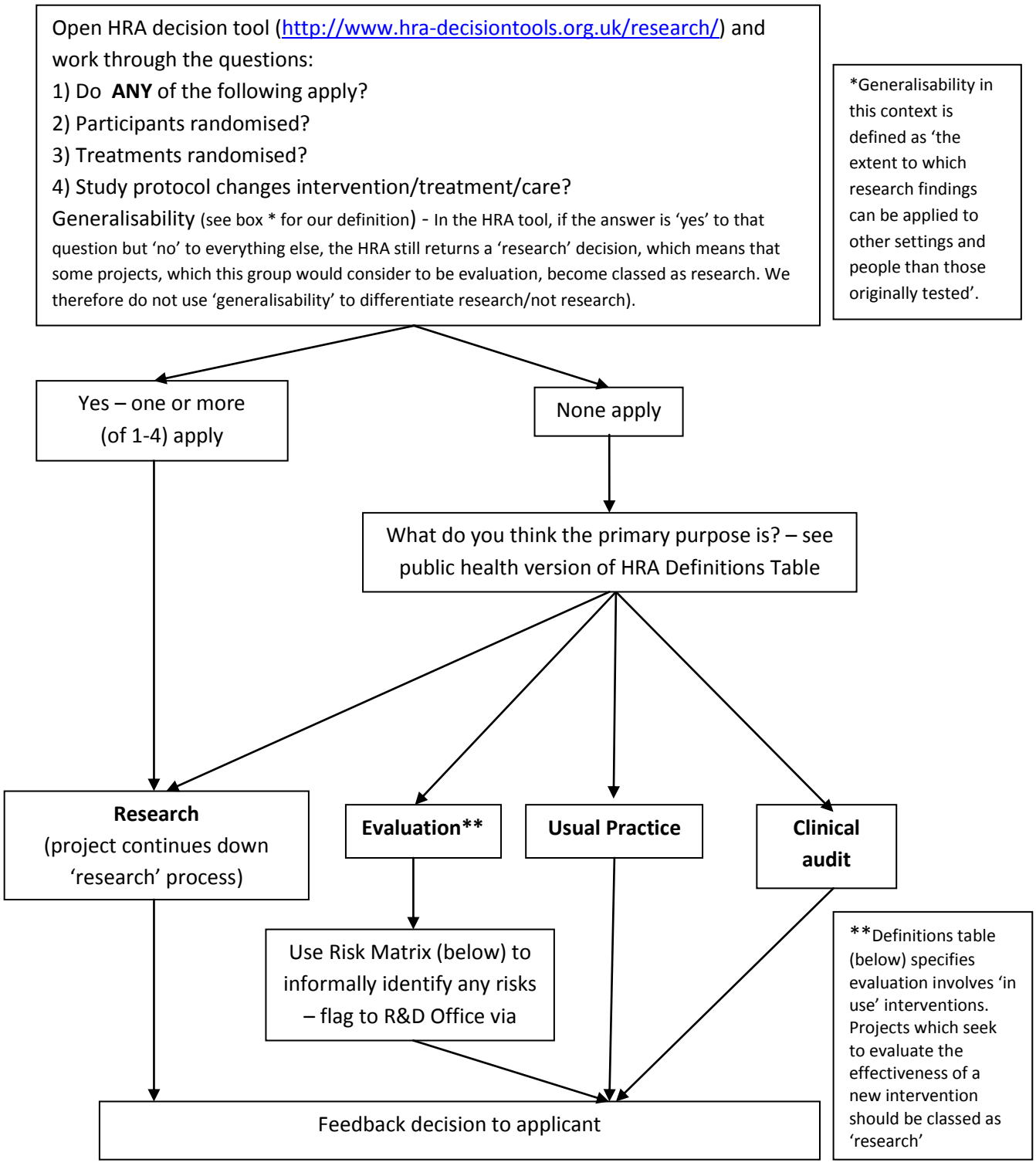
Health & Well-being Directorate R&D Group

Process to be used by group for deciding if a project is 'research' or not



RESEARCH	SERVICE EVALUATION*	CLINICAL AUDIT	USUAL PRACTICE (in public health including health protection)
The attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.	Designed and conducted solely to define or judge current care.	Designed and conducted to produce information to inform delivery of best care.	Designed to investigate the health issues in a population in order to improve population health Designed to investigate outbreak or incident to help in disease control and prevention
Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.	Designed to answer: "What standard does this service achieve?"	Designed to answer: "Does this service reach a predetermined standard?"	Designed to answer: "What are the health issues in this population and how do we address them?" Designed to answer: "What is the cause of this outbreak or incident and how do we manage it?"
Addresses clearly defined questions, aims and objectives.	Measures current service without reference to a standard.	Measures against a standard.	Systematic, statistical or qualitative methods may be used.
Quantitative research – may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced.	Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.	Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.	Involves an intervention in use only. Any choice of intervention is based on best public health evidence or professional consensus.
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.	Usually involves analysis of existing data but may include administration of interview or questionnaire.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.	May involve analysis of existing routine data supplied under license/agreement or administration of interview or questionnaire to those in the population of interest. May also require evidence review.
Quantitative research – study design may involve allocating patients to intervention groups. Qualitative research – uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.	No allocation to intervention: the health professional and patient have chosen intervention before service evaluation.	No allocation to intervention: the health professional and patient have chosen intervention before audit.	No allocation to intervention.
May involve randomisation.	No randomisation.	No randomisation.	May involve randomisation but not for intervention.
Normally requires REC review. Refer to http://www.hra.nhs.uk/resources/before-you-apply/is-nhs-rec-review-required/ for more information.	Does not require REC review.	Does not require REC review.	Does not require REC review.

Risk assessment tool for informal feedback to R&D Office where there are perceived risks to evaluation projects.

	Yes	No	Unclear
Are there any risks to Public Health Wales due to:			
• Financial loss including currency fluctuations	☐	☐	☐
• Reputational issues (e.g. by being involved)	☐	☐	☐
• Ethics (e.g. consent processes; confidentiality, data protection)	☐	☐	☐
• Liability e.g. liability arrangements with collaborators Responsibilities in the project not clear or understood by all parties	☐	☐	☐
• Feasibility (e.g. significant potential that a key deliverable will not be fulfilled)	☐	☐	☐
• Adverse effect on other PHW work	☐	☐	☐
• Does the project require scientific peer review (for projects that will not have independent scientific review as part of the funding application)	☐	☐	☐

The following are examples of areas that may present risk to Public Health Wales and should be considered during the review:

- **Financial** risk e.g. inappropriate cost identification and attribution; financial implications of continued treatment beyond the study.
- **Reputation** e.g. impact on services provision and resources; reputation of funding source; undesirable publicity from poor compliance with legal and governance frameworks; possible fraud and misconduct; undertaking research of poor quality. Is there the potential for significant delays to initiation or completion due to resource availability (internal and external)?
- **Ethics** e.g. consent processes; confidentiality and data protection; sensitive participant populations (e.g. children or adults lacking capacity to consent) or research area.
- **Liability** e.g. liability arrangements with collaborators; complaints. Are all the deliverables, tasks and responsibilities clearly understood by all parties and is there adequate project management? Could the conduct of a study with a collaborator/partner organisation impact on the relationships with other collaborators / partner organisations.
- **Feasibility** e.g. time for recruitment and the process; recruitment criteria and number of participants required. Will staff require additional training? Lack of study power or wrong eligibility criteria.
- **Service delivery** e.g. impact of changing patient/service user care pathways, or of implementing new procedures. Severe interruption to routine service delivery.