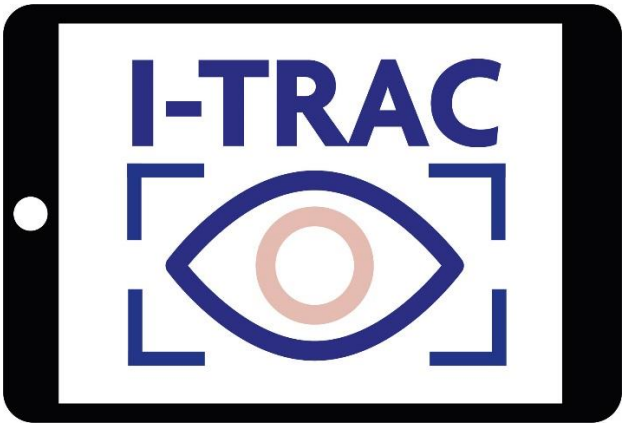
STUDY PROTOCOL



This document contains two linked Protocols for the NIHR HTA funded study 'In-home Tracking of glaucoma: Reliability, Acceptability, and Cost: the I-TRAC Study' [NIHR 129248]. The Protocols were developed separately on guidance from Sponsor as the first protocol describes a work package that does not require R&D approval (but do require Institutional REC approval) where as the second Protocol research activities do require NHS REC and R&D approval. These two Protocols detail the following:

1. In-home Tracking of glaucoma Work Package 1 [*pages 2-14*]. This Protocol details the first work package of the proposed project which aims to identify which glaucoma patients are most appropriate for home monitoring (e.g. all patients, or those with stable disease, or those with severe glaucoma?). This will be achieved through a survey of Consultant Ophthalmologists who routinely treat patients with glaucoma.
2. In-home Tracking of glaucoma Work Packages 2-4 [*pages 15 - 48*]. This second Protocol details the substantive component of the I-TRAC project which aims to determine the feasibility and acceptability of digital technologies to monitor glaucoma at home and inform the possible need and design of a definitive evaluative study. This will be achieved through a mixed methods multi-phase programme of activity using interviews, focus groups, questionnaires and assessment of digital technologies in practice.

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Non-CTIMP Protocol Template

Study Protocol

Full Title:	In-home Tracking of glaucoma Work Package 1:
Study Acronym:	**I-TRAC WP1**
Sponsor:	University of Aberdeen
Sponsor Reference Number:	Not applicable
Funder:	National Institute for Health Research, Health Technology Assessment Programme
Chief Investigator:	Dr Katie Gillies
REC Reference Number:	CERB/2020/5/1963
R&D Reference Number:	Not applicable
ISRCTN / Clinicaltrials.gov No:	Not applicable
Version Number and Date:	Version 2

Protocol Approval

Signatures

By signing this document I am confirming that I have read, understood and approve the protocol for the above study.

Dr Katie Gillies	K Gillies	21st September 2020
Chief Investigator	Signature	Date

Version	Date	Change
1	180820	Approval of V1
2	210920	Change to also include the UK & Eire Glaucoma Society (UKEGS) in survey.

List of Abbreviations

CI	Chief Investigator
CNORIS	Clinical Negligence and Other Risks Scheme
CRF	Case Report Form
DMC	Data Monitoring Committee
GCP	Good Clinical Practice
ISF	Investigator Site File
PI	Principal Investigator
PMG	Project Management Group
R&D	Research and Development
REC	Research Ethics Committee
SOP	Standard Operating Procedure
TMF/SMF	Trial/Study Master File
TSC	Trial/Study Steering Committee

Summary

Glaucoma is a common chronic eye condition and the second commonest cause of blindness in the UK. It is typically influenced by the pressure in the eye (intraocular pressure) being too high, for a particular person. Glaucoma impairs mainly the peripheral vision (visual field). Treatments reduce eye pressure to delay or stop glaucoma getting worse. However, in some glaucoma may still progress, so patients need regular monitoring at hospital eye services where they have their eye pressure and the visual field measured. This allows doctors to assess effectiveness of current treatment and detect glaucoma progression. Patients need these check-ups for the rest of their lives.

Hospital eye services are very busy, accounting for 10% of all NHS outpatient visits. Glaucoma patients represent a significant part of this workload, in England alone over 1 million visits per year are for glaucoma patients. Providing regular surveillance and treatment is already a major challenge for the NHS. The prevalence of glaucoma increases with age. Demand for glaucoma care is increasing (and will continue to do so) due to our aging population.

Recent advances in technology mean it is now possible for glaucoma patients to monitor eye pressure and visual fields in their own home. Their information could be transferred to the hospital for interpretation by a health care professional, or they could request hospital appointment if the home tests show their glaucoma has worsened or eye pressure has increased. Home monitoring could mean patients requiring fewer hospital check-ups, whilst increasing convenience and potentially reducing costs and increase capacity for the NHS.

Currently though, we do not know if home monitoring is acceptable to people with glaucoma, or if home monitoring in the general glaucoma population is feasible. The main aim of our study is to assess acceptability and feasibility of home monitoring, and to make recommendations about future research to test how the NHS could use home monitoring.

The project detailed in this protocol outlines the first work package (WP1) of a multiphase project. Work package 1 aims to identify which patients would be most appropriate for home monitoring. Frequency of monitoring for glaucoma patients is determined by severity of disease and rate of progression. At the moment it is uncertain which population would benefit most from home monitoring, e.g. those with stable and well controlled disease or those with severe glaucoma at high risk of progression. This first WP will then inform the subsequent phases of the project, which will involve NHS patients and is being reviewed by an NHS REC.

This research fits one of the top five research recommendations by the James Lind Alliance, i.e., “What can be done to improve early diagnosis of sight-threatening glaucoma”? We have included a patient as independent member of the Study Steering Committee who will be actively involved in the conduct and governance of the research. We will also involve the International Glaucoma Society in an advisory role. Results of the study will be shared with those who participated and with relevant stakeholders in Hospital Eye Services.

1.	Introduction
1.1.	**Background**
	Resource constraints resulting in delays in patients' access to glaucoma services have resulted in vision loss due to glaucoma [1]. Glaucoma services are overwhelmed and struggling to accommodate current demands [8]. Reducing the need for hospital based services will improve the ability to see those most at risk of vision loss, which could alleviate both demand on the service and improve patient outcomes. Digital technologies that provide opportunities for home monitoring of glaucoma progression have potential to contribute to solve these challenges and, potentially, improve outcomes. However, understanding which patients could benefit most, the acceptability of the technologies, and the implications for the service need to be resolved before a definitive evaluative study can be conducted. The feasibility study outlined in this application will address these uncertainties. There are recent advances for home monitoring of chronic diseases such as type 1 diabetes (e.g., real-time continuous glucose monitoring, where glucose levels can be accessed electronically by physicians) and high blood pressure (ambulatory blood pressure monitoring, ABPM). Glaucoma is the second leading cause of blindness in the UK and it is potentially preventable. Glaucoma is an age-related chronic and progressive eye condition that requires regular monitoring at hospital eye services (HES). When diagnosis of glaucoma is confirmed, treatment with anti-glaucoma therapy is started. Treatment is escalated when there is a diagnosis of progression of disease, typically with visual field testing, or when the intraocular pressure (IOP) is above the individualised target level. When patients receive additional treatment (e.g., additional eye drops) patients are reassessed at each subsequent visit to determine disease stability and IOP control, to decide whether further treatment escalation is necessary. Hospital eye services (HES) account for 10% of the NHS outpatient activity, and about ¼ of all outpatient visits to HES are due to glaucoma. Thus monitoring of patients with glaucoma generates a considerable burden for the NHS and for patients. Over £500m is currently spent on glaucoma care in the NHS [9]. This is likely to increase as the population ages and more people develop glaucoma during their lifetime and require longer periods of monitoring as they live longer [8]. Already there is evidence that burden of glaucoma follow-up on the NHS is exceeding resources to undertake it and there is UK-wide data that lack of timely monitoring has resulted in some glaucoma patients losing vision and even progressing to blindness [1]. Evaluations of digital technologies (such as apps) for home monitoring to reduce demand on the service whilst simultaneously improving patient outcomes through earlier detection of disease progression are an urgent priority.
1.2.	**Rationale for Study**

	The need for this research is multipronged and addresses calls from national funders, the Department of Health, and the James Lind Alliance. The work described in our proposal will generate evidence on the feasibility of home monitoring for glaucoma and whether the use of digital technologies in this context have the potential to improve efficiencies for the NHS and self-management for patients. Digital technologies are now available for regular monitoring of glaucoma by patients at home. Specifically, applications for self-monitoring of visual function (visual field test) and the Icare HOME technology, which has been developed to measure IOP at home. These technologies are safe, FDA approved and CE marked, and allow data to be acquired at home and potentially transmittable to a hospital without the need for patients to interpret tests results, making home monitoring of glaucoma practicable. In a new model of care implementing digital technologies in this setting, glaucoma patients would be monitored using the home monitoring tests rather than attending HES. If the tests confirmed that glaucoma is under control further HES visits would not be needed. If the home monitoring tests indicated a deterioration, the patient or the clinician would arrange an appointment and/or a prescription for additional treatment would be issued. Under this new model, the focus of NHS hospital glaucoma clinics would then shift to providing appointments to people with progressing or uncontrolled disease, rather than regular monitoring of patients with good disease control. This shift would allow amplifications in staff productivity by releasing time previously committed to regular monitoring appointments. However, before the benefits of digital technologies for glaucoma home monitoring are realised the feasibility of their use in practice and the potential benefits for patients and the health care service needs to be assessed. The project detailed in this protocol outlines the first work package (WP1) of a multiphase project. Work package 1 aims to identify which patients would be most appropriate for home monitoring. Frequency of monitoring for glaucoma patients is determined by severity of disease and rate of progression. At the moment it is uncertain which population would benefit most from home monitoring, e.g. those with stable and well controlled disease or those with severe glaucoma at high risk of progression. In order to identify which patents may be most appropriate for home monitoring we will use vignettes describing different clinical scenarios covering patients with low and high risk of disease progression. Clinical vignettes are simple, efficient tools used to measure variation in clinicians' beliefs, attitudes and behaviours in relation to diagnosis and management of patients with similar conditions . This first WP will then inform the subsequent phases of the project, which will involve NHS patients and is being reviewed by an NHS REC.
2.	**Study Objectives**
2.1.	**Objectives**
2.	**Primary Objective**

	Identify which glaucoma patients are most appropriate for home monitoring (e.g. all patients, or those with stable disease, or those with severe glaucoma?);
2.	**Secondary Objectives**
2.2.	**Outcomes**
2.	**Primary Outcome**
2.	**Secondary Outcomes**
3.	**Study Design**
3.1.	**Study Description**
	An online survey to identify glaucoma patients most suitable for home monitoring will be hosted and disseminated through the Survey Monkey platform. Consultants Ophthalmologists who are members of the Royal College or the UK & Eire Glaucoma Society (UKEGS) will be sent an invitation to participate in the study with a weblink to the survey through the Royal College Ophthalmologists (RCOphth) and the UKEGS distribution lists. The survey will ask clinicians to consider a variety of scenarios or vignettes. In this case the vignettes will take the form of brief narratives containing key items of information about glaucoma severity (mild, moderate, severe), current treatment, disease control (apparently well controlled, uncertain) and management options that are available to fictional patients. These vignettes will be developed by the Research Fellow through discussion with the three clinical leads for each of the recruiting sites in subsequent phases of the project. The order of the presentation of the vignettes will be randomised and presented. For each clinical vignette, Consultant Ophthalmologists will be asked to consider whether these patients would be appropriate for home monitoring using the digital technologies being assessed in this application. The data from the clinical vignette will be presented and the consultants will be asked to score a patient as either 'Appropriate'/'Not appropriate'/'Unclear' for home monitoring. If 'unclear' is selected further information will be requested (through open text comments boxes) for justification of this response.
3.2.	**Study Flowchart**
3.3.	**Study Matrix**

4.	**Study Population**
4.1.	**Number of Participants**
	The survey will be hosted and disseminated through the online Survey Monkey platform . Consultants Ophthalmologists who are members of the Royal College or the UKEGS will be sent an invitation to participate in the study with a weblink to the survey through the Royal College Ophthalmologists (RCOphth) and UKEGS distribution lists. The RCOphth and UKEGS distribution lists have previously been utilised for disseminating surveys for research purposes and the RCOphth have agreed to disseminate our survey. The RCOphth list can facilitate dissemination to approximately 100 clinical lead Consultant Ophthalmologists with a predicted response rate based on other RCOphth administered surveys of 45%. The UKEGS will enrich the sample for Consultant Ophthalmologists who are currently specialising in treating patients with glaucoma. We aim to recruit a suitable number of Consultant Ophthalmologists who are representative of those working in the UK and making decisions about the clinical care of patients with glaucoma.
4.2.	**Inclusion Criteria**
	Consultant Ophthalmologists who currently treat patients with glaucoma and are members of and included on the distribution list for the Royal College of Ophthalmologists.
4.3.	**Exclusion Criteria**
5.	**Participant Selection and Enrolment**
5.1.	**Identifying Participants**
	Consultants Ophthalmologists who are members of the Royal College or UKEGS will be sent an invitation to participate in the study with a weblink to the survey through the Royal College Ophthalmologists (RCOphth) and UKEGS distribution lists. The RCOphth and UKEGS distribution list has previously been utilised for disseminating surveys for research purposes
5.2.	**Consenting Participants**
5.3.	**Screening for Eligibility**
5.4.	**Ineligible and Non-Recruited Participants**
6.	**Randomisation and Blinding**
6.1.	**Randomisation Details**
6.2.	**Blinding**

6.3.	**Withdrawal Procedures**
	The only withdrawal criteria for the study would be that a participant does not regularly treat patients with glaucoma. If a participant is required to be withdrawn from the study (either through study exclusion or withdrawal of consent), aggregate level data on reason for exclusion will be collected, no direct efforts to replace individuals will be made, and data will be retained with the appropriate permissions as detailed in the PIL.
7.	**Study and Safety Assessments**
	This phase of the research is a staff only survey about identification of appropriate glaucoma patients who would be eligible for home monitoring. It does not raise any substantial safety issues.
8.	**Data Collection and Management**
8.1.	**Data Collection**
	Data will be collected through the online Survey monkey platform. Data downloads from the platform will be stored securely on a password protected shared drive on a University of Aberdeen server.
8.2.	**Data Management System**
	Participants will be assigned a unique identifier on their questionnaire. All electronic resources will be stored on the University of Aberdeen server, with access restricted to the study team.
9.	**Labs and Samples Analysis**
9.1.	
10.	**Statistics and Data Analysis**
10.1.	**Sample Size Calculation** No formal sample size has been calculated as the purpose of this survey is expert opinion. The sample will be a convenience sample generated from the membership of the Royal College of Ophthalmologists.
10.2.	**Proposed Analysis**
	Data will be analysed using descriptive statistics and reported using frequencies to identify which cases there is most agreement as being appropriate for home monitoring. Vignettes for which there is more than 50% of respondents listing as 'Unclear', analysis of the free text will be conducted using a content analysis approach to determine whether and how the patients presented in these vignettes could be suitable for home monitoring.
10.3.	**Missing Data**

10.4.	**Transfer of Data**
11.	**Trial/Study Management and Oversight Arrangements**
11.1.	**Trial/Study Management Group**
	The overall multi-stage study will be co-ordinated by a Study Management Group, consisting of the grant holder (CI), coapplicants, external PIs, PPI partner, and Research Fellow.
11.2.	**Trial/Study Management**
	A Research Fellow will oversee the study and will be accountable to the CI. The Research Fellow will be responsible for checking the completeness, plausibility and consistency of the data. However, this remains the overall responsibility of the CI. Any queries will be resolved by the CI or delegated member of the study team.
11.3.	**Trial/Study Steering Committee**
	An independent Study Steering Committee (SSC) will be established to oversee the conduct and progress of the entire study as per the recommendations from the funder.
11.4.	**Data Monitoring Committee**
	An independent Data Monitoring Committee (DMC) is not required for this study as confirmed by the funder.
12.	**Inspection of Records**
12.1	The CI, PIs and all institutions involved in the study shall permit study related monitoring, audits, and REC review. The CI agrees to allow the Sponsor or, representatives of the Sponsor, direct access to all study records and source documentation.
13.	**Good Research Practice**
13.1.	**Ethical Conduct of the Study**

	The study will be conducted in accordance with the principles of good clinical practice (GCP). In addition to Sponsorship approval, a favorable ethical opinion has been obtained from the appropriate REC prior to commencement of the study. CERB/2020/5/1963
13	**Confidentiality**
	All records will be identified in a manner designed to maintain participant confidentiality. All records will be kept in a secure storage area with limited access to study staff only. The CI and study staff involved with this study will not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the Sponsor or its designee will be obtained for the disclosure of any said confidential information to other parties.
13	**Data Protection**
	The study team involved with this project will comply with the requirements of the General Data Protection Regulations (GDPR) and the Data Protection Act 2018. The HRA recommended wording to fulfil transparency requirements under the GDPR for health and care research will been included in the survey. The CI and study staff will also adhere, if appropriate, to the current version of the NHS Scotland Code of Practice on Protecting Patient Confidentiality. Access to collated participant data will be restricted to the CI and appropriate study staff. Computers used to collate the data will have limited access measures via user names and passwords. Published results will not contain any personal data that could allow identification of individual participants.
13	**Insurance and Indemnity**

	The University of Aberdeen is sponsoring the study. **Insurance** • The University of Aberdeen will obtain and hold a policy of Public Liability Insurance for legal liabilities arising from the study. **Indemnity:** The Sponsor does not provide study participants with indemnity in relation to participation in the Study but has insurance for legal liability as described above.
14.	**Study Conduct Responsibilities**
14.1.	**Protocol Amendments, Deviations and Breaches**
	The CI will seek approval for any amendments to the Protocol or other study documents from the Sponsor (in the first instance), REC and NHS R&D Office(s). Amendments to the protocol or other study documents will not be implemented without these approvals. In the event that a CI needs to deviate from the protocol, the nature of and reasons for the deviation will be recorded in the CRF, documented and submitted to the Sponsor. If this necessitates a subsequent protocol amendment, this will be submitted to the Sponsor for approval and then to the appropriate REC and lead NHS R&D Office for review and approval. In the event that a serious breach of GCP is suspected, this will be reported to the Sponsor immediately using the form "Breach Report Form".
14.2.	**Study Record Retention**
	Study documents will be retained for 5 years after study end date.
14.3.	**End of Study**
	The end of study is defined as completion of data analysis and study reporting. The Sponsor, CI and/or the TSC have the right at any time to terminate the study for clinical or administrative reasons. The end of the study will be reported to the Sponsor and REC within 90 days, or 15 days if the study is terminated prematurely. The CI will ensure that any appropriate follow up is arranged for all participants. A summary report of the study will be provided to the Sponsor and REC within 1 year of the end of the study.
15.	**Reporting, Publication and Notification of Results**
15.1.	**Authorship Policy**

	Ownership of the data arising from this study resides with the study team and their respective employers. On completion of the study, the study data will be analyzed and tabulated, and a clinical study report will be prepared.
15.2.	**Publication**
	The study report will be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study. Summaries of results will also be made available to Investigators for dissemination within their clinical areas (where appropriate and according to their discretion).
15.3.	**Peer Review**
	We will not seek an additional internal review prior to submitting for CERB approval. This work package has already been externally peer reviewed within an application for the bigger project as part of the National Institute for Health Research funding process and this documentation will be submitted as part of the CERB application.

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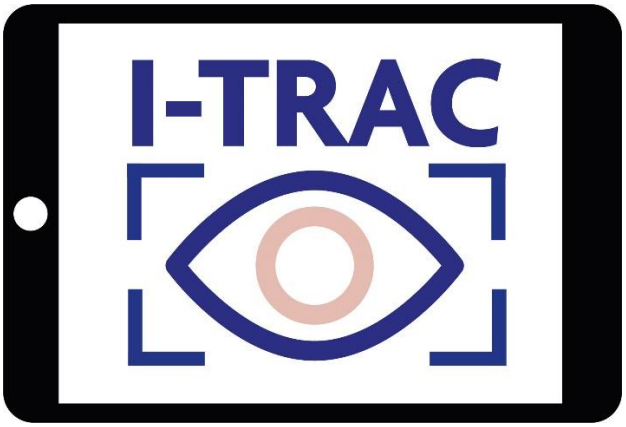
Study Protocol



Full Title:	In-home Tracking of glaucoma: Reliability, Acceptability, and Cost: the I-TRAC Study
Study Acronym:	I-TRAC
Sponsor:	University of Aberdeen
Sponsor Reference Number:	2-072-20
Funder:	National Institute for Health Research, Health Technology Assessment Programme
Chief Investigator:	Dr Katie Gillies
REC Reference Number:	20/EM/0244
R&D Reference Number:	TBC
ISRCTN / Clinicaltrials.gov No:	N/A
Version Number and Date:	Version 3 16th December 2020

Table of Contents

Protocol Approval

In-home Tracking of glaucoma: Reliability, Acceptability, and Cost: the I-TRAC Study **Signatures**

By signing this document I am confirming that I have read, understood and approve the protocol for the above study.

Dr Katie Gillies	K Gillies	16th December 2020
Chief Investigator	Signature	Date

Version	Date	Change
1	160920	Approval of V1
2	271120	• Inclusion of details for prompting participants to complete eye measurement – see page 22 • Inclusion of PPI activity as requested by funder for Protocol upload – see page 34 Deemed minor amendment by Sponsor
3	161220	Edit to update ethics being approved rather than submitted and include REC reference.

List of Abbreviations

CI	Chief Investigator
CFIR	Consolidated Framework for Implementation Research
CRF	Case Report Form
GAT	Goldmann Applanation Tonometry
GCP	Good Clinical Practice
HES	Hospital Eye Services
IOP	Intra-Occular Pressure
MRF	Melbourne Rapid Field
NHS	National Health Service
PI	Principal Investigator
PMG	Project Management Group
R&D	Research and Development
REC	Research Ethics Committee
RO	Research Objective
SMF	Study Master File
SSC	Study Steering Committee
SOP	Standard Operating Procedure
	Theoretical Framework of Acceptability

Summary

Glaucoma is a common chronic eye condition and the second commonest cause of blindness in the UK. It is typically influenced by the pressure in the eye (intraocular pressure) being too high, for a particular person. Glaucoma impairs mainly the peripheral vision (visual field). Treatments reduce eye pressure to delay or stop glaucoma getting worse. However, in some glaucoma may still progress, so patients need regular monitoring at hospital eye services where they have their eye pressure and the visual field measured. This allows doctors to assess effectiveness of current treatment and detect glaucoma progression. Patients need these check-ups for the rest of their lives.

Hospital eye services are very busy, accounting for 10% of all NHS outpatient visits. Glaucoma patients represent a significant part of this workload, in England alone over 1 million visits per year are for glaucoma patients. Providing regular surveillance and treatment is already a major challenge for the NHS. The prevalence of glaucoma increases with age. Demand for glaucoma care is increasing (and will continue to do so) due to our aging population.

Recent advances in technology mean it is now possible for glaucoma patients to monitor eye pressure and visual fields in their own home. Their information could be transferred to the hospital for interpretation by a health care professional, or they could request hospital appointment if the home tests show their glaucoma has worsened or eye pressure has increased. Home monitoring could mean patients requiring fewer hospital check-ups, whilst increasing convenience and potentially reducing costs and increase capacity for the NHS.

Currently though, we do not know if home monitoring is acceptable to people with glaucoma, or if home monitoring in the general glaucoma population is feasible. The main aim of our study is to assess acceptability and feasibility of home monitoring, and to make recommendations about future research to test how the NHS could use home monitoring.

In our project, 45 patients with glaucoma (15 each from Northern Ireland, Scotland and England) will get home monitoring equipment, an iPad tablet and a home tonometer to do home monitoring tests weekly for 4 months. We'll train patients to perform the tests and offer refresher training throughout the study. We have chosen a visual field test and eye pressure test that previous research has shown is suitable for home monitoring use. The visual field tests display lights or patterns on an iPad tablet and patients indicate by entering information on the touch screen whenever they see the light. The iCare HOME tonometer is a device designed to check the eye pressure at home. The information from both of these tests will be transferred to our research team for analysis. We'll also interview patients about their experiences of performing the tests, focusing on the difficulties experienced and what could be done to make the home tests more acceptable. We will also discuss the use of home monitoring with clinical care team, research teams, and NHS IT staff to identify the barriers and facilitators to evaluating and implementing technology of this type. Research activities may be conducted in person or remotely and will depend on current social distancing regulations in place at the time of data collection.

This research fits one of the top five research recommendations by the James Lind Alliance, i.e., "What can be done to improve early diagnosis of sight-threatening glaucoma"? We have included a patient as independent member of the Study Steering Committee who will be actively involved in the conduct and governance of the research. We will also involve the International Glaucoma Society in an advisory role. Results of the study will be shared with those who participated and with relevant stakeholders in Hospital Eye Services.

16.	Introduction
16.1.	**Background**
	Resource constraints resulting in delays in patients' access to glaucoma services have resulted in vision loss due to glaucoma [1]. Glaucoma services are overwhelmed and struggling to accommodate current demands [8]. Reducing the need for hospital based services will improve the ability to see those most at risk of vision loss, which could alleviate both demand on the service and improve patient outcomes. Digital technologies that provide opportunities for home monitoring of glaucoma progression have potential to contribute to solve these challenges and, potentially, improve outcomes. However, understanding which patients could benefit most, the acceptability of the technologies, and the implications for the service need to be resolved before a definitive evaluative study can be conducted. The feasibility study outlined in this application will address these uncertainties. There are recent advances for home monitoring of chronic diseases such as type 1 diabetes (e.g., real-time continuous glucose monitoring, where glucose levels can be accessed electronically by physicians) and high blood pressure (ambulatory blood pressure monitoring, ABPM). Glaucoma is the second leading cause of blindness in the UK and it is potentially preventable. Glaucoma is an age-related chronic and progressive eye condition that requires regular monitoring at hospital eye services (HES). When diagnosis of glaucoma is confirmed, treatment with anti-glaucoma therapy is started. Treatment is escalated when there is a diagnosis of progression of disease, typically with visual field testing, or when the intraocular pressure (IOP) is above the individualised target level. When patients receive additional treatment (e.g., additional eye drops) patients are reassessed at each subsequent visit to determine disease stability and IOP control, to decide whether further treatment escalation is necessary. Hospital eye services (HES) account for 10% of the NHS outpatient activity, and about ¼ of all outpatient visits to HES are due to glaucoma. Thus monitoring of patients with glaucoma generates a considerable burden for the NHS and for patients. Over £500m is currently spent on glaucoma care in the NHS [9]. This is likely to increase as the population ages and more people develop glaucoma during their lifetime and require longer periods of monitoring as they live longer [8]. Already there is evidence that burden of glaucoma follow-up on the NHS is exceeding resources to undertake it and there is UK-wide data showing that lack of timely monitoring has resulted in some glaucoma patients losing vision and even progressing to blindness [1]. Evaluations of digital technologies (such as apps) for home monitoring to reduce demand on the service whilst simultaneously improving patient outcomes through earlier detection of disease progression are an urgent priority.
16.2.	**Rationale for Study**

The need for this research is multipronged and addresses calls from national funders, the Department of Health, and the James Lind Alliance. The work described in our proposal will generate evidence on the feasibility of home monitoring for glaucoma and whether the use of digital technologies in this context have the potential to improve efficiencies for the NHS and self-management for patients.

Digital technologies are now available for regular monitoring of glaucoma by patients at home. Specifically, applications for self-monitoring of visual function (visual field test) and the Icare HOME technology, which has been developed to measure IOP at home. These technologies are safe, FDA approved and CE marked, and allow data to be acquired at home and potentially transmittable to a hospital without the need for patients to interpret tests results, making home monitoring of glaucoma practicable.

In a new model of care implementing digital technologies in this setting, glaucoma patients would be monitored using the home monitoring tests rather than attending HES. If the tests confirmed that glaucoma is under control further HES visits would not be needed. If the home monitoring tests indicated a deterioration, the patient or the clinician would arrange an appointment and/or a prescription for additional treatment would be issued. Under this new model, the focus of NHS hospital glaucoma clinics would then shift to providing appointments to people with progressing or uncontrolled disease, rather than regular monitoring of patients with good disease control. This shift would allow amplifications in staff productivity by releasing time previously committed to regular monitoring appointments. However, before the benefits of digital technologies for glaucoma home monitoring are realised the feasibility of their use in practice and the potential benefits for patients and the health care service needs to be assessed.

Evidence explaining why this research is needed now
Co-applicant AAB has conducted two reviews of home monitoring technologies for glaucoma. The first is a systematic review entitled “Icare Home Tonometer for intraocular pressure home monitoring [10]. A total of 16 studies were included. In brief, the Icare Home tonometer appears to be reliable and safe, with good agreement compared with the reference standard Goldmann applanation tonometry (GAT), and is able to detect clinically significant changes of IOP.

The second review was a comprehensive review of home perimetry techniques for glaucoma [11]. There are several technologies in early phase of development and there are cross-sectional comparative studies with standard automated perimetry. There is only one technique (Melbourne Rapid Field, MRF) that has been evaluated longitudinally in a cohort of patients with glaucoma. The MRF is reliable and has shown strong agreement with standard automated perimetry.

These studies demonstrate that the technologies described in this proposal (Icare home tonometer and the MRF) are reliable, increasingly used, and are able to detect uncontrolled glaucoma. However, uncertainties still remain

	about which patients this approach will benefit most, the acceptability of these technologies, and the implications for service. In addition to the quantitative data from the reviews of evaluations of home technologies, there is also qualitative evidence from studies of remote monitoring for chronic conditions that further supports the need for this research [12]. The recent qualitative evidence synthesis of remote monitoring across a range of chronic diseases (including chronic obstructive pulmonary disease, heart failure, diabetes, hypertension, and end stage kidney disease) highlighted that remote monitoring in these patients increased their disease-specific knowledge, enabled early identification of exacerbations, improved self-management and shared decision making. In addition, a study using focus groups to explore glaucoma patients experiences of visual field testing identified that the clinic environment, waiting times, efficiency of appointment booking and travel to the clinic all influenced the overall clinical experience [13]. Interestingly one of the patient recommendations for improvement was to 'modernise the visual field test'. Finally, other studies have sought to explore the feasibility of digital technologies for self-monitoring in glaucoma through the use of a web based diary tool [14]. This study highlights that glaucoma patients were willing to self-monitor symptoms through completion of a web-based diary every 3 days for a period of 8 weeks. Whilst only a small sample this study shows that glaucoma patients are willing to engage with home monitoring technology with most perceiving the technology as 'valuable'.

17.	**Study Objectives**
17.1.	**Objectives**
17	**Primary Objective**
	The overall aim of this study is to determine the feasibility and acceptability of digital technologies to monitor glaucoma at home and inform the possible need and design of a definitive evaluative study. The specific research objectives (RO) outlined in this protocol are to: 1. Understand the views of key stakeholders (patients, clinicians, IT personnel, researchers) on whether home monitoring is feasible and acceptable; 2. Developing a conceptual framework for the economic evaluation for home monitoring for glaucoma; 3. Explore the need for and provide evidence on the design of a future study to evaluate the clinical and cost effectiveness of digital technologies for home monitoring of glaucoma.
17	**Secondary Objectives**
	Not applicable
17.2.	**Outcomes**
17	**Primary Outcome**
	As this is a feasibility study there is no overall primary outcome. The overall outcome is the assessment of acceptability and feasibility of home monitoring for glaucoma.
17	**Secondary Outcomes**
	Not applicable for research question and study design.
18.	**Study Design**
18.1.	**Study Description**

	The study detailed in this protocol describes a mixed-methods sequential explanatory design feasibility study with key components informed by theoretical (i.e. the Consolidated Framework for Implementation Research and Theoretical Framework of Acceptability) and conceptual (ADePT) frameworks. The process of developing and evaluating new technology within a healthcare context is complex and challenging. The Medical Research Council's (MRC) framework on the development and evaluation of complex interventions recommends a structured methodological approach that can cycle through various phases including development, feasibility and piloting, evaluations, and implementation [15]. The work outlined in this protocol will focus on the feasibility stage of the framework but will reflect back to development and will look forward to plans for evaluation and implementation. Successful evaluation and future implementation of any new interventions requires in-depth understanding of the potential process modifiers. The introduction of home monitoring using digital technology for glaucoma will involve multiple stakeholders (patients, healthcare professionals and information technology personnel) and various care contexts (home and secondary care). To facilitate investigation of this technology prior to definitive evaluation the Consolidated Framework for Implementation Research (CFIR) will be used to focus on issues surrounding development and implementation [5]. The CFIR combines key concepts from several implementation theories and provides a structured framework to verify what works, where and in multiple contexts. It consists of five linked domains: 1. Intervention characteristics: determining the 'core components' and the 'active periphery'; 2. Outer setting: economic, social and political setting of the organisation; 3. Inner setting: structural, political, cultural contexts that envelope the intervention; 4. Characteristics of the individuals: exploring the influence of those involved in the process; 5. Process of Implementation: identifying the sub-processes. The CFIR has been used previously in feasibility studies of digital technologies [16] and will act as an overarching framework to inform the development, evaluation and implementation aspects of the work proposed. We will also learn from the Theoretical Framework of Acceptability (TFA) to explore intervention acceptability amongst stakeholders [4]. The TFA was developed based on acknowledgement that 'acceptability' should be considered when designing, evaluating and implementing healthcare interventions – yet mechanisms on how to define or assess acceptability were lacking. The TFA is comprised of seven constructs: affective attitude; burden; ethicality; intervention coherence; opportunity costs; perceived effectiveness; and self-efficacy [4]. Applying this theoretical framework to the question of intervention acceptability provides a rigorous, systematic analysis of the dimensions of acceptability in relation to the digital technologies for glaucoma self-monitoring. In addition, to the CFIR and TFA (which help to answer questions relating to acceptability and implementation) we will apply a conceptual framework (within objective 3) to facilitate decision making with regard to progression

from feasibility to definitive study. Whist recent guidance has been proposed for recommendations to inform stop/go criteria in internal pilot studies, equivalent recommendations do not exist for feasibility studies where more subjective interpretation of the (often mixed) data is required. However, we will use the ADePT framework (A process for Decision-making after Pilot and feasibility Trials) to inform overall decisions related to assessment of potential problems for a definitive study and identification of solutions for successful delivery [3].

Health technologies being assessed
Two digital health technologies for use in home monitoring glaucoma within the NHS will be assessed for feasibility and acceptability in this application.

1. Home-monitoring visual field tests:
Melbourne Rapid Field (MRF): The MRF has been validated as a tangent perimeter that can perform efficient and reliable thresholding comparable to Humphrey visual field testing [17, 18, 19, 20]. It has been shown to be robust to variations in ambient light, blur, and viewing distance. Test-retest repeatability for the MRF appears comparable to that reported for other perimeters [17]. In a longitudinal study MRF correlated strongly with Humphrey visual field testing across four visits [21].

2. Home-monitoring tonometry:
Icare HOME tonometer. The Icare HOME rebound tonometer is a hand-held tonometer designed for self-measurement of IOP by glaucoma patients or their caregivers. The measurement is based on rebound technology which is the same patented technology as is used in the Icare tonometers designed for healthcare professional use. The Icare HOME is easy to use, painless, and correlates with Goldmann IOP measurements. Home rebound tonometry can be effectively used for monitoring and managing glaucoma.
Several studies have compared the IOP readings from the Icare HOME tonometer to GAT. The reported mean differences between the Icare HOME and GAT measurements range from -1.31 mmHg to 0.7 mmHg in studies except for one study which gives a difference of -2.7 mmHg. Three of the studies report that the Icare HOME measurement results are within 3 mmHg from the GAT measurement value in 70%, 78.6% and 90.6% of cases respectively. One further study reports that the Icare HOME measurement value is within 5 mmHg from the GAT measurement value in 91.3% of cases. [21-31]. The studies also looked what percentage of glaucoma patients learn to use the Icare HOME correctly, ranging between 73% and 100%.

Research Objectives (RO) work plan
The overall aim of this study will be achieved through work delivered across four inter-linked phases brought together to determine overall feasibility and recommendations for next steps for use of home monitoring for glaucoma. Each phase is specified below with details on target populations, settings, recruitment, data collection, outcomes, and analysis. Highlighting where appropriate how one phase leads to another and where data generated feeds into overall assessments of feasibility. All participant procedures are laid out in an easy to follow format in Appendix 4

	RO1 - Understand the views of patients and clinicians on whether digital technologies for glaucoma home monitoring would be feasible and acceptable. Whilst there is preliminary quantitative data from existing studies on use of home perimetry and tonometry, there is no in-depth data on how patients and clinicians view home monitoring and broad acceptability of the technologies. To address this we will use mixed-methods to conduct an in-depth exploration of clinicians and patients views on home monitoring for glaucoma. This research objective will apply a theory-based approach to aid the understanding of barriers to implementation of digital technologies for home monitoring (both as a new model of care and within the context of a large evaluative study) and overall acceptability. *Data collection RO1 - Patients* Included patients will be provided with home monitoring equipment (iPad with the home perimetry app and home tonometer) and given explanations for use through demonstration and discussion with the Research Nurse. Training on how to use the home monitoring equipment will be delivered to patients by the research nurse (who will have received bespoke training from the I-TRAC Research Fellow on how to train the patients) at the baseline assessment. Percentages of patients learning to use the iCare home tonometer equipment correctly as reported in studies to date range between 73% and 100%. For the iCare home tonometer there will be a practical demonstration of the equipment use, visualisation of a video (https://www.youtube.com/watch?v=BiibqLxsql8), and written instructions. This training is currently used in clinical practice. For the home perimetry, research nurses will provide a practical demonstration. Patients will already be familiar with visual field testing from clinics and thus it may be easier for patients to understand the process (e.g., gaze fixation, maintain position, and answer when stimulus seen). However, training as recommended by the MRF developers will be provided. We expect patients who are familiar with the use of tablets may find easier to perform the test. Specifically, we will instruct participants unfamiliar with a tablet on how to switch it on and start the application. Once the application is open voice prompts will guide the user throughout the test. A patient's response to the presentation of a stimulus is recorded by touching the screen. A practice test will be done supervised by the research nurse. In addition to the practical aspects of the training, we will incorporate behaviour change techniques (informed by the behaviour change wheel and COM-B model) into the training during project development to ensure appropriate behavioural models are used to inform the training to maximise its potential for effective behaviour change. However, these behavioural components of the training will also be developed as part of the feasibility study through the use of the behavioural frameworks (e.g. Theoretical Domains Framework) in interviews to explore challenges to intervention use which can then be targeted during development of the training for use in the full scale evaluation. Patients will be asked to take measurements (IOP with the home tonometer and visual field with the home perimeter) weekly which will be stored within

	visioninhome.uk website and downloaded to the study website (this will contribute to adherence of intervention data). No identifiable data will be stored on the website. Patients will be asked to use the equipment every week for 4 months. Patients who require additional training on the technology will be offered opt-in refresher training at a return clinic visit (within 1 month of baseline). This quantitative data on requirements for additional training or reported problems with intervention will directly inform aspects of feasibility related to acceptability and adherence to intervention. We will also capture the number of participants approached and reasons regarding failure to recruit (if given, to inform aspects of feasibility linked to eligibility, recruitment and consent) and other key attributes to inform ADePT decisions e.g. retention, intervention adherence, self-referral back to HES etc. In addition to using the home monitoring equipment, patients will be invited to participate in interviews to explore acceptability of home monitoring generally and focus on the requirements (both in the short, medium, and long term) of the digital technologies under investigation. Interviews will be conducted by the I-TRAC Research Fellow once patients have completed the 4-month home monitoring measurements. Interviews will take place within the clinic at the time of the final visual field and IOP assessment. A purposive sample of patients will be selected based on site, age, gender and adherence levels (as per sampling for similar studies, an initial analysis sample of 10 patients will be conducted and a stopping criterion (when three further interviews have been conducted with no new themes emerging) defined to determine data saturation [36]. The topic guide to explore acceptability of the home monitoring technology will be informed by the theoretical framework for acceptability (TFA) of healthcare interventions [4]. Additional questions exploring aspects of evaluation and implementation will be informed by the CFIR [5]. *Data collection RO1 - Ophthalmologists* Similar to interview topic guides, focus groups with Ophthalmologists will be informed by the CFIR and explore the barriers and facilitators to implementing and delivering home monitoring and establishing a proposed new model of care. Items on design and delivery of a formal evaluative study of these technologies with patients will also be explored. *Data collection RO1 – Researchers and NHS Staff* Interviews with two members (Chief investigator and Trial Manager) of trial teams that have or are currently evaluating digital technologies for monitoring eye disease will be interviewed (n=6). In addition, one Research and one IT person from each of the 3 Trusts will also be invited. As previously, the topic guides for these interviews will be informed by the CFIR adapting it to explore aspects of implementing an evaluative study and, where relevant, to implementation of the technology in practice. **RO2 – Developing a conceptual framework for the economic evaluation of home monitoring glaucoma.** The first step of any economic evaluation is the understanding of the decision problem in order to decide an appropriate approach for the economic

	evaluation [37]. In addition to the work conducted in RO1 we will assess the resource use implications of alternative monitoring strategies, we will explore the feasibility of using different economic evaluation approaches and we will explore drivers of patient preferences for monitoring. *Data collection R02 – Healthcare staff* In focus groups we will ask staff about the current allocation of time related to glaucoma by HES staff within a typical working day and how staff would use the time expected to be released due to the implementation of home monitoring. Focus groups will be conducted, by the I-TRAC Research Fellow and a facilitator, at 2 of the recruiting sites and will include a mixture of Consultant Ophthalmologists (n=3), nurses (n=3) and administrative staff (n=3). In addition, we will retrieve the clinical outcome information on the eye measurements from the home monitoring devices (i.e. IOP and VF) and discuss with clinical colleagues in the project management group and the project advisory group the level at which the test results would trigger contacts with the NHS (e.g. GP or hospital telephone consultations or visits). *Data collection R02 – Patients* As part of RO2 we will conduct a characteristic identification exercise using interviews during RO1 to explore the drivers of patient preference linked to service features. Of particular interest are those characteristics that patients would be willing to give up in order to obtain or improve the level of another characteristic (e.g. fewer visits to the hospital eye services versus more frequent test readings at home). The interview data collected in RO1 will be analysed as reported previously using a Framework approach with attention being paid to the patient derived attributes important for informing glaucoma monitoring services. We will also ask patients' during the interviews in RO1 to complete a short questionnaire that will investigate if home monitoring would trigger NHS contacts beyond those expected from current routine glaucoma monitoring (e.g. by asking how many times they would have contacted HES). **RO3- Provide evidence on the optimal design of a future study to evaluate the use of digital technologies for home monitoring of glaucoma.** We will provide evidence to support a statement on feasibility and acceptability of an evaluative study (e.g. trial, longitudinal study, economic modelling) comparing current standard NHS glaucoma care with home monitoring See Section 8.1 Data Collection for more detail on methods planned.

18.2.	**Study Flowchart**
	Please see Appendix 3
18.3.	**Study Matrix**
	Please see Appendix 4
19.	**Study Population**
19.1.	**Number of Participants**
	RO1 - Understand the views of patients and clinicians on whether digital technologies for glaucoma home monitoring would be feasible and acceptable. *Patients (n=45)* A purposive sample of 45 patients (with varying disease severity informed by ongoing work) being monitored by HES for glaucoma in NHS hospitals in Belfast, Edinburgh and Nottingham will be invited to participate. The sample size of 45 is in line with previously proposed sample sizes of between 24 and 50 recommended to estimate standard deviations for future sample size calculations [34, 35]. Each of the three hospitals will aim to recruit 15 patients. A purposive sample of patients will be selected based on site, age, gender and adherence levels (as per sampling for similar studies, an initial analysis sample of 10 patients will be conducted and a stopping criterion (when three further interviews have been conducted with no new themes emerging) defined to determine data saturation [36]. *Ophthalmologists* (n=16) Two focus groups with 6–8 ophthalmologists per group (samples deemed appropriate in this context) will be conducted. *Researchers and NHS Staff (n=12)* Up to 6 members of relevant research teams will be invited to share their experience of delivering studies in this setting with a particular focus on the barriers and facilitators to design and delivery. We will aim for two members (Chief investigator and Trial Manager) of each of the trial teams will be interviewed (n=6). In addition, one Research and one IT person from each of the 3 Trusts will also be invited. **RO2 – Developing a conceptual framework for the economic evaluation of home monitoring glaucoma.** *Healthcare staff (n=18)* Focus groups will be conducted at 2 of the recruiting sites and will include a mixture of Consultant Ophthalmologists (n=3), nurses (n=3) and administrative staff (n=3) *Patients (no additional)* Same patients as per RO1 above – specific questions to address RO2 will be incorporated into the topic guide with interviews with purposive sample of 10 patients.

19.2.	**Inclusion Criteria**
	RO1 - Understand the views of patients and clinicians on whether digital technologies for glaucoma home monitoring would be feasible and acceptable. *Patients* Patients with glaucoma who are being treated at one of the three NHS sites (NHS Lothian, Nottingham University Hospital Trust, Belfast Health and Social Care Trust) . Clinical parameters to specify which patients to consider for inclusion (e.g. those with slow progression of disease)will be identified during a linked but separate survey of Consultant Ophthalmologists (received favourable opinion by University of Aberdeen's CERB committee - CERB/2020/5/1963). *Ophthalmologists* Consultant Ophthalmologists currently responsible for regular monitoring of glaucoma patients. *Researchers and NHS Staff* Research teams who have or are evaluating digital technologies for home monitoring of eye disease e.g. macular degeneration (e.g., MONARCH, HTA 15/97/02). Research Nurses involved in our feasibility study tasked with delivering the home monitoring training will also be invited to interview along with IT personnel from the relevant Trusts. **RO2 – Developing a conceptual framework for the economic evaluation of home monitoring glaucoma.** *Healthcare staff* Staff directly involved in HES monitoring e.g. clinicians, nurses, and administrative staff. *Patients* As above for RO1 – same patients.
19.3.	**Exclusion Criteria**
	Participants who are unable to give informed consent to participate and participants who are unable to understand English. There are no specific exclusion criteria
20.	**Participant Selection and Enrolment**
20.1.	**Identifying Participants**

	RO1 - Understand the views of patients and clinicians on whether digital technologies for glaucoma home monitoring would be feasible and acceptable. *Patients* Patients will be identified through clinical case load lists from the three recruiting centres: Edinburgh, Nottingham, and Belfast. Research Nurses at each site will identify potentially eligible participants. *Ophthalmologists* Ophthalmologists who have previously expressed an interest in participating the research and consented to further contact via a linked survey (received favourable opinion by University of Aberdeen's CERB committee - CERB/2020/5/1963) will be approached to participate in the focus groups. *Researchers and NHS Staff* Researchers who are or who have previously evaluated digital technologies for home monitoring of eye disease will be invited to participate. They will be emailed directly through publicly available email addresses on funder or Institution websites and provided with a participant information sheet and asked to contact the study team to express interest. Research Nurses and IT personnel will be identified by the local PI from the three recruiting sites and invited on behalf of the research team They will be sent a invite letter/email and participant information sheet and asked to contact the research team to express interest. **RO2 – Developing a conceptual framework for the economic evaluation of home monitoring glaucoma.** *Healthcare staff* Consultant Ophthalmologists, nurses, and administrative staff will be identified and invited from the three recruiting sites. *Patients* *As above for RO1.*
1.1.	**Consenting Participants**

	RO1 - Understand the views of patients and clinicians on whether digital technologies for glaucoma home monitoring would be feasible and acceptable. *Patients* Patients will be invited to participate in the study by their Ophthalmologist. They will be provided with an information leaflet outlining the study and its expectations of them as participants. This may be done in clinic or may be posted to them in advance depending local processes. After having the opportunity to ask any questions they have, written informed consent will be sought by a Research Nurse who will be appropriately trained in GCP. Consent for the interview study will be sought by the I-TRAC Research Fellow who will be appropriately trained in GCP. *Ophthalmologists* All Ophthalmologists who had previously consented to contact for this research (through a linked survey - - CERB/2020/5/1963) will be sent an invitation letter and participant information sheet in advance of the focus group. Written informed consent or verbal consent, if conducted via videoconferencing, will be sought by the I-TRAC Research Fellow. *Researchers and NHS Staff* All potential participants will be provided with a participant information sheet and asked to contact the study team to express interest. Verbal consent will be sought by the I-TRAC Research Fellow over the telephone before commencement of the interview. **RO2 – Developing a conceptual framework for the economic evaluation of home monitoring glaucoma.** *Healthcare staff* In advance of the focus group, interested participants will be provided with a participant information sheet and asked to provide written informed consent or verbal consent if conducted via videoconferencing. Consent will be sought by the I-TRAC Research Fellow. *Patients* As per RO1 above
1.2.	**Screening for Eligibility**

	RO1 - Understand the views of patients and clinicians on whether digital technologies for glaucoma home monitoring would be feasible and acceptable. *Patients* Patients with glaucoma who are being treated at one of the three NHS sites (NHS Lothian, Nottingham University Hospital Trust, Belfast Health and Social Care Trust) . Clinical parameters to specify which patients to consider for inclusion (e.g. those with slow progression of disease) will be identified during a linked but separate survey of Consultant Ophthalmologists (received favourable opinion by University of Aberdeen's CERB committee - CERB/2020/5/1963). Research nurses will apply the clinical parameters to patients presenting at the HES to identify eligible participants. *Ophthalmologists* Not applicable *Researchers and NHS Staff* Not applicable **RO2 – Developing a conceptual framework for the economic evaluation of home monitoring glaucoma.** *Healthcare staff* Not applicable *Patients* As per RO1 above.
1.3.	**Ineligible and Non-Recruited Participants**
	Anonymised data on eligible participants who decline study participation will be collected. Demographic data such as gender, age, disease status, and reason for non-participation (if offered) will be collected.
1.4.	**Withdrawal Procedures**
	Participants are free to withdraw at any time without having to give a reason. Identifiable data or tissue already collected with consent would be retained and used in the study, which participants will be made aware of at time of consent. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
2.	**Study and Safety Assessments**

	Procedure for any incidental/abnormal findings. The eye measurement data captured using the home monitoring devices will only be assessed at the end of the study. Therefore, there will be no opportunity to identify incidental or abnormal findings. However, we are not deviating from best practice as NICE recommendations suggest patients be monitored every 6-12 months. The final I-TRAC eye measurement will occur in hospital at 4 months after baseline, already more frequent than standard clinical care, and any change in disease progression will be treated accordingly. It is also worth noting that glaucoma has a slow rate of progression so it is unlikely that an abnormal result will be identified even within the 4 months. The purpose of the I-TRAC study is feasibility and acceptability of monitoring to patients and HCPs, not accuracy of measurement, hence why measurement data will not be reviewed in real time. **Safety information on devices** The perimetry assessment, the Melbourne Rapid Field (MRF) is the only home perimeter currently available in an online application, there are several studies confirming its reliability, and is the only home perimetry test that has been evaluated in a longitudinal cohort of patients. It is currently being used in another research Study run in Moorefields Hospital, London. Glance Optical, the developers of the MRF, will provide advice, free software downloads for 15 units, technical operating support. Glance Optical have agreed to use a University of Aberdeen template agreement to agree the terms of use of the MRF. The agreement will not include any obligations for the University to share study data with Glance Optical. Regarding home tonometry, icare HOME is CE marked and is the only device currently available in the UK. The icare HOME technology is used by some clinicians in the UK as part of routine clinical care, although we don't know how common is its use or which patients it is used with and what they think of it. Mainline instruments are the UK distributor for the icare HOME rebound self-tonometer. The University have agreed a discounted rate for the device and this purchase will be made under Mainline Instrument's standard terms of purchase. These purchase terms do not include any obligations for the University to share study data with Mainline Instruments.
3.	**Data Collection and Management**
3.1.	**Data Collection**

	RO1 - Understand the views of patients and clinicians on whether digital technologies for glaucoma home monitoring would be feasible and acceptable. *Data collection RO1 - Patients* Once consented, visual field and intra-ocular pressure data will be obtained from patients using a standard visual field test and IOP measurement in clinic at baseline and another at study completion (4 months). Data will be recorded (manually and then entered electronically) on a Baseline Case Report Form (CRF). Demographic data (e.g. age, gender, education, disease status, previous eye treatments) will also be collected from the medical notes and recorded on the case report form by the Research Nurse.. In addition to using the home monitoring equipment, patients will be invited to participate in interviews (using semi-structured topic guides to direct the conversation) to explore acceptability of home monitoring generally and focus on the requirements (both in the short, medium, and long term) of the digital technologies under investigation. Interviews will be conducted by the I-TRAC Research Fellow once patients have completed the 4-month home monitoring measurements. Patients will be sent (either by email or post) a weekly prompt to conduct their eye measurements. They will also be sent a prompt of their 4 month clinic visit a few days before attendance. Clinical sites will also be sent a prompt the day before a patient visit is due. *Data collection RO1 - Ophthalmologists* Two focus groups with 6–8 ophthalmologists per group (samples deemed appropriate in this context) will be conducted by the I-TRAC Research Fellow and a facilitator. Again data collection will be guided by semi-structured topic guides to facilitate discussion. *Data collection RO1 – Researchers and NHS Staff* Up to 6 members of relevant research teams will be invited to interview (with data collection guided by semi-structured topic guides) to share their experience of delivering studies in this setting with a particular focus on the barriers and facilitators to design and delivery. These interviews will be conducted by the I-TRAC Research Fellow. **RO2 – Developing a conceptual framework for the economic evaluation of home monitoring glaucoma.** *Data collection R02 – Healthcare staff* We will convene focus groups with staff directly involved in HES monitoring e.g. clinicians, nurses, and administrative staff. Focus groups will be guided by a semi-structured topic guide and conducted, by the I-TRAC Research Fellow and a facilitator, at 2 of the recruiting sites and will include a mixture of Consultant Ophthalmologists (n=3), nurses (n=3) and administrative staff (n=3). *Data collection R02 – Patients*

	We will also ask patients' during the interviews in RO1 to complete a short questionnaire that will investigate if home monitoring would trigger NHS contacts beyond those expected from current routine glaucoma monitoring (e.g. by asking how many times they would have contacted HES). This information will be posted back to the Study Office and then be inputted into the study database by a member of the Study team. All interviews and focus groups will be audio-recorded and transcribed verbatim. The external company who will be contracted to transcribe the interview transcripts has previously conducted work of this type for the University of Aberdeen (NJC Secreterial) and the necessary work order contracts are already in place. Personal data will be retained on password protected University computers, supported by secure servers, which are held in locked offices and can be accessed by authorised personnel only. Paper copies of consent forms will be stored in locked tambour filing systems, which are held in locked offices and can be accessed by authorised personnel only. In accordance with HSRU code of conduct (and wider University of Aberdeen policies), all data will be password protected against unauthorised access and stored in accordance with data protection legislation. All participants will be assigned a unique identifier so as to allow anonymisation of data. All identifiable and non-identifiable data will be stored separately with paper copies being held in locked tambour units that only the research team have access to. Direct quotes may be used in the publication of research findings but these will not be attributed to named individuals and any identifiable information will be removed. **It is important to highlight that research activities may be conducted in person or remotely (through telephone or videoconferencing facilities) and this will depend on current social distancing regulations in place at the time of data collection.**

3.2.	**Data Management System**

	A bespoke study database will be developed by HSRU programmers , details below: Bespoke database utilising the following: Website: .Net 4.5 framework Database: SQL Server 2014 Host Operating System: Windows Sever 2012 R2 (Virtual) Development Tools: C# in Visual Studio, .NET License: UOA Back-up and recovery procedures Databases are backed up onto hard disc at an offsite location. The programming team keep the last 5 nights backups to ensure timely response to any issues and for disaster recovery situations. After 5 days the backs ups are handled by IT Services in a normal rotation method. Data Query Rules / Validations Appropriate automated range checks and validation have been inbuilt to the database to ensure that, where possible, outlying values cannot be recorded. Details of any range checks and validation performed at time of data entry will be detailed within the testing documentation for CRF. An appropriate validation list for each CRF will contain the field name, the validation type, the values and any appropriate validation message. Query Handling Data will be monitored by the Research Fellow. Responsibilities include: • Ensuring data is entered on the trial database in an appropriate timely manner: • Identifying missing data and contacting the sites to ensure data completion. • Central monitoring will be undertaken throughout the trial by the TM. It is the responsibility of the Research fellow and the Statistician to ensure all data queries are resolved before data is locked for analysis Quality Assurance Two forms of Audit logs exist, these logs capture all data keystrokes entered in the CRF; date, time and by whom will be recorded. Also, values added and changes to values will be recorded. Any significant data quality issues identified during the trial will be reported to either the Project Management Group who will investigate as appropriate. **Security** **Usernames** Each user will have a unique username and password. **Roles**

	The website application supports the concept of defined roles at a component level which may be configurable on a per study basis. **Login** The website application will disable an account after a specified number of incorrect logins, this is currently set at 3. Participants will be assigned a unique identifier on their consent form. Consent forms and CRFs will be scanned at site and transferred to a secure area of the database. Hard copy consent forms will be stored securely in a locked filing cabinet at site for each patient in RO1 and all other hard copy consent forms and questionnaires stored at the study office. Field notes will be anonymised and not shared outside the research team. All electronic resources will be stored on the University of Aberdeen server, with access restricted to the study team.

4.	Statistics and Data Analysis
4.1.	**Sample Size Calculation**
	RO1 - Understand the views of patients and clinicians on whether digital technologies for glaucoma home monitoring would be feasible and acceptable. *Patients* A purposive sample of 45 patients (with varying disease severity informed by RO1) being monitored by HES for glaucoma in NHS hospitals in Belfast, Edinburgh and Nottingham will be invited to participate in using the home monitoring technology to measure their disease progression. The sample size of 45 is in line with previously proposed sample sizes of between 24 and 50 recommended to estimate standard deviations for future sample size calculations [34, 35]. Each of the three hospitals will aim to recruit 15 patients For the interviews, a purposive sample of patients will be selected based on site, age, gender and adherence levels (as per sampling for similar studies, an initial analysis sample of 10 patients will be conducted and a stopping criterion (when three further interviews have been conducted with no new themes emerging) defined to determine data saturation [36]. *Ophthalmologists* Two focus groups with 6–8 ophthalmologists per group (samples deemed appropriate in this context) will be conducted. *Researchers and NHS Staff* Up to 6 members of relevant research teams will be invited to share their experience of delivering studies in this setting with a particular focus on the barriers and facilitators to design and delivery. We will aim for two members (Chief investigator and Trial Manager) of each of the trial teams will be interviewed (n=6). In addition, one Research and one IT person from each of the 3 Trusts will also be invited. **RO2 – Developing a conceptual framework for the economic evaluation of home monitoring glaucoma.** *Healthcare staff* Two focus groups with a mixture of Consultant Ophthalmologists (n=3), nurses (n=3) and administrative staff (n=3) per group (samples deemed appropriate in this context) will be conducted. *Patients* As per RO1 above.
4.2.	**Proposed Analysis**

	RO1 - Understand the views of patients and clinicians on whether digital technologies for glaucoma home monitoring would be feasible and acceptable. *Patients* RO1 will collect qualitative data from interviews and focus groups and will also collect quantitative data through the weekly measurement using the home monitoring equipment. Two types of clinical outcome data will be collected: 1. Tonometry data; and 2. Perimetry data. The home tonometer measures intra-ocular pressure (IOP) and presents data on a scale of 0-70 (0 = low pressure, 70 = high pressure), with most patients measuring between 10-30. Visual field tests using the home perimeter present a mean deviation, which quantifies the severity of the visual field loss, presented on a scale of 0-30 (0 = no damage, 30 = very damaged). These clinical outcome data collected using the home perimetry (visual field, 0-30) and tonometry (IOP, 0-70) technology will be analysed using descriptive statistics to describe the patient sample and the changes (if any) in the measurements over time. We will also confirm that we are able to get repeated measures through home monitoring. The data collected using the home monitoring technology will be compared to the clinic visit measurements at 4 months to qualitatively assess the agreement between home and hospital-based monitoring. We will use Bland-Altman methodology to assess the limits of agreement between the two IOP measurements. An added feature of the data we are collecting is repeated measures of home IOP. There are several ways then to use the data. We will outline the full detail in a statistics analysis plan before the study commences, but in brief agreement comparisons of interest will be agreement between 4-month clinic IOP and: - Mean IOP over period (using random effect models outline in Myles and Cui [37] - Most recent home IOP measurement - Highest IOP measurement. The other quantitative data collected in RO2 relates to recruitment rates, adherence to intervention (assessed by number of weekly measurements completed), and requirements for further training (assessed by additional training received: face-to-face or over telephone). These data will be analysed using descriptive statistics and presented as frequencies. Interview data will be analysed using a Framework approach which will allow data to be coded both deductively (informed by the key constructs and domain from within the guiding theoretical frameworks) but also inductively, allowing identification of additional important themes to be identified. Constructs from the Theoretical Framework of Acceptability that will guide analysis include: affective attitude, burden; ethicality; intervention coherence; opportunity costs; perceived effectiveness; and self-efficacy. These will be supplemented with constructs from the Consolidated Framework for Intervention Research and include: intervention characteristics, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation. Data will be compared and coded through a process of constant comparison to provide a summary of key points that interviewees consider important in this context. Preliminary analysis will run concurrently with data collection to allow the topic guide to evolve as necessary. Two researchers will code the first

	three transcripts concurrently to develop a coding strategy, which will be informed by the theoretical frameworks (outlined above) and the inductive analysis. Subsequent transcripts will be coded by one researcher and a random 10% sample will be independently double coded. Data will be managed through NVivo. *Ophthalmologists* This will be conducted as per plans outlined above for the patient interviews but adapted accordingly for focus on impacts to service. *Researchers and NHS Staff* This will be conducted as per plans outlined above for the patient interviews but adapted accordingly to focus on researcher and service challenges and solutions to delivering large scale evaluations of home monitoring for eye disease. **RO2 – Developing a conceptual framework for the economic evaluation of home monitoring glaucoma.** *Healthcare staff* Based on staff responses in the focus groups to service use, ranges of staff time and staff time savings will be estimated and valued using standard sources such as Curtis and Burns [39]. Descriptive statistics will be used to report the data collected on resource use (e.g. staff time). The clinical data will be analysed as stated previously – see RO1 data analysis. *Patients* The interview data collected in RO1 will be analysed as reported previously using a Framework approach with attention being paid to the patient derived attributes important for informing glaucoma monitoring services. We will collect data on the number of contacts (hospital visits, phone calls or home visits) triggered by patients under home monitoring. Descriptive statistics will be used to analyse these data (i.e. mean, median, interquartile range, maximum and minimum values). These health care contacts will be subsequently valued using standard NHS unit cost sources [39].

4.3.	**Transfer of Data**
	All files relating to the I-TRAC Study will be stored on the University's secure network accessible only to those personnel with appropriate access rights as determined by the data owner in terms who has read/write access to a named drive or application. IT services implements access only when there is a written request from the data or application owner, or nominate depute if there is one. For the home monitoring applications, which are accessed via a secure website, this is handled via roles tailoring access to data as appropriate for the role of the user assigned to them by the researcher The data will be processed on PCs connected to the University's network and located within the Health Services Research Unit (HSRU). These require a login and password to be provided by the user. Access to University IT resources is restricted to users who are approved and issued with a user name and password. Password complexity is enforced. The system is maintained by the programming team and IT services at the University of Aberdeen who will also have responsibility for the physical security of the system. IT services are responsible for the physical security of the institutional data centres and their contents. The data storage and servers used to process the data are located in these data centres. Access to the web-based application is controlled by user name and password and only those personnel identified by the researcher as working on the I-TRAC study will be allowed access to the website and appropriate data. New users are assigned a strong password and advised they should change this to a password of their choice. IT services require that all users agree to their Terms and Conditions of use. Confidentiality agreements are a matter for HR and the individual Colleges. All staff agree, as part of their terms and conditions of employment, to abide by the University's Information Security Policy. HSRU's Protecting Information Policy is given to all new members of staff. All authorised users are fully trained in Good Clinical Practice. For any data required to be sent between sites, all files will be securely encrypted and transferred using ZendTo. All files uploaded and temporarily stored on ZendTo will be held on equipment owned and operated at the University of Aberdeen Data Centre. All data will be subject to the Data Protection regulations and laws. ZendTo is in no way a "cloud" service. Everything will be stored (even temporarily) on equipment directly owned by the University of Aberdeen, and managed by its own IT staff. All access to data will be very tightly and strictly controlled. All accesses to data on ZendTo will be logged. Furthermore, uploaded data will be only held on ZendTo for a maximum of 14 days, after which time it will be automatically deleted. There is no "undelete" facility available at all. No backups will be taken of the uploaded data. After an uploaded file has been deleted, there is no way of recovering the file.
5.	**Study Management and Oversight Arrangements**

5.1.	**Study Management Group**
	The study will be co-ordinated by a Study Management Group, consisting of the grant holder (CI), external PIs, co-applicants, and Research Fellow.
5.2.	**Study Management**
	A Research Fellow will oversee the study and will be accountable to the CI. The Research Fellow will be responsible for checking the CRFs, questionnaires, and other data collection forms for completeness, plausibility and consistency. However, this remains the overall responsibility of the CI. Any queries will be resolved by the CI or delegated member of the study team. A study-specific Delegation Log will be prepared for each site, detailing the responsibilities of each member of staff working on the study.
5.3.	**Study Steering Committee**
	An independent Study Steering Committee (SSC) will be established to oversee the conduct and progress of the study as per the recommendations from the funder. The terms of reference of the SSC, the draft template for reporting are detailed in Appendix 1.
5.4.	**Data Monitoring Committee**
	An independent Data Monitoring Committee (DMC) is not required for this study as confirmed by the funder.
6.	**Inspection of Records**
12.1	The CI, PIs and all institutions involved in the study shall permit study related monitoring, audits, and REC review. The CI agrees to allow the Sponsor or, representatives of the Sponsor, direct access to all study records and source documentation.
7.	**Good Research Practice**
7.1.	**Ethical Conduct of the Study**
	The study will be conducted in accordance with the principles of good clinical practice (GCP). In addition to Sponsorship approval, a favorable ethical opinion has been obtained from the appropriate REC (Ref id: 20/EM/0244) and appropriate NHS R&D approval(s) will be obtained prior to commencement of the study.
7.	**Confidentiality**

	All records will be identified in a manner designed to maintain participant confidentiality. All records will be kept in a secure storage area with limited access to study staff only. The CI and study staff involved with this study will not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the Sponsor or its designee will be obtained for the disclosure of any said confidential information to other parties. Participants involved in the interviews or focus groups will be assigned a pseudonym/study code on their consent form. We will keep consent forms securely in a locked filing cabinet. Any field notes will use the same pseudonym/study code and this will not be shared out with the study team. All audio-recordings and transcripts will be anonymised to ensure confidentiality.
7.	**Data Protection**
	The study team involved with this project will comply with the requirements of the General Data Protection Regulations (GDPR) and the Data Protection Act 2018. The HRA recommended wording to fulfil transparency requirements under the GDPR for health and care research has been included in the PIS. The CI and study staff will also adhere, if appropriate, to the current version of the NHS Scotland Code of Practice on Protecting Patient Confidentiality. Access to collated participant data will be restricted to the CI and appropriate study staff. Computers used to collate the data will have limited access measures via user names and passwords. Published results will not contain any personal data that could allow identification of individual participants.
7.	**Insurance and Indemnity**
	The University of Aberdeen is sponsoring the study. **Insurance** – • The University of Aberdeen will obtain and hold a policy of Public Liability Insurance for legal liabilities arising from the study. **Indemnity:** The Sponsor does not provide study participants with indemnity in relation to participation in the Study but has insurance for legal liability as described above.
8.	**Study Conduct Responsibilities**

8.1.	**Protocol Amendments, Deviations and Breaches**
	The CI will seek approval for any amendments to the Protocol or other study documents from the Sponsor (in the first instance), REC and NHS R&D Office(s). Amendments to the protocol or other study documents will not be implemented without these approvals. In the event that a CI needs to deviate from the protocol, the nature of and reasons for the deviation will be recorded in the CRF, documented and submitted to the Sponsor. If this necessitates a subsequent protocol amendment, this will be submitted to the Sponsor for approval and then to the appropriate REC and lead NHS R&D Office for review and approval. In the event that a serious breach of GCP is suspected, this will be reported to the Sponsor immediately using the form "Breach Report Form".
8.2.	**Study Record Retention**
	Archiving of study documents will be retained for 10 years after study end date in line with the Sponsor's archiving SOP.
8.3.	**End of Study**
	The end of study is defined as completion of data analysis and study reporting. The Sponsor, CI and/or the SSC have the right at any time to terminate the study for clinical or administrative reasons The end of the study will be reported to the Sponsor and REC within 90 days, or 15 days if the study is terminated prematurely. The CI will ensure that any appropriate follow up is arranged for all participants. A summary report of the study will be provided to the Sponsor and REC within 1 year of the end of the study.
9.	**Reporting, Publication and Notification of Results**
9.1.	**Authorship Policy**
	Ownership of the data arising from this study resides with the study team and their respective employers. On completion of the study, the study data will be analyzed and tabulated, and a study report will be prepared. See Appendix 5.
9.2.	**Publication**
	The study report will be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study. Summaries of results will also be made available to Investigators for dissemination within their clinical areas (where appropriate and according to their discretion).

9.3.	**Peer Review**
	This study has been externally peer reviewed as part of the National Institute for Health Research funding process and a cope of these reviews, and our responses, will be submitted as part of the application.
10.	Patient Public Involvement
	Research to 'improve early diagnosis of sight-threatening glaucoma' is a top priority (for patients and clinicians) for funding (JLA PSP). Therefore, patients have been directly involved in identifying and prioritising this research question. We have worked closely with Darian Shotton, user of the glaucoma service, who has agreed that this is an important research question and is willing to act as PPI coapplicant and member of the study steering committee. Ms Shotton has provided input into the overall plan of activities. However, Mrs Shotton was unable to complete the activities required on the online MIS form due to being out of the country but had confirmed she was happy to continue to contribute. We will identify at least one other PPI partner to contribute to the study going forward. There will be ongoing PPI input in the design and piloting of all aspects of the study. In particular, guidance during the preparation of all patient facing documentation will be particularly important, for example, on the information leaflets but also critical input to the topic guides for interviews will be key and co-production of the study results to participants. The International Glaucoma Association (UK-based charity to support people with glaucoma) will act as advisors across the project.

APPENDIX 1: References

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APPENDIX 2: Study Steering Committee Charter

In-home Tracking of glaucoma: Reliability, Acceptability, and Cost: the I-TRAC Study

<<LOGO>>

STUDY STEERING COMMITTEE CHARTER

NB: Documents shaded in grey are only relevant to CTIMPs

Funder number	**NIHR129248**
REC number	
Sponsor number	**2-072-20**

Prepared by:

Name: Dr Katie Gillies Role: CI

Signature: K Gillies Date: 11th June 2020

1. Introduction

The I-TRAC study is funded by the National Institute for Health Research Health Technology Assessment Programme. Research Ethics Committee approval has been given by <<name>> (<<ref. no.>>). The sponsor(s) of the study is University of Aberdeen. The Study Office is located in Aberdeen at the Services Research Unit (HSRU), University of Aberdeen.

1.1 Study Aims

The aim of this study is to determine the feasibility and acceptability of digital technologies to monitor glaucoma at home and inform the possible need and design of a definitive evaluative study.

1.2 Scope

The purpose of this document is to describe the membership, terms of reference, roles, responsibilities, authority, decision-making and relationships of the Study Steering Committee (SSC) for I-TRAC, including the timing of meetings, methods of providing information to and from the SSC, frequency and format of meetings and relationships with other trial committees.

1.3 Facilitation

The I-TRAC Research Fellow will be nominated as a Facilitator for the trial. The Facilitator will be responsible for the organisation of meetings and should be copied into all communications with and between the SSC.

2. Roles and responsibilities

2.1 Aims of SSC

To act as the oversight body for the I-TRAC study on behalf of the Sponsor and Funder.

2.2 Terms of reference

The role of the SSC is to provide oversight for the trial. It should also provide advice through its independent Chairman to the Project Management Group (PMG), and the funder, as appropriate, on all aspects of the study.

2.3 Specific roles of SSC

The rights, safety and well-being of the trial participants are the most important considerations and should prevail over the interests of science and society. The SSC's role will include, but not be restricted to, the following:

- provide expert oversight of the study
- maintain confidentiality of all study information that is not already in the public domain
- make decisions as to the future continuation (or otherwise) of the study
- monitor recruitment rates and encourage the PMG to develop strategies to deal with any recruitment problems including sites who fail to recruit adequately
- approve the protocol(s) and ensure appropriate ethical, & other approvals, are obtained
- review regular reports (e.g. follow-up rates) of the study (sent on behalf of the Project Management Group (PMG))
- assess the impact and relevance of any accumulating external evidence
- review protocol adherence and advise on sites that are deviating from the protocol
- approve any proposals by the PMG concerning any change to the design of the study, including additional substudies
- oversee the timely reporting of study results
- comment on the publication policy
- comment on the main study manuscript
- approve external requests for release of data or subsets of data including clinical data
- monitor compliance with the protocol and any amendments

- monitor compliance with previous SSC recommendations

2.4 Agreement and conflicts of interest

The independent SSC members will not be asked to formally sign a contract but should formally register their agreement to join the group by confirming (1) that they agree to be a member of the SSC and (2) that they agree with the contents of this Charter. Competing interests should be disclosed at this time. These are not restricted to financial matters – involvement in other studies or intellectual investment could be relevant. Although members may well be able to act objectively despite such connections, complete disclosure enhances credibility (see Annexe 1). SSC members should not use any study data to inform trading in pharmaceutical shares, and careful consideration should be given to trading in stock of companies with competing products. Changes in declarations of real or potential competing interests should be declared at the start of each meeting.

3. Before or early in the trial

3.1 SSC input into the protocol

All potential independent SSC members should have opportunity to comment on the protocol as early as possible. I-TRAC has been reviewed by the Sponsor, Funder and the research ethics committee. Therefore, if a potential independent SSC member has major reservations about the study (eg the protocol, the logistics, ethical concerns) they should report these to the Chief Investigator and may decide not to accept the invitation to join. SSC members should be constructively critical of the ongoing study, but also supportive of aims and methods of the study.

3.2 Timing of first SSC meeting

The first meeting of the SSC will take place early in the course of the study, to discuss the protocol, the study, future meetings and to enable the SSC independent members to clarify any aspects with the principal investigators.

4. Composition

4.1 SSC membership

The SSC has a minimum of 75% majority of independent members. The independent members of the I-TRAC TSC are:
Professor Daniel Hinds (Chair)
Dr Jen Burr
Mrs Karen Osborn
Professor Luke Vale

The University of Aberdeen insurance policies cover the activities of the SSC independent members for their work on the committee.

The Chief Investigator (Dr Katie Gillies) or an appropriate deputy, is also a member. The other I-TRAC grant-holders and key members of the central office (e.g. the trial manager) may attend SSC meetings but are not members. The funder and Sponsor will be notified in advance of meetings and a representative invited to attend. Other relevant experts may be invited to attend as appropriate. Quoracy and voting rights are described in sections 7.3 and 7.4.

4.2 Responsibilities of the Study Office
The Chief Investigator and staff from the Study office will produce a short report on the study before each meeting of the SSC, including an update on recruitment, retention and serious adverse events.

4.3 Responsibilities of the Facilitator
The Facilitator will be responsible for arranging meetings of the SSC, coordinating reports, producing and circulating minutes and action points. The Facilitator will be the central point for all SSC communications between the SSC and other bodies, will be copied into all correspondence between SSC members and will be kept aware of trial issues as they arise.

4.4 Relationship between study committees
The responsibilities of each trial committee are detailed in the protocol and in the respective Charters.

5. Organisation of meetings
5.1 Frequency
The SSC will meet approximately annually. At the request of the SSC, interim meetings, in person or by teleconference, will be organised. Major study issues may need to be dealt with between meetings, by phone or by email. SSC members should be prepared for such instances.

5.2 Attendance
Effort will be made to ensure that all members can attend. The CI or a deputy will try to attend all meetings, especially if major actions are expected. Members who cannot attend in person should be encouraged to participate by teleconference.

The meeting report will be circulated at least one week before the meeting in order to enable SSC members who will not be able to attend the meeting to pass comments for consideration during the discussions at the meeting to the Facilitator, SSC Chair and/or CI.

5.3 SSC payments
I-TRAC SSC members will be reimbursed for travel and accommodation. No other payments or rewards are anticipated. However, a fee is paid to members of the public which covers their contribution to the trial, e.g. for meeting attendance and preparation work. The fee will be paid by the University of Aberdeen as it is part of the grant award from the NIHR. Members of the public are responsible for paying appropriate income tax and National Insurance contributions and must make their own arrangements for this.

5.4 Independent members who fail to attend meetings
If an independent member does not attend a meeting or provide comments when requested between meetings, it should be ensured that the independent member is available for the next meeting. If an independent member does not attend the next meeting or provide comments when next requested, they should be asked if they wish to remain part of the SSC. If an independent member does not attend a third meeting, strong consideration should be given to replacing this member.

5.5 Resignation and replacement of independent members due to change in circumstances
If an independent Committee member's circumstances change (eg if he/she moves job to the same institution as the CI) he/she would resign from the committee. A replacement independent member would be identified and appointed.

6. Study documentation and procedures to ensure confidentiality and proper communication

6.1 Material to be considered during meetings

A short report will be prepared by the central co-ordinating office. This will report on accrual and any matters affecting the study (e.g. results of pilot/feasibility study). Additionally, the material may include requests from the PMG or draft publications. Where relevant, accrual, compliance with and collection of primary and key secondary outcomes, treatment may be presented by centre.

6.2 Accumulating data

The accumulating study data will be reviewed by the SSC.

6.3 External evidence

It is the responsibility of the PMG to make the SSC aware of any external evidence (e.g. from other studies, trials/systematic reviews) and possible impact on I-TRAC at SSC meetings.

6.4 Retention of papers after the meeting

The central co-ordinating office will keep a central record of all minutes, reports and correspondence by the SSC. SSC members will be expected to delete, destroy or store securely copies of the reports to and from the SSC, agenda and minutes, as well of copies of communications between meetings. All documentation should be considered confidential.

7. Decision making

7.1 Possible SSC decisions/recommendations

Possible decisions could include:

- No action needed, study continues as planned
- Modifying target recruitment, or pre-analysis follow-up, based on any change to the assumptions underlying the original study design.
- Sanctioning and/or proposing protocol changes

7.2 SSC decision making methods

Every effort should be made to achieve consensus. The role of the Chair is to summarise discussions and encourage consensus; therefore, it may be best for the Chair to give their own opinion last. It is important that the implications (e.g. ethical, statistical, practical and financial) for the study be considered before any decision is made.

7.3 When the SSC is quorate

The minimum quoracy for a meeting to conduct business is 67% of appointed members. Therefore at least members of the SSC should be expected to be present including the Chair.

If, at very short notice, a SSC member who was expected to participate cannot do so, the SSC meeting may still go ahead at the discretion of those present. In such cases, if the SSC has considered a major action or recommendation, the SSC Chair (or, in the absence of the Chair, the independent member who has chaired the meeting) should communicate with the absent members as soon after the meeting as possible to check they agree. If they do not agree, a further meeting/teleconference should be arranged with the full SSC.

7.4 Voting rights

If a vote is required, all independent members will have a full vote. In addition, the CI, or appropriate deputy if CI is unable to attend the meeting, may also vote. In the event of a tied vote, the independent SSC Chair will have the casting vote.

8. Reporting

8.1 Communication of SSC recommendations

The SSC will report their decisions either at the SSC meeting or, if not possible, within 3 weeks of the meeting date (via the central co-ordinating office/CI) to the PMG who will be responsible for implementing any actions. The SSC may also provide feedback where appropriate, to the Sponsor/Funder. Copies of communications will pass through the central co-ordinating office/CI.

8.2 SSC Minutes

Notes of key points and actions will be made by the central co-ordinating office. The draft minutes will be initially circulated for comment to the SSC Chair who will sign off the final version of minutes or notes. A copy of these minutes will then be sent to all SSC members, the Sponsor, the funder and should also be filed in the Study Master File (SMF).

8.3 Conflict resolution with other study Committees

The SSC is the oversight body for the study. However, the SSC should have good reason before deciding not to accept requests from the PMG. To resolve any conflict between the oversight bodies, PMG and/or funder, a joint meeting should be held. The information to be shown would depend upon the action proposed and each Committee's concerns. Depending on the reason for the disagreement confidential data may have to be revealed to all or some of those attending such a meeting: this would be minimised where possible. The meeting would be chaired by a senior member of the central Studys Office or an external expert who is not directly involved with the study.

9. After the study

9.1 Publication of results

The SSC will oversee the timely analysis, writing up and publication of the main study results. The independent members of the SSC will have the opportunity to read and comment on the proposed main publications of study data prior to submission and abstracts and presentations during the study. This review may be concurrent to that of the study investigators.

9.2 SSC acknowledgement in publications

SSC members will be named and their affiliations listed in the main report, unless they explicitly request otherwise.

Annexe 1: Agreement and competing interests form for independent members

I-TRAC Study Steering Committee: Agreement to join the Study Steering Committee as an independent member and disclosure of potential competing interests

Please complete the following document and return to the SSC Facilitator.

(Please initial box to agree)

☐	I have read and understood the SSC Charter version 1, dated 160620
☐	I agree to join the Study Steering Committee for this study as an independent member
☐	I agree to treat all sensitive study data and discussions confidentially

The avoidance of any perception that independent members of a SSC may be biased in some fashion is important for the credibility of the decisions made by the SSC and for the integrity of the study.

Potential competing interests should be disclosed via the SSC facilitator. In many cases simple disclosure up front should be sufficient. Otherwise, the (potential) independent SSC member should remove the conflict or stop participating in the SSC. **Table 1** below lists potential competing interests.

☐ **Yes,** I have potential competing interests to declare (please detail below)

☐ **No,** I have no potential competing interests to declare

Please provide details of any potential competing interests:

_____

_____

_____

Name: _____

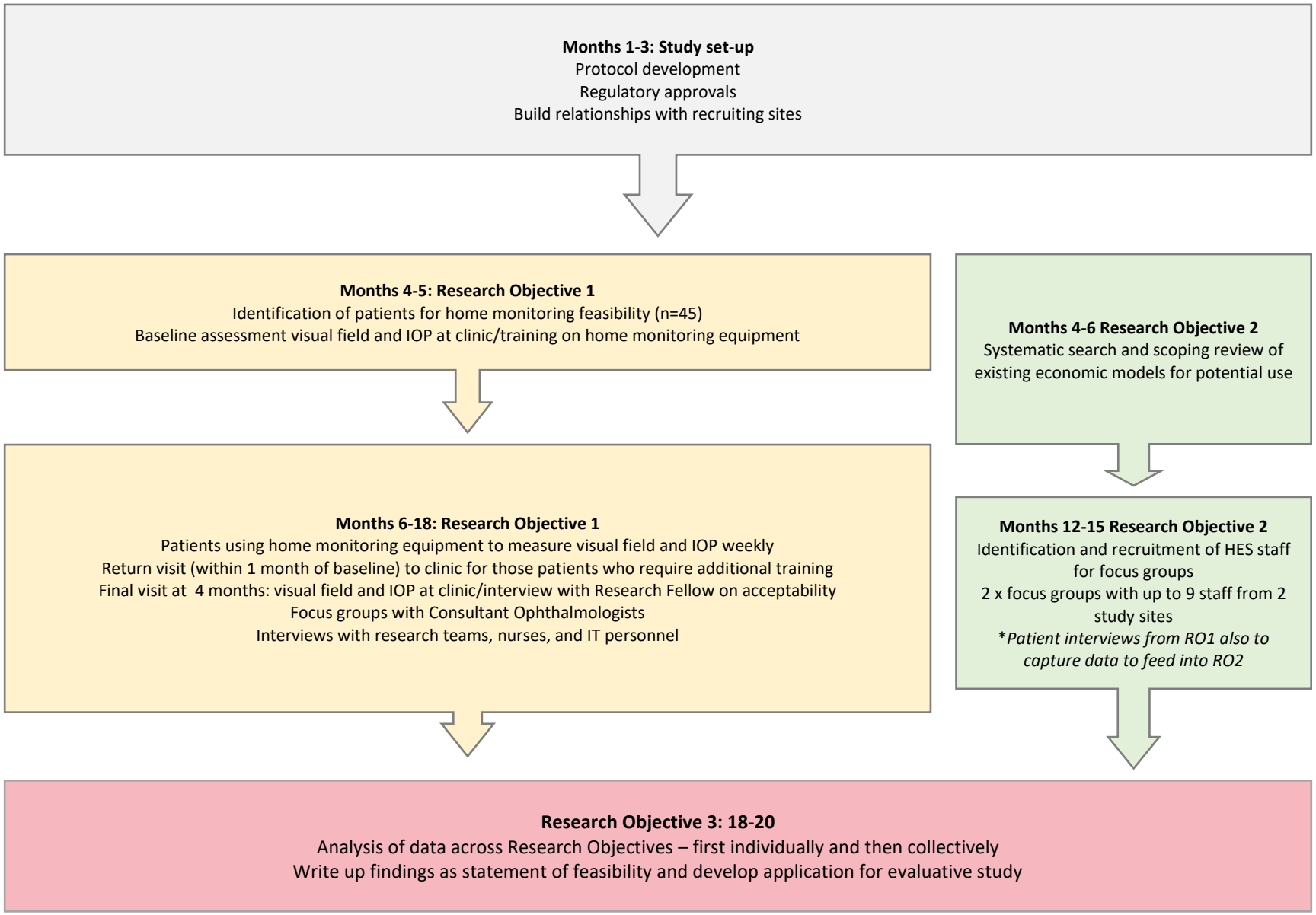
Signed: _____ Date: _____

Please return to the I-TRAC Study Office, HSRU, University of Aberdeen, Health Sciences Building, Foresterhill, Aberdeen, AB25 2ZD.

18.1.1.17.1 Table 1: Potential competing interests for independent members

Stock ownership in any commercial companies involved
Stock transaction in any commercial company involved (if previously holding stock)
Consulting arrangements with the Sponsor/Funder
Frequent speaking engagements on behalf of the intervention
Career tied up in a product or technique assessed by study
Hands-on participation in the study
Involvement in the running of the study
Emotional involvement in the study
Intellectual conflict e.g. strong prior belief in the study's experimental arm
Involvement in regulatory issues relevant to the study procedures
Investment (financial or intellectual) or career tied up in competing products
Involvement in the writing up of the main study results in the form of authorship

APPENDIX 3: Study Flow Diagram



Appendix 4: Study Matrix

Participants	**Study Processes**	
Research Objective 1: Understand the views of patients and clinicians on whether digital technologies for glaucoma home monitoring would be feasible and acceptable		
	Data collection	**Timing and frequency**
Patients	• 45 patients will: ○ Have a baseline study visit in HES clinic where demographic data ((e.g. age, gender, education, disease status, previous eye treatments) will be collected from the medical notes and visual field test and IOP will be taken. ○ Be asked to take measurements (IOP with the home tonometer and visual field with the home perimeter) at home using the home tonometer and the perimeter. Data will be stored within the visioninhome.uk website and downloaded to the study website . Patients who require additional training on the technology will be offered opt-in refresher training at a return clinic visit (within 1 month of baseline). ○ Have end of study visit in HES clinic for final visual field test and IOP and also a short resource use questionnaire • Approximately 10 patients will be invited to participate in interviews to explore acceptability of home monitoring generally and focus on the requirements (both in the short, medium, and long term) of the digital technologies	• Baseline data collection and training on home monitoring equipment to last 90 mins (60 mins of which is standard care and 30 minutes is the research activity). Baseline eye measurement may be provided from home monitoring equipment if not able to attend HES. • Patients will be asked to use the equipment every week for 4 months. ○ Perimetry measurement take approximately 15 minutes ○ Tonometer measurement takes approximately 5 minutes • Final eye measurements at 4 months – approx. 30 mins – and participant completed questionnaire – approx. 10 minutes. May be provided from home monitoring equipment if not able to attend HES.

	under investigation. Interviews will take place within the clinic at the time of the final visual field and IOP assessment	• Interviews will be conducted once after patients have completed the 4-month home monitoring measurements. • Interviews are anticipated to last between 45-60 minutes. Interviews will be done either face to face in clinic or via video/audio call if necessary.
Ophthalmologists	• Two focus groups with 6–8 ophthalmologists per group will be conducted.	• One off focus groups will be conducted within months 6-18 – likely to coincide with a professional event (e.g. conference – dependent on social distancing regulations). • Focus groups are anticipated to last between 60-90 minutes. Focus groups may be done via video/audio call if necessary.
Researchers and NHS Staff	• Up to 6 members of relevant research teams, ideally two members (Chief investigator and Trial Manager) of three trial teams will be interviewed. • One Research and one IT person from each of the 3 recruiting Trusts will also be invited.	• Interviews will be conducted once with each participant within months 6-18 • Interviews are anticipated to last between 45-60 minutes. Interviews will be done either face to face or via video/audio call if necessary.
Research Objective 2: Developing a conceptual framework for the economic evaluation of home monitoring glaucoma.		
Patients	• Patient interviews - No additional interviews required: questions to address this objective will be included in RO1 patient interviews.	• No additional interviews required – questions to address this objective will be included in RO1 patient interviews

	• Survey of all patients included in RO1(n=45) to explore actual and perceived need for HES during the study period.	• One time completion of questionnaire at 4 months. May be completed verbally at online 4 month call if necessary. • Anticipated to take 10 minutes.
Healthcare staff	• Two focus groups with a mixture of Consultant Ophthalmologists (n=3), nurses (n=3) and administrative staff (n=3) per group, identified from recruiting sites, will be conducted.	• One off focus groups will be conducted within months 12-15 – likely to coincide with a professional event (e.g. conference – dependent on social distancing regulations). • Focus groups are anticipated to last between 60-90 minutes. Focus groups may be done via video/audio call if necessary.

Appendix 5: Authorship Policy

AUTHORSHIP POLICY FOR I-TRAC STUDY

1. DEFINING AUTHORSHIP

Authorship of published or presented papers is based on the following criteria[1]:

i. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

ii. Drafting the work or revising it critically for important intellectual content; AND

iii. Final approval of the version to be published; AND

iv. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

2. PRINCIPLES OF AUTHORSHIP

The following principles of authorship have been derived from editorial publications from leading journals[2,3] and are in accordance with the rules of the International Committee of Medical Journal Editors (ICMJE)[1].

All contributors must fulfil the criteria detailed in section 1: DEFINING AUTHORSHIP in order to qualify for authorship.

Contributors who meet fewer than all four of the criteria for authorship listed above should not be listed as authors, but they should be acknowledged. For example, participation solely in the acquisition of funding, collection of data or technical editing, language editing or proofreading the article is insufficient by itself to justify authorship[1]. Those persons may be acknowledged and their contribution described. See section 3: ACKNOWLEDGEMENTS.

a. Preferred CHaRT authorship

Where possible, all HSRU studies should publish using all the named contributors who qualify for authorship in the byline i.e. Jane Doe, John Doe, John Smith and Ann Other.

However, there may be situations where this is not possible, for example if the journal limits the number of authors. In such circumstance, group authorship may be appropriate using bylines similar to “The I-TRAC study group” or “Jane Doe, John Doe, John Smith, Ann Other and the I-TRAC study group”. The article should carry a footnote of the names of the people (and their institutions) represented by the corporate title. For some journals the journal will provide instructions on how to ensure the names of the collaborators appear on PubMed or equivalent.

Group authorship may also be appropriate for publications where one or more authors take responsibility for a group, in which case the other group members are not authors but may be listed in the acknowledgement (the byline would read 'Jane Doe *for* the Study Group')[2]. Again, the article should carry a footnote of the names of the people (and their institutions) represented by the corporate title.

b. Determining authorship

These authorship criteria are intended to reserve the status of authorship for those who deserve credit and can take responsibility for the work. The criteria are not intended for use as a means to disqualify colleagues from authorship who otherwise meet authorship criteria by denying them the opportunity to meet criterion numbers (ii) or (iii). Therefore, all individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript[1].

Tentative decisions on authorship should be made as early as possible[3]. These should be justified to, and agreed by, the Project Management Group. Any difficulties or disagreements will be resolved by the Study Steering Committee (SSC).

c. Ordering of authors

The following rules may help with the ordering of authors, particularly for publications with individual authorship:

i. The person who has taken the lead in writing may be the first author.
ii. The senior author may wish to be the last named author.
iii. Those who have made a major contribution to analysis or writing (i.e. have done more than commenting in detail on successive drafts) may follow the first author immediately; where there is a clear difference in the size of these contributions, this should be reflected in the order of these authors.
iv. All others who fulfil the four authorship criteria described in Section 1: DEFINING AUTHORSHIP may complete the list in alphabetical order of their surnames.

3. ACKNOWLEDGEMENTS

All those who make a contribution to a publication, but who do not fulfil the criteria for authorship, such as interviewers, data processors, staff at the recruiting sites, secretaries and funding bodies, should be acknowledged by name, usually in an 'Acknowledgements' section specifying their contributions. Because acknowledgment may imply endorsement by acknowledged individuals of a study's data and conclusions, authors are advised to obtain written permission to be acknowledged from all acknowledged individuals[1].

4. DISCLAIMERS

All papers arising from HSRU must include the full title of the Health Services Research Unit (HSRU) and the appropriate disclaimer specified by the Chief Scientist Office (CSO). For the current disclaimer please see Q-Pulse.

Authors should also ensure they include the study funder's disclaimer: refer to the funders website for details. Be aware that other disclaimers may also be required.

5. QUALITY ASSURANCE

Ensuring quality assurance is essential to the good name of the trial group. All reports of work arising from the I-TRAC study, including conference abstracts, should be peer reviewed by the Project Management Group. The Project Management Group will be responsible for decisions about submission following internal peer review. Submission may be delayed or vetoed if there are serious concerns about the scientific quality of the report. If individual members of the group are dissatisfied by decisions, the matter may be referred to the SSC.

It is hoped that the adoption and dissemination of this policy will prevent disputes that cannot be resolved by informal discussion. However, any member of the study team with a concern about authorship should discuss it with the relevant Chief Investigator, SSC, Line Manager or Programme Director as appropriate.

REFERENCES

1. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. Developed by members of the ICMJE, the document is revised regularly and the current version (updated Dec 2018) is available at (www.icmje.org/#authors)
2. Huth EJ (1986). Guidelines on authorship of medical papers. *Annals of Internal Medicine*, **104**, 269-274.
3. Glass RM (1992). New information for authors and readers. Group authorship, acknowledgements and rejected manuscripts. *Journal of the American Medical Association*, **268**, 99.

4.

Appendix 6: COVID-19 Contingency Plan

This appendix outlines aspects of study design and conduct that would have to change for the I-TRAC research study should COVID-19 cause restrictions on research at any point during the study timeline. The potential changes to process required are presented below for each of the Research Objectives and the associated participants.

RO1 - Understand the views of patients and clinicians on whether digital technologies for glaucoma home monitoring would be feasible and acceptable.

Patients

Consenting participants

Patients will be sent an invitation letter, information sheet and consent form in the post. Research nurses (appropriately GCP trained) will then telephone the patients to provide an opportunity to ask any questions they have and seek verbal consent. They will then arrange a time convenient for the patient to introduce them to the home monitoring equipment and be trained in its use. The research nurse will then arrange for the patient to be sent the home monitoring equipment and provide instruction on how to return it at 4 months.

For participants who agree to be interviewed, verbal consent will be reconfirmed by the I-TRAC Research Fellow who will be appropriately trained in GCP before the interview commences.

If a participant does not wish to be recorded for any of these steps, we will arrange for an independent witness to observe the consent process. The witness and the researcher will complete the verbal consent script annexe to document that consent was given.

Data collection

Once consented, patients will be trained by the research nurses in how to conduct the measurements using the home monitoring equipment over MS Teams. Visual field and intra-ocular pressure data will be obtained from patient. If this has to be done remotely (via MS Teams), patients will be asked for the readings from the home monitoring equipment. This process will also be followed for the 4 month end of study measurement should the patient not be able to attend HES in person.

Data will be recorded (manually and then entered electronically) on a Baseline Case Report Form (CRF). Demographic data (e.g. age, gender, education, disease status, previous eye treatments) will also be collected from the medical notes and recorded on the case report form by the Research Nurse. The Research Nurse will also ask the patient to complete the resource use questionnaire during the end of study call at 4 months. The Research Nurse will read out the questions and the patient will answer verbally for the Research nurse to record manually and the upload electronically to the study database.

Interviews will be conducted by the I-TRAC Research Fellow once patients have completed the 4-month home monitoring measurements. These will be conducted through MS Teams.

Ophthalmologists

The only change required for participants in this phase would be to the mode of data collection with the option of online (MS Teams enabled) focus groups or interviews being implemented rather than in person. All other aspects would remain the same.

Researchers and NHS Staff

The only change required for participants in this phase would be to the mode of data collection with the option of online (MS Teams enabled) being implemented rather than in person. Verbal consent will be taken as described above for patients. All other aspects would remain the same.

RO2 – Developing a conceptual framework for the economic evaluation of home monitoring glaucoma.
Healthcare staff
The only change required for participants in this phase would be to the mode of data collection with the option of online (MS Teams enabled) focus groups or interviews being implemented rather than in person. Verbal consent will be taken as described above for patients. All other aspects would remain the same.

Patients
As per RO1 above

Study oversight
Other aspects of study process that require contingency plans relate to overall study management. If the Chief Investigator (Dr Katie Gillies) becomes unwell, Professor Graeme MacLennan will take over the role of Chief Investigator. If the clinical lead (Professor Augusto Azuara-Blanco) becomes unwell, one of the other clinical collaborators (Dr Andrew Tatham or Dr Anthony King) will take on responsibility for clinical lead.