

Supporting Information

Supplementary figures and tables

This appendix was part of the submitted manuscript and has been peer reviewed.
It is posted as supplied by the authors.

Appendix to: Haas MA, Boughtwood T, Quinn MCJ; Australian Genomics. The ethics approval process for multisite research studies in Australia: changes sought by the Australian Genomics initiative. *Med J Aust* 2019; doi: 10.5694/mja2.50397.

Table 1. Summary of requirements of research governance offices for SSA for sites involved in Australian Genomics. Refer to footnote for abbreviations.

<i>SITE</i>	<i>Participating in NMA, recognising Melbourne Health HREC review</i>	<i>original NEAF document required in submission</i>	<i>New Investigator form and/or CV</i>	<i>Document Checklist template</i>	<i>Application requirements</i>	<i>Other requirements</i>	<i>Australian Genomics RCA accepted</i>	<i>Hard copy application requirements</i>	<i>Party to Australian Genomics MIA</i>	<i>Charge for service (\$)</i>	<i>Charge for amendments (\$)</i>	<i>Reason for approval delay</i>
A	yes	yes	yes	yes	contracts approval and study execution form	financial costing of in kind clinical contribution, Queensland Health SFO check	with review	yes x 1	no	\$700	\$150	understaffing of RGO
B	no	no	no	yes	application form	no	N/A	yes x 8	no	no	no	N/A
C	yes	yes	yes	no	SSA, RCA, Site-specific PICF's, Pathology [‡]	no	review with review	yes x 1	no	no	no	research contract / busy RGO
D	yes	no	yes	no	SSA, RCA, Site-specific PICF's, Pathology	Master PICFs customised for each flagship project	review	no	no	no	no	N/A
E	yes	yes	yes	yes	SSA, RCA, Site-specific PICF's	Master PICFs customised for each flagship project required for latest amendment	N/A	RCA x3	yes	\$165	no	N/A
F	yes	yes	yes	yes	SSA, RCA, Site-specific PICF's	Master PICFs customised for each flagship project required for latest amendment	N/A	RCA x3	yes	\$165	no	N/A
G	yes	yes	yes	yes	SSA, RCA, Site-specific PICF's, Pathology	General Manager signoff	No - replaced with CTRA CRG	CTRA x3	no	no		understaffing of RGO / research contract
H	yes	yes	yes	yes	SSA, RCA, Site-specific PICF's, Pathology	no	N/A	RCA x3	yes	no	no	N/A
I	yes	yes	yes	yes	SSA, RCA, Site-specific PICF's, Pathology	N/A	No	N/A	no	no	no	research contract
J	yes	yes	yes	yes	SSA, RCA, Site-specific PICF's, Pathology	no	No - replaced with CTRA CRG	yes	no	no	no	N/A
K	yes	yes	yes	yes	SSA, RCA, Site-specific PICF's, Pathology	no	No - replaced with CTRA CRG	RCA x3	no	no	no	additional questions
L	yes	yes	yes	yes	SSA, RCA, Site-specific PICF's, Pathology	Study budget to include PI/AI time commitment, costs and to be signed by Business Manager	yes	no	no	no	no	understaffing of RGO
M	yes	yes	yes	yes	SSA, RCA, Site-specific PICF's, Pathology	Perinatal Academic Group (PAG) Study Review to be approved by PAG Committee	No - replaced with CTRA CRG	RCA x3	no	no	no	unclear review process requirements
N	yes	yes	yes	yes	SSA, RCA, Site-specific PICF's, Pathology	no	yes	yes x 1, RCA x 1	no	no	no	understaffing of RGO / busy RGO

O	yes	yes	no	no	SSA, RCA, Site-specific PICF's, Pathology	no	with review	no	no	\$265	no	N/A
P	yes	yes	yes	yes	SSA, RCA, Site-specific PICF's, Pathology	VSM	with review	yes x 1	yes	no	no	N/A
Q	yes	yes	yes	yes	SSA, RCA, Site-specific PICF's, Pathology	VSM, Good Clinical Practice (CGP) training, Health Information Services declaration	with review	yes x 1, RCA x 3	no	\$660	\$165	understaffing of RGO, unfamiliarity with the project
R	yes	yes	yes	yes	SSA, RCA, Site-specific PICF's, Pathology	VSM	with review	yes x 1, RCA x 3	no	\$330	no	N/A
S	yes	yes	yes	no	SSA, RCA, Site-specific PICF's	no	with review	no	yes	no	no	research contract
T	yes	yes	yes	yes	SSA, RCA, Site-specific PICF's, Pathology	VSM, detailed budget	N/A	yes x 1, RCA x 3	yes	no	no	N/A
U	yes	yes	yes	no	SSA, RCA, Site-specific PICF's, Pathology	VSM	CTRA CRG	yes x 1, RCA x 1	no	no	no	N/A
V	yes	yes	yes	yes	SSA, Site-Specific PICF's, RCA, VSM, Pathology	all HREC correspondence, Health Information Services request, budget	with review	RCA x 1	no	\$600	no	research contract, review HREC correspondence
W	no	yes*	no	no	Tasmania Health Service SSA, RCA?, Site-specific PICF, Pathology	financial analysis template, clinical trial request form, study summary	unclear	yes x 1	no	no	no	understaffing of RGO/unknown
X	yes	yes	yes	yes	SSA, RCA, Site-specific PICF's, Pathology	confidentiality agreement, budget, site specific modification to wording on consent	with review	no	no	no	no	N/A
Y	yes	yes	no	yes	SSA, RCA, Site-specific PICF's, Pathology	SA DCSI screen, confidentiality agreement, site specific modification to wording on consent	with review	yes x1 (all documents)	no	no	no	request for changes to study documents approved by the lead HREC
Z	no	no	no	yes	SSA, RCA, Site-specific PICFs, detailed Budget, electronic only via RGS	detailed budget, amendments via email	yes	RCA x3 (wet ink signature)	no	in kind	in kind	N/A
AA	no	no	no	no	SSA, RCA, Site-specific PICFs, detailed Budget,electronic only via RGS	detailed budget, amendments via email	yes	RCA x3	no	in kind	in kind	Budget requirements, signature requirements
AB	no	no	no	no	SSA, RCA, Site-specific PICFs, detailed Budget,electronic only via RGS	detailed budget, amendments via email	yes	RCA x3	no	in kind	in kind	RGO process
AC	no	no	no	no	SSA, RCA, Site-specific PICFs, detailed Budget,electronic only via RGS	detailed budget, amendments via email	yes	RCA x3	no	in kind	in kind	RGO process, staff changes
AD	no	no	no	no	SSA, RCA, Site-specific PICFs, detailed Budget,electronic only via RGS	detailed budget, amendments via email	yes	RCA x3 (wet ink signature)	no	in kind	in kind	Budget requirements, signature requirements

AE	no	yes^	yes	yes	SSA, RCA	Part D, Aboriginal and Torres Strait Islander core values section	N/A	yes x 1	no	no	no	no RGO for site at start of process, long legal review of RCA
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NMA: National Mutual Acceptance

HREC: Human Research Ethics Committee

PICF: Participant Information and Consent Form

SSA: Site Specific Assessment

RCA: Research Collaboration Agreement

NEAF: National Ethics Application Form

DCSI: The Department for Communities and Social
Inclusion

MIA: Multi-Institute Agreement

VSM: Victorian Specific Module

SFO: Senior Financial Officer

CTRA: Clinical Trial Research Agreement

*reviewed as a prior ethics approval application

^accepted by and reviewed as a new application

¥includes Pathology quote for samples / shipping