HSC Public Health Agency
Research and Development

Northern Ireland Implementation Plan for Clinical Research Recovery, Resilience and Growth May 2022

Introduction

There is a growing recognition and acceptance that health and social care should follow the science, be driven by the data and be evidence based. This is important for the decisions and choices of policy makers, practitioners and the public and requires high quality, relevant research. Achieving this will require improvements in the conduct of the science that will generate the data to provide the evidence. Research needs to become integral to routine practice and be efficient and effective if it is to recover, become resilient and grow. This will require actions to allow research to be delivered amidst the pressures that the health and social care system is under even at the best of times, and to be able to respond at times of crisis, such as during the COVID-19 pandemic.

This Northern Ireland Implementation Plan was prepared by a Taskforce, established in March 2021, and its subgroups (Appendix 1). It recommends a series of actions to support recovery, resilience and growth (RRG) in clinical research in Northern Ireland, where "clinical research" is used to cover research intended to improve health, whether it is delivered in health or social care, and whether it is commercial or non-commercial. This Plan complements the UK-wide recommendations for RRG. The actions should lead to improvements in the effectiveness and efficiency of clinical research studies, allowing the most important questions to be answered more clearly and more quickly. The Plan should ensure that this research can achieve the ultimate aim of influencing future decisions that will improve health and well-being and prevent premature deaths. The actions would also allow health and social care to build on the willingness of patients to be involved in research and provide them with relevant opportunities to do so, not only as participants in research studies but also in their design, conduct and interpretation. In Northern Ireland, this work is against a backdrop of the new City Deals, the establishment of which shows a recognition of the importance of research, and a failure to deliver clinical research recovery, resilience and growth may pose a threat to those projects.

This Plan is divided into sections, arising from the work of subgroups of the Taskforce. There is some overlap between the sections, reflecting overlaps in the ecosystem for research and practice in health and social care in Northern Ireland and each section includes recommendations for actions. Abbreviations used in the Plan are explained in Appendix 2.

1. Overarching actions

This section features some overarching recommendations for Northern Ireland clinical research recovery, resilience and growth as a whole.

1. Activity	Metrics	Impact	Responsibility	Resources needed	Timing
1.1.01 Establish a group to support recovery, resilience and growth in health and social care (HSC) research by overseeing the uptake of this Implementation Plan and facilitating closer working together of those responsible for research, practice and the data infrastructure in HSC in Northern Ireland (including the City Deals) with representation from key stakeholders, including patients and the public.	Successful implementation of the actions in the Implementation Plan. Better collaboration within the HSC infrastructure. Number and types of health and social care research study and speed of their set-up and delivery.	Increased efficiency in the conduct of health and social research, leading to faster resolution of the uncertainties they address.	Department of Health. Research infrastructure leads*. Key people within relevant initiatives (such as the City Deals and HIRANI) and the Northern Ireland HSC ecosystem.	Willingness to change and good engagement.	Needs to be in place within 2 to 4 months after publication of the Implementation Plan and be ongoing thereafter.
1.1.02 Facilitate the incorporation of research into routine practice in HSC in Northern Ireland.	Proportion of HSC practitioners who are research active.	Increased efficiency in the conduct of HSC research and greater uptake of the findings into practice.	Department of Health. Entire Northern Ireland HSC ecosystem.	Willingness to change and good engagement.	Needs to start during the first year after publication of the Implementation Plan and be ongoing thereafter.

1.1.03 Ensure that HSC research in Northern Ireland is sustainable and low carbon, uses efficient and effective methods and processes and attracts new investment.	Carbon output of studies and their efficiency (e.g., achievement of recruitment and retention targets and completion to time and budget), and the proportion of these funded by different sources (e.g. industry or public funds) to determine if Northern Ireland becomes a more attractive venue for clinical research studies.	Reduced environmental impact and increased efficiency in the conduct of HSC research, leading to faster resolution of the uncertainties addressed.	Research infrastructure leads*. Chief investigators. People working on research methodology, which is likely to include collaboration with, for example, UK Clinical Trials Unit Network, UK Trial Managers' Network, Trials Methodology Research Partnership, Trial Forge and Cochrane Methodology Review Group.	Grant capture for relevant studies. Monitoring will need to be done.	Needs to start during the first year after publication of the Implementation Plan and be ongoing thereafter.
1.1.04 Facilitate efficient use of research infrastructure resources for HSC across Northern Ireland.	Proportion of studies that use research infrastructure resources and align with NICRN priorities.	Increased efficiency in the conduct of HSC research, leading to faster resolution of the uncertainties addressed.	Research infrastructure leads*. Chief investigators.	Willingness to change and good engagement.	Needs to start during the first year after publication of the Implementation Plan and be ongoing thereafter.

1.1.05 Improve communication with the public about research in HSC and increase public awareness of the value of this research.	Dedicated communications support for promoting HSC research. At least one public awareness campaign about research (perhaps linked to International Clinical Trials Day) Public awareness of, and attitudes towards research.	Greater public engagement in the research process.	Research infrastructure leads*. Chief investigators.	New activities related to communisations about HSC research (including new posts as in 2.1.03). This would be appropriate for funding from the NI CRRRG Fund in the first instance (in order to support recovery, resilience and growth).	Needs to start with the launch of the Implementation Plan (if not before).
1.1.05 Improve communication across the Northern Ireland health and life science ecosystem (including with and between HSC Trusts, commercial companies and universities) about HSC research and the opportunities for research to increase awareness of research.	Dedicated communications support for promoting HSC research. Awareness of, and attitudes towards research across Northern Ireland health and life science ecosystem.	Greater engagement in the research process.	Research infrastructure leads*. Chief investigators. HIRANI.	New activities related to communisations about HSC research. This would be appropriate for funding from the NI CRRRG Fund in the first instance (in order to support recovery, resilience and growth).	Needs to start with the launch of the Implementation Plan (if not before).

1.1.07 Provide case studies of how Northern Ireland has missed or taken opportunities to play a fuller role in HSC research locally, in the UK and internationally.	Case studies showing how Northern Ireland has missed or taken opportunities to play a fuller role in HSC research.	Improved evidence base for the need for improvements in how HSC is done in Northern Ireland.	Research infrastructure leads*. Chief investigators and local principal investigators.	Personnel to do this survey, who might be new appointments or seconded. This would be appropriate for funding from the NI CRRRG Fund.	Needs to start within 2 to 4 months after publication of the Implementation Plan and be completed in the subsequent 4 months. Examples might come from cancer, dementia (or other aspects of care in the community), primary care, social care and respiratory medicine.

* Research infrastructure leads include those involved in R&D in the HSC Trusts, PHA, NICRN, NICRF, NICTU as well as academics in QUB and UU.

2. Personal and Public Involvement and Priority Setting

Successful recovery, resilience and growth in health and social care (HSC) research will require strong patient/person and public involvement (PPI) and strong engagement of HSC practitioners with the research process. This will require partnerships between patients, the public, practitioners, researchers and funders of research (both commercial and non-commercial) throughout the research life cycle to ensure that the right research questions are asked, in the right way, and that the findings are used to inform policy and practice. Research needs to be seen to be an integral part of HSC, not an add-on or a luxury.

The actions proposed in this section focus on how to achieve this and how to ensure that research in Northern Ireland will be of high value to, and have high impact on HSC here, while also providing robust and reliable evidence for use elsewhere.

2.1. Priority Setting	**Metrics**	**Impact**	**Responsibility**	**Resources**	**Timing**
2.1.01 Commission a priority setting partnership/James Lind Alliance (JLA) exercise to set priorities across the NICRN within areas of expertise and capacity, aligning with local, regional and UK priorities, to improve access for funding and ensure the necessary buy-in from the HSC Trusts and primary care, researchers and industry.	Priorities defined for each Clinical Interest Group within the NICRN.	New research is of high quality and aligns with the priorities.	HSC R&D.	Commission JLA exercise (anticipated cost: £25k). This would be appropriate for funding from the NI CRRRG Fund.	Establish a working group to select general areas for the JLA exercise within 2 months of publication of the Implementation Plan and conduct the exercise and complete the process within the subsequent 7 months.

2.1.02 NICRN to list on its website which priorities had been set and how they link to local and national priorities.	Priorities listed on NICRN and other relevant websites.	Raised public awareness of research being delivered in Northern Ireland.	NICRN.	Internal resources at NICRN.	In tandem with 1.01 and ongoing.
2.1.03 The Community Engagement Network within PHA and other similar forums to be approached as a resource to involve patients, service users and the public in the priority setting partnership where there are no existing clinical groups or patient and public representatives aligned to the NICRN Clinical Interest Groups.	Patients, service users and public involved in priority setting partnership as named partners in published reports.	Raised public awareness of research being delivered in Northern Ireland.	Internal links within PHA.	Communications post, which would be appropriate for funding from the NI CRRRG Fund.	Communications activity needs to start within 3 months of publication of the Implementation Plan.

2.2. Aligning our research needs and process with the needs of the UK health care systems and alignment with existing group priorities in Northern Ireland (i.e. NICRN)	**Metrics**	**Impact**	**Responsibility**	**Resources**	**Timing**
2.2.01 Undertake local mapping exercise against national opportunities to address gaps and areas of future need in research capacity.	Mapping exercise commissioned and completed.	Capacity of NI R&D Infrastructure increased through a stable and sustainable workforce.	NICRN.	NICRN.	Needs to start within 3-4 months of publication of the Implementation Plan and be completed in the subsequent 6 months in tandem with 1.01.
2.2.02 Support professional pathways in research for all levels of HSC staff and disciplines in all settings, with agreed gateways and milestones in order to establish local research leaders.	Evidence of research capacity being built through funding for Clinical Academic Pathways for all professions, substantive research nurse posts, discipline-specific research and multidisciplinary research.	Clear and consistent message communicated to commercial and non-commercial sponsors that Northern Ireland is investing in a coordinated UK approach to research.	DoH. HSC R&D. HSC Trusts.	DoH. HSC R&D. HSC Trusts.	Conversations should start immediately with a view to having a proposal within 1-2 years but implementation will depend on DoH commitment.

2.2.03 Department of Health to endorse Chief Executives' public commitment to research and its importance in HSC Trusts.	Evidence of research capacity being built through joint clinical/academic posts and further training opportunities. Published metrics on R&D activity within HSC Trusts to show research as an essential part of clinical service.	Improved patient outcomes.	DoH. HSC Trusts. Research Directors. Director R&D.	DoH. HSC R&D. HSC Trusts.	Process of engagement should start within 3 months of publication of the Implementation Plan and. deliverables around metrics should be evident within one year.
2.3. Improving visibility and making research matter to the NHS	**Metrics**	**Impact**	**Responsibility**	**Resources**	**Timing**
2.3.01 The DoH should drive the requirement for research job plans for all HSC staff, including those in primary care.	Research included in all HSC professionals' job descriptions.	Improved staff engagement in research and increased system capacity in R&D infrastructure. All staff supported to get involved in research across HSC.	DoH. HSC Trust HR Departments. Chief Executives. Clinical Directors. Clinical Leads. HSC R&D.	Willingness to change and good engagement.	Process of engagement should start within 3 months of publication of the Implementation Plan and deliverables around metrics should be evidence within 1 to 3 years.

2.3.02 Scope for creation of lead posts for PPI in research within HSC Trusts and primary care.	Lead posts for PPI in research funded across HSC Trusts and primary care. Numbers of participants recruited to trials and other research studies in Northern Ireland and number of PPI partners.	Increased awareness among the Northern Ireland public of value and impact of research on patient care and more opportunities to participate. Demonstration of the positive impact of research on patient outcomes, patient care and revenue.	HSC Trust Directors. HSC R&D.	Funding for scoping exercise, which would be appropriate for funding from the NI CRRRG Fund.	Process of engagement (CEOs and Directors of Research) needs to commence within 3 to 4 months of publication of the Implementation Plan and be in tandem with 3.01. PPI posts to be in place within 1 to 3 years.
2.3.03 DoH should ensure that Research Directors are part of HSC Trust Boards.	Research Directors listed as members of HSC Trust Board Committees and in attendance at meetings. Metrics submitted by HSC Trust R&D teams on research activity reported as essential part of clinical services.	Increased visibility of research delivery, enabling all staff to see its value and supporting more effective delivery for the benefits of patients, service users, researchers, sponsors and clinicians.	DoH. HSC Trust CEOs.	HSC Trusts DoH	Ongoing from the publication of the Implementation Plan.

2.4. Making research more diverse and relevant to the whole of the UK	**Metrics**	**Impact**	**Responsibility**	**Resources**	**Timing**
2.4.01 Ensure a coordinated approach to increase public participation and involvement in research.	Demographic data on people recruited to NICRN trials and PPI partners.	Increased access to research for those with greatest needs, reducing disparity between research activity and disease outcomes.	HSC R&D. NICRN. Host institutions of researchers.	Funding for single PPI lead for research in Northern Ireland. This would be appropriate for funding from the NI CRRRG Fund (in the first instance at least).	Post filled within 1 year of publication of the Implementation Plan.
2.4.02 Align with UK work streams to identify strategies to ensure that communities traditionally under served by research have opportunities to take part in research, both as participants and PPI partners.	Northern Ireland representation noted on membership list of UK work streams and evidenced as part of UK Strategies and resources through display of HSC R&D logo.	Northern Ireland aligned with UK strategy.	HSC R&D.	HSC R&D Infrastructure	Ongoing from the publication of the Implementation Plan.

2.4.03 Work with the Community Engagement Network, PHA, community leaders, Together NI and other fora to promote opportunities for involvement and participation of people from seldom heard groups.	Evidence of people from seldom heard groups taking part in PPI training and as members of research user forums (e.g. PIER) and as research participants.	Greater diversity of participants in research in Northern Ireland. Adaption of research methods to improve access for more diverse communities.	PPI leads (currently these exist for clinical and social care services but not for research).	Funding for scoping exercise. This would be appropriate for funding from the NI CRRRG Fund (in the first instance, at least).	Process of engagement (CEOs and Directors of Research) needs to commence within 3 to 4 months of publication of the Implementation Plan and PPI posts to be in place within 1 to 3 years.

2.5. Strengthening public, patient and service user involvement in research	Metrics	Impact	Responsibility	Resources	Timing
2.5.01 Ensure PPI from the start and throughout the research cycle, including the choice of the research question, design of the study, development and implementation of the study, and dissemination of its findings. This will ensure that PPI is a strong and meaningful component in any application for R&D funding as part of the RRG process and aligns with UK standards.	PPI evidenced in bids for research funding and awards of HSC R&D funding.	Improved quality and relevance of health and social research, including ensuring that the research focuses on the most important questions and outcomes.	HSC R&D. Research infrastructure leads*. Chief investigators.	HSC R&D Division.	Ongoing from the publication of the Implementation Plan.
2.5.02 Create a PPI Co-ordinator/lead role to increase practical training for researchers, service users and the public in implementing PPI in the research process.	Increased training for researchers and PPI representatives and pathways developed for role development of PPI representatives. Number of courses delivered and trainers (targeted increase of at least 50%).	Researchers will be empowered to use innovate research methods to implement PPI in their research proposals and PPI representatives will have confidence and skills to become involved in research as patient partners.	Research infrastructure leads*. Chief investigators.	Funding for PPI Co-ordinator/Lead Role. This would be appropriate for funding from the NI CRRRG Fund (in the first instance at least).	Post filled within 1 year of publication of the Implementation Plan.

2.5.03 Develop a mechanism to ensure that researchers can access patients, service users and public as partners and/or participants in research.	Register of PPI representatives willing to become partners in research, review research applications and participate in research.	Improved and effective partnerships between researchers and the public.	HSC R&D.	HSC R&D Division with relevant local, regional and national stakeholders.	Ongoing from the publication of the Implementation Plan.
2.5.04 Continue to build on communications and media work around COVID-19 to maintain public awareness of the importance of research with service users and public through the appointment of a dedicated communications officer.	Funding secured for dedicated communications support for R&D. At least 1 annual public awareness campaign delivered on International Clinical Trials Day.	Funding secured for dedicated communications support for R&D. At least 1 annual public awareness campaign delivered on International Clinical Trials Day.	HSC R&D.	Dedicated funding for communications role or time within an existing post. This would be appropriate for funding from the NI CRRRG Fund.	Comms activity needs to start within 3 months of publication of the Implementation Plan and the process of appointing a comms person needs to run in tandem with the Implementation Plan.

2.5.05 Ensure that Northern Ireland is represented on UK working groups and commits to 4-nation initiatives on PPI (e.g. Public Standards for Involvement; NIHR/HRA Joint Statement/Payments policy).	Northern Ireland representation on relevant UK work streams and evidenced as part of UK strategies and resources (e.g. through display of HSC R&D logo). Pragmatic processes for PPI involvement (e.g. for payment for public involvement activities).	Working with the public involvement and engagement community and organisations across the UK should overcome barriers to public engagement in research.	HSC R&D.	Internal.	Ongoing from the publication of the Implementation Plan.

* Research infrastructure leads include those involved in R&D in the HSC Trusts, PHA, NICRN, NICRF, NICTU as well as academics in QUB and UU.

3. Innovation

A key element for recovery, resilience and growth in clinical research in Northern Ireland will be the introduction of innovation in the design, conduct, reporting and use of studies in health and social care (HSC). Some of these innovations might be Northern Ireland-specific but some will need to take place at the UK level and reflect the UK-wide Implementation Plan. Others will need global action. They are all likely to need to overcome some long-standing challenges faced by the HSC research ecosystem in Northern Ireland, so that we do not miss out on opportunities because the time taken to get prepared means that the study is on the verge of ending by the time Northern Ireland is ready to contribute to a piece of UK or international clinical research.

Innovations will include the introduction of novel approaches (such as new trial methods developed to cope with the impact of the COVID-19 pandemic), the modification of existing approaches, and the increased uptake of approaches that have existed for some time but that have not had widespread adoption. Whether the innovation is new, adapted or adopted, it will need to be evaluated to assess its impact and to assess whether it is fit for purpose for future use.

The recovery of research will require innovation that recognises the challenges of restarting research in a HSC system that is, in parts, depleted or exhausted. Resilience in recovered and new research will be vital. This was made all too apparent by the initial impact of the COVID-19 pandemic and the restrictions that this led to, and then by the arrival of the Omicron variant in late 2021, which showed that the research system in Northern Ireland and UK-wide did not have the resilience needed to cope. Future resilience will need to be able to deal with acute shocks to the system which might last days or weeks (e.g. a disaster caused by natural hazards, a cyber-attack or major incident causing damage to key infrastructure), and with the more prolonged effects of those shocks and long-term disruption (e.g. climate change, a future pandemic or economic recession). Finally, growth of research in Northern Ireland will require efforts to make the region more attractive as a place to do HSC research. All of this will require innovations recommended in this section and actions recommended elsewhere in the Implementation Plan in order to make HSC research in Northern Ireland more effective and efficient.

3.1. Overarching	Metrics	Impact	Responsibility	Resources needed	Timing
3.1.01 Identify and understand the barriers and enablers facing researchers across HSC in Northern Ireland in delivering innovation in clinical research studies.	Information on these barriers and enablers.	Identification of the information that would be used to identify and design interventions that might support the delivery of innovation in HSC research studies in Northern Ireland.	Research infrastructure leads*.	Personnel to do this survey, who might be new appointments or seconded. This would be appropriate for funding from the NI CRRRG Fund.	Needs to start within 2 to 4 months after publication of the Implementation Plan and be completed in the subsequent 4 months.
3.1.02 Use the understanding of the barriers and enablers identified under 3.1.01 for the identification and design of interventions that might support the delivery of innovation in HSC research (coupled with activity 3.1.03).	Interventions that are identified or developed to support the delivery of innovation in research.	Sustainable change in the conduct of research across Northern Ireland and consequent improvements in HSC.	Research infrastructure leads*. People working on research methodology.	Personnel to identify or design appropriate interventions, who might be new appointments or seconded. This would be appropriate for initial funding from the NI CRRRG Fund.	Needs to start within 4 to 12 months after publication of the Implementation Plan and be completed in the subsequent 12 months, with ongoing review thereafter.

3.1.03 Ensure that the implementation of innovation in HSC research studies is based on the best available evidence.	Information on the evidence base that was used to support the implementation of innovation in research.	Sustainable change in the conduct of research across Northern Ireland and consequent improvements in HSC.	Cochrane Methodology Review Group (based in Northern Ireland) to help identify evidence base, perhaps in collaboration with Trial Forge (based in Scotland). Research infrastructure leads*.	Resources to support an accessible evidence base.	Resources need to be put in place during the first year after publication of the Implementation Plan and continue thereafter.
3.1.04 Promote Northern Ireland as a place in which to use effective and efficient innovative research designs to both the commercial and non-commercial sectors.	Number of external researchers (commercial and non-commercial) who place their study in Northern Ireland and number of such studies.	Attraction of HSC research studies to Northern Ireland.	PHA R&D's Industry Liaison Manager. HIRANI.	This should be part of the role of the PHA R&D's Industry Liaison Manager and HIRANI in the future.	Needs to start in the first year after publication of the Implementation Plan, increase substantially in the second year and be ongoing thereafter.
3.2. Innovation areas	**Metrics**	**Impact**	**Responsibility**	**Resources needed**	**Timing**
3.2.01 Increased use of adaptive designs for HSC research studies.	Opportunities taken (and missed) for the appropriate use of adaptive designs.	More efficient use of resources when answering the questions posed for HSC research.	Research infrastructure leads*. Research governance (to streamline approvals).	Grant capture for the studies that will use these designs. Monitoring will need to be done by the relevant research infrastructure leads*.	Ongoing from the publication of the Implementation Plan.

3.2.02 Increased use of platform designs for HSC research studies.	Opportunities taken (and missed) for the appropriate use of platform designs.	More efficient use of resources when answering the questions posed for HSC research (but noting that platform trials can lead to greater workload than standard 2-group trials because of multiple interventions, variety of adverse effects, etc).	Research infrastructure leads*. Research governance (to streamline approvals).	Grant capture for the studies that will use these designs. Monitoring will need to be done by the relevant research infrastructure leads*.	Ongoing from the publication of the Implementation Plan.
3.2.03 Better selection of outcomes to collect in HSC research (e.g., through leaner protocols and use of core outcomes sets).	Opportunities taken (and missed) for the use of core outcome sets and for minimising the collection of outcomes that are not key to the analyses.	More efficient use of resources when answering the questions posed for HSC research.	Research infrastructure leads*. Chief investigators. People working on research methodology, perhaps in collaboration with the COMET initiative, based in England.	Grant capture for the studies that will use these designs. Monitoring will need to be done by the relevant research infrastructure leads*.	Ongoing from the publication of the Implementation Plan.

3.2.04 Better use of routine data to identify potential participants for HSC research.	Identification of participants who are recruited to and retained in HSC research using routine data.	Increased efficiency in the identification of participants for HSC research, leading to faster recruitment.	Research infrastructure leads*. Chief investigators. People responsible for data infrastructure in Northern Ireland (e.g., safe havens, data custodians, governance) to facilitate access to these data.	Greater willingness to allow routine data to be used inside and between HSC Trusts and primary care to identify potential participants for research. Resources from the NI CRRRG Fund for demonstrator projects that would allow the development of mechanisms to identify potential participants for a clinical research study, which could be used in other studies.	Need to identify demonstrator projects (ideally in primary care and community care) in the first 2 to 4 months after publication of the Implementation Plan.

3.2.05 Increased, appropriate use of public “advertising” (e.g. social media) to identify potential participants for HSC research, bearing in mind the need to ensure that expectations of the public are properly managed and that these approaches to recruitment may need approval as part of the ethical approval for the trial.	Identification of participants who are recruited to and retained in HSC research studies using this “advertising”.	Increased efficiency in the identification of participants for HSC research, leading to faster recruitment.	Research infrastructure leads*. Chief investigators. PHA R&D Communications to publicise HSC research generally. People working on research methodology, perhaps in collaboration with Trial Forge and the use of Studies Within A Trial (SWAT) to identify effective strategies.	Grant capture for the studies that will use these methods. Resources to support chief investigators and study teams and evaluations of methods. Resources for PHA R&D Communications, which would be appropriate for initial funding from NI CRRRG Fund.	Needs to start during the first year after publication of the Implementation Plan, increase substantially in the second year and be ongoing thereafter

3.2.06 Improved methods for identifying people in hard-to-reach groups who would be potential participants for HSC research.	Identification of participants who are recruited to and retained in HSC research studies from hard-to-reach groups.	Better opportunities for people in hard-to-reach groups to take part in HSC research and increased efficiency in the identification of participants for these studies, leading to faster recruitment.	HSC Trusts and Northern Ireland's HSC data infrastructure to improve capture of the relevant data. Research infrastructure leads*. Chief investigators. People responsible for data infrastructure in Northern Ireland (e.g., safe havens, data custodians, governance) to facilitate access to these data. People working on research methodology, perhaps in collaboration with Trial Forge and the use of SWAT to identify effective strategies.	Investment in the necessary infrastructure in the HSC. Grant capture for the studies that will use these methods. Resources to support chief investigators and study teams and evaluations of methods. Resources from the NI CRRRG Fund for demonstrator projects that would allow the development of mechanisms to identify hard-to-reach potential participants for a HSC research study, which could be used in other studies.	Needs to start during the first year after publication of the Implementation Plan and increase substantially in the second year and be ongoing thereafter.

3.2.07 Development of methods to support e-consent for HSC research.	Replacement of in-person consent with e-consent in HSC research studies, where appropriate.	More efficient use of resources (including participant and researcher time) in the consent process for HSC research.	HSC Trusts and Northern Ireland's HSC data infrastructure to make it easier to use online methods. Research infrastructure leads*. Chief investigators. Governance/Ethics to agree and facilitate this type of consent.	Investment in the necessary infrastructure in the HSC. Resources from the NI CRRRG Fund for demonstrator projects that would allow the development of mechanisms to obtain e-consent for participation in a HSC research study, which could be used in other studies.	Needs to start within the first year after publication of the Implementation Plan. increase substantially in the second year and be ongoing thereafter.

3.2.08 Better use of routine data as a source of information on the outcomes of participants in HSC research.	Use of routine data for the follow-up of participants in HSC research.	Increased efficiency in the follow-up of participants in HSC research.	Research infrastructure leads*. Chief investigators. People responsible for data infrastructure in Northern Ireland (e.g., safe havens, data custodians, governance) to facilitate access to these data.	May need a Northern Ireland Commission, given that patients who consent to take part in HSC research might wish these barriers to be overcome to allow use of their routine data. Greater willingness to allow routine data to be used (inside and between HSC Trusts and with primary care) in HSC research. May need a memorandum of understanding to allow use of data from GPs or a mechanism to allow patients to state willingness for data to be shared for research. Resources for the NI CRRRG Fund for demonstrator projects to develop ways to use routine data for follow-up of participants in a HSC research study, which could be used in other studies.	Need to identify demonstrator projects (perhaps in cancer and critical care) within the first 2 to 4 months after publication of the Implementation Plan.

3.2.09 Increased number of HSC research studies using online delivery of interventions.	Opportunities taken (and missed) for HSC research studies to use online delivery of interventions, where appropriate.	More efficient use of resources when answering the questions posed for HSC research.	Research infrastructure leads*. Chief investigators.	Grant capture for the studies that will use these designs. Monitoring will need to be done by the relevant research infrastructure leads*.	Ongoing from the publication of the Implementation Plan.
3.2.10 Development of methods to support online follow-up of participants in HSC research.	Reduction in the number of in-person visits needed to collect data from participants in HSC research.	More efficient use of resources (including participant and researcher time) in the collection of follow-up data in HSC research and increased resilience against future shocks such as the COVID-19 pandemic.	HSC Trusts and Northern Ireland's HSC data infrastructure to make it easier to use online methods for follow-up. Governance/Ethics to agree and facilitate this type of follow-up. Streamlined study design to minimise visits/outcome measurement.	Investment in the necessary infrastructure in the HSC. Willingness to move to online visits (for research as well as practice). Resources from the NI CRRRG Fund for demonstrator projects that would allow the development of mechanisms to obtain online follow-up in a HSC research study, which could be used in other studies.	Needs to start during the first year after publication of the Implementation Plan, increase substantially in the second year and be ongoing thereafter.

3.2.11 Development of methods to ensure effective dissemination of the findings of HSC research to those involved in PPI for the study and the participants.	Improved dissemination to patients and the public who were involved in research.	Improved and effective partnerships between researchers and the public.	Research infrastructure leads*. Chief investigators.	Willingness to change.	Needs to start during the first year after publication of the Implementation Plan, increase substantially in the second year and be ongoing thereafter.
3.2.12 Switch from centralised laboratory testing in clinical research studies to local testing that would be acceptable for routine practice.	Opportunities taken (and missed) for the use of routine local laboratory testing, where appropriate.	More efficient use of resources for laboratory testing in clinical research studies.	Sponsors and regulators (to facilitate switching from centralised testing). Sufficient local testing capacity.	Willingness to change.	Needs to start during the first year after publication of the Implementation Plan, increase substantially in the second year and be ongoing thereafter.
3.2.13 Increased use of electronic signatures to replace the need for wet-ink signatures in HSC research.	Use of electronic signatures (e.g. using DocuSign), rather than wet-ink signatures in HSC research studies.	More efficient processes for sign-off in HSC research studies.	HSC Trusts and Northern Ireland's HSC data infrastructure to make it easier to use online methods. Research infrastructure leads*. Chief investigators and local principal investigators. Governance/Ethics to agree and facilitate this type of consent.	Investment in the necessary infrastructure. Willingness to change.	Needs to start during the first year after publication of the Implementation Plan, increase substantially in the second year and be ongoing thereafter.

3.2.14 Develop a Hub & Spoke model for research in a primary care context with spokes feeding information on potential study participants to Primary Care Research Hubs, and evaluation of contact methods (e.g. “cold calling” or contact by the responsible GP).	Evidence of a structure and emerging active participation of GP practices in HSC research and evidence on the effects of different contact methods.	Distributed model with greater reach and engagement, perhaps including a central repository of patient details, and an improved evidence base on its use.	PHA R&D. NICRN primary care.	This might become part of the role of NICRN primary care and might benefit from an initial demonstrator project.	Need to identify a demonstrator project in primary care during the first year after publication of the Implementation Plan.

3.3. Evaluation of innovation	Metrics	Impact	Responsibility	Resources needed	Timing
3.3.1 Ensure that the introduction of innovation in HSC research is accompanied by an appropriate evaluation ("no innovation without evaluation").	Proportion of HSC research studies that have implemented innovation (which was not based on a robust evidence base) that included an evaluation of the impact of the innovation on the study.	Identification of effective and efficient innovations that should be more widely used, and identification of ineffective or inefficient innovations that should be avoided.	Grant bodies who will need to support this evaluation within HSC research studies, perhaps as a comparison of methods or an assessment of acceptability. Research infrastructure leads*. Chief investigators. Governance/Ethics to agree and facilitate this type of evaluation.	Funding for the evaluations. Willingness to evaluate innovation.	Needs to start during the first year after publication of the Implementation Plan, increase substantially in the second year and be ongoing thereafter
3.3.2 Contribute to the evidence base on the effects of innovation in HSC research.	Dissemination of the findings of these evaluations and their inclusion in, for example, guidelines for the conduct of HSC research.	Improvements in the conduct of HSC research studies.	Research infrastructure leads*. Chief investigators. People working on research methodology, perhaps in collaboration with Trial Forge and the use of SWAT to identify effective strategies.	Funding for the evaluations. Willingness to evaluate innovation.	Ongoing from the publication of the Implementation Plan.

* Research infrastructure leads would include those involved in R&D in the HSC Trusts, PHA, NICRN, NICRF, NICTU as well as academics in QUB and UU.

4. Data/Digital

During the COVID-19 pandemic, the potential benefits of better use of data and an improved digital infrastructure became even more apparent for Northern Ireland. A substantial public health platform was developed by the Department of Health (DHCNI) and the Public Health Agency. However, known problems also became even more apparent with Northern Ireland badly under-represented in many trials and other research studies because of the inability to recruit patients and the public due to weaknesses in the data digital infrastructure and difficulties with governance relating to access to data. If the aspirations in this Implementation Plan are met through successful demonstrator projects, this would represent a step change to the ability of Northern Ireland to be involved in health and social care (HSC) research.

For example, two potential datasets for some of the actions suggested here come from intensive care and renal transplantation. Intensive care information systems were particularly useful during the COVID-19 pandemic as they provide insight into the burden of the disease faced by the NHS and enabled some of the most important clinical trials to take place. The information that was vital to those processes could be used in a more systematic way by co-hosting and archiving intensive care data sets as a cloud asset, which is then linked to a population registry enabling the follow up of patients with, for example, long COVID and a greater understanding of impact on the NHS. In regard to renal transplantation and dialysis populations, at the start of the pandemic, Northern Ireland was the only part of the UK to continue living related kidney transplant services, which led to an unprecedented level of activity despite the onset of the UK's greatest healthcare emergency. Since then, living related kidney transplantation has been postponed on numerous occasions and the use of a cloud environment for legacy data sets would provide an excellent opportunity for a natural experiment exploring the effects of COVID-19 on this group of patients and amongst patients with renal disease in general, and providing a platform for their participation in future research within a secure data environment.

4.1. Technology	Metrics	Impact	Responsibility	Resources	Timeline
4.1.01 Commission citizen data and technical development work to optimise the ability of the Microsoft Analytics platform to facilitate population derived HSC research studies.	New methodologies identified and evaluated.	Increased efficiency in the conduct of HSC research.	QUB. PHA. Department of Health (DHCNI). HSC R&D.	Investment by the Department of Health (DHCNI) and PHA helped develop a platform to manage the COVID-19 pandemic and this was part funded by HDRUK through the Northern Ireland trusted research environment (NITRE) and additional funding may be possible from this route, to build on core funding related to government strategic planning for population health research. Funding from the NICRRG Fund could leverage funding from other research and public bodies.	Need to identify demonstrator projects (perhaps in primary care) within the first 2 to 4 months after publication of the Implementation Plan.

4.1.02 Enablement of population based epidemiological studies and interventional public recruitment studies based on ability to select at risk individuals identified within population data: Find, Recruit, Follow (FRF).	Number of citizens and primary care practices (or other sites as relevant) involved. FRF metrics.	Increased efficiency in HSC research, and greater involvement of Northern Ireland in trials coordinated from elsewhere.	NITRE. HSC R&D. DoH. NICRN. Research infrastructure leads*. Chief investigators	As under 4.1.01.	Need to identify demonstrator projects (perhaps in primary care) within the first 2 to 4 months after publication of the Implementation Plan.
4.1.03 On boarding a complex data set into a flexible analytics cloud environment to provide Northern Ireland with new methodology and a more accessible environment for population health research.	Number of participants recruited to and retained in HSC research studies using these new tools.	More accessible environment in which to carry out population health research, for service delivery and for development of research studies.		As under 4.1.01.	Need to identify demonstrator projects (perhaps in intensive care and renal transplantation) within the first 2 to 4 months after publication of the Implementation Plan.

4.2. Aligning our research needs and process with the needs of the UK health care systems	**Metrics**	**Impact**	**Responsibility**	**Resources**	
4.2.01 Build on the close links that Northern Ireland has with others in the UK (e.g. NI Wales Hub & National TRE Network, HDRUK and NIHR Digital, Data and Technology (DDaT) Board.	Close synergy between regional data research initiatives and those commissioned UK wide.	This work will provide Northern Ireland with a template with which to deliver its requirements for wider UK data research.	HSC R&D. NICRN. DHCNI. BSO.	Commissioning of skilled resources through CRRRG funding will be part of the initial build out to establish, sustain and engage over the years.	Ongoing from the publication of the Implementation Plan.
4.2.02 Enactment of secondary use legislation in Northern Ireland enabling the appropriate sharing of data, where legal and, proportionate, with colleagues in the UK, and further afield to assess performance and to lead to improvements in HSC in Northern Ireland.	Number of national audits returned too, research which requires national data sharing, and Data Use Register reported through NITRE.	Participation in UK National Audits, generating evidence and improving care and services for patients and the public.	PHA and the Strategic Planning & Performance Group of the DoH remain the key agents in the potential use of these systems.	DoH accelerated programme of work began (12 months commencing April 2022, led D West).	Ongoing from the publication of the Implementation Plan.

4.3. Improving visibility and making research matter to the NHS	Metrics	Impact	Responsibility	Resources	
4.3.01 Develop and implement public-facing dashboards for research using the Microsoft Azure platform to build trust through transparency in the research and allow HSC staff to see elements of their work being displayed for the rest of the population, covering both commercial and non-commercial research.	Number and variety of dashboards viewed.	Greater public engagement in the research process, including opportunities for the public to participate in policy creation and decision making in the use of their data for research, and potential revenue generation.	NITRE. Northern Ireland Public Data Panel (NIPDP). PHA. HSC R&D.	Funding of the Information Institute as a direct enabler of the NI Data Strategy with PHA acting as a coordinator of all of the above using NITRE as its vehicle of action.	Need to identify demonstrator projects (perhaps in intensive care and renal transplantation) within the first 2 to 4 months after publication of the Implementation Plan.

4.4. Strengthening public, patient and service user involvement	Metrics	Impact	Responsibility	Resources	
4.4.01 Establishment of the NIPDP to support patient and public engagement. Themes (common to panels in other jurisdictions) might include identification of perceived benefit, social impact of digital innovation, research ethics and governance, legislative provisions for data use, creation and promotion of Open Data, data linkage methodologies and impact on population science, trusted research and digital research environments, federation of data access and registers for the public to indicate willingness to join research (see also 2.5.03).	Scope and diversity of NIPDP topics (Health, Civic, Policy, Research, Privacy, Ethics). Publication of NIPDP reports and recommendations in range of media and formats and use of these reports and the NIPDP (e.g. involvement with funders and research delivery stakeholders). Registration of members of the public indicating their willingness to participate in research.	Facilitation of public dialogue and purposeful engagement in critical topics of data utility and improved and effective partnerships between researchers and the public.	NITRE. QUB / UU (City Deals). PHA. Belfast City Council.	A report from the NIPDP Pilot (which was jointly led by the Public Engagement, Communication and Impact lead for ADRC NI and Programme Lead for NITRE in conjunction with the Belfast City Council City Innovation Team and a contracted UK service design consultancy) is complete (final report expected in April 2022). A full business case is being prepared but is reliant on securing funding to build beyond phase 1 (2022-2023), which will be supported by ADRC NI and NITRE. Funding is also required to support marketing and service facilitation costs.	NIPDP to be established within 2 to 4 months of publication of the Implementation Plan and be ongoing thereafter.

4.4.02 Develop a NIPDP participation register to ensure panels may be called which are demographically targeted or diversified as necessary.	Scope and diversity of NIPDP topics (Health, Civic, Policy, Research, Privacy, Ethics).	Identification and prioritisation by the public of the use of their data for improvements to services, interventions, practice and research.	NITRE. QUB / UU (City Deals). PHA. Belfast City Council.	As under 4.4.01	NIPDP participation register to be developed within first year after publication of the Implementation Plan and be ongoing thereafter.

* Research infrastructure leads would include those involved in R&D in the HSC Trusts, PHA, NICRN, NICRF, NICTU as well as academics in QUB and UU.

5. Research & Development Governance

Research is a global endeavour, with significant regulatory requirements, which demands collaboration at a local, national and international level.

In Northern Ireland, the management of ethics and research governance is currently distributed across multiple organisations (R&D Offices (HSC Trusts), HSC Research Applications Gateway (WHSCT), ORECNI, (BSO)), and can be complex for researchers to navigate. In particular, this may be a disincentive for collaborators, whether clinical, academic or commercial, to include Northern Ireland sites in their research study.

Incremental changes in regulatory requirements at the UK and global level over a number of years have led to additional bureaucracy, which has been absorbed by the current workforce, creating increasing demands and workload pressures for the staff within the five HSC Trust research governance offices. The knock-on effect of this is increased response times and delays for researchers wishing to proceed with their studies, while staff have limited time to perform other research office-related business that is integral to their roles. These challenges were identified as the single biggest issue with the HSC R&D funded infrastructure in a consultative review carried out in 2017-18.

HSC R&D Division intends to set up a new centralised service within Public Health Agency for overall leadership and delivery of research governance for the HSC in Northern Ireland. This central facility will not only focus on ensuring seamless provision of research governance support services in Northern Ireland, but will link with counterparts across the UK, Ireland and internationally.

This service re-design will centralise functions and optimise links with existing regional functions to reduce duplication and complexity where possible, creating a shared purpose and accountability framework for the delivery of 'once for NI' research governance approvals.

5. Activity	Metrics	Impact	Responsibility	Resources	Timing
5.1.1 Establish a new HSC R&D Approvals service as a central facility within PHA.	Delivery of HSC approval (study-wide) for R&D at least in line with other UK Nations. Trust R&D Offices will link with the new R&D Approvals service to agree performance metrics to ensure rapid and efficient start-up of HSC research.	Co-ordination across the system to provide a single approval for HSC research in Northern Ireland and improve its efficiency. Centralised facility will remove duplication and alleviate bottlenecks in the governance system, delivering a once-for-NI HSC R&D approval, in partnership with ORECNI. HSC Trust R&D Offices will be freed up to focus on capacity and capability to deliver on local aspects of study delivery. Processes will continue to develop in line with other UK Nations and provide a consistent experience for chief investigators, irrespective of their home nation.	HSC R&D.	A £13.5m business case has been approved for 6 new posts with recruitment underway. Existing HSC R&D Approvals Gateway team will join PHA as part of new service. All to be funded from HSC R&D fund. Existing HSC Trust R&D Office resource will be retained and reviewed in light of changed roles There will no call on funding from the NI CRRRG Fund.	Recruit full team within 2 to 4 months of publication of the Implementation Plan and move Gateway to PHA within the subsequent 4 months. Agree functions to be delivered by central facility/Trust research offices during first 6 months after publication of the Implementation Plan.

5.1.02 Appoint a new Head of HSC R&D Governance to support the Assistant Director of R&D with regional and national responsibilities, and to build on and improve collaboration with ORECNI towards the delivery of a single HSC R&D approval for Northern Ireland.	As under 5.1.01.	As under 5.1.01.	As under 5.1.01.	This new post is part of the business case noted under 5.1.01. There will no call on funding from the NI CRRRG Fund.	Appointment to be made within 2 to 4 months of publication of the Implementation Plan.
5.1.03 Through collaborative working, define roles and responsibilities within the City Deals (in particular iREACH) to ensure complementary, effective and efficient processes for the HSC R&D Approvals Service alongside the eventual internal governance structure.	Metrics to be agreed that align with iREACH outputs.	The intended impact of iREACH is to create a centre of excellence in clinical research for Northern Ireland, bringing together elements of the R&D infrastructure and other stakeholders to attract investment and grant income to NI.	HSC R&D. Belfast City Deal. HSC Trusts.	Additional resource may be sought from NI CRRRG fund in due course.	Ongoing from the publication of the Implementation Plan.

6. Post-EU exit IMP supply

The Northern Ireland protocol was agreed as part of the EU Withdrawal Agreement and came into effect on 1 January 2021. Under the Protocol, Northern Ireland will continue to follow EU rules and regulations for medicines, whereas Great Britain (GB) will not. This had major implications for both the supply and regulation of medicines (including IMPs and medical devices) in Northern Ireland. The key issues included, but were not limited to:

- Medicines licensing.
- Medicines supply chain and ending of grace period.
- Medical devices.
- New requirements and procedures for medicines (including IMPs and medical devices for clinical trials) being imported from GB to Northern Ireland. (**Note**: there are various legislative differences in GB and Northern Ireland legislation; specifically changes relating to medical devices. This particular area continues to be closely monitored by PHA R&D Division.)

A project manager was recruited to take forward this workstream and has been working across the HSC Trusts, networks and pharmacy leads to identify studies at risk and advise sponsors on how best to proceed. This support has proven extremely valuable both internally and externally to HSC and has been able to prevent the loss of a number of studies to Northern Ireland participants.

Following the recent EU amendment to directive regarding IMP (Reg. EU No. 536/ 2014), there is now an indefinite derogation on the supply of medicines (including IMPs) imported from GB to Northern Ireland. While this removes the immediate need for new structures, resources and processes in Northern Ireland to oversee this, the group is now focused on ensuring appropriate communication around this update to the legislative position, especially with sponsors who had planned to withdraw studies, continued monitoring of any further issues, and taking forward the additional work around Medical Devices and In Vitro Diagnostics Regulations, which will have implications for Northern Ireland on account of the Protocol.

6. Activity	Metrics	Impact	Responsibility	Resources	Timing
6.1.01 Lead on a project to manage the transition to new post-EU Exit IMP supply arrangements, on account of the Northern Ireland protocol, with particular focus on importation of IMPs from GB.	Measures put in place to ensure that new requirements for approval and release of IMPs imported to Northern Ireland from GB (including licence, trained staffing, processes and premises).	Continuity of supply of IMPs to Northern Ireland trial participants, which may be an integral part of their treatment.	HSC R&D Division. HSC Trusts.	Project Manager is in post to lead on project, funded from HSC R&D Fund. Additional funding for infrastructure may be sought through EU Programme Board from DoH, with funding bid put through to DoF, contingency plan agreed via PHA for up to 2 years if required. There will no call on funding from the NI CRRRG Fund.	Ongoing from publication of the Implementation Plan.
6.1.02 Work with HSC Trusts to identify clinical trials of IMPs and medical devices at risk of interruptions to supply of medications at any point during the transition period.	List of at-risk studies and planned mitigations.	Efficient importation of IMPs to Northern Ireland.	HSC R&D Division. HSC Trusts.	As under 6.1.01.	Ongoing from publication of the Implementation Plan.

6.1.03 Work with Sponsors of commercial and non-commercial clinical trials of IMPs with Northern Ireland sites to ensure arrangements are in place for continuity of supply.	Record of communication with all sponsors, and responses received to provide sufficient information for decision-making on at-risk studies.	Prevent sponsors from withdrawing trials from Northern Ireland on the basis of additional bureaucracy or costs. This will be important for ongoing business, including the R&D infrastructure and City Deals as retrieval of lost business could be challenging.	HSC R&D Division. HSC Trusts.	As under 6.1.01.	Ongoing from publication of the Implementation Plan.
6.1.04 Provide communication and assurance to sponsors of Northern Ireland's continued ability to host clinical trials.	Record of communication to ensure ongoing placement of studies with Northern Ireland sites.	Prevent sponsors from withdrawing trials from Northern Ireland on the basis of additional bureaucracy or costs. This will be important for ongoing business, including the R&D infrastructure and City Deals as retrieval of lost business could be challenging.	HSC R&D Division. HSC Trusts.	As under 6.1.01.	Ongoing from publication of the Implementation Plan.
6.1.05 Monitor issues around supply of Medical Devices.	List of at-risk studies and planned mitigations.	Efficient importation of IMPs to Northern Ireland.	HSC R&D Division. HSC Trusts.	As under 6.1.01.	Ongoing from publication of the Implementation Plan.

6.1.06 Monitor issues surrounding divergence of legislation between EU and GB.	Participation in working groups and a record of measures taken to ensure issues are raised and mitigations are in place.	Continuity of supply of IMPs to Northern Ireland trial participants, which may be an integral part of their treatment.	HSC R&D Division.	As under 6.1.01.	Ongoing from publication of the Implementation Plan.

7. COVID-19

The overarching aim of this Implementation Plan is to provide a series of recommendations for action to allow recovery, resilience and growth in health and social care (HSC) research in Northern Ireland. These actions should lead to improvements in the effectiveness and efficiency of clinical trials across HSC and include the need to protect non-COVID-19 research from any spill-over negative impacts of COVID-19 research. The recommendations in this section seek to do this by providing dedicated support for COVID-19 research.

Since March 2020, all HSC Trusts have been engaged in Urgent Public Health (UPH) COVID-19 studies. More than a dozen of these prioritised UPH COVID-19 studies have been supported by the Northern Ireland Clinical Research Network (NICRN), recruiting several thousand participants in Northern Ireland. The results generated have made major national and global contributions to the management of the COVID-19 pandemic, including the identification of effective interventions. The great majority of the UPH COVID-19 study burden fell on respiratory and critical care specialty groups in Cluster 3 of the NICRN, but support has also been provided from clinical research nurse teams in other NICRN Clinical Specialty Groups.

Recruitment to virtually all non-UPH studies on the NICRN portfolio was paused at the onset of the pandemic. The reasons for this included the prioritisation of UPH studies, disruption of non-urgent clinical services that precluded patient recruitment and redeployment of NICRN staff to support acute clinical services. However, as the COVID-19 pandemic recedes and routine clinical services resume, NICRN is restarting its non-COVID-19 clinical research, which includes not only studies that were on the portfolio in early 2020 but also new studies. This is against a back-drop of providing ongoing support for many COVID-19 studies over the next year or more. Therefore, as a first step in clinical research recovery, resilience and growth in Northern Ireland, there is a need to try to ensure that the infrastructure resources for non-COVID-19 research are available and no longer need to be diverted to support COVID-19 research. This will help the wider portfolio of research to restart fully and to grow.

7. Activity	Metrics	Impact	Responsibility	Resources needed	Timing
7.1.01 Put in place a COVID-19 Study Delivery Team to deliver existing and new COVID-19 studies.	A) Number of existing non-COVID-19 studies successfully re-started because of the release of NICRN research nurses from work on COVID-19 and number of patients subsequently recruited and retained. B) Number of new non-COVID-19 studies started, and number of patients recruited and retained. C) Number of COVID-19 studies open to recruitment or follow-up and number of patients recruited and retained. D) Proportion of working time spent by members of the COVID-19 Study Delivery Team on NICRN supported COVID-19 studies and on other tasks.	Freeing up of research infrastructure capacity to enable the restart and growth of non-COVID-19 HSC research.	NICRN Coordinating Centre. HSC Trusts.	Funding for the members of the COVID-19 Study Delivery Team. This would be appropriate for funding from the NI CRRRG Fund.	Before the launch of the Implementation Plan.

7.1.02 Put in place additional programmed activities (PAs) for consultant physicians affording them protected time to deliver COVID-19 studies.	A) Number of non-COVID-19 studies successfully re-started because of the release of PIs from work on COVID-19 studies and numbers of patients recruited and retained. B) Number of new non-COVID-19 studies started, and numbers of patients recruited and retained. C) Number of COVID-19 studies open to recruitment or follow-up and numbers of patients recruited and retained. D) Proportion of allocated PAs spent on COVID-19 and other trial-related activity.	Freeing up of researcher capacity to enable the restart and growth of non-COVID-19 HSC research.	NICRN Coordinating Centre. HSC Trusts.	Funding for the additional PAs. This would be appropriate for funding from the NI CRRRG Fund.	Before the launch of the Implementation Plan.

8. Funding Acquisition and Income Management

Successful recovery, resilience and growth in health and social care (HSC) research in Northern Ireland will require issues relating to research income management and effective income generation and reinvestment to be identified and addressed. This is recognised to be a substantial task, and it needs to reflect the environment that is current after the Implementation Plan is launched, given how much has changed with the COVID-19 pandemic and the potential impact of uptake of the actions in the Implementation Plan. Therefore, the first step should be to gather the necessary information, so that a series of recommendations can be made.

8. Activity	Metrics	Impact	Responsibility	Resources needed	Timing
8.1.01 Gather information to describe challenges relating to HSC research income generation and management and reinvestment in Northern Ireland and make recommendations to overcome these issues.	Recommendations for ways to improve HSC research income management and effective income generation and reinvestment in Northern Ireland.	Development and implementation of strategies to improve HSC research income management and effective income generation and reinvestment	DoH. HSC R&D.	Appointment of a project manager, which would be appropriate for funding from the NI CRRRG Fund.	Needs to be in place within 2 to 4 months after publication of the Implementation Plan and to report within the subsequent 6 months.
8.1.02 Implement the recommendations identified under 8.1.01	HSC research income generation and reinvestment in Northern Ireland.	Improved income management, generation and reinvestment to improve the quality and relevance of HSC research.	To be included in the recommendations from 8.1.01.	To be included in the recommendations from 8.1.01.	To begin during the first year after the publication of the Implementation Plan and be ongoing thereafter.

Appendix 1. Members of the Taskforce and its subgroups (at some point March 2021 to May 2022)

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Appendix 2. Abbreviations

ABPI	Association of the British Pharmaceutical Industry
ADRC	Administrative Data Research Centre
BHSCT	Belfast Health and Social Care Trust
BSO	Business Services Organisation
CHITIN	Cross-border Healthcare Intervention Trials in Ireland Network
CRRRG	Clinical research recovery, resilience and growth
DDaT	Digital, Data and Technology (NIHR)
DoF	Department of Finance
DoH	Department of Health
EU	European Union
GB	Great Britain
HDRUK	Health data research UK
HIRANI	Health Innovation Research Alliance Northern Ireland
HR	Human resources
HSC	Health and social care
IMP	Investigational medicinal products
JLA	James Lind Alliance
NHSCT	Northern Health and Social Care Trust
NI	Northern Ireland
NICHS	Northern Ireland Chest Heart and Stroke
NICRF	Northern Ireland Clinical Research Facility
NICRN	Northern Ireland Clinical Research Network
NICTN	Northern Ireland Cancer Trials Network
NICTU	Northern Ireland Clinical Trials Unit
NIPDP	Northern Ireland Public Data Panel
NITRE	Northern Ireland trusted research environment
ORECNI	Office for Research Ethics Committees Northern Ireland
PHA	Public Health Agency
PIER	Public Involvement Enhancing Research
PPI	Patient (personal) and public involvement
QUB	Queen's University Belfast
R&D	Research and development
RRG	Recovery, resilience and growth
SEHSCT	South Eastern Health and Social Care Trust
SHSCT	Southern Health and Social Care Trust
UK	United Kingdom
UU	Ulster University
WHSCT	Western Health and Social Care Trust