

# Getting it Right First Time

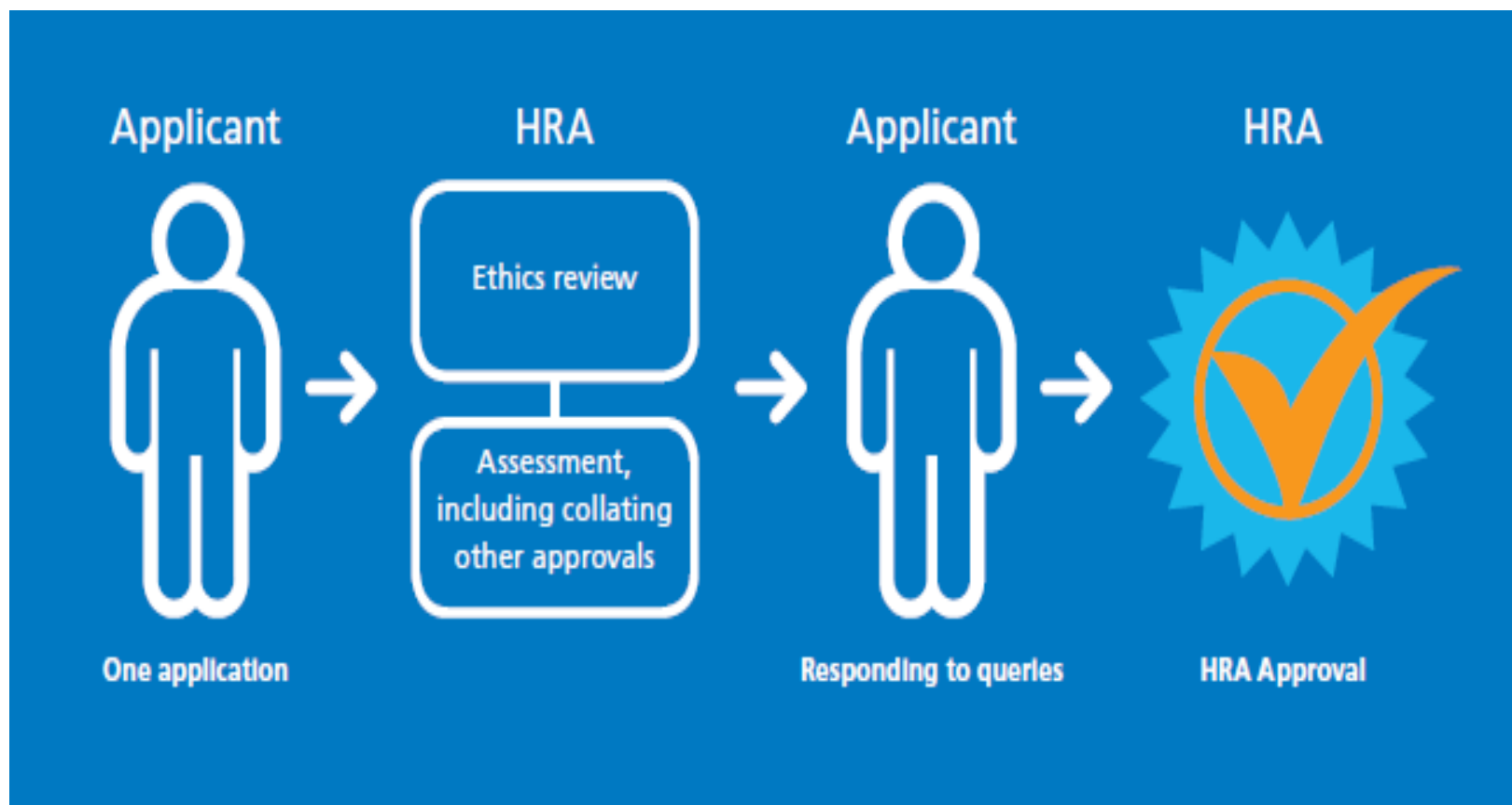
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# HRA Approval



# Its not brain surgery.....

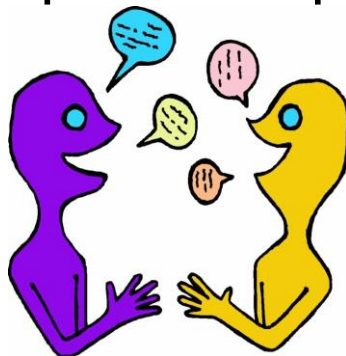


# It's the simple things that make a difference.....




# Before you start


- Read the guidance available to you
  - IRAS
  - HRA Website
- Speak to your sponsor representative or RD/I support department





# Step 1. Preparing your application

- Involving the public can help to demonstrate that the project would be ethically acceptable.
- Read the questions in IRAS and guidance 
  - Answer the question
- Documentation
  - Use templates available
  - [Information Sheet Guidance](#)
  - PIS read by lay person
  - Version control and date




Read the [Best Practice](#) page  
on the HRA  
website

## Step 2. Submitting your application

Check the following **before** submitting:

- IRAS project filter completed correctly (and ask for advice if unsure)
- All questions in IRAS completed
- Check for copy/paste errors and inconsistencies
- Check your form
- Documents uploaded with version and dates
- E-authorisations in place
- Verification tool



Don't make  
any changes to  
IRAS form after  
authorisations

## Step 3. Booking for HRA review

- Have a copy of the application form in front of you when you book.
- Ensure the person making the booking will be able to answer questions about the study.
- Let the booker know if you have previously been informed that the application is not suitable for Proportionate Review.
- Check the website for [REC meeting dates](#) if you have a certain meeting in mind.
- Be ready to submit on the day of the booking.





# Step 4. HRA Validation

- Remember it is a joined up validation
- HRA staff check that the required documents for the ethical review and assessment have been submitted.
- NB: More applications are incomplete on submission than complete.



# Step 5. Attending a REC meeting

- Researchers are recommended to attend the meeting.
- If full REC review, attend in person or be available on the telephone to answer questions.
- If Proportionate Review, ensure that someone with knowledge of the study will be available to answer questions.



# What does the REC look at?



Health Research  
Authority

- Ethical domains REC considers:
  - ✓ Social or scientific value
  - ✓ Recruitment arrangements and access to health information, and fair research participant selection
  - ✓ Favourable risk benefit ratio
  - ✓ Care and protection of research participants
  - ✓ Informed consent process and the adequacy and completeness of research participant information
  - ✓ Suitability of the applicant and supporting staff
  - ✓ Independent review
  - ✓ Suitability of supporting information
  - ✓ Other general issues

# Reasons for Provisional Opinions

Health Research  
Authority

- Unclear standard clinical care versus study related.
- Recruitment strategy, who will approach and when?
- Clarity required on who will access data.
- Inclusion of adults lacking capacity/vulnerable population not adequately justified.
- Feeding back to participants (incidental findings/ study results)
- Clarification needed regarding the complaints procedure.

# What do the Assessment team look at?

- Assessment against HRA Assessment and Criteria
  - UK wide standards
- Key areas with commons queries raised
  - Identification and consent of participants
  - Data Protection
  - Insurance arrangements
  - Use of human tissue
  - Radiation
  - Intellectual Property



# Step 6. Responding to HRA

- Respond to queries raised by HRA promptly
- Submit the response to REC using IRAS
  - For REC Include a covering letter explaining how you have addressed the points raised by the Committee.
- Answer queries from assessor via email
- Any changes to document are submitted using IRAS
- Ensure any changes you have made are tracked or highlighted.
- Be sure to update version numbers and dates.
  - Including file name



# Questions?



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