Beaumont Hospital Research Approval Pathway RESEARCH PROPOSAL Health Products Does research involve Regulatory Agency Medicinal Product? https://www.hpra.ie HPRA Approval Provided RADIATION SAFETY Does research involve exposure Beaumont Hospital to Ionising Radiation? Radiation Safety Committee Radiation Safety Approval Provided ETHICS REVIEW **BH Ethics Department** Do you have Ethics Approval? beaumontethics@rcsi.com https://www.beaumontethics.ie/ 01 809 2680 / 01 797 4711 LOCAL STUDY Does research involve Is research proposal, including Is a Health Research Consent Local Study can proceed subject to requirements outlined by BH Ethics Committee 3rd Party consent process approved Declaration required? REQUIRED: Clinical Trial Agreement **Health Research Consent** Has HRCDC Dedaration Committee And / or dedaration been provided Data Sharing Agreement https://www.hrcdc.ie/ Material Sharing Agreement ${\bf Must\ be\ i\ nclusive\ of\ DPIA\ } ({\it External}$ No Ethics Approval) and undertaking to comply with GDPR REQUIRED: REQUIRED (as applicable): INSURANCE REVIEW LEGAL REVIEW Clinical Trial Agreement / Contact Data Sharing Agreement Clinical Trial Indemnity Form Clinical Trial Agreement Insurance Officer Via Clinical Risk Management Material Sharing Agreement Ethics Approval lynneher bert@beaumont.ie crm@beaumont.ie 01 809 2611 01 809 2611 if 3rd Party Involvement: Review indudes GDPR compliance 3rd Party Insurance Cert (€6.5m) 3rd Party signed Clinical Trial Indemnity Form 3rd Party Agreement / Contract REQUIRED: FINANCE REVIEW Ethics Review Evidence of Insurance Cover Adam O'Hare 3rd Party Insurance Cert. (if Guide timeline for completion adamohare@beaumont.ie applicable) 01 809 2107 Letter declaring no financial implications on BH REQUIRED (HARD COPY): **QPS REVIEW** Clinical Trial Indemnity Form Clinical Trial Agreement / **Sharon Dwyer** Contract sharondwyer@beaumont.ie Ethics Review 01 809 3921 Insurance Review Finance Review HPRA Approval (if applicable) SSA Form (if applicable) Evidence all conditions of HRCDC have been complied with REQUIRED: Memo of recommendation from Director of QPS **CEO APPROVAL** Supporting documentation as above REQUIRED: Copy of completed Request for Signature Document sent to BH RESEARCH APPROVAL $Ethics\,R\,esearch\,Committee$ Annual Report on status of research sent to BH Ethics Research Committee and copy to QPS Director