiM) software tool created to support and standardize all aspects of biospecimen consent, collection, annotation, storage and release operations (publicly available through web portal)
- Launch of a Web-based biospecimen catalogue of CTRNet member banks' stocks to enhance access
 - Over 62,000 cases available through catalogue (<http://www.ctrnet.ca/materials>)
 - Blood and derivatives, other fluids and derivatives, fresh-frozen tissue, FFPE tissue
- Contribution to harmonization of international biobanking through support, promotion and participation in the Marble Arch International Working Group on Human Specimen Biobanking for Research Purposes (www.marblearchgroup.org) and ISBER.



Initiatives Currently Underway

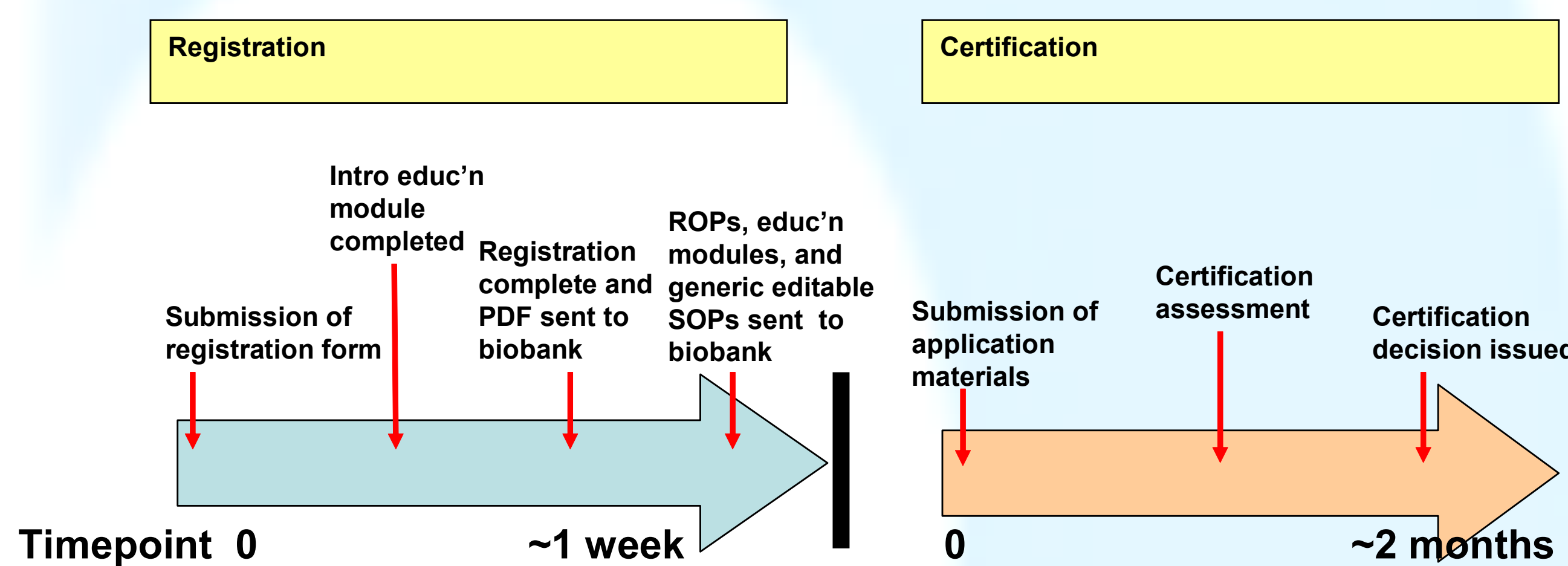
1. Expanding the Scope and Size of the CTRNet Collection
2. Development of new SOPs and Policies
3. Service and Content Brokering for Member Banks
4. Coordination of Purpose-Designed Prospective Collections
5. Sample Quality Assurance
6. Biospecimen Research Platform
7. Promoting Utilization
8. Biobank Certification Program
9. Development of Training and Educational materials

Biobank Certification Initiative

Why Develop a Biobank Certification Program?

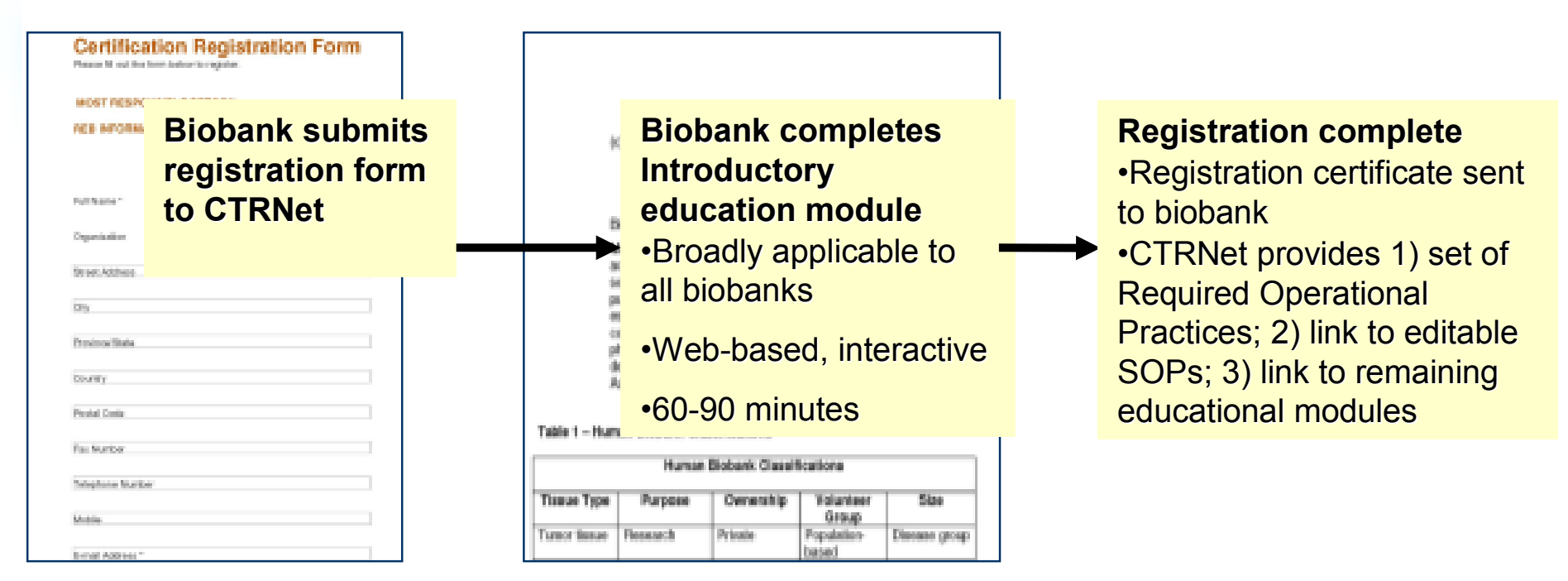
- To ensure public confidence in biobanking is maintained in Canada
 - Currently in Canada only oversight comes from Research Ethics Boards (REBs/IRBs), but no bodies assess aspects outside of the REB scope
- To ensure there are high quality biospecimens to support translational research
 - Certification will provide comprehensive Quality Assurance for all aspects of biobanking operations; this is different from Quality Control by testing end products
- To provide educational resources for new and existing biobanks
 - This will lead to increased capacity for quality biospecimen collection

Overview of the Biobank Certification Program

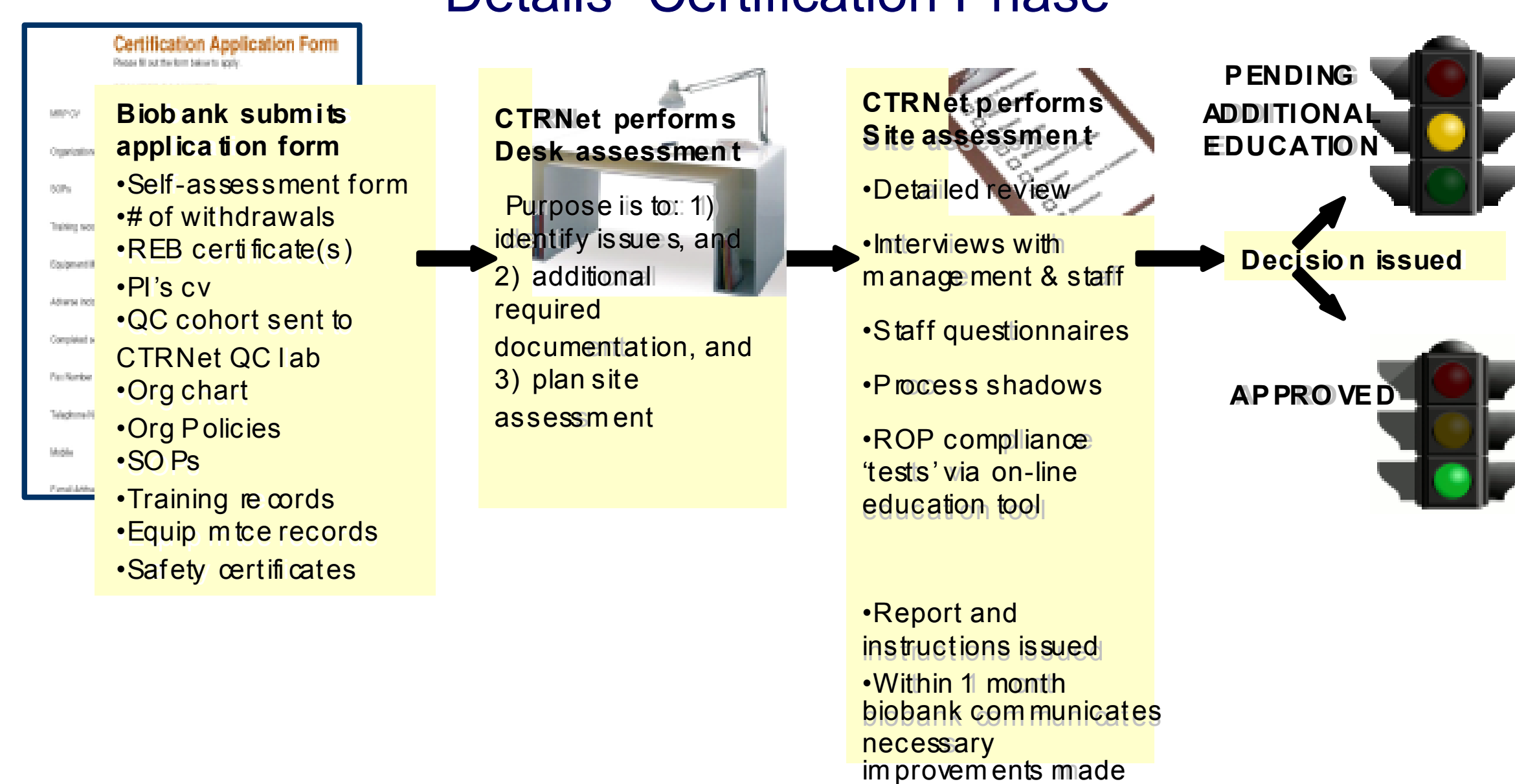


ROP (Required Operational Practice)= Brief documents that define the key principles of biobank operations that a biobank should adhere to in order to meet the current best practice standards. Different from SOPs (Standard Operating Procedures) which are meant to provide the details for a given procedure such that personnel can repeat the process correctly each time with no operator-variability.

Details- Registration Phase



Details- Certification Phase



Education Initiative

Why is Biobank Education Needed?



- There are currently very limited educational resources for the complex discipline of biobanking
 - 100% of individuals recently surveyed by CTRNet indicated that biobanking education materials are needed (survey respondents included biobankers, researchers, pathologists, ethicists and members of the public)
- Training (=targeted to biobank personnel) and Education (=targeted to researchers/ biobank users) are vitally important to ensure:
 - Data capture and maintenance is efficient and standardized (training)
 - Biobank personnel have the necessary skills to deploy biospecimen and data SOPs (training and education)
 - Research users are knowledgeable in biobank processes to efficiently access biobanks, to initiate and operate their own biobanks, and to work optimally with biospecimens and data received from other tissue resources (education)
- Both Training and Education will be important for the CTRNet Biobank Certification Program

Status of Certification and Education Initiatives

- Certification Program was developed from Apr-Nov 2010
 - Based on a foundation of self-assessment and guided process improvements to comply with international Best Practices (i.e., ISBER, NCI, OECD)
- Certification Program was presented to 80 key stakeholders in January 2011 during a two-day Workshop held in Vancouver, BC, Canada
 - Attendees included Canadian biobankers, researchers, ethicists, public, and international experts
- Educational modules required to support certification were defined and the first 'introductory' module was developed by a national working group composed of individuals nominated by CTRNet leaders (working group included CTRNet affiliates and external biobankers)
 - Introductory module was tested by attendees of the January Workshop
- Feedback on both initiatives has been overwhelmingly positive and stakeholders voiced: 1) support for CTRNet's development of a certification process and development of educational resources, and 2) expressed value in providing a searchable 'biobank registry'
- CTRNet plans to launch the 'registration phase' of the Certification Program in September 2011
 - This will coincide with completion of the remaining educational modules

