

# **Data sharing, access and release**

Working group report

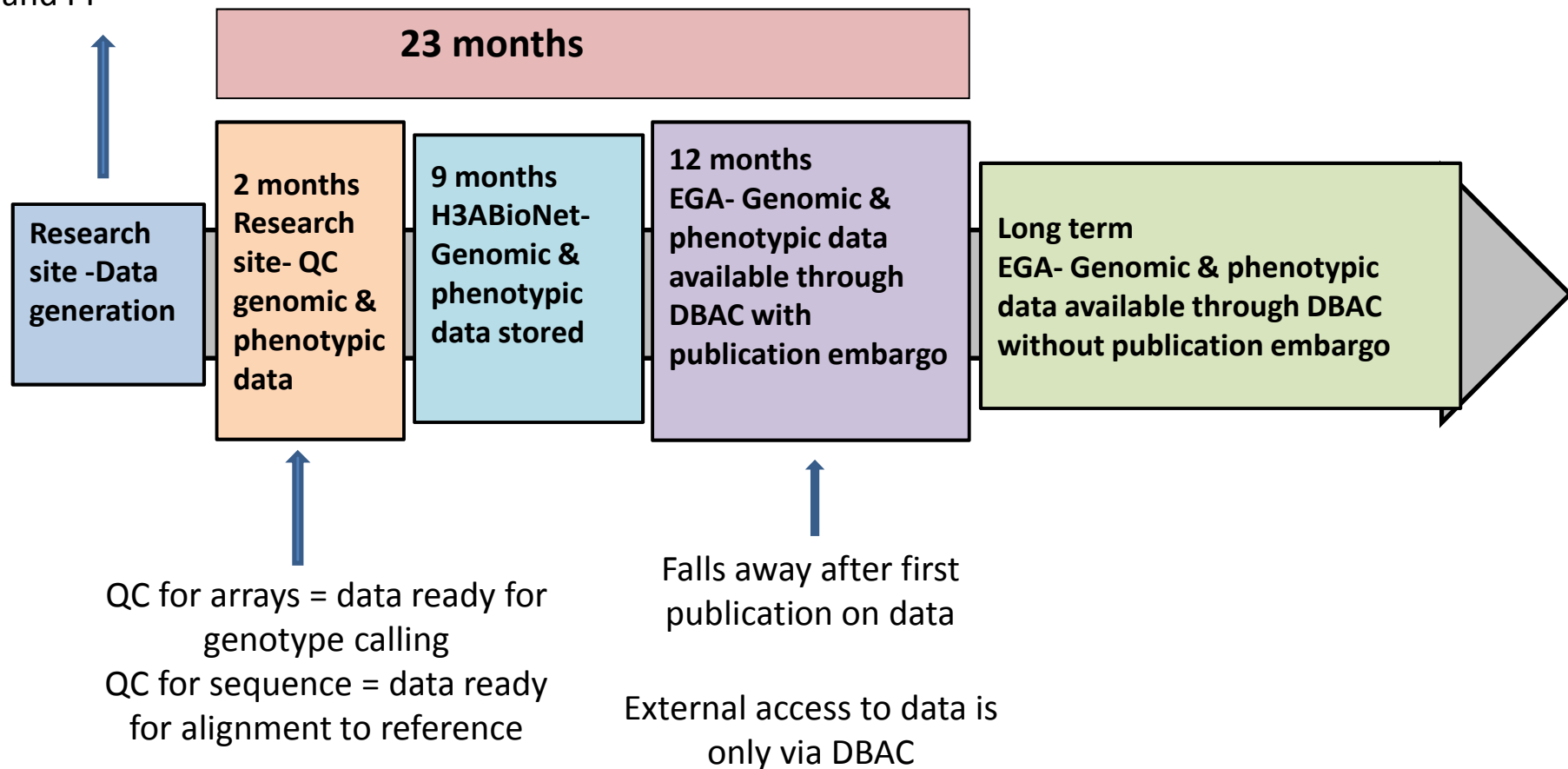
# Policy documents

- H3Africa Consortium Data Sharing, Access and Release (DSAR) Policy
- Related documents (appendices):
  - A. Data Quality Control and Validation Guidelines
  - B. H3ABioNet Data Submission Guidelines
  - C. EGA Submission Guidelines
  - D. Data and Biospecimen Access Committee Guidelines
  - E. Data Access Request Form (Form for researchers to request access to data)
  - F. Data Access Agreement (Form for researchers who have access to data)
  - G. Policy Statement & Institutional Certification (Form for PIs to submit to EGA)

# Process for data submission

Publishable dataset –can be subset of complete project, but standalone. To be agreed between grant officer and PI

Datasets can be submitted before they are complete but clock won't start ticking!



# Responsibilities

- H3ABioNet responsible for:
  - Keeping data secure
  - Will have copy + replicated sites
  - Helping with transfer of data
- H3ABioNet not responsible for:
  - Deciding on who gets access
  - Ensuring ethics is in place
  - Ensuring validity of data
- H3ABioNet can help with:
  - Accessibility for data analysis/mining
  - Preparation for submission to EGA

# Data access agreement

- Agreeing to:
  - H3Africa not liable for use of data
  - Only use data for agreed purpose
  - Maintain data confidentiality
  - Make sure data is secure
  - Acknowledge source of data
  - Submit annual reports
  - Project put onto website
  - Access is granted for 1 year

# Future plans

- DSAR WG –data access agreement, monitor implementation plan
- Data management/support working group
  - Meet monthly to discuss different aspects of data management and analysis
  - Will have some structure –topics planned but with flexibility
  - Please send names
- Work with Genome Analysis group on meta-analysis or consortium-wide research projects

# Data Sharing, Access and Release Working Group Members

Akin Abayomi	Alan Christoffels	Nicola Mulder	<b>Nicky Mulder</b>
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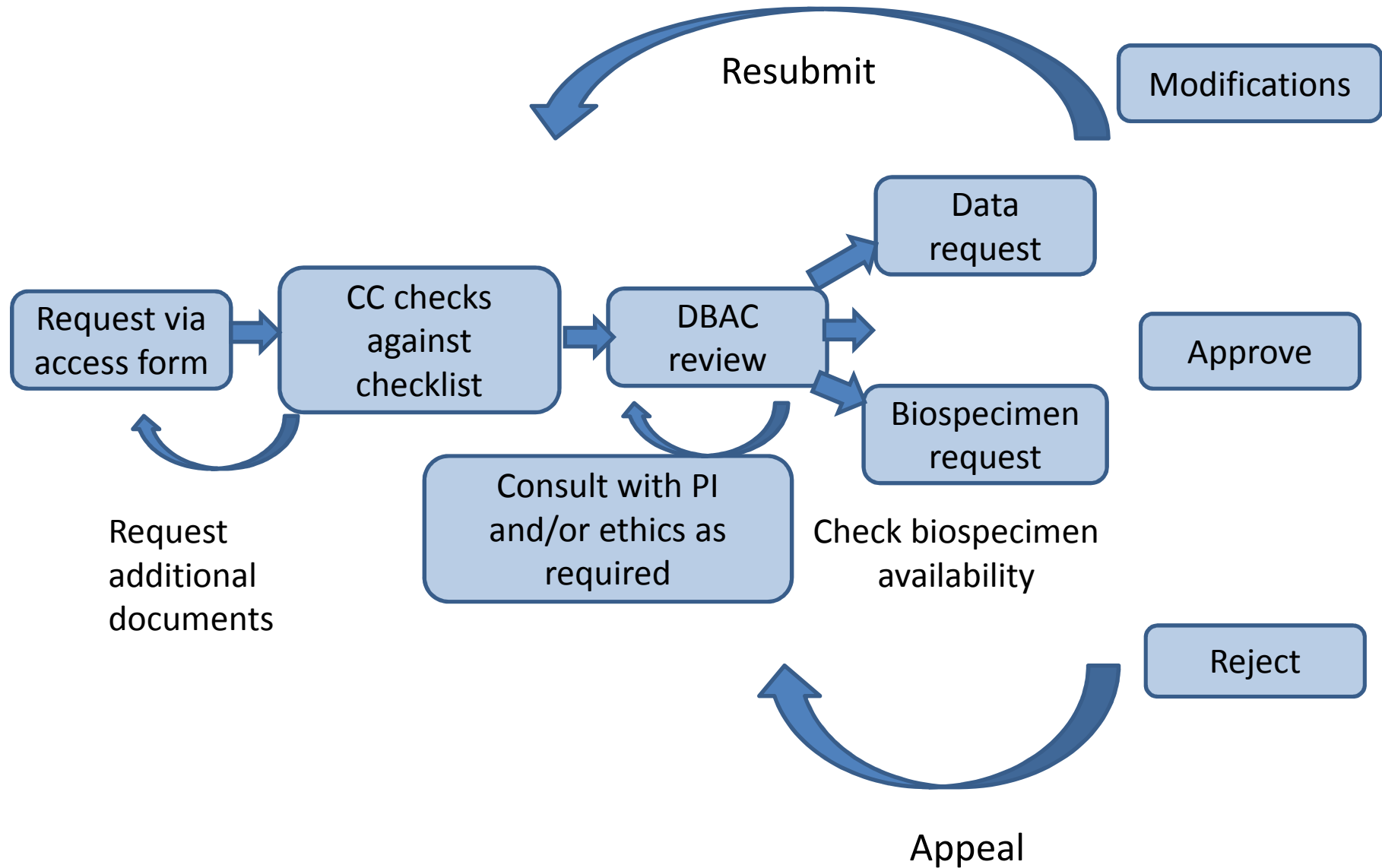
# DBAC Guidelines

- 8 members unrelated to H3Africa consortium (preferably with majority residing in Africa)
  - Scientists with relevant research experience
  - Biobanking expertise
  - Data expert
  - Ethics expert
  - Legal representative
  - Community representative, advocacy group or nurse
- Can call on external expertise as required
- Accountable to H3Africa SC
- Quorum is 5/8 members
- Appointed for 3 years + 3 extra possible
- 3 should stay on with any change in committee

# Role of DBAC

- Review and approve requests for data and/or biospecimens via access request form
- Give feedback within 30-60 days of request
- Biospecimens
  - first 3 years only access outside H3Africa for those collaborating in Africa
  - Use info on availability in biobanks
  - Data generated must be submitted to EGA
  - Scientific review/funding available
- Data
  - DBAC will ensure requestor has expertise and resources
  - Scientific review
- Evaluation criteria
  - Scientific merit
  - Institutional capacity for the research
  - Potential for publication or translation, e.g. new therapies

# Request process



# After approval, prior to release

- Requestor may still need to apply for funding
- Data:
  - Sign data access agreement
  - Data released –applicable for one year
  - Submit progress report
- Biospecimen:
  - Sign MTA
  - Funding award letter or evidence of resources submitted with MTA
  - Biospecimen released
  - Data generated off biospecimen submitted to EGA
  - Submit progress report

# Issues to address

- Make sure guidelines conform to your ethics approval and MTA (for biorepositories when available)
- If not –consult with ethics committee, if no resolution, consult with DBAC WG
- Nominate members of DBAC

# Data and biospecimen access request form (1)

- **Name, position, affiliation and full postal and email address of applicant and co-applicant(s):**
  - Only principal investigators and supervisors are eligible to apply, all students involved in the project must be listed. Project title
- **Project title**
- **Research question**
  - Clear description of the project and its specific aims. Include: a. outline of the study design; b. which disease and/or control genotypes you require; c. timeline; d. key references
  - **For Biospecimen requests:** Please provide a **clear** description of a. the methodologies to be used on the biospecimens; b. specific details of what you plan to do with the biospecimens.
  - **For Data requests:** Please provide a **clear** description of a. the methodologies to be used on the data; b. specific details of what you plan to do with the data;

# Data and biospecimen access request form (2)

- **Details of data/biospecimens requested**
  - **For Biospecimen requests:** The Project Biospecimen applied for
  - **For Data requests:** The Project data applied for
- Select **phenotypes** required
- **Research ethics**
  - Do you foresee any ethical issues, including potential harms to data subjects such as potential stigmatisation of ethnic groups, arising as a result of your research? If so, how do you plan to address such issues?
- **Benefits to Africa**
  - **Please list your African collaborators** (this is required for biospecimens for the first 3 years after submission)
- **Resources, Feasibility & Expertise**
- **Consent and Approvals**
- **Agreement to abide by the relevant policies or MTAs**

# Implementation

- Need list of project aims on H3Africa website (**end of 2014**)
- Recruitment database
- Managing consortium access before EGA
- Setting up DBAC (**nomination deadline 31 Jan, decision March**)
- Develop access request form(s) (**DB WG**)
- Develop review checklist (**SC and CC**)
- Receiving applications and checking them before sending to DBAC
- Long term management/support of DBAC
- Capturing info on H3Africa website about approved requests
- Monitoring publications (rs feed?)
- Monitoring access requests
- Monitor progress reports (set up template for progress reports)
- Monitoring that data generated off biospecimens is submitted to the EGA under the H3Africa project (goes into biospecimen progress report)

# DBAC task force

- Nicky Mulder
- Jennifer Troyer
- Audrey Duncanson
- Maria Giovanni
- Julia Puzak
- Michelle Skelton
- Katherine Littler
- Jantina De Vries
- Ken Wiley
- Akin Abayomi
- Louise Wideroff
- Quynh Nguyen