De registratie van bezwaren/toestemmingen van afname tot uitgifte

Organisatie translationeel onderzoek in het NKI-AVL

Het NKI-AVL heeft zich gecommitteerd aan de ontwikkeling en versterking van een infrastructuur, met in acht neming van de relevante wet en regelgeving, voor het verzamelen, opslaan, beheren en gebruiken van lichaamsmateriaal en bijbehorende klinische en research data .

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Translationeel onderzoek in het NKI-AVL

gecentraliseerd

- Centrale uitgifte humane data – Datadesk (data warehouse)
  - Subloketten

- Centrale uitgifte humaan materiaal- Core Facility Molecular Pathology & Biobanking (CFMPB)

  - Registratie studies: approval (METC/IRB)check
  - Consent check (EPD)
  - Uitgifte borging
  - Kwaliteit van de data & materiaal
  - Track & Trace materiaal

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Registratie en toetsing
WMO (METC) <> niet WMO (IRB)

Onderzoek valt onder de WMO als het aan de volgende twee voorwaarden voldoet:

Er is sprake van medisch wetenschappelijk onderzoek

én

Personen worden aan handelingen onderworpen of hen worden gedragsregels opgelegd.

> METC

Onderzoek buiten de scope van de WMO:

Er geen sprake is van een op voorhand gedefinieerde wetenschappelijke hypothese (zoals bij aanleg biobank voor toekomstig onderzoek),

en/of,

Personen worden niet aan handelingen onderworpen of hen worden geen gedragsregels opgelegd (zoals o.a. bij nader gebruik rest materiaal en of data)

> IRB

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IRB (*niet WMO, WMO light, toetsing op maat*)

De Institutional Review Board (IRB) is een board voor toetsing op maat van niet-WMO onderzoek
Code Goed Gebruik (FEDERA)

Samenstelling
Committee Secretary
Chair
Legal issues/METC
Statistician
Clinical genetics
Research IT/ISO
Legal issues/ TTO
patient advocate
Topic dependent additional reviewers
Data protection officer (FG) auditor

de IRB toetst:

- aanleg biobanken
- (nader) gebruik humaan materiaal in research
- (nader) gebruik humane data in research

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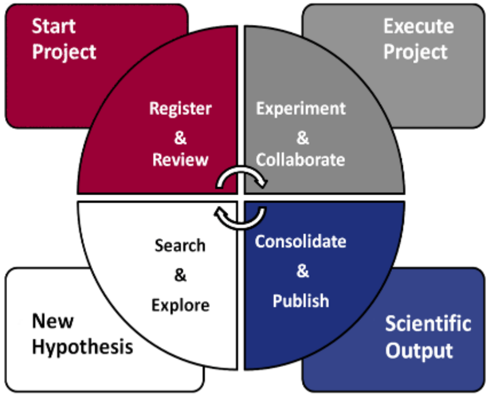
https://antonet.nki.nl/Organisatie/TRP/Pages/trpmain.aspx | MyAntonet | Translational research portal | Translational research portal

SharePoint — Annegien Broeks — VOLGEN — SYNC

U bevindt zich hier: Home > Organisatie > Translational Research Portal > Translational research portal



Aim of this portal

This translational Research Portal will guide you through processes necessary for translational research and it can direct you to relevant sites.

A. To start a project;
Relevant links for registration & review of new projects/studies: what you need to consider in advance, were and how to register your project and start the relevant review precision process.

B. To execute a project;
Relevant links to perform experiments and to collaborate: data guidance and experimental support.

C. To help with scientific output;
Relevant links to consolidation and publication aspects: how to handle, publish and communicate results.

D. To generate new hypothesis;
Relevant links to search and explore: available data and biobank resources, published data and projects & grants.

TRB

The Translational Research Board (TRB) aims to:

- Strengthen the translational cancer research activities
- Identify and solve current problems (e.g., improve infrastructure; what is needed, who can contribute)
- Brainstorm on new initiatives (e.g., build integrative IT environment, improve Biobank/CFMPB pipelines).

A. Start Project

Consider

Seven important issues to consider before submitting or starting a research project.

ELSI (Ethical, Legal and Social Implications) for your project.

WMO

Start 'WMO Study' - METC review (Medical Ethical committee):
It is obligatory that each research study involving human (material) and/or derived data according to the ' Law on Medical Research Involving Human Subjects (WMO) will be reviewed regarding medical and ethical aspects by an accredited medical ethical committee (METC).

Non WMO

... WMO Study' - IRB review (Institutional Review Board)
Research that does not meet the WMO criteria (e.g. secondary use, biobank studies), does not have to be reviewed by an accredited METC however is eligible for review by the Institutes Review Board.

1. register & Review Secondary use (with opt-out) ART-CFMPB.
2. Register & Review Secondary use (with informed consent) ART-CFMPB.
3. Register & Review new biobank (secondary use or de novo) ART-BAVL.
4. Register & Review DATA request (in progres) word document
   Procedure IRB ART-data 2018.pdf

B. Execute Project

PTRC

PTRC: **Pathology Translational Research Core.**

PTRC@nki.nl please submit your relevenat requests CFMPB (Core Facility Molecular Pathology & Biobanking)

For more info contact: Gerrit Meijer, Janneke van Denderen and Annegien broeks.

WA

WA: We... appelijke Administratie / Biometrics:
Departm... for research support of clinical trials.

For clinical i... mation contact WA: wa.info@nki.nl

Clini... a information request.

CRU

CRU (Clinica... search Unit) for more info contact: Jan Schellens, Neeltje Steeghs or Christian Blank.

Webonderdeel Overzichtskoppeling

NKI Newsletter
NKI Newsletter, published 4 times a year.

Huidige weergave ...

Naam	Gewijzigd	Gewijzigd door
Michener-Michener-2015-PLoS Comput. Biol	October 30 2015	Robbert Hardenberg
Mistaken Identifiers Gene name errors can be introduced inadvertently when using Excel in bioinformatics	August 26 2016	Robbert Hardenberg
Perverse prikkels of rotte appels	August 14 2014	Robbert Hardenberg

Name	E-mail	Function
Nadine Boke	n.boke@nki.nl	Science Communication Advisor
Mariet van den Berg	ma.vd.berg@nki.nl	Office Manager Cell biology I
Annegien Broeks	CFMP@nki.nl	Head CFMPB
Ineke de Wit	i.d.wit@nki.nl	Quality Assurance Officer

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ART

Application and Request tool
ART- IRB

- **Nieuwe biobank (ART-BAVL)**
- Gebruik humaan materiaal (ART-CFMPB)
- Gebruik humane data (ART-DATA)

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Biobanken NKI-AVL

De Nader gebruik biobanken:

- Consent:

  tot 25 Mei 2018

  – ‘opt-out’: geen bezwaar regeling (EPD)

  – ‘opt-in’: specifiek onderzoek e.g. organoids, PDX, cell lines (onsterfelijk) (EPD)

  > 25 Mei 2018 (1 okt 2018)

  – ‘opt-in’: toestemming aan de poort (EPD)

De ‘*de novo*’ biobanken:

- Consent;

  - ‘opt-in’ procedure (EPD)

Picture 4. Radix Polaris: two freezing aisles in a cool room. Each aisle consists of twelve sections of one cubic metre each. The resulting 24 m² storage space replaces 36 conventional ultrafreezers.

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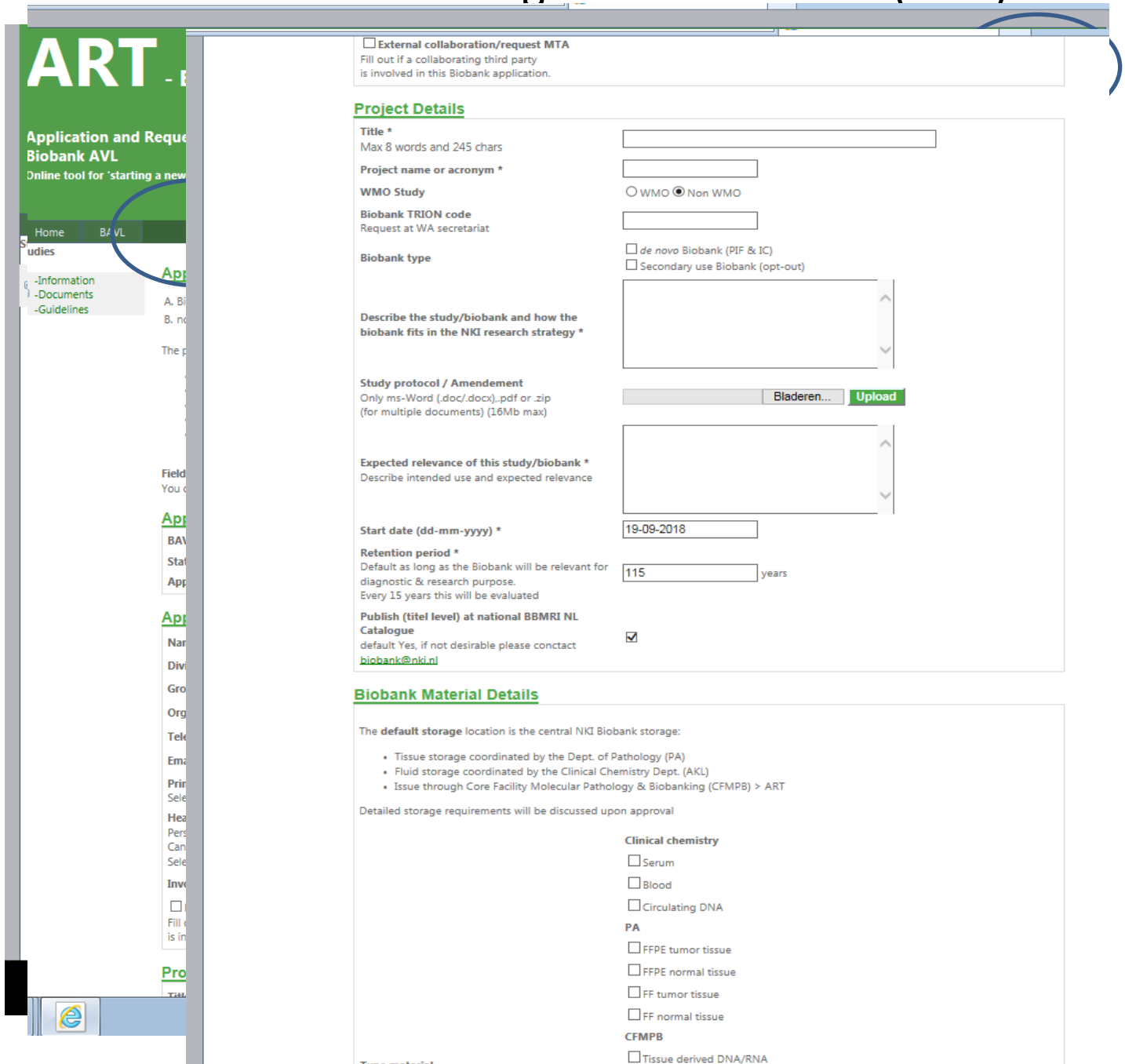
IRB ART-BAVL – Register and Review (new) biobank



External collaboration/request MTA
Fill out if a collaborating third party is involved in this Biobank application.

Project Details

Title *
Max 8 words and 245 chars

Project name or acronym *

WMO Study ○ WMO ◉ Non WMO

Biobank TRION code
Request at WA secretariat

Biobank type
☐ *de novo* Biobank (PIF & IC)
☐ Secondary use Biobank (opt-out)

Describe the study/biobank and how the biobank fits in the NKI research strategy *

Study protocol / Amendement
Only ms-Word (.doc/.docx)..pdf or .zip (for multiple documents) (16Mb max)
Bladeren... Upload

Expected relevance of this study/biobank *
Describe intended use and expected relevance

Start date (dd-mm-yyyy) * 19-09-2018

Retention period *
Default as long as the Biobank will be relevant for diagnostic & research purpose.
Every 15 years this will be evaluated
115 years

Publish (titel level) at national BBMRI NL Catalogue
default Yes, if not desirable please conctact biobank@nki.nl
☑

Biobank Material Details

The **default storage** location is the central NKI Biobank storage:

- Tissue storage coordinated by the Dept. of Pathology (PA)
- Fluid storage coordinated by the Clinical Chemistry Dept. (AKL)
- Issue through Core Facility Molecular Pathology & Biobanking (CFMPB) > ART

Detailed storage requirements will be discussed upon approval

Clinical chemistry
☐ Serum
☐ Blood
☐ Circulating DNA

PA
☐ FFPE tumor tissue
☐ FFPE normal tissue
☐ FF tumor tissue
☐ FF normal tissue

CFMPB
☐ Tissue derived DNA/RNA

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Registration & IRB review process Biobanken non WMO

ART-BAVL – Institutional review board ('WMO light / toetsing op maat')

Nieuwe (niet WMO) Biobank > ART Registration & IRB Review

IRB secretaris

IRB > ethics/logistics/**IC/PIF** + Biobank lab coordinators AKL/PA > costs + data & sample handling and storage

WMO studie met Biobank component (METC review) > ART Registration

IRB sectretaris

Biobank lab coordinators AKL/PA > costs + data & sample handling and storage

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ART

Application and Request tool
ART- IRB

- **Nieuwe biobank (ART-BAVL)**
- Gebruik humaan materiaal (ART-CFMPB)
- Gebruik humane data (ART-DATA)

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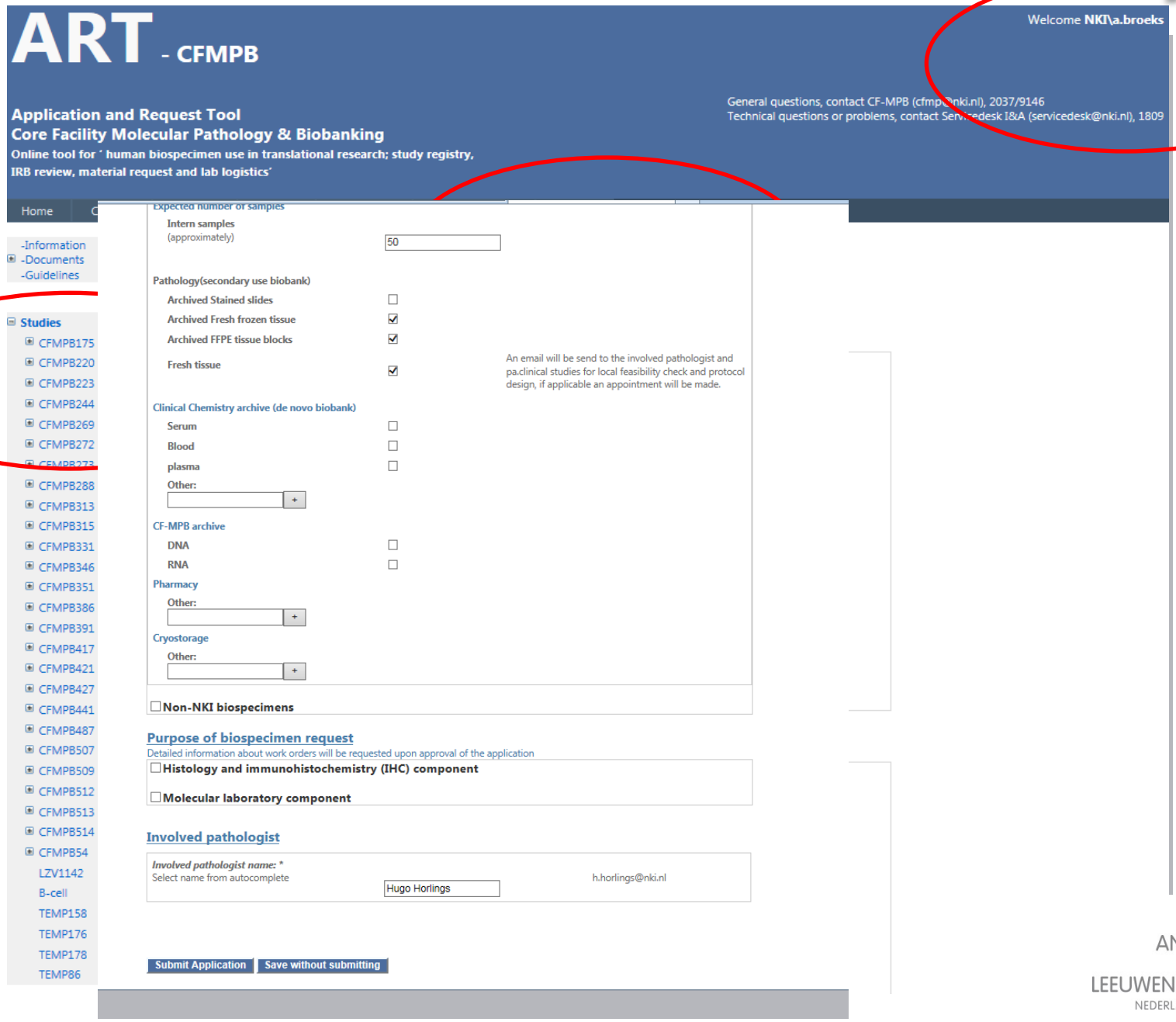
IRB ART-CFMPB – Register and Review new study with human material



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Registration & IRB review process **ART – CFMPB**

Elke studie met humane biospecimens moet worden geregistreerd en (op maat) getoetst

De IRB wordt aangevuld met relevante reviewers bv research commissie pathologie, de tumorwerk groep etc

- Is de consent correct?
- materiaal delen > MTA nodig

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Core Facility Molecular Pathology & BioBanking **CFMPB**

De CFMPB; registreert, coördineert, assisteert faciliteert research met humaan, (patiënten) materiaal

Team:
Hoofd
office managers
Research technician
IT-ers
Research patholoog
Biobank coordinatoren
Pathology & AKL

Histologie/ ImmunoHistoChemie & (pre) Moleculair lab.

LIMS: Web application the Application and Request Tool (ART) Lab management tool

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Following Approval : Translational Research Lab

The Core Facility coordinator will make a planning with the applicant for execution of the study, involvement of a pathologist, estimation of the cost, duration, lab assistance etc.

The Applicant can I. Request materials : ART searchtool en consent check

- Pathology: HE/IHC slides, FFPE tissue, frozen tissue, fresh tissue.
- Clinical chemistry: serum, blood, plasma, circulating DNA etc.
- CFMPB/Mol diagnostics: DNA /RNA
- External material (DNTP)

The Applicant can II. place work order requests in ART (details will be discussed in the study plan)

- Histology (cutting blancs 3,5,10 um, HOPV blancs, HE)
- Immunohistochemistry (list t of available AB protocols can be found in ART, new AB protocols can be requested);
- TMA construction
- Digital Pathology
- Molecular (DNA/RNA/PCR etc) (coordinating technician Linde Braaf)

The Applicant has to: resubmit results (e.g. IHC scores) to be uploaded in ART or the DWH.

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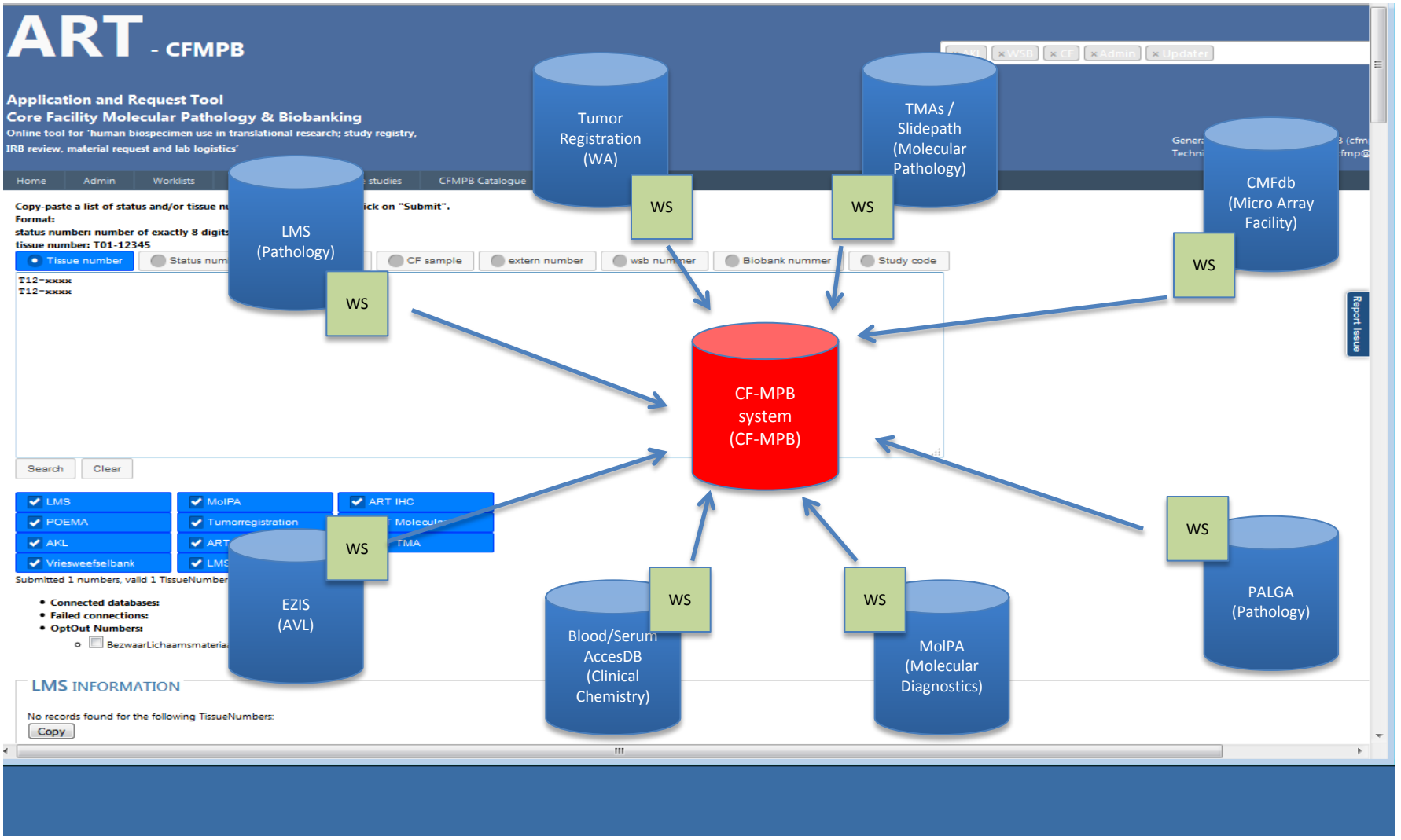
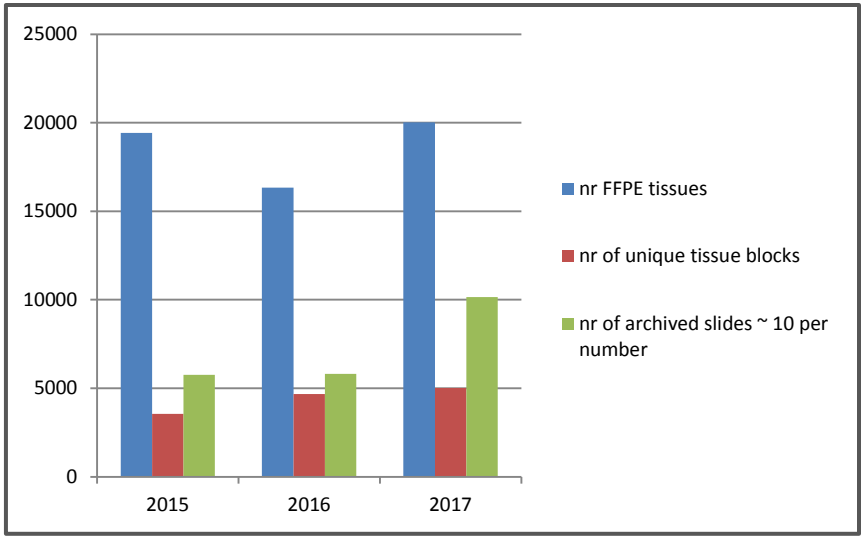
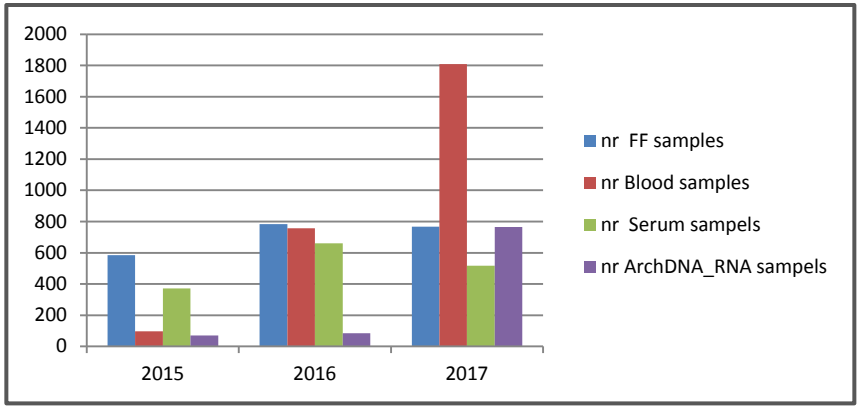
Searchtool – consent check



Gebruik pathologie weefsel





Following Approval : Translational Research Lab

The Core Facility coordinator will make a planning with the applicant for execution of the study, involvement of a pathologist, estimation of the cost, duration, lab assistance etc.

The Applicant can I. Request materials

- Pathology: HE/IHC slides, FFPE tissue, frozen tissue. Material will be obtained within 2 weeks (depending of the size of the request) and stored under temporarily supervision of the CF-MPB in a separate dedicated archive.
- Clinical chemistry: serum, blood, etc. Material will be obtained within 2 weeks (depending of the size of the request).
- CFMPB/Mol diagnostics: DNA and or RNA.
- External material

The Applicant can II. place work order requests in ART

- Histology (cutting blancs 3,5,10 um, HPV blancs, HE)
- Immunohistochemistry (list of available AB can be found in ART, new AB protocols can be requested);
  - BenchMark Ultra (Ventana, Roche) , Discovery Ultra (Ventana, Roche)
  - Brightfield & IF
  - Multiplexing
- TMA construction
  - GrandMaster (Sysmex)
- Digital Pathology, (multispectral) image analysis
  - Aperio scanner, Vectra PerkinElmer
- SOP Molecular (DNA/RNA/QQC) > coded storage in DNA/RNA biobank

The Applicant has to: resubmit results (e.g. IHC scores) to be uploaded in ART or the DWH.
All (material) costs will be reimbursed through the Financial department.

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Application and Request tool
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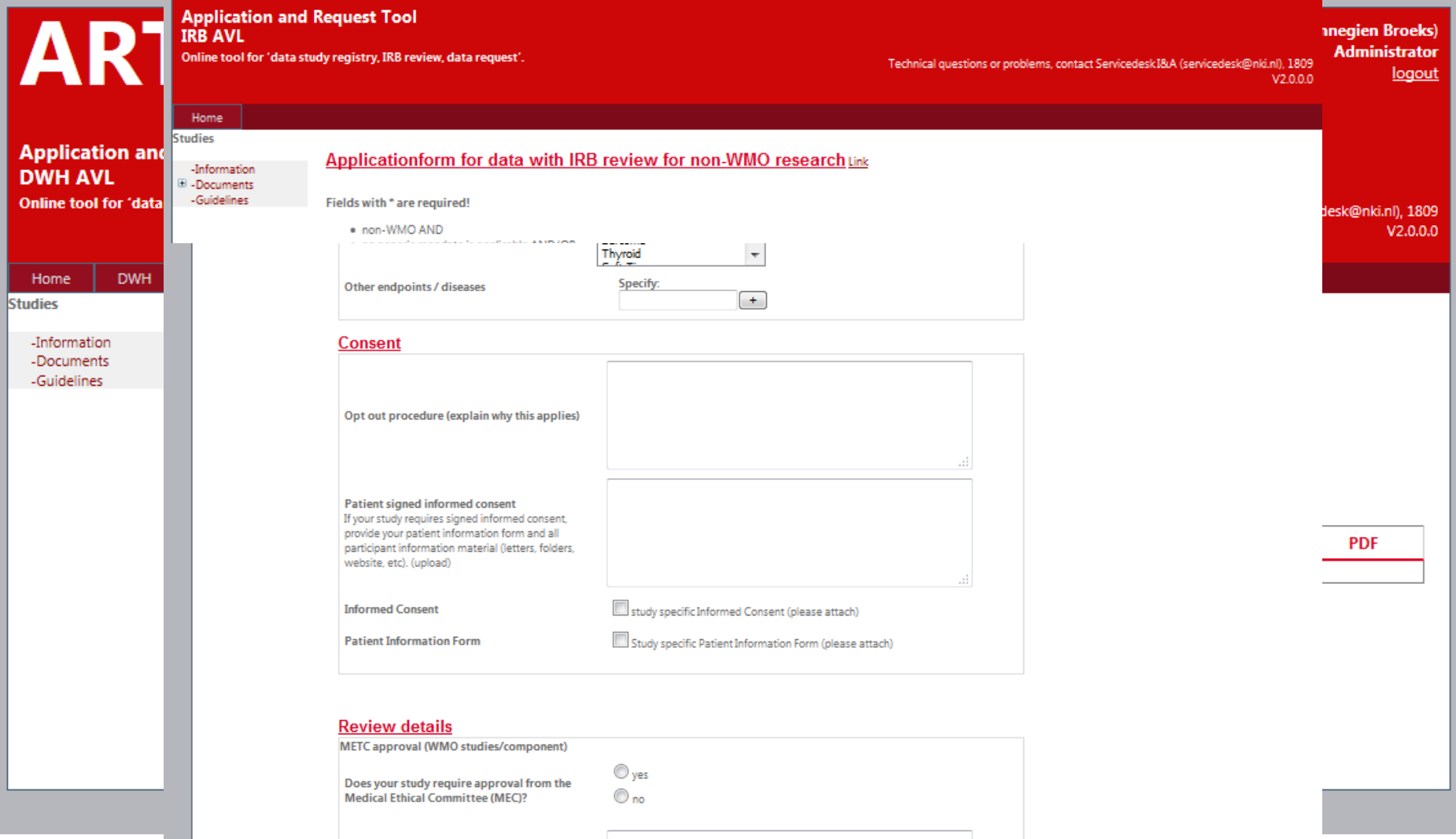

Application and Request Tool
IRB AVL
Online tool for 'data study registry, IRB review, data request'.
Technical questions or problems, contact Servicedesk I&A (servicedesk@nki.nl), 1809
V2.0.0.0
Home
Studies
-Information
-Documents
-Guidelines
Applicationform for data with IRB review for non-WMO research Link
Fields with * are required!
non-WMO AND
Thyroid
Other endpoints / diseases
Specify:
Consent
Opt out procedure (explain why this applies)
Patient signed informed consent
If your study requires signed informed consent, provide your patient information form and all participant information material (letters, folders, website, etc). (upload)
Informed Consent
study specific Informed Consent (please attach)
Patient Information Form
Study specific Patient Information Form (please attach)
Review details
METC approval (WMO studies/component)
Does your study require approval from the Medical Ethical Committee (MEC)?
yes
no
How do you know?
- Own judgement
- Checked with MEC secretary
Data IRB The IRB will review your data request and has the mandate from board of directors to judge the application (see also IRB regulations document and IRB workinstructions document)
Save
Save & Submit
Pdf
Administrator
logout
PDF
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Registration & IRB review process **ART-IRB DATA**

Alle data moet worden opgevraagd via de DataDesk – registratie

hoofdloket & subloktten (wetenschappelijk en BI)

consent check!

IRB is alleen noodzakelijk als :

- Patient identifiers nodig zijn EN/OF
- De data kan niet gepseudonymiseerd worden geanalyseerd EN/OF
- De data verzameling is prospectief (PIF/IC) EN/OF
- De data gebruik/ verzamling is invasief (PIF/IC) EN/OF
- De data wordt gedeeld (met derden/extern) > DTA nodig

- Is de consent correct?

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Take home message

- Elke nieuwe studie moet worden geregistreerd

  DataDesk & ART

- Een studie moet worden getoetst

  METC & IRB

- Data en materiaal uitgifte gecentraliseerd

  Consent check waarborging!

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